REGULATION (EU) 2025/327 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 欧洲议会和理事会（欧盟）2025/327 号条例

of 11 February 2025 2025 年 2 月 11 日

on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 关于欧洲健康数据空间并修订第 2011/24/EU 号指令和第(EU)2024/2847 号条例

(Text with EEA relevance) （与欧洲经济区相关的文本）

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,欧洲议会和欧洲联盟理事会，

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,鉴于《欧洲联盟运行条约》，特别是其第 16 条和第 114 条，

Having regard to the proposal from the European Commission,考虑到欧洲委员会的提案，

After transmission of the draft legislative act to the national parliaments,在将该立法法案草案传送至各国议会后，

Having regard to the opinion of the European Economic and Social Committee [1],考虑到欧洲经济和社会委员会的意见(1)，

Having regard to the opinion of the Committee of the Regions [2],考虑到区域委员会的意见(2)，

Acting in accordance with the ordinary legislative procedure [3],按照普通立法程序行事(3)，

Whereas: 鉴于：

(1)The aim of this Regulation is to establish the European Health Data Space (EHDS) in order to improve natural persons' access to and control over their personal electronic health data in the context of healthcare, as well as to better achieve other purposes involving the use of electronic health data in the healthcare and care sectors that would benefit society, such as research, innovation, policymaking, health threats preparedness and response, including preventing and addressing future pandemics, patient safety, personalised medicine, official statistics or regulatory activities. In addition, this Regulation's goal is to improve the functioning of the internal market by laying down a uniform legal and technical framework in particular for the development, marketing and use of electronic health record systems ('EHR systems') in conformity with Union values. The EHDS will be a key element in the creation of a strong and resilient European Health Union.本条例的目的是建立欧洲健康数据空间（EHDS），以改善自然人在医疗保健领域对其个人电子健康数据的访问和控制，同时更好地实现其他涉及在医疗和护理领域使用电子健康数据且有益于社会的目的，例如研究、

创新、政策制定、健康威胁的防范和应对（包括预防和应对未来的流行病）、患者安全、个性化医疗、官方统计或监管活动。此外，本条例的目标是通过制定统一的法律和技术框架（特别是为符合欧盟价值观的电子健康记录系统（“EHR 系统”）的开发、销售和使用），来改善内部市场的运作。欧洲健康数据空间将是建立强大且具有韧性的欧洲健康联盟的关键要素。

(2)The COVID-19 pandemic highlighted the imperative of having timely access to quality electronic health data for health threats preparedness and response, as well as for prevention, diagnosis and treatment and for secondary use of such electronic health data. Such timely access could potentially contribute, through efficient public health surveillance and monitoring, to more effective management of future pandemics, to a reduction of costs and to improving the response to health threats, and ultimately could help to save more lives. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by Commission Implementing Decision (EU) 2019/1269 (4), to allow Member States to share electronic health data of COVID-19 patients moving between healthcare providers and Member States during the peak of that pandemic. However, that adaptation was only an emergency solution, showing the need for a structural and consistent approach at Member State and Union level, both in order to improve the availability of electronic health data for healthcare and to facilitate access to electronic health data in order to steer effective policy responses and contribute to high standards of human health.新冠肺炎疫情凸显了及时获取高质量电子健康数据的必要性，这对于应对和防范健康威胁、开展预防、诊断与治疗工作，以及对这类电子健康数据进行二次利用都至关重要。通过高效的公共卫生监测，及时获取这些数据有可能助力更有效地应对未来的大流行病、降低成本、增强对健康威胁的应对能力，并最终有助于挽救更多生命。2020 年，欧盟委员会紧急调整了其临床患者管理系统（该系统由欧盟委员会实施决定（EU）2019/1269(4)设立），以便成员国在疫情高峰期共享在医疗服务提供者和成员国之间流动的新冠肺炎患者的电子健康数据。然而，这种调整只是一种应急方案，这表明在成员国和欧盟层面都需要采取结构化且一致的方法，既要提高医疗领域电子健康数据的可用性，又要为获取电子健康数据提供便利，从而指导有效的政策应对，并助力实现高水平的人类健康标准。

(3)The COVID-19 crisis strongly cemented the work of the eHealth Network, a voluntary network of authorities responsible for digital health, as the main pillar for the development of contact-tracing and contact-warning applications for mobile devices and the technical aspects of the EU Digital COVID Certificates. It also highlighted the need for sharing electronic health data that are findable, accessible, interoperable and reusable (the ‘FAIR principles’), and ensuring that electronic health data are as open as possible, while respecting the data minimisation principle as set out in Regulation (EU) 2016/679 of the European Parliament and of the Council (5). Synergies between the EHDS, the European Open Science Cloud and the European Research Infrastructures should be ensured, and lessons should be learned from data-sharing solutions developed under the European COVID-19 Data Platform.新冠疫情危机有力地巩固了电子健康网络的工作，该网络是一个由负责数字健康的机构组成的自愿性网络，成为开发移动设备接触追踪和接触预警应用以及欧盟数字新冠证书技术方面的主要支柱。这也凸显了共享符合可查找、可访问、可互操作和可重用（即“FAIR 原则”）的电子健康数据的必要性，并确保电子健康数据尽可能开放，同时遵守欧洲议会和理事会第 2016/679 号条例(5)中规定的数据最小化原则。应确保电子健康数据空间（EHDS）、欧洲

开放科学云与欧洲研究基础设施之间的协同作用，并从欧洲新冠数据平台下开发的数据共享解决方案中吸取经验教训。

(4)Given the sensitivity of personal electronic health data, this Regulation seeks to provide sufficient safeguards at both Union and national level to ensure a high degree of data protection, security, confidentiality and ethical use. Such safeguards are necessary to promote trust in safe handling of electronic health data of natural persons for primary use and secondary use as defined in this Regulation.鉴于个人电子健康数据的敏感性，本条例旨在在欧盟和国家层面提供充分的保障措施，以确保高度的数据保护、安全性、保密性和合乎道德的使用。此类保障措施对于增进人们对自然人电子健康数据在本条例所定义的主要用途和次要用途中的安全处理的信任而言，是必不可少的。

(5)The processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 and, for Union institutions, bodies, offices and agencies, of Regulation (EU) 2018/1725 of the European Parliament and of the Council (6). References to the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions, bodies, offices and agencies, where relevant.个人电子健康数据的处理须遵守《欧盟条例（EU）2016/679》的规定，对于欧盟各机构、团体、办事处和代办处，还须遵守欧洲议会和理事会的《欧盟条例（EU）2018/1725》(6)。在相关情况下，提及《欧盟条例（EU）2016/679》的规定时，也应理解为同时提及《欧盟条例（EU）2018/1725》中适用于欧盟各机构、团体、办事处和代办处的相应规定。

(6)More and more individuals living in the Union cross national borders to work, study, visit relatives, or for other reasons. To facilitate the exchange of health data, and in line with the need to empower citizens, they should be able to access their health data in an electronic format that can be recognised and accepted across the Union. Such personal electronic health data could include personal data related to the physical or mental health of a natural person, including related to the provision of healthcare services, and which reveal information about that natural person's health status, personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question, as well as data determinants of health, such as behaviour, environmental and physical influences, medical care, and social or educational factors. Electronic health data also include data that have been initially collected for research, statistical, health threat assessment, policymaking or regulatory purposes and it should be possible to make them available in accordance with the rules laid down in this Regulation. Electronic health data consist of all categories of those data, irrespective of whether such data are provided by the data subject or other natural or legal persons, such as health professionals, or are processed in relation to a natural person's health or well-being and should also include inferred and derived data, such as diagnostics, tests and medical examinations, as well as data observed and recorded by automated means.在欧盟境内，越来越多的人出于工作、学习、探亲或其他原因跨越国界。为了促进健康数据的交流，同时也为了增强公民的自主能力，他们应当能够以在整个欧盟范围内可被识别和接受的电子格式获取自己的健康数据。此类个人电子健康数据可包括与自然人的身体或精神健康相关的个人数据（包括与医疗服务提供相关的数据），这些数据会揭示该自然人的健康状

况信息；还包括与自然人的遗传或获得性基因特征相关的个人数据，这些数据能提供关于该自然人的生理或健康状况的独特信息，尤其来自对相关自然人的生物样本的分析；此外，还包括健康决定因素数据，如行为、环境和物理影响、医疗护理以及社会或教育因素。电子健康数据还包括最初为研究、统计、健康威胁评估、政策制定或监管目的而收集的数据，并且应当能够依照本条例规定的规则提供这些数据。电子健康数据涵盖所有类别的上述数据，无论这些数据是由数据主体提供的，还是由其他自然人或法人（如卫生专业人员）提供的，也无论这些数据是针对自然人的健康或福祉进行处理的，同时还应包括推断和衍生数据，如诊断结果、检测和医学检查数据，以及通过自动化方式观察和记录的数据。

(7)In health systems, personal electronic health data are usually gathered in electronic health records, which typically contain a natural person's medical history, diagnoses and treatment, medications, allergies and vaccinations, as well as radiology images, laboratory results and other medical data, spread between different actors in the health system, such as general practitioners, hospitals, pharmacies or care services. In order to allow electronic health data to be accessed, shared and modified by natural persons or health professionals, some Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. In addition, some Member States provide support to public and private healthcare providers to set up personal electronic health data spaces to enable interoperability between different healthcare providers. Several Member States also support or provide electronic health data access services for patients and health professionals, for instance through patient or health professional portals. Those Member States have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data to the central EHR system, for instance by providing a system of certification. However, not all Member States have put in place such systems, and those Member States that have implemented them have done so in a fragmented manner. In order to facilitate the free movement of personal electronic health data across the Union and avoid negative consequences for patients when receiving healthcare in a cross-border context, Union action is needed to improve natural persons' access to their own personal electronic health data and to empower them to share those data. In this respect, appropriate action at Union and national level should be taken as a means of reducing fragmentation, heterogeneity and division, and to create a system that is user-friendly and intuitive in all Member States. Any digital transformation in the healthcare sector should aim to be inclusive and also benefit natural persons with limited ability to access and use digital services, including people with disabilities.在医疗系统中，个人电子健康数据通常汇集在电子健康记录中，这些记录通常包含自然人的病史、诊疗情况、用药信息、过敏史和疫苗接种记录，以及放射影像、实验室检查结果和其他医疗数据，这些数据分散在医疗系统的不同参与方之间，如全科医生、医院、药房或护理服务机构。为了让自然人或医疗专业人员能够访问、共享和修改电子健康数据，一些成员国已采取必要的法律和技术措施，并建立了集中式基础设施，连接医疗服务提供者和自然人使用的电子健康记录系统。此外，一些成员国为公立和私立医疗服务提供者提供支持，建立个人电子健康数据空间，以实现不同医疗服务提供者之间的互操作性。多个成员国还通过患者或医疗专业人员门户网站等方式，为患者和医疗专业人员提供电子健康数据访问服务或支持。这些成员国还采取了措施，确保电子健康记录系统或健康应用程序能够将电子健康数据传输到中央电子健康记录系统，例如通过提供认证体系。然而，并非所有成员国都

建立了此类系统，而已实施这些系统的成员国在做法上也较为分散。为了促进个人电子健康数据在欧盟范围内的自由流动，并避免患者在跨境就医时面临不良后果，欧盟需要采取行动，改善自然人对自身个人电子健康数据的访问，并赋予他们共享这些数据的权利。在这方面，应在欧盟和国家层面采取适当行动，以减少分散性、异质性和分割状态，并在所有成员国建立一个用户友好且直观的系统。医疗领域的任何数字化转型都应旨在实现包容性，同时惠及获取和使用数字服务能力有限的自然人，包括残疾人。

(8)Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. The EHDS builds upon those rights and complements some of them as applied to personal electronic health data. Those rights apply regardless of the Member State in which the personal electronic health data are processed, type of healthcare provider, sources of those data or Member State of affiliation of the natural person. The rights and rules related to the primary use of personal electronic health data under this Regulation concern all categories of those data, irrespective of how they have been collected or who has provided them, the legal ground for the processing under Regulation (EU) 2016/679 or the status of the controller as a public or private organisation. The additional rights of access and portability of personal electronic health data provided for in this Regulation should be without prejudice to the rights of access and portability as established under Regulation (EU) 2016/679. Natural persons continue to have those rights under the conditions set out in that Regulation.《欧盟条例》（EU）2016/679 规定了有关自然人在其个人数据处理方面权利的具体条款。《电子健康数据条例》（EHDS）以这些权利为基础，并对适用于个人电子健康数据的部分权利进行了补充。无论个人电子健康数据在哪个成员国处理、医疗服务提供者的类型如何、这些数据的来源是什么以及自然人所属的成员国是哪个，这些权利都适用。本条例中与个人电子健康数据的主要使用相关的权利和规则适用于所有类别的此类数据，无论其收集方式如何、提供者是谁、依据《欧盟条例》（EU）2016/679 进行处理的法律依据是什么，以及控制者是公共组织还是私营组织。本条例规定的个人电子健康数据的额外访问权和可携带权不应损害《欧盟条例》（EU）2016/679 所确立的访问权和可携带权。自然人在该条例规定的条件下继续享有这些权利。

(9)While the rights conferred by Regulation (EU) 2016/679 should continue to apply, the right of access to data by a natural person, established in Regulation (EU) 2016/679, should be further complemented in the healthcare sector. Under that Regulation, controllers do not have to provide access immediately. The right of access to health data is still commonly implemented in many places through the provision of the requested health data in paper format or as scanned documents, which is time-consuming for the controller, such as a hospital or other healthcare provider that provides access. That situation slows down access to health data by natural persons, and can have a negative impact on them if they need such access immediately due to urgent circumstances pertaining to their health condition. It is therefore necessary to provide for a more efficient way for natural persons to access their own personal electronic health data. They should have the right to have free-of-charge and immediate access, while respecting the need for technological practicability, to specific priority categories of personal electronic health data, such as the patient summary, through an electronic health data access service. That right should apply regardless of the Member State in which the personal electronic health data are processed, the type of healthcare provider, the sources of those data or the Member State of affiliation of the natural person. The scope of that

complementary right established under this Regulation and the conditions for exercising it differ in certain ways from the right of access to personal data under Regulation (EU) 2016/679, which covers all personal data held by a controller and is exercised against an individual controller, which has up to one month to reply to a request. The right to access personal electronic health data under this Regulation should be limited to the categories of data falling within its scope, be exercised via an electronic health data access service and entail an immediate answer. The rights under Regulation (EU) 2016/679 should continue to apply, allowing natural persons to benefit from their rights under both legal frameworks, in particular the right to obtain a paper copy of the electronic health data.虽然《欧盟条例》（EU）2016/679 所赋予的权利应继续适用，但该条例中规定的自然人获取数据的权利在医疗领域应得到进一步补充。根据该条例，控制者无需立即提供访问权限。在许多地方，获取健康数据的权利通常仍通过提供纸质形式或扫描文档形式的所需健康数据来实现，这对医院或其他提供访问权限的医疗服务提供者等控制者而言十分耗时。这种情况减缓了自然人获取健康数据的速度，若他们因自身健康状况的紧急情况而需要立即获取此类数据，可能会对他们产生负面影响。因此，有必要为自然人提供一种更高效的方式来访问自己的个人电子健康数据。他们应有权通过电子健康数据访问服务，免费且立即访问特定优先类别的个人电子健康数据（如患者摘要），同时需考虑技术可行性。无论个人电子健康数据在哪个成员国处理、医疗服务提供者的类型如何、这些数据的来源是什么以及自然人所属的成员国是哪个，这项权利都应适用。本条例所确立的这一补充性权利的范围及其行使条件，与《欧盟条例》（EU）2016/679 中规定的个人数据访问权在某些方面存在差异。后者涵盖控制者持有的所有个人数据，且是针对单个控制者行使的，控制者最多有一个月的时间对请求作出答复。根据本条例，访问个人电子健康数据的权利应仅限于其范围内的数据类别，通过电子健康数据访问服务行使，且需立即作出回应。《欧盟条例》（EU）2016/679 规定的权利应继续适用，使自然人能够从这两个法律框架中获益，特别是获取电子健康数据纸质副本的权利。

(10)It should be considered that immediate access of natural persons to certain categories of their personal electronic health data could be harmful for the safety of those natural persons or unethical. For example, it could be unethical to inform a patient through an electronic channel about a diagnosis of an incurable disease that is likely to be terminal instead of first providing that information in a consultation with the patient. Therefore, it should be possible to delay the provision of the access to personal electronic health data in such situations for a limited amount of time, for instance until the moment when the health professional can explain the situation to the patient. Member States should be able to establish such an exception where it constitutes a necessary and proportionate measure in a democratic society, in line with restrictions as provided for in Article 23 of Regulation (EU) 2016/679.应当考虑到，自然人立即获取其某些类别的个人电子健康数据可能会对这些自然人的安全造成危害或有违伦理。例如，通过电子渠道告知患者其患有可能致命的不治之症，而非首先在与患者的会诊中提供该信息，这可能是不道德的。因此，在这种情况下，应当可以在有限的时间内延迟提供个人电子健康数据的访问权限，例如延迟到医疗专业人员能够向患者解释情况之时。成员国应当能够设立此类例外情况，只要其构成民主社会中必要且相称的措施，且符合《欧盟条例》（EU）2016/679 第 23 条规定的限制条件。

(11)This Regulation does not affect Member States' competences concerning the initial registration of personal electronic health data, such as making the registration of genetic data

subject to the natural person's consent or other safeguards. Member States may require that data be made available in an electronic format prior to the application of this Regulation. This should not affect the obligation to make personal electronic health data, registered after the date of application of this Regulation, available in an electronic format.本条例不影响成员国在个人电子健康数据初始注册方面的权限，例如规定基因数据的注册需以自然人的同意或其他保障措施为前提。成员国可要求在本条例适用前，数据应以电子格式提供。但这不应影响在本条例适用日期后注册的个人电子健康数据以电子格式提供的义务。

(12)In order to complement the information available to them, natural persons should be able to add electronic health data to their EHRs or to store additional information in their separate personal health record which could be accessed by health professionals. However, information inserted by natural persons might not be as reliable as electronic health data entered and verified by health professionals and does not have the same clinical or legal value as information provided by health professionals. Therefore, data added by natural persons in their EHR should be clearly distinguishable from data provided by health professionals. That possibility for natural persons to add and complement personal electronic health data should not entitle them to change personal electronic health data which have been provided by health professionals.为了补充他们可获取的信息，自然人应当能够向其电子健康记录中添加电子健康数据，或者将额外信息存储在可由医疗专业人员访问的独立个人健康记录中。然而，自然人录入的信息可能不如医疗专业人员录入并核实的电子健康数据可靠，且其临床价值或法律价值也与医疗专业人员提供的信息不同。因此，自然人在其电子健康记录中添加的数据应当与医疗专业人员提供的数据有明确区分。自然人添加和补充个人电子健康数据的这一权利不应使他们有权更改医疗专业人员已提供的个人电子健康数据。

(13)Enabling natural persons to more easily and quickly access their personal electronic health data will enable them to notice possible errors such as incorrect information or incorrectly attributed patient records. In such cases, natural persons should be able to request online the rectification of the incorrect personal electronic health data, immediately and free of charge, through an electronic health data access service. Such rectification requests should then be treated by the relevant controllers in line with Regulation (EU) 2016/679, if necessary involving health professionals with a relevant specialisation and responsible for the natural persons' treatment.让自然人能够更轻松、快速地获取其个人电子健康数据，将使他们能够发现可能存在的错误，例如信息不正确或患者记录归属错误。在这种情况下，自然人应当能够通过电子健康数据访问服务，在线申请立即且免费地更正不正确的个人电子健康数据。相关控制者随后应依照《欧盟条例（EU）2016/679》处理此类更正请求，必要时可让具备相关专业知识且负责该自然人治疗的医疗专业人员参与其中。

(14)Under Regulation (EU) 2016/679, the right to data portability is limited to data processed based on consent or contract and provided by the data subject to a controller. Additionally, under that Regulation, natural persons have the right to have the personal data transmitted directly from one controller to another only where technically feasible. Regulation (EU) 2016/679, however, does not impose an obligation to make that direct transmission technically feasible. The right to data portability should be complemented under this Regulation, thereby empowering natural persons to provide access to, at least, priority categories of their personal electronic health data to the health professionals of their choice,

to exchange such health data with such health professionals and to download such health data. In addition, natural persons should have the right to request a healthcare provider to transmit a part of their electronic health data to a clearly identified recipient in the social security or reimbursement services sector. Such a transfer should be one-way only.根据《欧盟条例（EU）2016/679》，数据可携带权仅限于基于同意或合同处理的、由数据主体提供给控制者的数据。此外，根据该条例，只有在技术可行的情况下，自然人有权要求个人数据从一个控制者直接传输给另一个控制者。然而，《欧盟条例（EU）2016/679》并未规定使这种直接传输在技术上可行的义务。本条例应补充数据可携带权，从而使自然人能够授权其选择的医疗专业人员访问其个人电子健康数据中至少优先类别的数据，与这些医疗专业人员交换此类健康数据，并下载此类健康数据。此外，自然人应有权要求医疗服务提供者将其部分电子健康数据传输给社会保障或报销服务领域中明确标识的接收者。此类传输应仅为单向传输。

(15)The framework laid down by this Regulation should build on the right to data portability established in Regulation (EU) 2016/679 by ensuring that natural persons as data subjects can transmit their personal electronic health data, including inferred data, in the European electronic health record exchange format, irrespective of the legal basis for processing the electronic health data. Health professionals should refrain from hindering the application of the rights of natural persons, for example by refusing to take into account personal electronic health data originating from another Member State and which are provided through the interoperable and reliable European electronic health record exchange format.本条例确立的框架应基于《欧盟条例》（EU）2016/679 中规定的数据可携带权，确保作为数据主体的自然人能够以欧洲电子健康记录交换格式传输其个人电子健康数据（包括推断数据），无论处理电子健康数据的法律依据如何。医疗专业人员不应妨碍自然人行使这些权利，例如，不应拒绝考虑来自另一成员国且通过可互操作、可靠的欧洲电子健康记录交换格式提供的个人电子健康数据。

(16)Access to electronic health records by healthcare providers or other individuals should be transparent to the natural persons concerned. Electronic health data access services should provide detailed information on access to data, such as when and which entity or natural person accessed data and which data were accessed. Natural persons should also be able to enable or disable automatic notifications regarding access to personal electronic health data relating to them through the health professional access services.医疗服务提供者或其他个人对电子健康记录的访问情况应向相关自然人透明。电子健康数据访问服务应提供有关数据访问的详细信息，例如何时、哪个实体或自然人访问了数据以及访问了哪些数据。自然人还应能够通过健康专业人员访问服务，开启或关闭关于与其相关的个人电子健康数据被访问的自动通知。

(17)Natural persons might not want to allow access to some parts of their personal electronic health data while enabling access to other parts. This could especially be relevant in cases of sensitive health issues such as those related to mental or sexual health, sensitive procedures such as abortions, or data on specific medication which could reveal other sensitive issues. Such selective sharing of personal electronic health data should therefore be supported and implemented through restrictions set by the natural person concerned in the same way within the territory of a given Member State and for cross-border data sharing. Those restrictions should allow for sufficient granularity to restrict parts of datasets, such as

elements of the patient summaries. Before setting the restrictions, natural persons should be informed of the risks for patient safety associated with limiting access to health data. Given that the unavailability of the restricted personal electronic health data may impact the provision or quality of health services provided to the natural person, natural persons making use of such access restrictions should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services. The restrictions on access to personal electronic health data could have life-threatening consequences and, therefore, access to those data should nevertheless be possible where necessary to protect vital interests in emergency situations. More specific legal provisions on the mechanisms of restrictions placed by natural persons on parts of their personal electronic health data could be provided for by Member States in their national law, in particular as regards medical liability in cases where restrictions have been placed by the natural person concerned.自然人可能不希望允许他人访问其个人电子健康数据的某些部分，同时又允许访问其他部分。这在涉及敏感健康问题的情况下可能尤为相关，例如与心理或性健康相关的问题、堕胎等敏感医疗程序，或可能揭示其他敏感问题的特定药物数据。因此，应支持并通过相关自然人设定的限制来实现这种个人电子健康数据的选择性共享，且在特定成员国境内以及跨境数据共享中都应采用相同方式。这些限制应具备足够的细致度，以对数据集的部分内容（如患者摘要的要素）进行限制。在设定限制之前，应告知自然人限制健康数据访问可能对患者安全带来的风险。鉴于受限制的个人电子健康数据无法获取可能会影响向该自然人提供的健康服务的提供方式或质量，因此，利用此类访问限制的自然人应承担相应责任，即医疗服务提供者在提供健康服务时无法将这些数据纳入考量。对个人电子健康数据访问的限制可能会产生危及生命的后果，因此，在紧急情况下为保护重大利益时，仍应能够访问这些数据。成员国可在其国内法中就自然人对其个人电子健康数据部分内容设置限制的机制作出更具体的法律规定，特别是在相关自然人已设置限制的情况下涉及的医疗责任方面。

(18)In addition, due to the different sensitivities in the Member States on the degree of patients' control over their health data, Member States should be able to provide for an absolute right to opt out from access to their personal electronic health data by anyone other than the original controller, without any possibility to override that opt-out in emergency situations. In such a case, Member States should establish the rules and specific safeguards regarding such opt-out mechanisms. Those rules and specific safeguards could also relate to specific categories of personal electronic health data, for example genetic data. The right to opt out means that personal electronic health data relating to the natural person who exercises that right would not be made available through the services set up under the EHDS other than to the healthcare provider that provided the treatment. Member States should be able to require the registration and storage of personal electronic health data in an EHR system used by the healthcare provider who provided the health services and accessible only to that healthcare provider. If a natural person has exercised the right to opt out, healthcare providers will still document the treatment provided in accordance with applicable rules, and will be able to access the data registered by them. Natural persons who exercise the right to opt out should be able to reverse their decision. In such cases, personal electronic health data generated during the period of the opt-out might not be available via the access services and MyHealth@EU.此外，由于成员国对患者对其健康数据的控制程度存在不同的敏感度，成员国应当有权规定，个人享有绝对权利，可选择不让原始控制者以外的任何人访

问其个人电子健康数据，且在紧急情况下也不得推翻该选择退出的决定。在这种情况下，成员国应制定关于此类选择退出机制的规则和具体保障措施。这些规则和具体保障措施还可涉及特定类别的个人电子健康数据，例如基因数据。选择退出权意味着，行使该权利的自然人的个人电子健康数据，除提供治疗的医疗服务提供者外，不得通过根据《电子健康数据条例》（EHDS）设立的服务获取。成员国应有权要求，个人电子健康数据须在提供健康服务的医疗服务提供者所使用的电子健康记录（EHR）系统中进行登记和存储，且仅该医疗服务提供者可访问。如果自然人行使了选择退出权，医疗服务提供者仍将根据适用规则记录所提供的治疗，并能够访问其登记的数据。行使选择退出权的自然人应当能够撤销其决定。在这种情况下，在选择退出期间生成的个人电子健康数据可能无法通过访问服务和“我的健康@欧盟”（MyHealth@EU）获取。

(19)Timely and full access by health professionals to the medical records of patients is fundamental for ensuring continuity of care, avoiding duplications and errors, and reducing costs. However, due to a lack of interoperability, in many cases health professionals cannot access the complete medical records of their patients and cannot make optimal medical decisions for their diagnosis and treatment, which adds considerable costs both for health systems and for natural persons and can lead to worse health outcomes for natural persons. Electronic health data made available in an interoperable format and which can be transmitted between healthcare providers can also reduce the administrative burden on health professionals of manually entering or copying health data between electronic systems. Therefore, health professionals should be provided with appropriate electronic means, such as electronic devices and health professional portals or other health professional access services, to use personal electronic health data for the exercise of their duties. As it is difficult to exhaustively determine in advance which data from the existing data in priority categories are medically relevant in a specific episode of care, health professionals should have a wide access to data. When accessing data relating to their patients, health professionals should comply with the applicable law, codes of conduct, deontological guidelines or other provisions governing ethical conduct with respect to sharing or accessing information, particularly in life-threatening or extreme situations. In accordance with Regulation (EU) 2016/679, in order to limit their access to what is relevant in a specific episode of care, healthcare providers should follow the data minimisation principle when accessing personal electronic health data, limiting the data accessed to data that are strictly necessary and justified for a given service. Providing health professional access services is a task assigned in the public interest by this Regulation and the performance of such task requires the processing of personal data as referred to in Article 6(1), point (e), of Regulation (EU) 2016/679. This Regulation provides for conditions and safeguards for the processing of electronic health data by the health professional access service in accordance with Article 9(2), point (h), of Regulation (EU) 2016/679, for instance detailed provisions regarding logging of access to personal electronic health data and that aim to provide transparency towards data subjects. However, this Regulation should be without prejudice to national law concerning the processing of health data for the delivery of healthcare, including national law establishing categories of health professionals that can process different categories of electronic health data.医疗专业人员及时、全面地获取患者的医疗记录，对于确保医疗的连续性、避免重复和错误以及降低成本至关重要。然而，由于缺乏互操作性，在许多情况下，医疗专业人员无法获取患者完整的医疗记录，也就无法为诊断和治疗做出最佳的

医疗决策，这不仅给医疗系统和个人都带来了相当大的成本，还可能导致个人健康状况恶化。以互操作格式提供且可在医疗服务提供者之间传输的电子健康数据，还能减轻医疗专业人员在电子系统之间手动输入或复制健康数据的行政负担。因此，应向医疗专业人员提供适当的电子手段，如电子设备、医疗专业人员门户或其他医疗专业人员访问服务，以便他们在履行职责时使用个人电子健康数据。由于很难预先详尽确定优先类别中现有数据里哪些在特定的医疗过程中具有医学相关性，医疗专业人员应拥有广泛的数据访问权限。在访问其患者的相关数据时，医疗专业人员应遵守适用的法律、行为准则、职业道德指南或其他规范信息共享或访问相关道德行为的规定，尤其是在危及生命或极端情况下。根据《欧盟条例（EU）2016/679》，为了将访问权限限制在特定医疗过程的相关范围内，医疗服务提供者在访问个人电子健康数据时应遵循数据最小化原则，将访问的数据限制在特定服务严格必需且合理的数据范围内。提供医疗专业人员访问服务是本条例赋予的符合公共利益的任务，履行该任务需要按照《欧盟条例（EU）2016/679》第 6 条第（1）款（e）项的规定处理个人数据。本条例根据《欧盟条例（EU）2016/679》第 9 条第（2）款（h）项，为医疗专业人员访问服务处理电子健康数据规定了条件和保障措施，例如关于个人电子健康数据访问日志的详细规定，其目的是向数据主体提供透明度。然而，本条例不应妨碍关于为提供医疗服务而处理健康数据的国家法律，包括规定可处理不同类别电子健康数据的医疗专业人员类别的国家法律。

(20)In order to facilitate the exercise of the complementary access and portability rights established under this Regulation, Member States should establish one or more electronic health data access services. Those services could be provided at national, regional or local level, or by healthcare providers, in the form of an online patient portal, an application for mobile devices or by other means. They should be designed in an accessible way, in particular for persons with disabilities. Providing such a service to enable natural persons to have easy access to their personal electronic health data is a substantial public interest. The processing of personal electronic health data through those services is necessary for the performance of that task assigned by this Regulation in the sense of Article 6(1), point (e), and Article 9(2), point (g), of Regulation (EU) 2016/679. This Regulation lays down the necessary conditions and safeguards for the processing of electronic health data in electronic health data access services, such as electronic identification of natural persons accessing such services.为便于行使本条例所确立的补充访问权和可携带权，成员国应建立一个或多个电子健康数据访问服务。这些服务可在国家、地区或地方层面提供，也可由医疗服务提供者以在线患者门户、移动设备应用程序或其他方式提供。这些服务的设计应便于使用，特别是对残疾人而言。提供此类服务，使自然人能够便捷地访问其个人电子健康数据，具有重大的公共利益。通过这些服务处理个人电子健康数据，对于履行本条例根据《欧盟条例》（EU）2016/679 第 6 条第（1）款（e）项和第 9 条第（2）款（g）项所赋予的任务而言是必要的。本条例规定了在电子健康数据访问服务中处理电子健康数据的必要条件和保障措施，例如访问此类服务的自然人的电子身份识别。

(21)Natural persons should be able to provide an authorisation to other natural persons of their choice, such as their relatives or other close natural persons, enabling such persons of their choice to access or control the access to the personal electronic health data of the natural persons who provide the authorisation or to use digital health services on their behalf. Such authorisations could also be convenient for other usage by natural persons provided with such an authorisation. Proxy services for enabling and implementing such authorisations

should be established by Member States, and be linked to personal electronic health data access services such as patient portals or patient-facing applications for mobile devices. Those proxy services should also enable guardians to act on behalf of their dependents, including minors; in such situations, authorisations could be automatic. In addition to those proxy services, Member States should also establish easily accessible support services to be provided by adequately trained staff dedicated to assisting natural persons when exercising their rights. In order to take into account cases in which the display of some personal electronic health data of dependent persons to their guardians could be contrary to the interests or the will of their dependents, including minors, Member States should be able to provide in national law for limitations and safeguards as well as for mechanisms for their technical implementation. Personal electronic health data access services, such as patient portals or patient-facing applications for mobile devices, should make use of such authorisations and thus enable authorised natural persons to access personal electronic health data falling within the scope of the authorisation. In order to provide a horizontal solution with increased user-friendliness, digital proxy solutions should be aligned with Regulation (EU) No 910/2014 of the European Parliament and of the Council (7) and the technical specifications of the European Digital Identity Wallet. That alignment would contribute to reducing both the administrative and financial burden for Member States by lowering the risk of developing parallel systems that are not interoperable across the Union.
自然人应当能够向其选择的其他自然人（例如其亲属或其他关系密切的自然人）提供授权，使这些被选择的人能够访问或控制对提供授权的自然人的个人电子健康数据的访问，或代表他们使用数字健康服务。此类授权也可为获得授权的自然人的其他用途提供便利。成员国应建立用于启用和实施此类授权的代理服务，并将其与个人电子健康数据访问服务（如患者门户网站或面向患者的移动设备应用程序）相链接。这些代理服务还应使监护人能够代表其受监护人（包括未成年人）行事；在这种情况下，授权可以是自动的。除了这些代理服务外，成员国还应建立易于获取的支持服务，由受过充分培训的工作人员专门协助自然人行使其权利。考虑到向监护人展示受监护人（包括未成年人）的某些个人电子健康数据可能违背受监护人的利益或意愿，成员国应能在国内法中规定限制和保障措施，以及这些措施的技术实施机制。个人电子健康数据访问服务（如患者门户网站或面向患者的移动设备应用程序）应利用此类授权，从而使获得授权的自然人能够访问授权范围内的个人电子健康数据。为了提供一个更具用户友好性的横向解决方案，数字代理解决方案应与欧洲议会和理事会第 910/2014 号条例（EU）(7)以及欧洲数字身份钱包的技术规范保持一致。这种一致性将有助于降低成员国的行政和财政负担，因为它降低了开发在欧盟范围内无法互操作的并行系统的风险。

(22) In some Member States, healthcare is provided by primary care management teams, which are groups of health professionals focused on primary care, such as general practitioners, that carry out their primary care activities based on a healthcare plan that they draw up. Other types of healthcare teams also exist in several Member States for other care purposes. In the context of primary use in the EHDS, access should be provided to the health professionals belonging to such teams.在一些成员国，医疗服务由初级保健管理团队提供，这些团队是专注于初级保健的卫生专业人员群体，例如全科医生，他们根据自己制定的医疗计划开展初级保健活动。多个成员国还存在其他类型的医疗团队，用于其他护理目的。在电子健康数据空间的主要使用场景下，应向此类团队中的卫生专业人员提供访问权限。

(23)The supervisory authorities established pursuant to Regulation (EU) 2016/679 are competent for monitoring and enforcing the application of that Regulation, in particular for the monitoring of the processing of personal electronic health data and for handling any complaints lodged by the natural persons concerned. This Regulation establishes additional rights for natural persons regarding primary use, which go beyond and complement access and portability rights enshrined in Regulation (EU) 2016/679. Since those additional rights should also be enforced by the supervisory authorities established pursuant to Regulation (EU) 2016/679, Member States should ensure that those supervisory authorities are provided with the financial and human resources, premises and infrastructure necessary for the effective performance of those additional tasks. The supervisory authority or authorities responsible for the monitoring and enforcement of the processing of personal electronic health data for primary use in compliance with this Regulation should be competent to impose administrative fines. The legal system of Denmark does not allow for administrative fines as set out in this Regulation. The rules on administrative fines may be applied in such a manner that in Denmark the fines are imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent effect to administrative fines imposed by supervisory authorities. In any event, the fines imposed should be effective, proportionate and dissuasive.根据《欧盟条例（EU）2016/679》设立的监管机构有权监督和执行该条例的适用，特别是监督个人电子健康数据的处理以及处理相关自然人提出的任何投诉。本条例为自然人确立了关于主要用途的额外权利，这些权利超越并补充了《欧盟条例（EU）2016/679》所规定的访问权和可携带权。由于这些额外权利也应由根据《欧盟条例（EU）2016/679》设立的监管机构执行，成员国应确保为这些监管机构提供有效履行这些额外任务所需的财力、人力资源、办公场所和基础设施。负责监督和执行符合本条例的、用于主要用途的个人电子健康数据处理的一个或多个监管机构应有权处以行政罚款。丹麦的法律体系不允许本条例所规定的行政罚款。有关行政罚款的规则可在丹麦以如下方式适用，即由主管国家法院作为刑事处罚处以罚款，前提是这些规则的适用效果与监管机构处以的行政罚款相当。在任何情况下，所处以的罚款都应有效、适当且具有威慑力。

(24)Member States ought to strive to adhere to ethical principles, such as the European ethical principles for digital health adopted by the eHealth Network on 26 January 2022 and the principle of health professional-patient confidentiality, in the application of this Regulation. Recognising the importance of ethical principles, the European ethical principles for digital health provide guidance to practitioners, researchers, innovators, policy-makers and regulators.成员国在适用本条例时，应努力遵守伦理原则，例如电子健康网络于 2022 年 1 月 26 日通过的欧洲数字健康伦理原则，以及卫生专业人员与患者的保密原则。欧洲数字健康伦理原则认识到伦理原则的重要性，为从业者、研究人员、创新者、政策制定者和监管机构提供了指导。

(25)The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity as regards standardisation, and therefore the implementation of mechanisms for their exchange may be more or less complex depending on the category. Therefore, the improvement of interoperability and data sharing should be gradual and prioritisation of certain categories of electronic health data is needed. Categories of electronic health data such as patient

summaries, electronic prescriptions and dispensations, medical imaging studies and related imaging reports, medical test results such as laboratory results and related reports, and discharge reports have been selected by the eHealth Network as most relevant for the majority of healthcare situations and should be considered as priority categories for Member States to implement access to them and their transmission. Where such priority categories of data represent groups of electronic health data, this Regulation should apply to both the groups as a whole and to the individual data entries included in those groups. For example, given that vaccination status is part of a patient summary, the rights and requirements linked to the patient summary should also apply to such vaccination status even if it is processed separately from the patient summary as a whole. When further needs for the exchange of additional categories of electronic health data are identified for healthcare purposes, access to and exchange of those additional categories should be possible under this Regulation. The additional categories should be first implemented at Member State level and the exchange on a voluntary basis of such categories of data in cross-border situations between the cooperating Member States should be provided for in this Regulation. Particular attention should be given to data exchange in border regions of neighbouring Member States where the provision of cross-border health services is more frequent and needs even quicker procedures than across the Union in general.不同类别的电子健康数据在不同医疗场景中的相关性各不相同。就标准化而言，不同类别也达到了不同的成熟度，因此，其交换机制的实施复杂程度可能因类别而异。因此，互操作性和数据共享的改进应循序渐进，且需要对某些类别的电子健康数据确定优先顺序。电子健康网络已选定患者摘要、电子处方和配药记录、医学影像研究及相关影像报告、实验室结果等医学检测结果及相关报告、出院报告等电子健康数据类别，认为它们与大多数医疗情况最相关，成员国应将其视为优先类别，以实现对这些数据的访问和传输。如果此类优先数据类别构成电子健康数据组，本条例应适用于整个数据组以及这些组中包含的各个数据条目。例如，鉴于疫苗接种状态是患者摘要的一部分，与患者摘要相关的权利和要求也应适用于此类疫苗接种状态，即使其是与患者摘要整体分开处理的。当为医疗目的确定了对更多类别电子健康数据进行交换的进一步需求时，应能根据本条例对这些额外类别的数据进行访问和交换。这些额外类别应首先在成员国层面实施，本条例应规定合作成员国之间在跨境情况下自愿交换此类数据。应特别关注相邻成员国边境地区的数据交换，在这些地区，跨境医疗服务的提供更为频繁，且相较于欧盟整体而言，需要更快的流程。

(26)The level of availability of personal health and genetic data in an electronic format varies between Member States. The EHDS should make it easier for natural persons to have those data available in electronic format and to control better the access to and sharing of their personal electronic health data. This would also contribute to the achievement of the target of 100 % of Union citizens having access to their electronic health records by 2030, as referred to in Decision (EU) 2022/2481 of the European Parliament and of the Council [8]. In order to make electronic health data accessible and transmissible, such data should be accessed and transmitted in an interoperable common European electronic health record exchange format, at least for certain categories of electronic health data such as patient summaries, electronic prescriptions and dispensations, medical imaging studies and related imaging reports, medical test results and discharge reports, subject to transition periods. Where personal electronic health data are made available to a healthcare provider or a pharmacy by a natural person, or are transmitted by another controller in the European

electronic health record exchange format, that format should be accepted, and the recipient should be able to read the data and use them for the provision of healthcare or for dispensation of a medicinal product, thus supporting the provision of the healthcare services or the dispensation of the electronic prescription. The European electronic health record exchange format ought to be designed in a way that facilitates translation of electronic health data communicated using that format into the official languages of the Union, to the extent possible. Commission Recommendation (EU) 2019/243 (9) provides the foundations for such a common European electronic health record exchange format. The interoperability of the EHDS should contribute to having European health datasets of a high quality. The use of a European electronic health record exchange format should become more widespread at Union and national level. The European electronic health record exchange format could allow for different profiles for its use at the level of EHR systems and at the level of the national contact points for digital health in MyHealth@EU for cross-border data exchange.各成员国以电子格式提供个人健康和基因数据的水平存在差异。电子健康数据系统（EHDS）应使自然人能更便捷地以电子格式获取这些数据，并更好地控制其个人电子健康数据的访问和共享。这也将有助于实现到 2030 年欧盟所有公民都能访问其电子健康记录的目标，正如欧洲议会和理事会第（EU）2022/2481 号决定所述(8)。为了使电子健康数据可访问和可传输，此类数据应以可互操作的欧洲通用电子健康记录交换格式进行访问和传输，至少对于某些类别的电子健康数据是如此，例如患者摘要、电子处方和配药记录、医学影像研究及相关影像报告、医学检验结果和出院报告，但需遵循过渡期规定。当自然人向医疗服务提供者或药房提供个人电子健康数据，或另一控制者以欧洲电子健康记录交换格式传输这些数据时，接收方应接受该格式，并且能够读取这些数据，并将其用于提供医疗服务或配药，从而支持医疗服务的提供或电子处方的配药。欧洲电子健康记录交换格式的设计应尽可能便于将使用该格式传输的电子健康数据翻译成欧盟的官方语言。欧盟委员会第（EU）2019/243 号建议(9)为此类欧洲通用电子健康记录交换格式奠定了基础。电子健康数据系统的互操作性应有助于形成高质量的欧洲健康数据集。欧洲电子健康记录交换格式的使用应在欧盟和国家层面得到更广泛的推广。该欧洲电子健康记录交换格式可针对电子健康记录系统层面以及“我的健康@欧盟”中用于跨境数据交换的国家数字健康联络点层面的使用，设定不同的规范。

(27)While EHR systems are widespread, the level of digitalisation of health data varies in Member States depending on data categories and on the coverage of healthcare providers that register health data in electronic format. In order to support the application of data subjects' rights of access to and exchange of electronic health data, Union action is needed to avoid further fragmentation. In order to contribute to a high quality and continuity of healthcare, certain categories of health data should be registered in electronic format systematically and in accordance with specific data quality requirements. The European electronic health record exchange format should form the basis for specifications related to the registration and exchange of electronic health data.虽然电子健康记录系统已得到广泛应用，但各成员国健康数据的数字化水平因数据类别以及以电子格式记录健康数据的医疗服务提供者的覆盖范围而异。为了支持数据主体行使访问和交换电子健康数据的权利，欧盟需要采取行动，避免进一步的碎片化。为了助力高质量和连续性的医疗服务，某些类别的健康数据应当按照特定的数据质量要求，系统地以电子格式进行记录。欧洲电子健康记录交换格式应成为与电子健康数据记录和交换相关规范的基础。

(28)Telemedicine is becoming an increasingly important tool that can provide patients with access to care and tackle inequities. It has the potential to reduce health inequalities and reinforce the free movement of Union citizens across borders. Digital and other technological tools can facilitate the provision of care in remote regions. When digital services accompany the physical provision of a healthcare service, the digital service should be included in the overall care provision. Under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Member States are responsible for their health policy, in particular for the organisation and delivery of health services and medical care, including the regulation of activities such as online pharmacies, telemedicine and other services that they provide and provide reimbursement for, in line with their national legislation. Different healthcare policies should not, however, constitute barriers to the free movement of electronic health data in the context of cross-border healthcare, for example telemedicine and online pharmacy services.远程医疗正成为一种日益重要的工具，它能让患者获得医疗服务，并解决医疗不公平问题。远程医疗有望减少健康不平等现象，加强欧盟公民的跨境自由流动。数字及其他技术工具能够为偏远地区的医疗服务提供便利。当数字服务伴随实体医疗服务提供时，该数字服务应被纳入整体医疗服务范畴。根据《欧洲联盟运行条约》（TFEU）第168条，成员国对其卫生政策负责，特别是卫生服务和医疗护理的组织与提供，包括对在线药房、远程医疗及其他他们所提供并予以报销的服务等活动的监管，且需符合其国家立法。然而，在跨境医疗（例如远程医疗和在线药房服务）背景下，不同的医疗政策不应成为电子健康数据自由流动的障碍。

(29)Regulation (EU) No 910/2014 lays down the conditions under which Member States perform identification of natural persons in cross-border situations using identification means issued by another Member State, establishing rules for the mutual recognition of such electronic identification means. The EHDS requires secure access to electronic health data, including in cross-border situations. Electronic health data access services and telemedicine services should enable natural persons to exercise their rights regardless of their Member State of affiliation, and should therefore support the identification of natural persons using any electronic identification means recognised pursuant to Regulation (EU) No 910/2014. Given the possibility of challenges regarding identity matching in cross-border situations, it might be necessary for Member States of treatment to provide complementary access mechanisms such as tokens or codes to natural persons who arrive from other Member States and receive healthcare. The Commission should be empowered to adopt implementing acts to determine the requirements for the interoperable and cross-border identification and authentication of natural persons and health professionals, including any complementary mechanisms that are necessary to ensure that natural persons can exercise their rights related to personal electronic health data in cross-border situations.《(欧盟)第910/2014号条例》规定了成员国在跨境情况下使用另一成员国签发的身份识别工具对自然人进行身份识别的条件，确立了此类电子身份识别工具的互认规则。电子健康数据交换系统（EHDS）要求能够安全访问电子健康数据，包括在跨境情况下。电子健康数据访问服务和远程医疗服务应使自然人能够行使其权利，无论其所属的成员国为何，因此应支持使用根据《(欧盟)第910/2014号条例》获得认可的任何电子身份识别工具对自然人进行身份识别。鉴于在跨境情况下可能存在身份匹配方面的挑战，治疗所在成员国可能有必要向来自其他成员国并接受医疗服务的自然人提供补充性访问机制，如令牌或代码。应赋予欧盟委员会通过

实施法案的权力，以确定自然人及医疗专业人员的互操作性和跨境身份识别与认证要求，包括为确保自然人能在跨境情况下行使与其个人电子健康数据相关的权利所必需的任何补充机制。

(30)Member States should designate relevant digital health authorities for the planning and implementation of standards for access to and transmission of electronic health data and the enforcement of the rights of natural persons and health professionals, as separate organisations or as part of already existing authorities. The digital health authority staff should not have any financial or other interests in industries or economic activities which could affect their impartiality. Digital health authorities already exist in most of the Member States and they deal with EHRs, interoperability, security or standardisation. When carrying out their tasks, digital health authorities should cooperate in particular with the supervisory authorities established pursuant to Regulation (EU) 2016/679 and supervisory bodies established pursuant to Regulation (EU) No 910/2014. Digital health authorities can also cooperate with the European Artificial Intelligence Board established by Regulation (EU) 2024/1689 of the European Parliament and of the Council (10), the Medical Device Coordination Group established by Regulation (EU) 2017/745 of the European Parliament and of the Council (11), the European Data Innovation Board established pursuant to Regulation (EU) 2022/868 of the European Parliament and of the Council (12) and the competent authorities under Regulation (EU) 2023/2854 of the European Parliament and of the Council (13). Member States should facilitate the participation of national actors in the cooperation at Union level, the conveying of expertise and the provision of advice on the design of solutions necessary to achieve the goals of the EHDS.成员国应指定相关数字健康机构，负责电子健康数据访问和传输标准的规划与实施，以及自然人与卫生专业人员权利的执行。这些机构可以是独立组织，也可以是现有机构的组成部分。数字健康机构的工作人员不得在可能影响其公正性的行业或经济活动中拥有任何财务或其他利益。大多数成员国已设有数字健康机构，它们负责电子健康记录、互操作性、安全性或标准化方面的工作。在执行任务时，数字健康机构应特别与根据《欧盟条例（EU）2016/679》设立的监管机构以及根据《欧盟条例（EU）第 910/2014 号》设立的监督机构开展合作。数字健康机构还可与欧洲议会和理事会《欧盟条例（EU）2024/1689》设立的欧洲人工智能委员会(10)、欧洲议会和理事会《欧盟条例（EU）2017/745》设立的医疗器械协调小组(11)、根据欧洲议会和理事会《欧盟条例（EU）2022/868》设立的欧洲数据创新委员会(12)以及欧洲议会和理事会《欧盟条例（EU）2023/2854》规定的主管机构(13)开展合作。成员国应促进国家行为体参与欧盟层面的合作，协助传递专业知识，并就实现电子健康数据空间目标所需解决方案的设计提供建议。

(31)Without prejudice to any other administrative or non-judicial remedy, any natural or legal person should have the right to an effective judicial remedy against a legally binding decision of a digital health authority concerning them or where a digital health authority does not handle a complaint or does not inform the natural or legal person within three months about the progress or outcome of the complaint. Proceedings against a digital health authority should be brought before the courts of the Member States where the digital health authority is established.在不损害任何其他行政或非司法救济措施的前提下，任何自然人或法人应有权针对数字卫生机构作出的与其相关的具有法律约束力的决定，或者当数字卫生机构未处理投诉、或未在三个月内将投诉的进展情况或结果告知该自然人或法人时，获得有

效的司法救济。针对数字卫生机构的诉讼应向该机构所在成员国的法院提起。

(32)Digital health authorities should have sufficient technical skills, possibly by bringing together experts from different organisations. The activities of digital health authorities should be well-planned and monitored in order to ensure their efficiency. Digital health authorities should take the necessary measures to protect the rights of natural persons by setting up national, regional, and local technical solutions such as national EHR intermediation solutions and patient portals. When taking such necessary protective measures, digital health authorities should apply common standards and specifications in such solutions, promote the application of the standards and specifications in procurement procedures and use other innovative means including reimbursement of solutions that are compliant with interoperability and security requirements of the EHDS. Member States should ensure that appropriate training initiatives are taken. In particular, health professionals should be informed and trained with regard to their rights and obligations under this Regulation. To carry out their tasks, the digital health authorities should cooperate at Union and national level with other entities, including with insurance bodies, healthcare providers, health professionals, manufacturers of EHR systems and of wellness applications, as well as other stakeholders from the health or information technology sector, entities handling reimbursement schemes, health technology assessment bodies, medicinal products regulatory authorities and agencies, medical devices authorities, procurers and cybersecurity or e-ID authorities.数字健康主管部门应具备足够的技术技能，或许可以通过汇集不同组织的专家来实现。数字健康主管部门的活动应经过周密规划和监控，以确保其效率。数字健康主管部门应采取必要措施保护自然人的权利，建立国家、地区和地方层面的技术解决方案，例如国家电子健康档案中介解决方案和患者门户网站。在采取此类必要的保护措施时，数字健康主管部门应在这些解决方案中采用通用标准和规范，推动这些标准和规范在采购流程中的应用，并采用其他创新手段，包括为符合电子健康数据空间互操作性和安全要求的解决方案提供报销。成员国应确保开展适当的培训举措。特别是，应向卫生专业人员宣传并培训本条例规定的他们的权利和义务。为履行职责，数字健康主管部门应在欧盟和国家层面与其他实体开展合作，包括保险机构、医疗服务提供者、卫生专业人员、电子健康档案系统和健康应用程序制造商，以及卫生或信息技术领域的其他利益相关者、处理报销计划的实体、卫生技术评估机构、药品监管机构、医疗器械主管部门、采购方以及网络安全或电子身份主管部门。

(33)Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it can support continuity of healthcare when natural persons travel to other Member States or change their place of residence. Continuity of care and rapid access to personal electronic health data is even more important for residents in border regions who cross the border frequently to get healthcare. In many border regions, some specialised healthcare services might be available closer across the border than in the same Member State. Infrastructure is needed for the transmission of personal electronic health data across borders, in situations where a natural person is using services of a healthcare provider established in another Member State. The gradual expansion of such infrastructure and its funding should be considered. A voluntary infrastructure for that purpose, MyHealth@EU, was established as part of the actions to achieve the objectives set up in Directive 2011/24/EU of the European Parliament and of the Council [14]. Through MyHealth@EU,

Member States started to provide natural persons with the possibility of sharing their personal electronic health data with healthcare providers when travelling abroad. Building on that experience, the participation of Member States in MyHealth@EU as established by this Regulation should be mandatory. Technical specifications for MyHealth@EU should enable the exchange of priority categories of electronic health data as well as additional categories supported by the European electronic health record exchange format. Those specifications should be defined by means of implementing acts and should be based on the cross-border specifications of the European electronic health record exchange format, complemented by further specifications on cybersecurity, technical and semantic interoperability, operations and service management. Member States should be required to join MyHealth@EU, comply with its technical specifications and connect healthcare providers, including pharmacies, to it, as this is necessary for enabling natural persons to exercise their rights under this Regulation to access and make use of their personal electronic health data regardless of the Member State where the natural persons are located.在跨境医疗场景中，电子健康数据的获取和传输至关重要，因为当自然人前往其他成员国或变更居住地时，这有助于保障医疗的连续性。对于频繁跨境就医的边境地区居民而言，医疗的连续性以及快速获取个人电子健康数据尤为重要。在许多边境地区，一些专业医疗服务在邻国可能比在本国更容易获得。当自然人使用其他成员国境内医疗机构提供的服务时，需要有相应的基础设施来支持个人电子健康数据的跨境传输。应当考虑逐步扩展此类基础设施并解决其资金问题。作为实现《欧洲议会和理事会第 2011/24/EU 号指令》(14)所设定目标的行动之一，已建立了一个用于此目的的自愿性基础设施——MyHealth@EU。通过 MyHealth@EU，成员国开始让自然人能够在出国旅行时与医疗机构共享其个人电子健康数据。基于这一经验，本条例规定成员国必须参与 MyHealth@EU。MyHealth@EU 的技术规范应支持优先类别的电子健康数据以及欧洲电子健康记录交换格式所支持的其他类别的数据交换。这些规范应通过实施法案来确定，并以欧洲电子健康记录交换格式的跨境规范为基础，辅以关于网络安全、技术和语义互操作性、运营及服务管理的进一步规范。成员国应被要求加入 MyHealth@EU，遵守其技术规范，并将包括药房在内的医疗机构接入该系统，因为这是使自然人能够行使本条例赋予的权利、无论其身处哪个成员国都能获取和使用其个人电子健康数据所必需的。

(34)MyHealth@EU provides a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way to support cross-border healthcare, without affecting Member States' responsibilities before and after the transmission of personal electronic health data through it. Member States are responsible for the organisation of their national contact points for digital health and for the processing of personal data for the purposes of the delivery of healthcare, before and after the transmission of those data through MyHealth@EU. The Commission should monitor through compliance checks the compliance of national contact points for digital health with the necessary requirements regarding the technical development of MyHealth@EU as well as with detailed rules concerning the security, confidentiality and protection of personal electronic health data. In the event of serious non-compliance by a national contact point for digital health, the Commission should be able to suspend the services affected by the non-compliance provided by that national contact point for digital health. The Commission should act as a processor on behalf of the Member States within MyHealth@EU and should provide central services for it. To ensure compliance with data protection rules and to

provide a risk management framework for the transmission of personal electronic health data, the specific responsibilities of the Member States, as joint controllers, and the Commission's obligations as processor on their behalf should be specified by means of implementing acts. Each Member State is solely responsible for data and services in that Member State. This Regulation provides the legal basis for the processing of personal electronic health data in MyHealth@EU as a task carried out in the public interest assigned by Union law referred to in Article 6(1), point (e), of Regulation (EU) 2016/679. That processing is necessary for the provision of healthcare in cross-border situations, as mentioned in Article 9(2), point (h), of that Regulation.MyHealth@EU 为成员国提供了一个通用基础设施，确保以高效、安全的方式实现互联互通，以支持跨境医疗，同时不影响成员国在通过该基础设施传输个人电子健康数据前后的责任。成员国负责建立其国家数字健康联络点，并负责在通过 MyHealth@EU 传输个人数据前后，为提供医疗服务之目的处理这些个人数据。欧盟委员会应通过合规检查，监督国家数字健康联络点是否符合 MyHealth@EU 技术开发的必要要求，以及有关个人电子健康数据安全、保密和保护的详细规则。若国家数字健康联络点出现严重不合规情况，欧盟委员会应有权暂停该联络点提供的受不合规影响的服务。欧盟委员会应在 MyHealth@EU 内作为代表成员国的处理者，并为其提供中央服务。为确保符合数据保护规则，并为个人电子健康数据的传输提供风险管理框架，应以实施法案的形式明确作为联合控制者的成员国的具体责任，以及作为其代表的处理者的欧盟委员会的义务。每个成员国对其境内的数据和服务负全部责任。本条例为在 MyHealth@EU 中处理个人电子健康数据提供了法律依据，将其视为欧盟法律（《欧盟条例》2016/679 第 6 条第 1 款 e 项所指）赋予的为公共利益开展的任务。如该条例第 9 条第 2 款 h 项所述，此类处理对于跨境医疗服务的提供而言是必要的。

(35) In addition to services in MyHealth@EU for the exchange of personal electronic health data based on the European electronic health record exchange format, other services or supplementary infrastructures could be needed, for example in cases of public health emergencies or where the architecture of MyHealth@EU is not suitable for the implementation of some use cases. Examples of such use cases include support for vaccination card functionalities, including the exchange of information on vaccination plans, or verification of vaccination certificates or other health-related certificates. Such additional use cases would also be important for introducing additional functionality for handling public health crises, such as support for contact tracing for the purposes of containing infectious diseases. MyHealth@EU should support exchanges of personal electronic health data with national contact points for digital health of relevant third countries and systems established at international level by international organisations in order to contribute to the continuity of healthcare. This is particularly relevant for individuals travelling to and from neighbouring third countries, candidate countries, and the associated overseas countries and territories. The connection of such national contact points for digital health of third countries to MyHealth@EU and the interoperability with digital systems established at international level by international organisations should be subject to a check ensuring the compliance of those contact points and digital systems with the technical specifications, data protection rules and other requirements of MyHealth@EU. In addition, given that the connection to MyHealth@EU will entail transfers of personal electronic health data to third countries, such as sharing a patient summary when the patient seeks care in that third country, relevant transfer instruments under Chapter V of Regulation (EU) 2016/679 should be put in place.

The Commission should be empowered to adopt implementing acts to facilitate the connection of such national contact points for digital health of third countries and systems established at international level by international organisations to MyHealth@EU. When preparing those implementing acts, the Commission should take into account Member States' national security interests.除了"我的健康@欧盟"（MyHealth@EU）中基于欧洲电子健康记录交换格式的个人电子健康数据交换服务外，可能还需要其他服务或补充性基础设施，例如在突发公共卫生事件中，或者当"我的健康@欧盟"的架构不适用于某些用例的实施时。此类用例包括支持疫苗接种卡功能（含疫苗接种计划信息的交换），或疫苗接种证明及其他健康相关证明的验证。这些额外的用例对于增加应对公共卫生危机的功能也很重要，例如为控制传染病而提供的接触者追踪支持。 "我的健康@欧盟"应支持与相关第三国的国家数字健康联络点以及国际组织在国际层面建立的系统交换个人电子健康数据，以保障医疗服务的连续性。这一点对于往返于邻近第三国、候选国以及相关海外国家和地区的人员来说尤为重要。第三国的此类国家数字健康联络点与"我的健康@欧盟"的连接，以及与国际组织在国际层面建立的数字系统的互操作性，都应经过检查，以确保这些联络点和数字系统符合"我的健康@欧盟"的技术规范、数据保护规则及其他要求。此外，鉴于与"我的健康@欧盟"的连接将涉及向第三国传输个人电子健康数据（例如，当患者在第三国就医时共享患者摘要），应落实《欧盟条例（EU）2016/679》第五章规定的相关传输工具。应赋予欧盟委员会通过实施法案的权力，以促进第三国的此类国家数字健康联络点以及国际组织在国际层面建立的系统与"我的健康@欧盟"的连接。在制定这些实施法案时，欧盟委员会应考虑成员国的国家安全利益。

(36)In order to enable the seamless exchange of electronic health data and ensure respect for the rights of natural persons and health professionals, EHR systems marketed in the internal market should be able to store and transmit, in a secure way, high quality electronic health data. It is a key objective of the EHDS to ensure the secure and free movement of electronic health data across the Union. To that end, a mandatory conformity self-assessment scheme for EHR systems processing one or more priority categories of electronic health data should be established to overcome market fragmentation while ensuring a proportionate approach. Through the self-assessment, EHR systems will prove compliance with the requirements on interoperability, security and logging for communication of personal electronic health data established by the two mandatory EHR software components harmonised by this Regulation, namely the European interoperability software component for EHR systems and the European logging software component for EHR systems (the 'harmonised software components of EHR systems'). The harmonised software components of EHR systems mainly concern data transformation, although they may imply the need for indirect requirements for data registration and data presentation in EHR systems. Technical specifications for the harmonised software components of EHR systems should be defined by means of implementing acts and should be based on the use of the European electronic health record exchange format. The harmonised software components of EHR systems should be designed to be reusable and to integrate seamlessly with other components within a larger software system. The security requirements of the harmonised software components of EHR systems should cover elements specific to EHR systems, as more general security properties should be supported by other mechanisms such as those under Regulation (EU) 2024/2847 of the European Parliament and of the Council [15]. To support that process, European digital testing environments should be set up to provide automated means to test whether the functioning

of the harmonised software components of an EHR system is compliant with the requirements laid down in this Regulation. To that end, implementing powers should be conferred on the Commission to determine the common specifications for those environments. The Commission should develop the necessary software for the testing environments and make it available as open source. Member States should be responsible for the operation of the digital testing environments, as they are closer to manufacturers and better placed to support them. Manufacturers should use those digital testing environments to test their products before placing them on the market while continuing to bear full responsibility for the compliance of their products. The results of the test should become part of the product's technical documentation. Where the EHR system or any part of it complies with European standards or common specifications, the list of the relevant European standards and common specifications should also be indicated in the technical documentation. To support the comparability of EHR systems, the Commission should prepare a uniform template for the technical documentation accompanying such systems.为了实现电子健康数据的无缝交换，并确保尊重自然人与卫生专业人员的权利，在内部市场销售的电子健康记录（EHR）系统应当能够以安全的方式存储和传输高质量的电子健康数据。电子健康数据空间（EHDS）的一个关键目标是确保电子健康数据在欧盟范围内的安全且自由流动。为此，应当建立一套针对处理一种或多种优先类别电子健康数据的电子健康记录系统的强制性合规自我评估机制，以克服市场碎片化问题，同时确保采取适度的方法。 通过自我评估，电子健康记录系统将证明其符合本条例所协调的两个强制性电子健康记录软件组件（即电子健康记录系统的欧洲互操作性软件组件和电子健康记录系统的欧洲日志软件组件，以下简称"电子健康记录系统的协调软件组件"）所规定的关于个人电子健康数据通信的互操作性、安全性和日志记录要求。电子健康记录系统的协调软件组件主要涉及数据转换，不过它们可能意味着电子健康记录系统在数据注册和数据呈现方面需要满足间接要求。 电子健康记录系统协调软件组件的技术规范应当通过实施法案来确定，并应以欧洲电子健康记录交换格式的使用为基础。电子健康记录系统的协调软件组件应当设计为可重用的，并且能够与更大软件系统中的其他组件无缝集成。电子健康记录系统协调软件组件的安全要求应当涵盖电子健康记录系统特有的要素，而更通用的安全属性则应由其他机制来支持，例如欧洲议会和理事会第（EU）2024/2847 号条例所规定的机制（15）。 为支持这一过程，应当建立欧洲数字测试环境，以提供自动化手段来测试电子健康记录系统的协调软件组件的功能是否符合本条例规定的要求。为此，应当赋予欧盟委员会制定这些环境的共同规范的实施权。欧盟委员会应当开发测试环境所需的软件，并以开源形式提供。 成员国应当负责数字测试环境的运营，因为它们更接近制造商，也更有能力为制造商提供支持。制造商在将产品投放市场前，应当使用这些数字测试环境对其产品进行测试，同时仍需对其产品的合规性承担全部责任。测试结果应当成为产品技术文档的一部分。如果电子健康记录系统或其任何部分符合欧洲标准或共同规范，相关的欧洲标准和共同规范清单也应当在技术文档中注明。 为支持电子健康记录系统的可比性，欧盟委员会应当为随此类系统提供的技术文档制定统一模板。

(37) EHR systems should be accompanied by an information sheet that includes information for its professional users and by clear and complete instructions for use, including in accessible formats for persons with disabilities. If an EHR system is not accompanied by such information, the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators should be required to add to the EHR system that

information sheet and those instructions for use.电子健康记录系统应附带一份信息表，其中包含面向专业用户的信息，以及清晰完整的使用说明，包括为残障人士提供的易获取格式版本。如果电子健康记录系统未附带此类信息，则相关电子健康记录系统的制造商、其授权代表及所有其他相关经济运营商应被要求为该电子健康记录系统补充上述信息表和使用说明。

(38)While EHR systems specifically intended by the manufacturer to be used for processing one or more specific categories of electronic health data should be subject to mandatory self-certification, software for general purposes should not be considered to be an EHR system, even when used in a healthcare setting, and should therefore not be required to comply with this Regulation. That covers cases such as text-processing software used for writing reports that would then become part of written electronic health records, general-purpose middleware, or database management software that is used as part of data storage solutions.虽然制造商明确意图用于处理一种或多种特定类别的电子健康数据的电子健康记录系统应接受强制性自我认证，但通用软件不应被视为电子健康记录系统，即使是在医疗环境中使用，因此也不应被要求遵守本条例。这包括诸如用于编写报告（这些报告随后将成为书面电子健康记录的一部分）的文字处理软件、通用中间件，或用作数据存储解决方案一部分的数据库管理软件等情况。

(39)This Regulation imposes a mandatory conformity self-assessment scheme for the harmonised software components of EHR systems to ensure that EHR systems placed on the Union market are able to exchange data in the European electronic health record exchange format and that they have the required logging capabilities. That mandatory conformity self-assessment, which would be in the form of an EU declaration of conformity by the manufacturer, should ensure that those requirements are fulfilled in a proportionate way, while avoiding an undue burden on Member States and manufacturers.本条例对电子健康记录系统的统一软件组件实施强制性合格自我评估计划，以确保投放欧盟市场的电子健康记录系统能够以欧洲电子健康记录交换格式交换数据，并具备所需的日志记录能力。这种强制性合格自我评估将以制造商出具欧盟合格声明的形式进行，其应确保这些要求以适当的方式得到满足，同时避免给成员国和制造商带来不必要的负担。

(40)Manufacturers should affix in the accompanying documents of the EHR system, and where applicable on its packaging, a CE marking of conformity indicating that the EHR system is in conformity with this Regulation and, in respect of aspects not covered by this Regulation, with other applicable Union law which also requires the affixing of such marking. Member States should build upon existing mechanisms to ensure the correct application of the provisions on the CE marking of conformity under relevant Union law and should take appropriate action in the event of improper use of that marking.制造商应在电子健康记录系统的随附文件中，以及在适用情况下在其包装上，加贴 CE 合格标志，以表明该电子健康记录系统符合本法规的要求，并且在本法规未涵盖的方面，符合其他要求加贴此类标志的适用欧盟法律。成员国应利用现有机制，确保相关欧盟法律中关于 CE 合格标志规定的正确实施，并在该标志被不当使用时采取适当行动。

(41)Member States should remain competent to define requirements relating to any other software components of EHR systems and the terms and conditions for connection of healthcare providers to their respective national infrastructures, which could be subject to third-party assessment at national level. In order to facilitate the smooth functioning of the

internal market for EHR systems, digital health products and associated services, it is necessary to ensure as much as possible transparency as regards national law establishing requirements for EHR systems and provisions on their conformity assessment in relation to aspects other than the harmonised software components of EHR systems. Therefore, Member States should inform the Commission of those national requirements so it has the necessary information to ensure that they do not adversely affect the harmonised software components of EHR systems.成员国应保留权限，以制定与电子健康记录系统的任何其他软件组件相关的要求，以及医疗服务提供者接入其各自国家基础设施的条款和条件，这些可能需要在国家层面接受第三方评估。为促进电子健康记录系统、数字健康产品及相关服务内部市场的顺畅运行，有必要在国家法律方面确保尽可能高的透明度，这些法律规定了电子健康记录系统的要求以及除电子健康记录系统的统一软件组件之外其他方面的合格评定条款。因此，成员国应将这些国家要求告知委员会，以便委员会掌握必要信息，确保这些要求不会对电子健康记录系统的统一软件组件产生不利影响。

(42)Certain software components of EHR systems could be considered medical devices under Regulation (EU) 2017/745 or *in vitro* diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council ([16]). Software or modules of software which fall within the definition of a medical device, *in vitro* diagnostic medical devices or an artificial intelligence (AI) system considered to be high-risk (the 'high-risk AI system') should be certified in accordance with Regulations (EU) 2017/745, (EU) 2017/746 and (EU) 2024/1689, as applicable. While such products are required to fulfil the requirements under the respective Regulation governing those products, Member States should take appropriate measures to ensure that the respective conformity assessment is carried out as a joint or coordinated procedure in order to limit the administrative burden on manufacturers and other economic operators. The essential requirements on interoperability of this Regulation should only apply to the extent that the manufacturer of a medical device, an *in vitro* diagnostic medical device, or a high-risk AI system, which is providing electronic health data to be processed as part of the EHR system, claims interoperability with such EHR system. In such case, the provisions on common specifications for EHR systems should be applicable to those medical devices, *in vitro* diagnostic medical devices and high-risk AI systems.根据欧洲议会和理事会的《(EU) 2017/745 号条例》，电子健康记录（EHR）系统的某些软件组件可被视为医疗器械；根据《(EU) 2017/746 号条例》，则可被视为体外诊断医疗器械(16)。符合医疗器械、体外诊断医疗器械定义的软件或软件模块，以及被视为高风险的人工智能（AI）系统（即"高风险 AI 系统"），应根据适用的《(EU) 2017/745 号条例》《(EU) 2017/746 号条例》和《(EU) 2024/1689 号条例》进行认证。虽然此类产品须满足管辖这些产品的相应条例的要求，但成员国应采取适当措施，确保以联合或协调程序开展相应的合格评定，以减轻制造商和其他经济运营商的行政负担。本条例中关于互操作性的基本要求，仅适用于以下情况：提供将作为电子健康记录系统一部分进行处理的电子健康数据的医疗器械、体外诊断医疗器械或高风险 AI 系统的制造商，声称其与该电子健康记录系统具有互操作性。在这种情况下，关于电子健康记录系统通用规范的规定应适用于这些医疗器械、体外诊断医疗器械和高风险 AI 系统。

(43)To further support interoperability and security, Member States should be able to maintain or define specific rules for the procurement, reimbursement or financing of EHR systems at national level in the context of the organisation, delivery or financing of health services. Such

specific rules should not impede the free movement of EHR systems in the Union. Some Member States have introduced mandatory certification of EHR systems or mandatory interoperability testing for their connection to national digital health services. Such requirements are commonly reflected in procurement procedures organised by healthcare providers and national or regional authorities. The mandatory certification of EHR systems at Union level should establish a baseline that can be used in procurement procedures at national level.为进一步支持互操作性和安全性，成员国应能够在医疗服务的组织、提供或融资范围内，在国家层面维持或制定关于电子健康记录系统采购、报销或融资的具体规则。此类具体规则不应阻碍电子健康记录系统在欧盟内的自由流通。一些成员国已引入电子健康记录系统的强制认证，或对其与国家数字健康服务的连接实施强制互操作性测试。这些要求通常体现在医疗服务提供者以及国家或地区当局组织的采购程序中。欧盟层面的电子健康记录系统强制认证应确立一个基准，该基准可用于国家层面的采购程序。

(44)In order to guarantee the effective exercise by patients of their rights under this Regulation, healthcare providers developing and using an EHR system 'in-house' to carry out internal activities without placing it on the market in return for payment or remuneration should also comply with this Regulation. In that context, such healthcare providers should comply with all requirements applicable to manufacturers as regards such EHR systems that are developed 'in-house' and that such healthcare providers put into service. However, given that the healthcare providers may need additional time to prepare for compliance with this Regulation, those requirements should only apply to such systems after an extended transitional period.为确保患者有效行使本条例规定的权利，自行开发和使用电子健康记录系统（EHR 系统）以开展内部活动、且不将该系统投放市场以换取报酬或薪酬的医疗服务提供者，也应遵守本条例。在此情况下，此类医疗服务提供者应遵守适用于制造商的所有要求，这些要求涉及他们自行开发并投入使用的电子健康记录系统。然而，鉴于医疗服务提供者可能需要额外时间为遵守本条例做准备，这些要求仅应在延长的过渡期后适用于此类系统。

(45)It is necessary to provide for a clear and proportionate distribution of obligations corresponding to the role of each economic operator in the supply and distribution process of EHR systems. Economic operators should be responsible for compliance in relation to their respective roles in such process and should ensure that they make available on the market only EHR systems which comply with relevant requirements.有必要根据每个经济运营商在电子健康记录系统供应和分销过程中所扮演的角色，明确且适度地分配责任。经济运营商应负责在该过程中履行与其各自角色相关的合规义务，并确保其投放市场的电子健康记录系统均符合相关要求。

(46)Compliance with essential requirements on interoperability and security should be demonstrated by the manufacturers of EHR systems through the implementation of common specifications. To that end, implementing powers should be conferred on the Commission to determine such common specifications regarding datasets, coding systems, technical specifications, standards, specifications and profiles for data exchange, as well as requirements and principles related to patient safety and the security, confidentiality, integrity and protection of personal data, and specifications and requirements related to identification management and the use of electronic identification. Digital health authorities

should contribute to the development of such common specifications. Where applicable, those common specifications should be based on existing harmonised standards for the harmonised software components of EHR systems and be compatible with sectoral law. Where common specifications have a particular importance in relation to personal data protection requirements concerning EHR systems, they should be subject to consultation with the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) before their adoption, pursuant to Article 42(2) of Regulation (EU) 2018/1725.电子健康记录系统制造商应通过实施通用规范，证明其符合互操作性和安全性方面的基本要求。为此，应赋予欧盟委员会制定此类通用规范的执行权，这些规范涉及数据集、编码系统、技术规范、标准、数据交换规范和概要，以及与患者安全、个人数据的安全性、保密性、完整性和保护相关的要求和原则，还有与身份管理和电子身份使用相关的规范和要求。数字健康主管部门应助力此类通用规范的制定。在适用情况下，这些通用规范应以电子健康记录系统统一软件组件的现有统一标准为基础，并与行业法律相兼容。若通用规范在涉及电子健康记录系统的个人数据保护要求方面具有特殊重要性，则根据《欧盟条例》（EU）2018/1725 第 42（2）条，在通过前应征求欧洲数据保护委员会（EDPB）和欧洲数据保护监督员（EDPS）的意见。

(47)In order to ensure there is appropriate and effective enforcement of the requirements and obligations laid down in this Regulation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 of the European Parliament and of the Council [17] should apply. Depending on the organisation defined at national level, such market surveillance activities could be carried out by the digital health authorities ensuring the proper implementation of Chapter II of this Regulation or by a separate market surveillance authority responsible for EHR systems. While designating digital health authorities as market surveillance authorities could have significant practical advantages for the implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.为确保本条例规定的要求和义务得到适当且有效的执行，应适用欧洲议会和理事会第(EU)2019/1020 号条例(17)所确立的产品市场监督与合规体系。根据国家层面确定的组织架构，此类市场监督活动可由负责确保本条例第二章正确实施的数字健康主管部门执行，也可由负责电子健康记录系统的独立市场监督机构执行。虽然指定数字健康主管部门作为市场监督机构可能为医疗和护理的实施带来显著的实际优势，但应避免任何利益冲突，例如通过分离不同任务来实现。

(48)The staff of market surveillance authorities should have no direct or indirect economic, financial or personal conflicts of interest that might be considered prejudicial to their independence and, in particular, they should not be in a situation that could, directly or indirectly, affect the impartiality of their professional conduct. Member States should determine and publish the selection procedure for market surveillance authorities. They should ensure that the procedure is transparent and does not allow conflicts of interest.市场监管机构的工作人员不应存在可能被视为损害其独立性的直接或间接经济、财务或个人利益冲突，特别是不应处于可能直接或间接影响其职业行为公正性的境地。成员国应确定并公布市场监管机构的选拔程序。它们应确保该程序透明且不存在利益冲突。

(49)Users of wellness applications, including applications for mobile devices, should be informed about the capacity of such applications to be connected and to supply data to EHR systems or to national electronic health solutions in cases where data produced by wellness applications

are useful for healthcare purposes. The capability of those applications to export data in an interoperable format is also relevant for data portability purposes. Where applicable, users should also be informed about the compliance of such wellness applications with interoperability and security requirements. However, given the large number of wellness applications and the limited relevance for healthcare purposes of the data produced by many of them, a certification scheme for these applications would not be proportionate. A mandatory labelling scheme for wellness applications for which interoperability with EHR systems is claimed should therefore be established as an appropriate mechanism for providing transparency for the users of wellness applications regarding compliance with requirements under this Regulation, thereby supporting users in their choice of appropriate wellness applications with high standards of interoperability and security. The Commission should set out by means of implementing acts the details regarding the format and content of such label.健康类应用程序（包括移动设备应用程序）的用户应当了解，当这些应用程序生成的数据可用于医疗保健目的时，此类应用程序能够连接并向电子健康记录（EHR）系统或国家电子健康解决方案提供数据。这些应用程序以互操作格式导出数据的能力，对于数据可携带性而言也十分重要。在适用情况下，还应告知用户此类健康类应用程序是否符合互操作性和安全性要求。然而，鉴于健康类应用程序数量众多，且其中许多应用程序生成的数据与医疗保健目的的相关性有限，为这些应用程序制定认证计划并不合理。因此，对于声称可与电子健康记录系统互操作的健康类应用程序，应建立强制性标签制度，以此作为一种适当机制，向健康类应用程序用户透明化展示其是否符合本条例的要求，从而帮助用户选择具有高标准互操作性和安全性的合适健康类应用程序。欧盟委员会应通过实施法案，规定此类标签的格式和内容细节。

(50)Member States should remain free to regulate other aspects of the use of wellness applications, provided that the corresponding rules are in compliance with Union law.成员国应保留对健康应用程序使用的其他方面进行监管的自由，前提是相应规则符合欧盟法律。

(51)The distribution of information on certified EHR systems and labelled wellness applications is necessary to enable procurers and users of such products to find interoperable solutions for their specific needs. A database of interoperable EHR systems and wellness applications, which do not fall within the scope of Regulations (EU) 2017/745 and (EU) 2024/1689, should therefore be established at Union level, similar to the European database on medical devices (Eudamed) established by Regulation (EU) 2017/745. The objectives of the EU database for registration of EHR systems and wellness applications should be to enhance overall transparency, to avoid multiple reporting requirements and to streamline and facilitate the flow of information. For medical devices and AI systems, the registration should be maintained under the existing databases established, respectively, under Regulations (EU) 2017/745 and (EU) 2024/1689, but the compliance with interoperability requirements should be indicated by manufacturers when they claim such compliance, in order to provide information to procurers.对经过认证的电子健康记录系统和带有标签的健康应用程序的信息进行分发是必要的，这能让此类产品的采购者和用户找到符合其特定需求的互操作性解决方案。因此，应在欧盟层面建立一个互操作性电子健康记录系统和健康应用程序数据库，这些系统和应用程序不在《欧盟条例》（EU）2017/745 和（EU）2024/1689 的范围内，该数据库类似于根据《欧盟条例》（EU）2017/745 建立的欧洲医疗器械数据库

（Eudamed）。欧盟电子健康记录系统和健康应用程序注册数据库的目标应是提高整体透明度，避免多重报告要求，并简化和促进信息流动。对于医疗器械和人工智能系统，注册应分别在根据《欧盟条例》（EU）2017/745 和（EU）2024/1689 建立的现有数据库中进行维护，但制造商在声称符合互操作性要求时，应注明其符合情况，以便向采购者提供信息。

(52)Without hindering or replacing contractual arrangements or other mechanisms in place, this Regulation is aimed at establishing a common mechanism to access electronic health data for secondary use across the Union. Under that mechanism, health data holders should make the data they hold available on the basis of a data permit or a health data request. For the purpose of processing electronic health data for secondary use, one of the legal bases referred to in Article 6(1), points (a), (c), (e) or (f), of Regulation (EU) 2016/679 in conjunction with Article 9(2) thereof is required. Accordingly, this Regulation provides for a legal basis for the secondary use of personal electronic health data, including the safeguards required under Article 9(2), points (g) to (j), of Regulation (EU) 2016/679 to allow the processing of special categories of data, in terms of lawful purposes, trusted governance for providing access to health data through the involvement of health data access bodies, and processing in a secure processing environment, as well as arrangements for data processing, set out in the data permit. Consequently, Member States should no longer be able to maintain or introduce under Article 9(4) of Regulation (EU) 2016/679 further conditions, including limitations and specific provisions requesting the consent of natural persons, with regard to the processing for secondary use of personal electronic health data under this Regulation, with the exception of the introduction of stricter measures and additional safeguards at national level aimed at safeguarding the sensitivity and value of certain data as laid down in this Regulation. Health data applicants should also demonstrate a legal basis referred to in Article 6 of Regulation (EU) 2016/679 that allows them to request access to electronic health data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV thereof. In addition, the health data access body should assess the information provided by the health data applicant, based on which it should be able to issue a data permit for the processing of personal electronic health data pursuant to this Regulation that should fulfil the requirements and conditions set out in Chapter IV of this Regulation. For processing of electronic health data held by the health data holders, this Regulation creates the legal obligation within the meaning of Article 6(1), point (c), of Regulation (EU) 2016/679, in accordance with Article 9(2), points (i) and (j), of that Regulation, for the health data holder to make available the personal electronic health data to health data access bodies, while the legal basis for the purpose of the initial processing, for example the delivery of healthcare, is unaffected. This Regulation also assigns tasks in the public interest within the meaning of Article 6(1), point (e), of Regulation (EU) 2016/679 to the health data access bodies, and meets the requirements of Article 9(2), points (g) to (j), as applicable, of that Regulation. If the health data user relies upon a legal basis set out in Article 6(1), point (e) or (f), of Regulation (EU) 2016/679, this Regulation should provide for the safeguards required under Article 9(2) of Regulation (EU) 2016/679.在不妨碍或替代现行合同安排或其他机制的前提下，本条例旨在建立一个在欧盟范围内获取电子健康数据用于二次使用的共同机制。根据该机制，健康数据持有者应基于数据许可或健康数据请求，提供其持有的数据。为将电子健康数据用于二次处理，需依据《欧盟条例（EU）2016/679》第 6 条第（1）款（a）、

（c）、（e）或（f）项，并结合该条例第 9 条第（2）款所述的法律依据之一。因此，本条例为个人电子健康数据的二次使用提供了法律依据，包括《欧盟条例（EU）2016/679》第 9 条第（2）款（g）至（j）项所要求的保障措施，以允许处理特殊类别的数据，具体体现在合法目的、通过健康数据访问机构参与提供健康数据访问的可信治理、在安全处理环境中进行处理，以及数据许可中规定的数据处理安排。 因此，成员国不应再能够根据《欧盟条例（EU）2016/679》第 9 条第（4）款，针对本条例所规定的个人电子健康数据二次使用处理，维持或引入进一步的条件，包括限制和要求自然人同意的具体规定，但本条例规定的在国家层面为保护某些数据的敏感性和价值而引入的更严格措施和额外保障除外。健康数据申请人还应证明其具备《欧盟条例（EU）2016/679》第 6 条所述的法律依据，使其能够根据本条例请求访问电子健康数据，并应满足该条例第四章规定的条件。此外，健康数据访问机构应评估健康数据申请人提供的信息，并据此能够根据本条例签发用于处理个人电子健康数据的数据许可，该许可应满足本条例第四章规定的要求和条件。 对于健康数据持有者持有的电子健康数据的处理，本条例根据《欧盟条例（EU）2016/679》第 9 条第（2）款（i）和（j）项，为健康数据持有者设定了《欧盟条例（EU）2016/679》第 6 条第（1）款（c）项所指的法律义务，要求其向健康数据访问机构提供个人电子健康数据，而初始处理（例如提供医疗服务）的法律依据不受影响。本条例还为健康数据访问机构分配了《欧盟条例（EU）2016/679》第 6 条第（1）款（e）项所指的公共利益任务，并符合该条例第 9 条第（2）款（g）至（j）项（如适用）的要求。如果健康数据使用者依据《欧盟条例（EU）2016/679》第 6 条第（1）款（e）或（f）项规定的法律依据，本条例应提供《欧盟条例（EU）2016/679》第 9 条第（2）款所要求的保障措施。

(53)Electronic health data used for secondary use can bring great societal benefits. The uptake of real-world data and real-world evidence, including patient-reported outcomes, for evidence-based regulatory and policy purposes as well as for research, health technology assessment and clinical objectives should be encouraged. Real-world data and real-world evidence have the potential to complement health data currently made available. To achieve that goal, it is important that datasets made available for secondary use pursuant to this Regulation be as complete as possible. This Regulation provides the necessary safeguards to mitigate certain risks involved in the achievement of those benefits. The secondary use of electronic health data is based on pseudonymised or anonymised data, in order to preclude the identification of the data subjects.用于二次使用的电子健康数据可带来巨大的社会益处。应鼓励将真实世界数据和真实世界证据（包括患者报告的结局）用于循证监管和政策目的，以及研究、卫生技术评估和临床目标。真实世界数据和真实世界证据有望对当前可获取的健康数据起到补充作用。为实现这一目标，根据本条例可供二次使用的数据集应尽可能完整，这一点至关重要。本条例提供了必要的保障措施，以降低在实现这些益处过程中涉及的某些风险。电子健康数据的二次使用基于假名化或匿名化的数据，以防止识别数据主体。

(54)To balance the need of health data users to have exhaustive and representative datasets with the need for autonomy of natural persons over personal electronic health data of theirs that are considered particularly sensitive, natural persons should be able to make the decision as to whether their personal electronic health data can be processed for secondary use under this Regulation, in the form of a right to opt out from having those data being made available for secondary use. An easily understandable and accessible user-friendly mechanism to

exercise that right to opt out should be provided for. Moreover, it is imperative to provide natural persons with sufficient and complete information regarding their right to opt out, including on the benefits and drawbacks entailed by exercising that right. Natural persons should not be required to give any reasons for opting out and should have the possibility of reconsidering their choice at any time. However, for certain purposes with a strong link to the public interest, such as activities for protection against serious cross-border threats to health or scientific research for important reasons of public interest, it is appropriate to provide for a possibility for Member States to establish, taking into account their national context, mechanisms to provide access to personal electronic health data of natural persons who have exercised their right to opt out, to ensure that complete datasets can be made available in those situations. Such mechanisms should comply with the requirements established for secondary use under this Regulation. Scientific research for important reasons of public interest could for example include research addressing unmet medical needs, including for rare diseases, or emerging health threats. The rules on such overrides should respect the essence of the fundamental rights and freedoms and be a necessary and proportionate measure in a democratic society to fulfil the public interest in relation to legitimate scientific and societal objectives. Such overrides should only be available to health data users that are public sector bodies, or relevant Union institutions, bodies, offices or agencies, entrusted with the performance of tasks in the area of public health, or to another entity entrusted with the performance of public tasks in the area of public health or acting on behalf of or commissioned by a public authority, and only where the data cannot be obtained by alternative means in a timely and effective manner. Those health data users should justify that the use of the override is necessary for an individual health data access application or health data request. When such an override is applied, the safeguards under Chapter IV should continue to be applied by health data users, in particular the prohibition of re-identification or attempting to re-identify the natural persons concerned.为了平衡健康数据使用者对详尽且具代表性数据集的需求，与自然人对其被视为特别敏感的个人电子健康数据的自主控制权之间的关系，自然人应当有权决定其个人电子健康数据是否可依据本条例用于二次处理，具体形式为有权选择不将其数据用于二次用途。应当提供一种易于理解、便于获取且用户友好的机制，以行使这种退出权。此外，必须向自然人提供关于其退出权的充分且完整的信息，包括行使该权利所带来的益处和弊端。自然人无需为选择退出提供任何理由，并且应当能够随时重新考虑其选择。 然而，对于某些与公共利益密切相关的目的，例如为防范严重的跨境健康威胁而开展的活动，或出于重要公共利益原因进行的科学研究，成员国应当有权根据本国国情，建立相关机制，允许访问已行使退出权的自然人的个人电子健康数据，以确保在这些情况下能够提供完整的数据集。此类机制应符合本条例中关于二次使用的规定。出于重要公共利益原因的科学研究可包括，例如针对未被满足的医疗需求（包括罕见疾病）或新出现的健康威胁所开展的研究。 有关此类例外情况的规定应当尊重基本权利和自由的本质，并且是民主社会中为实现与合法的科学和社会目标相关的公共利益所采取的必要且相称的措施。此类例外情况仅应适用于公共部门机构、或受委托执行公共卫生领域任务的相关欧盟机构、团体、办事处或代理机构，或受委托执行公共卫生领域公共任务、或代表公共当局行事或受公共当局委托的其他实体，且仅在无法通过其他方式及时有效地获取数据时适用。这些健康数据使用者应当证明，在特定的健康数据访问申请或健康数据请求中，使用该例外情况是必要的。当适用此类例外情况时，健康数据使用者应当继续遵守第四章规定的保障

措施，特别是禁止识别或试图识别相关自然人的规定。

(55)In the context of the EHDS, electronic health data already exist and are being collected by, among others, healthcare providers, professional associations, public institutions, regulators, researchers and insurers in the course of their activities. Those data should also be made available for secondary use, that is to say for processing of data for purposes other than those for which they were collected or produced, however, many of such data are not made available for processing for such purposes. This limits the ability of researchers, innovators, policy-makers, regulators and doctors to use those data for different purposes, including research, innovation, policymaking, regulatory purposes, patient safety or personalised medicine. In order to fully exploit the benefits of secondary use, all health data holders should contribute to this effort in making different categories of electronic health data they are holding available for secondary use, provided that such effort is always made through effective and secured processes, with due respect for professional duties, such as confidentiality duties.在电子健康数据空间（EHDS）的背景下，电子健康数据已经存在，并且在医疗服务提供者、专业协会、公共机构、监管机构、研究人员和保险公司等机构的活动过程中被收集。这些数据还应可供二次使用，也就是说，用于除最初收集或生成数据的目的之外的其他数据处理目的。然而，许多此类数据并未用于这些目的的处理。这限制了研究人员、创新者、政策制定者、监管机构和医生将这些数据用于不同目的的能力，包括研究、创新、政策制定、监管目的、患者安全或个性化医疗。为了充分利用二次使用的益处，所有健康数据持有者都应为此做出贡献，提供其持有的各类电子健康数据供二次使用，但前提是，此类工作必须通过有效且安全的流程进行，并适当尊重职业义务，如保密义务。

(56)The categories of electronic health data that can be processed for secondary use should be broad and flexible enough to accommodate the evolving needs of health data users, while remaining limited to data related to health or known to influence health. They can also include relevant data from the health system, for example electronic health records, claims data, dispensation data, data from disease registries or genomic data, as well as data with an impact on health, for example data on consumption of different substances, socioeconomic status or behaviour, and data on environmental factors such as pollution, radiation or the use of certain chemical substances. The categories of electronic health data for secondary use include some categories of data that were initially collected for other purposes such as research, statistics, patient safety, regulatory activities or policymaking, for example, policymaking registries or registries concerning the side effects of medicinal products or medical devices. European databases that facilitate use or reuse of data are available in some areas, such as cancer (the European Cancer Information System) or rare diseases (for example, the European Platform on Rare Disease Registration and European reference networks (ERN) registries). The categories of electronic health data that can be processed for secondary use should also include automatically generated data from medical devices and person-generated data, such as data from wellness applications. Data on clinical trials and clinical investigations should also be included in the categories of electronic health data for secondary use when the clinical trial or clinical investigation has ended, without affecting any voluntary data sharing by the sponsors of ongoing trials and investigations. Electronic health data for secondary use should be made available preferably in a structured electronic format

that facilitates their processing by computer systems. Examples of structured electronic formats include records in a relational database, XML documents or CSV files and free text, audios, videos and images provided as computer-readable files.可用于二次使用的电子健康数据类别应足够广泛和灵活，以适应健康数据用户不断变化的需求，同时仅限于与健康相关或已知会影响健康的数据。这些数据还可包括来自卫生系统的相关数据，例如电子健康记录、理赔数据、配药数据、疾病登记数据或基因组数据，以及对健康有影响的数据，例如不同物质的消费数据、社会经济地位或行为数据，以及环境因素数据（如污染、辐射或某些化学物质的使用数据）。用于二次使用的电子健康数据类别包括一些最初为其他目的（如研究、统计、患者安全、监管活动或政策制定）而收集的数据类别，例如政策制定登记册或有关药品或医疗器械副作用的登记册。在某些领域，已有便于数据使用或再利用的欧洲数据库，如癌症领域（欧洲癌症信息系统）或罕见病领域（例如，欧洲罕见病登记平台和欧洲参考网络（ERN）登记册）。可用于二次使用的电子健康数据类别还应包括来自医疗设备的自动生成数据和个人生成数据，如健康应用程序的数据。当临床试验或临床研究结束后，其相关数据也应纳入用于二次使用的电子健康数据类别，且不应影响正在进行的试验和研究的赞助商自愿共享数据。用于二次使用的电子健康数据最好以结构化电子格式提供，以便计算机系统对其进行处理。结构化电子格式的示例包括关系数据库中的记录、XML 文档或 CSV 文件，以及以计算机可读文件形式提供的自由文本、音频、视频和图像。

(57)Health data users who benefit from access to datasets provided for under this Regulation could enrich the data in those datasets with various corrections, annotations and other improvements, for instance by supplementing missing or incomplete data, thus improving the accuracy, completeness or quality of the data in the datasets. Health data users should be encouraged to report critical errors in datasets to health data access bodies. To support the improvement of the initial database and further use of the enriched dataset, Member States should be able to establish rules for the processing and the use of electronic health data containing improvements related to the processing of those data. The improved dataset should be made available free of charge to the original health data holder together with a description of the improvements. The health data holder should make the new dataset available, unless it provides a justified notification to the health data access body for not doing so, for instance in cases in which the enrichment by the health data user is of low quality. It should be ensured that non-personal electronic health data are available for secondary use. In particular, pathogen genomic data hold significant value for human health, as shown during the COVID-19 pandemic during which timely access to and sharing of such data proved to be essential for the rapid development of detection tools, medical countermeasures and responses to public health threats. The greatest benefit from pathogen genomics efforts will be achieved when public health and research processes share datasets and cooperate to inform and improve each other.从本条例规定获取数据集的健康数据使用者，可以通过各种更正、注释和其他改进来丰富这些数据集中的数据，例如补充缺失或不完整的数据，从而提高数据集中数据的准确性、完整性或质量。应鼓励健康数据使用者向健康数据访问机构报告数据集中的严重错误。为支持初始数据库的改进以及丰富后数据集的进一步使用，成员国应能够制定有关处理和使用包含与这些数据处理相关的改进内容的电子健康数据的规则。改进后的数据集应连同改进说明一起免费提供给原始健康数据持有者。健康数据持有者应提供新的数据集，除非其向健康数据访问机构提供合理的不提供理由通知，例如在健康数据使用者的丰富内容质量较低的情况下。应确保

非个人电子健康数据可用于二次使用。特别是，病原体基因组数据对人类健康具有重要价值，正如在新冠肺炎疫情期间所显示的那样，及时获取和共享此类数据被证明对于快速开发检测工具、医疗对策以及应对公共卫生威胁至关重要。当公共卫生和研究过程共享数据集并开展合作、相互借鉴和改进时，病原体基因组学工作将带来最大益处。

(58)In order to increase the effectiveness of the secondary use of personal electronic health data, and to fully benefit from the possibilities offered by this Regulation, the availability in the EHDS of electronic health data described in Chapter IV should be such that the data are as accessible, high-quality, ready and suitable for the purpose of creating scientific, innovative and societal value and quality as possible. Work on the implementation of the EHDS and further dataset improvements should be conducted in a manner that prioritises the datasets that are the most suitable for creating such value and quality.为提高个人电子健康数据二次使用的有效性，并充分利用本条例所提供的可能性，《电子健康数据条例》（EHDS）中第四章所述电子健康数据的可获取性应确保这些数据尽可能易于获取、质量高、随时可用，且适合用于创造科学、创新和社会价值及提升质量。《电子健康数据条例》的实施工作以及进一步的数据集改进应以优先处理最适合创造此类价值和质量的数据集的方式进行。

(59)Public or private entities often receive public funding from national or Union funds to collect and process electronic health data for research, official or unofficial statistics, or other similar purposes, including in areas where the collection of such data is fragmented or difficult, such as in relation to rare diseases or cancer. Such data, collected and processed by health data holders with the support of Union or national public funding, should be made available to health data access bodies, in order to maximise the impact of the public investment and support research, innovation, patient safety or policymaking, benefiting society. In some Member States, private entities, including private healthcare providers and professional associations, play a pivotal role in the health sector. The health data held by such providers should also be made available for secondary use. The health data holders in the context of secondary use should therefore be entities that are healthcare providers or care providers or carry out research with regard to the healthcare or care sectors, or develop products or services intended for the healthcare or care sectors. Such entities can be public, not for profit or private. In line with this definition, nursing homes, day-care centres, entities providing services for people with disabilities, entities carrying out business and technological activities related to care such as orthopaedics and companies providing care services should be considered health data holders. Legal persons developing wellness applications should also be considered health data holders. Union institutions, bodies, offices or agencies that process those categories of health and healthcare data as well as mortality registries should also be considered health data holders.In order to avoid a disproportionate burden for natural persons and microenterprises, they should be, as a general rule, exempted from the obligations on health data holders. Member States should, however, be able to extend the obligations of health data holders to natural persons and microenterprises in their national law. To reduce the administrative burden, and in light of the effectiveness and efficiency principles, Member States should be able to require in their national law that health data intermediation entities carry out the duties of certain categories of health data holders. Such health data intermediation entities should be legal persons able to process, make available,

register, provide, restrict access to, and exchange electronic health data for secondary use provided by health data holders. Such health data intermediation entities perform tasks that differ from those of data intermediation services under Regulation (EU) 2022/868.公共或私人实体经常从国家或欧盟基金获得公共资金，用于收集和处理电子健康数据，以用于研究、官方或非官方统计，或其他类似目的，包括在这类数据收集较为分散或困难的领域，如罕见病或癌症相关领域。由健康数据持有者在欧盟或国家公共资金支持下收集和处理的此类数据，应向健康数据访问机构开放，以最大限度地发挥公共投资的影响，支持研究、创新、患者安全或政策制定，从而造福社会。 在一些成员国，包括私人医疗服务提供者和专业协会在内的私人实体在卫生部门发挥着关键作用。这些提供者持有的健康数据也应可供二次使用。因此，二次使用场景下的健康数据持有者应是医疗服务提供者、护理服务提供者、从事医疗或护理领域研究的实体，或开发面向医疗或护理领域的产品或服务的实体。此类实体可以是公共的、非营利的或私人的。根据这一定义，养老院、日间护理中心、为残疾人提供服务的实体、从事与护理相关的商业和技术活动（如骨科）的实体以及提供护理服务的公司都应被视为健康数据持有者。开发健康应用程序的法人也应被视为健康数据持有者。处理这些类别健康和医疗数据的欧盟机构、团体、办事处或代理机构以及死亡登记处也应被视为健康数据持有者。 为避免给自然人及微型企业带来过重负担，一般而言，应免除其作为健康数据持有者的义务。然而，成员国应有权在其国内法中将健康数据持有者的义务扩展至自然人及微型企业。为减轻行政负担，并依据有效性和效率原则，成员国应有权在其国内法中要求健康数据中介实体履行特定类别健康数据持有者的职责。此类健康数据中介实体应为法人，能够处理、提供、登记、供应、限制访问和交换健康数据持有者提供的用于二次使用的电子健康数据。此类健康数据中介实体所执行的任务与《欧盟条例（EU）2022/868》规定的数据中介服务的任务不同。

(60)Electronic health data protected by intellectual property rights or trade secrets, including data on clinical trials, investigations and studies, can be very useful for secondary use and can foster innovation within the Union for the benefit of Union patients. In order to incentivise continuous Union leadership in this domain, it is important to encourage the sharing of clinical trials and clinical investigations data through the EHDS for secondary use. Clinical trials and clinical investigations data should be made available to the extent possible, while taking all necessary measures to protect intellectual property rights and trade secrets. This Regulation should not be used to reduce or circumvent such protection and should be consistent with the relevant transparency provisions laid down in Union law, including for clinical trials and clinical investigations data. Health data access bodies should assess how to preserve such protection while enabling access to such data for health data users to the extent possible. If a health data access body is unable to provide access to such data, it should inform the health data user and explain why it is not possible to provide such access. Legal, organisational and technical measures to protect intellectual property rights or trade secrets could include common electronic health data access contractual arrangements, specific obligations within the data permit in relation to such rights, pre-processing the data to generate derived data that protect a trade secret but nonetheless have a utility for the health data user or configuration of the secure processing environment so that such data are not accessible to the health data user.受知识产权或商业秘密保护的电子健康数据，包括临床试验、调查和研究方面的数据，对于二次使用非常有用，并且能够促进欧盟内部的创新，从而造福欧盟患者。为了激励欧盟在这一领域持续保持领先地位，鼓励通过电子健

康数据空间（EHDS）共享临床试验和临床调查数据以用于二次使用至关重要。临床试验和临床调查数据应尽可能提供，但同时要采取一切必要措施保护知识产权和商业秘密。本条例不应被用于削弱或规避此类保护，且应与欧盟法律中规定的相关透明度条款保持一致，包括关于临床试验和临床调查数据的条款。健康数据访问机构应评估如何在保护此类权益的同时，尽可能让健康数据用户能够访问这些数据。如果健康数据访问机构无法提供对此类数据的访问，应通知健康数据用户并解释无法提供访问的原因。保护知识产权或商业秘密的法律、组织和技术措施可包括通用的电子健康数据访问合同安排、数据许可中与这些权利相关的具体义务、对数据进行预处理以生成既能保护商业秘密又对健康数据用户有用的衍生数据，或配置安全处理环境以使健康数据用户无法访问此类数据。

(61)The secondary use of health data under the EHDS should enable public, private and not-for-profit entities, as well as individual researchers, to have access to health data for research, innovation, policymaking, educational activities, patient safety, regulatory activities or personalised medicine, in line with the purposes as set out in this Regulation. Access to data for secondary use should contribute to the general interest of society. In particular, the secondary use of health data for research and development purposes should contribute to benefiting society in the form of new medicines, medical devices, and healthcare products and services at affordable and fair prices for Union citizens, as well as to enhancing access to and the availability of such products and services in all Member States. Activities for which access in the context of this Regulation is lawful could include using the electronic health data for tasks carried out by public sector bodies, such as the exercise of public duty, including public health surveillance, planning and reporting duties, health policymaking, and ensuring patient safety, quality of care and the sustainability of healthcare systems. Public sector bodies and Union institutions, bodies, offices and agencies might need to have regular access to electronic health data for an extended period of time, including in order to fulfil their mandate, as is provided for in this Regulation. Public sector bodies could carry out such research activities by using third parties, including sub-contractors, as long as the public sector body remains at all times the supervisor of those activities. The provision of the data should also support activities related to scientific research. The notion of scientific research purposes should be interpreted in a broad manner, including technological development and demonstration, fundamental research, applied research and privately funded research. Activities related to scientific research include innovation activities such as training of AI algorithms that could be used in healthcare or the care of natural persons, as well as the evaluation and further development of existing algorithms and products for such purposes. It is necessary that the EHDS also contribute to fundamental research, and, although its benefits to end-users and patients might be less direct, such fundamental research is crucial for societal benefits in the longer term. In some cases, the information of some natural persons, such as genomic information of natural persons with a certain disease, could contribute to the diagnosis or treatment of other natural persons. There is a need for public sector bodies to go beyond the scope of ‘exceptional need’ of Chapter V of Regulation (EU) 2023/2854. However, health data access bodies should be allowed to provide support to public sector bodies when processing or linking data. This Regulation provides for a channel for public sector bodies to obtain access to information that they require for fulfilling the tasks assigned to them by law, but does not extend the mandate of such public sector bodies.

根据《欧洲健康数据空间条例》（EHDS），健康数据的二次使用应使公共、私人和非营利实体以及个体研究人员能够获取健康数据，用于研究、创新、政策制定、教育活动、患者安全、监管活动或个性化医疗，且需符合本条例规定的目的。为二次使用而获取数据应有助于社会公共利益。特别是，为研发目的二次使用健康数据，应以欧盟公民能够负担的合理价格提供新药品、医疗器械、医疗产品和服务的形式造福社会，并增进所有成员国对这类产品和服务的获取及可及性。 在本条例框架下，合法获取数据的活动可包括公共部门机构利用电子健康数据开展工作，例如履行公共职责，包括公共卫生监测、规划和报告职责、卫生政策制定，以及确保患者安全、医疗质量和医疗系统的可持续性。公共部门机构及欧盟各机构、团体、办事处和 agencies 可能需要在较长时间内定期获取电子健康数据，包括为履行本条例规定的职责。公共部门机构可通过第三方（包括分包商）开展此类研究活动，前提是公共部门机构始终对这些活动进行监督。 提供数据还应支持与科学研究相关的活动。科学研究目的这一概念应作广义解释，包括技术开发与演示、基础研究、应用研究和私人资助的研究。与科学研究相关的活动包括创新活动，如训练可用于医疗保健或自然人护理的人工智能算法，以及为此类目的对现有算法和产品进行评估与进一步开发。EHDS 有必要为基础研究做出贡献，尽管其对终端用户和患者的益处可能不够直接，但这类基础研究对长期的社会利益至关重要。 在某些情况下，一些自然人的信息，例如患有某种疾病的自然人的基因组信息，可能有助于其他自然人的诊断或治疗。公共部门机构有必要超越《欧盟条例（EU）2023/2854》第五章中“特殊需求”的范围。然而，健康数据访问机构在处理或关联数据时，应被允许为公共部门机构提供支持。本条例为公共部门机构获取其依法履行 assigned 任务所需的信息提供了渠道，但并未扩大此类公共部门机构的职责范围。

(62)Any attempt to use electronic health data for measures detrimental to natural persons, such as to increase insurance premiums, to engage in activities potentially detrimental to natural persons related to employment, pensions or banking, including mortgaging of properties, to advertise products or treatments, to automate individual decision-making, to re-identify natural persons or to develop harmful products should be prohibited. That prohibition should also apply to activities contrary to ethical provisions under national law, with the exception of ethical provisions relating to consent to the processing of personal data and ethical provisions relating to the right to opt out, since this Regulation takes precedence over national law in accordance with the general principle of the primacy of Union law. It should also be prohibited to provide access to, or otherwise make available, electronic health data to third parties not mentioned in the data permit. The identity of authorised persons, in particular the identity of the principal investigator, who will have the right pursuant to this Regulation to access electronic health data in the secure processing environment should be indicated in the data permit. The principal investigators are the main persons responsible for requesting access to the electronic health data and for processing the requested data within the secure processing environment on behalf of the health data user.任何利用电子健康数据从事对自然人不利行为的尝试都应被禁止，例如提高保险费、从事可能对自然人的就业、养老金或银行业务（包括房产抵押）不利的活动、为产品或治疗方法做广告、进行自动化个人决策、重新识别自然人身份或开发有害产品。这一禁令也应适用于违反国内法中伦理规定的活动，但涉及同意处理个人数据的伦理规定和与退出权相关的伦理规定除外，因为根据欧盟法律优先的一般原则，本条例优先于国内法。向数据许可中未提及的第三方提供电子健康数据的访问权限或以其他方式使其获取该数据，也应被禁止。数据许可中应注明有权根据本条例在安全处理环境中访问电子健康数据的授权人员的身

份，特别是主要研究者的身份。主要研究者是负责代表健康数据使用者申请访问电子健康数据并在安全处理环境中处理所申请数据的主要人员。

(63)This Regulation does not create an empowerment for the secondary use of health data for the purpose of law enforcement. The prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties by the competent authorities should not be among the secondary use purposes covered under this Regulation. Therefore, courts and other entities of the justice system should not be considered health data users for the secondary use of health data under this Regulation. In addition, courts and other entities of the justice system should not be covered under the definition of health data holders and should not therefore be addressees of obligations on health data holders under this Regulation. Moreover, the powers of the competent authorities for the prevention, investigation, detection and prosecution of criminal offences established by law to obtain electronic health data are unaffected by this Regulation. Likewise, electronic health data held by courts for the purpose of judicial proceedings are outside the scope of this Regulation.本条例并未授权将健康数据二次用于执法目的。主管机关对刑事犯罪的预防、调查、侦查、起诉或刑事处罚的执行，不应属于本条例所涵盖的二次使用目的。因此，法院及司法系统的其他实体不应被视为本条例下健康数据二次使用的健康数据使用者。此外，法院及司法系统的其他实体不应被纳入健康数据持有者的定义范围，因此也不应是本条例规定的健康数据持有者义务的承担者。再者，法律规定的主管机关为预防、调查、侦查和起诉刑事犯罪而获取电子健康数据的权力不受本条例影响。同样，法院为司法程序之目的而持有的电子健康数据也不在本条例的适用范围内。

(64)The establishment of one or more health data access bodies, supporting access to electronic health data in Member States, is essential to promoting the secondary use of health-related data. Member States should therefore establish one or more health data access bodies to reflect, inter alia, their constitutional, organisational and administrative structure. However, one of those health data access bodies should be designated as a coordinator in the event there is more than one health data access body. Where a Member State establishes several health data access bodies, it should lay down rules at national level to ensure the coordinated participation of those bodies in the European Health Data Space Board (the 'EHDS Board'). That Member State should, in particular, designate one health data access body to function as a single contact point for the effective participation of those bodies, and ensure swift and smooth cooperation with other health data access bodies, the EHDS Board and the Commission. Health data access bodies could vary in terms of organisation and size, spanning from a dedicated fully fledged organisation to a unit or department in an existing organisation. Health data access bodies should not be influenced in their decisions on access to electronic data for secondary use and should avoid any conflicts of interest. Therefore, members of the governance and decision-making bodies of each health data access body and its staff should refrain from any action that is incompatible with their duties and should not engage in any incompatible occupation. However, the independence of the health data access bodies should not mean that they cannot be subject to control or monitoring mechanisms regarding their financial expenditure or to judicial review. Each health data access body should be provided with the financial, technical and human resources, premises and infrastructure necessary for the effective performance of its tasks, including those

related to cooperation with other health data access bodies throughout the Union. The members of the governance and decision-making bodies of health data access bodies and their staff should have the necessary qualifications, experience and skills. Each health data access body should have a separate public annual budget, which could be part of the overall state or national budget. In order to enable better access to health data and complementing Article 7(2) of Regulation (EU) 2022/868, Member States should entrust health data access bodies with powers to take decisions on access to and secondary use of health data. This could consist in allocating new tasks to the competent bodies designated by Member States under Article 7(1) of Regulation (EU) 2022/868 or in designating existing or new sectoral bodies responsible for such tasks in relation to access to health data.建立一个或多个健康数据访问机构，支持成员国获取电子健康数据，对于促进健康相关数据的二次使用至关重要。因此，成员国应建立一个或多个健康数据访问机构，以反映其宪法、组织和行政结构等方面的情况。然而，若存在多个健康数据访问机构，其中一个应被指定为协调者。当成员国设立多个健康数据访问机构时，应在国家层面制定规则，确保这些机构协调参与欧洲健康数据空间委员会（以下简称“EHDS 委员会”）的工作。该成员国尤其应指定一个健康数据访问机构作为单一联络点，以保障这些机构的有效参与，并确保与其他健康数据访问机构、EHDS 委员会及欧盟委员会开展迅速且顺畅的合作。 健康数据访问机构在组织形式和规模上可能存在差异，既可以是专门的成熟组织，也可以是现有组织中的一个单位或部门。健康数据访问机构在就电子数据的二次使用访问作出决策时，不应受到任何影响，且应避免任何利益冲突。因此，每个健康数据访问机构的治理和决策机构成员及其工作人员应避免从事与其职责不符的任何行为，且不应担任任何不相容的职务。不过，健康数据访问机构的独立性并不意味着它们在财务支出方面不受控制或监督机制的约束，也不意味着不受司法审查。 每个健康数据访问机构都应配备有效履行其职责所需的财务、技术和人力资源，以及办公场所和基础设施，包括与欧盟范围内其他健康数据访问机构开展合作相关的资源。健康数据访问机构的治理和决策机构成员及其工作人员应具备必要的资质、经验和技能。每个健康数据访问机构都应有独立的公共年度预算，该预算可纳入国家总预算。 为了更好地促进健康数据的获取，并作为《欧盟条例（EU）2022/868》第 7 条第 2 款的补充，成员国应赋予健康数据访问机构就健康数据的访问和二次使用作出决策的权力。这可以包括向成员国根据《欧盟条例（EU）2022/868》第 7 条第 1 款指定的主管机构分配新任务，或指定现有的或新的行业机构负责与健康数据访问相关的此类任务。

(65)Health data access bodies should monitor the application of Chapter IV of this Regulation and contribute to its consistent application throughout the Union. For that purpose, health data access bodies should cooperate with each other and with the Commission. Health data access bodies should also cooperate with stakeholders, including patient organisations. Health data access bodies should support health data holders that are small enterprises in accordance with Commission Recommendation 2003/361/EC [18], in particular medical practitioners and pharmacies. Since the secondary use of health data involves the processing of personal data concerning health, the relevant provisions of Regulations (EU) 2016/679 and (EU) 2018/1725 apply and the supervisory authorities under those Regulations should remain the only authorities competent for enforcing those provisions. Health data access bodies should inform the data protection authorities of any penalties imposed and any potential issues related to data processing for secondary use and exchange any relevant information at their disposal to ensure enforcement of the relevant rules. In addition to the tasks necessary

to ensure effective secondary use of health data, the health data access body should strive to expand the availability of additional health datasets, and promote the development of common standards. They should apply tested state-of-the-art techniques that ensure electronic health data are processed in a manner that preserves the privacy of the information contained in the data for which secondary use is allowed, including techniques for pseudonymisation, anonymisation, generalisation, suppression and randomisation of personal data. Health data access bodies can prepare datasets for the health data user as required under the issued data permit. In that regard, health data access bodies should cooperate across borders to develop and exchange best practices and techniques. This includes rules for pseudonymisation and anonymisation of micro datasets. When relevant, the Commission should set out the procedures and requirements, and provide technical tools, for a unified procedure for pseudonymising and anonymising electronic health data.健康数据访问机构应监督本条例第四章的实施情况，并促进其在整个欧盟范围内的统一适用。为此，健康数据访问机构应相互合作，并与欧盟委员会合作。健康数据访问机构还应与包括患者组织在内的利益相关者开展合作。健康数据访问机构应依据欧盟委员会第2003/361/EC 号建议(18)，为小型企业性质的健康数据持有者提供支持，特别是执业医师和药房。由于健康数据的二次使用涉及对健康相关个人数据的处理，因此《(欧盟)2016/679 号条例》和《(欧盟)2018/1725 号条例》的相关规定适用，且这些条例所规定的监管机构应仍是唯一有权执行这些规定的机构。健康数据访问机构应将施加的任何处罚以及与二次使用数据处理相关的任何潜在问题告知数据保护机构，并交流其掌握的任何相关信息，以确保相关规则得到执行。除了为确保健康数据的有效二次使用所必需的任务外，健康数据访问机构还应努力扩大额外健康数据集的可用性，并推动通用标准的制定。它们应采用经过测试的最先进技术，确保电子健康数据的处理方式能够保护允许二次使用的数据中所包含信息的隐私，包括个人数据的假名化、匿名化、泛化、屏蔽和随机化技术。健康数据访问机构可以按照所签发的数据许可的要求，为健康数据使用者准备数据集。在这方面，健康数据访问机构应开展跨境合作，以开发和交流最佳实践与技术。这包括微观数据集的假名化和匿名化规则。在适当时，欧盟委员会应制定电子健康数据统一假名化和匿名化程序的相关流程与要求，并提供技术工具。

(66)Health data access bodies should ensure that secondary use is transparent by providing public information about the data permits granted and their justifications, the measures taken to protect the rights of natural persons, the means for natural persons to exercise their rights in relation to secondary use, and the outcomes of secondary use including through links to scientific publications. Where appropriate, that information on the outcomes of secondary use should also include a lay summary to be provided by the health data user. Those transparency obligations complement the obligations laid down in Article 14 of Regulation (EU) 2016/679. The exceptions provided for in Article 14(5) of that Regulation could apply. Where such exceptions do apply, the transparency obligations established in this Regulation should contribute to ensuring fair and transparent processing as referred to in Article 14(2) of Regulation (EU) 2016/679, for example through providing information on the purpose of the processing and the data categories processed, thereby enabling natural persons to understand whether their data are being made available for secondary use pursuant to data permits.健康数据访问机构应确保二次使用的透明度，为此需公开以下信息：已授予的数据许可及其理由、为保护自然人权利所采取的措施、自然人针对二次使用行使自身权利的途径，以及二次使用的成果（包括通过链接指向相关科学出版物）。

在适当情况下，关于二次使用成果的信息还应包含由健康数据使用者提供的通俗摘要。这些透明度义务是对《欧盟条例（2016/679）》第 14 条所规定义务的补充。该条例第 14 条第 5 款中规定的例外情况可适用。当此类例外情况确实适用时，本条例所确立的透明度义务应有助于确保《欧盟条例（2016/679）》第 14 条第 2 款所述的公平且透明的处理，例如通过提供有关处理目的和所处理数据类别的信息，从而使自然人能够了解其数据是否根据数据许可被用于二次使用。

(67)Natural persons should be informed by the health data holders about significant findings related to their health made by health data users. Natural persons should have the right to request not to be informed of such findings. Member States could lay down conditions on the arrangements for the provision by the health data holders of such information to the natural persons concerned and on the exercise of the right not to be informed. Member States should be able, in accordance with Article 23(1), point (i), of Regulation (EU) 2016/679, to restrict the scope of the obligation to inform natural persons whenever necessary for their protection based on patient safety and ethics, by delaying the communication of their information until a health professional can communicate and explain to the natural persons concerned information that potentially can have an impact on their health.健康数据持有者应向自然人告知健康数据使用者做出的与该自然人健康相关的重要发现。自然人应有权要求不被告知此类发现。成员国可对健康数据持有者向相关自然人提供此类信息的安排以及行使不被通知权的条件作出规定。根据《欧盟条例（EU）2016/679》第 23 条第（1）款（i）项，为保护自然人，在基于患者安全和伦理有必要的情况下，成员国应有权限制告知义务的范围，可推迟信息的传达，直至健康专业人员能够向相关自然人传达并解释可能对其健康产生影响的信息。

(68)In order to promote transparency, health data access bodies should also publish activity reports, every two years, providing an overview of their activities. Where a Member State has designated more than one health data access body, the coordinating body should prepare and publish a common report every two years. Activity reports should follow a structure agreed by the EHDS Board and provide an overview of activities, including information regarding decisions on applications, audits and engagement with relevant stakeholders. Such stakeholders can include representatives of natural persons, patient organisations, health professionals, researchers and ethical committees.为提高透明度，健康数据访问机构还应每两年发布一次活动报告，概述其各项活动。如果某成员国指定了多个健康数据访问机构，那么协调机构应每两年编制并发布一份共同报告。活动报告应遵循欧洲健康数据空间委员会商定的结构，概述各项活动，包括与申请决定、审计以及与相关利益相关者互动有关的信息。这些利益相关者可包括自然人代表、患者组织、卫生专业人员、研究人员和伦理委员会。

(69)In order to support secondary use, health data holders should refrain from withholding the data, requesting unjustified fees that are not transparent or proportionate to the costs of making the data available or, where relevant, to marginal costs of data collection, requesting the health data users to co-publish the research or other practices that could dissuade the health data users from requesting the data. Where a health data holder is a public sector body, the part of the fees linked to its costs should not cover the costs of the initial collection of the data. Where ethical approval is necessary for providing a data permit, the evaluation related to ethical approval should be based on its own merits.为支持数据的二次使用，健康

数据持有方不应拒绝提供数据，不应收取不合理的费用（这些费用不透明，或与数据提供成本不相称，或在相关情况下与数据收集的边际成本不相称），不应要求健康数据使用者联合发表研究成果，也不应采取其他可能阻碍健康数据使用者申请数据的做法。如果健康数据持有方是公共部门机构，那么与该机构成本相关的那部分费用不应包含数据的初始收集成本。在提供数据许可需要获得伦理审批的情况下，与伦理审批相关的评估应基于其自身的价值。

(70) Health data access bodies should be allowed to charge fees, taking into account the horizontal rules provided by Regulation (EU) 2022/868, in relation to their tasks. Such fees could take into account the situation and interest of small and medium-sized enterprises (SMEs), individual researchers or public sector bodies. In particular, Member States should be able to establish measures for health data access bodies in their jurisdiction which make it possible to charge certain categories of health data users reduced fees. Health data access bodies should be able to cover the costs of their operations with fees set up in a proportionate, justified and transparent manner. This could result in higher fees for some health data users, if handling their health data access applications and health data requests requires more work. Health data holders should be allowed to also ask for fees for making data available which reflect their costs. Health data access bodies should decide on the amount of such fees, which could also include the fees requested by health data holders. The health data user ought to be charged such fees by the health data access body in a single invoice. The health data access body should then transfer the relevant part of the paid fees to the health data holder. In order to ensure a harmonised approach concerning fee policies and structure, implementing powers should be conferred on the Commission. Article 10 of Regulation (EU) 2023/2854 should apply to fees charged under this Regulation. 健康数据访问机构应获准收取费用，同时考虑到《欧盟条例（EU）2022/868》就其任务规定的横向规则。此类费用可考虑中小企业、个体研究人员或公共部门机构的情况和利益。特别是，成员国应能为其管辖范围内的健康数据访问机构制定相关措施，使其能够向特定类别的健康数据用户收取减免费用。健康数据访问机构应以适当、合理且透明的方式设定费用，以覆盖其运营成本。如果处理某些健康数据用户的访问申请和数据请求需要更多工作，可能会向这些用户收取更高的费用。健康数据持有机构也应获准就提供数据收取费用，以反映其成本。健康数据访问机构应确定此类费用的金额，其中还可包含健康数据持有机构要求收取的费用。健康数据用户应通过健康数据访问机构的一张发票支付这些费用。之后，健康数据访问机构应将已收费用中的相关部分转交给健康数据持有机构。为确保在费用政策和结构方面采取统一做法，应赋予欧盟委员会执行权。《欧盟条例（EU）2023/2854》第 10 条应适用于根据本条例收取的费用。

(71) In order to strengthen the enforcement of the rules on secondary use, appropriate measures that can lead to administrative fines or enforcement measures by health data access bodies or temporary or definitive exclusions from the EHDS framework of health data users or health data holders that do not comply with their obligations should be envisaged. Health data access bodies should be empowered to verify compliance of health data users and health data holders and give them the opportunity to reply to any findings and to remedy any infringement. When deciding on the amount of the administrative fine or on an enforcement measure for each individual case, health data access bodies should take into account the cost margins and the criteria set out in this Regulation, ensuring that those fines or measures are

proportionate.为加强对二次使用相关规则的执行力度，应考虑采取适当措施，对不履行义务的健康数据使用者或持有者，可由健康数据访问机构处以行政罚款或采取执行措施，或暂时或永久将其排除在 EHDS 框架之外。应赋予健康数据访问机构权力，以核实健康数据使用者和持有者的合规情况，并给予他们对任何调查结果作出回应以及纠正任何违规行为的机会。在就个案决定行政罚款金额或执行措施时，健康数据访问机构应考虑本条例规定的成本幅度和标准，确保这些罚款或措施具有相称性。

(72)Given the sensitivity of electronic health data, it is necessary to reduce risks for the privacy of natural persons by applying the data minimisation principle. Therefore, non-personal electronic health data should be made available in all cases where the provision of such data is sufficient. If the health data user needs to use personal electronic health data, it should clearly indicate in its request the justification for the use of that type of data and the health data access body should assess whether that justification is valid. The personal electronic health data should only be made available in pseudonymised format. Taking into account the specific purposes of the processing, personal electronic health data should be pseudonymised or anonymised as early as possible in the process of making data available for secondary use. It should be possible for pseudonymisation and anonymisation to be carried out by health data access bodies or by health data holders. As controllers, health data access bodies and health data holders should be allowed to delegate those tasks to processors. When providing access to a pseudonymised or anonymised dataset, a health data access body should use state-of-the-art pseudonymisation or anonymisation technology and standards, ensuring to the maximum extent possible that natural persons cannot be re-identified by health data users. Such technology and standards for data pseudonymisation or anonymisation should be further developed. Health data users should not attempt to re-identify natural persons from the dataset provided under this Regulation, and where they do so they should be subject to administrative fines and enforcement measures laid down in this Regulation or possible criminal penalties, where national law so provides. Moreover, a health data applicant should be able to request a response to a health data request in an anonymised statistical format. In such cases, the health data user will only process non-personal data, and the health data access body will remain sole controller for any personal data necessary to provide the response to the health data request.鉴于电子健康数据的敏感性，有必要通过应用数据最小化原则来降低自然人的隐私风险。因此，在提供非个人电子健康数据已足够的所有情况下，都应提供此类数据。如果健康数据使用者需要使用个人电子健康数据，其应在请求中明确说明使用此类数据的正当理由，且健康数据访问机构应评估该理由是否有效。个人电子健康数据仅应以假名化形式提供。考虑到处理的特定目的，在为二次使用提供数据的过程中，应尽早对个人电子健康数据进行假名化或匿名化处理。假名化和匿名化工作可由健康数据访问机构或健康数据持有方实施。作为控制者，健康数据访问机构和健康数据持有方应被允许将这些任务委托给处理者。在提供对假名化或匿名化数据集的访问权限时，健康数据访问机构应使用最先进的假名化或匿名化技术及标准，尽可能确保健康数据使用者无法重新识别自然人身份。此类数据假名化或匿名化技术及标准应得到进一步发展。健康数据使用者不得试图从根据本条例提供的数据集重新识别自然人身份，若其实施了此类行为，应受到本条例规定的行政罚款和执行措施的处罚，若国家法律有规定，还可能面临刑事处罚。此外，健康数据申请人应有权要求以匿名统计格式获取对健康数据请求的回应。在这种情况下，健康数据使用者将仅处理非个人数据，而健康数据访问机构将仍是为回应健康数据请求而必

需的任何个人数据的唯一控制者。

(73)In order to ensure that all health data access bodies issue data permits in a similar way, it is necessary to establish a standard common process for the issuance of data permits, with similar requests in different Member States. The health data applicant should provide health data access bodies with several elements of information that would help the body evaluate the health data access application and decide if the health data applicant can receive a data permit, and coherence should be ensured between different health data access bodies. The information provided as part of the health data access application should comply with the requirements established under this Regulation in order to enable it to be thoroughly assessed, as a data permit should only be issued if all the necessary conditions set out in this Regulation are met. In addition, where relevant, that information should include a declaration by the health data applicant that the intended use of the health data requested does not pose a risk of stigmatisation, or of causing harm to the dignity, of natural persons or groups to which the dataset requested relates. An ethical assessment could be requested based on national law. In that case, it should be possible for existing ethics bodies to carry out such assessments for the health data access body. Existing ethics bodies of Member States should make their expertise available to the health data access body for that purpose. Alternatively, Member States should be able to provide for ethics bodies to be part of the health data access body. The health data access body, and where relevant health data holders, should assist health data users in the selection of the suitable datasets or data sources for the intended purpose of secondary use. Where the health data applicant needs data in an anonymised statistical format, it should submit a health data request, requiring the health data access body to provide the result directly. A refusal of a data permit by the health data access body should not preclude the health data applicant from submitting a new health data access application. In order to ensure a harmonised approach between health data access bodies and to limit the administrative burden for the health data applicants, the Commission should support the harmonisation of health data access applications, as well as health data requests, including by establishing the relevant templates. In justified cases, such as in the case of a complex and burdensome request, the health data access body should be allowed to extend the time period for health data holders to make the requested electronic health data available to it.为确保所有健康数据访问机构以类似方式签发数据许可，有必要针对数据许可的签发制定一套标准的通用流程，以应对不同成员国中的类似请求。健康数据申请人应向健康数据访问机构提供若干信息要素，这些信息将有助于该机构评估健康数据访问申请，并决定申请人是否可获得数据许可，同时还应确保不同健康数据访问机构之间的一致性。作为健康数据访问申请的一部分所提供的信息，应符合本条例规定的要求，以便能够对其进行全面评估，因为只有在满足本条例规定的所有必要条件时，方可签发数据许可。此外，在相关情况下，该信息应包含健康数据申请人的一项声明，即所请求的健康数据的预期用途不会对所请求数据集相关的自然人或群体造成污名化风险，也不会损害其尊严。根据国家法律，可能会要求进行伦理评估。在这种情况下，应有可能由现有的伦理机构为健康数据访问机构开展此类评估。成员国现有的伦理机构应为此向健康数据访问机构提供其专业知识。或者，成员国应能够规定伦理机构成为健康数据访问机构的组成部分。健康数据访问机构以及相关的健康数据持有者，应协助健康数据使用者为二次使用的预期目的选择合适的数据集或数据源。如果健康数据申请人需要匿名统计格式的数据，其应提交健康数据请求，要求健康数据访问机构直接提供结

果。健康数据访问机构拒绝签发数据许可，不应妨碍申请人提交新的健康数据访问申请。为确保健康数据访问机构之间采用统一方法，并减轻健康数据申请人的行政负担，欧盟委员会应支持统一健康数据访问申请以及健康数据请求的格式，包括通过制定相关模板来实现这一目标。在合理情况下，例如对于复杂且繁琐的请求，应允许健康数据访问机构延长健康数据持有者向其提供所请求的电子健康数据的期限。

(74)As their resources are limited, health data access bodies should be allowed to apply prioritisation rules, for instance prioritising public institutions over private entities, but they should not discriminate between the national organisations and organisations from other Member States within the same category of priorities. A health data user should be able to extend the duration of the data permit in order, for example, to allow access to the datasets to reviewers of scientific publications or to enable additional analysis of the dataset based on the initial findings. This should require an amendment of the data permit and could be subject to an additional fee. However, in all cases, the data permit should reflect such additional uses of the dataset. Preferably, the health data user should mention them in their initial health data access application. In order to ensure a harmonised approach between health data access bodies, the Commission should support the harmonisation of data permits.由于健康数据访问机构的资源有限，应允许其采用优先级规则，例如优先考虑公共机构而非私营实体，但在同一优先级类别内，不得歧视本国组织与其他成员国的组织。健康数据使用者应有权延长数据许可的期限，例如，允许科学出版物的评审人员访问数据集，或能基于初步研究结果对数据集进行额外分析。这需要修改数据许可，并且可能需要支付额外费用。然而，在所有情况下，数据许可都应反映数据集的此类额外用途。理想情况下，健康数据使用者应在其初始的健康数据访问申请中提及这些用途。为确保各健康数据访问机构采用统一的方法，欧盟委员会应支持数据许可的统一化。

(75)As the COVID-19 crisis has shown, the Union institutions, bodies, offices and agencies with a legal mandate in the field of public health, especially the Commission, need access to health data for a longer period and on a recurring basis. This may be the case not only for specific circumstances provided for in Union or national law in times of crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data could be required in specific Member States or throughout the whole territory of the Union. Such Union institutions, bodies, offices and agencies should be able to benefit from an accelerated procedure for having data made available, ordinarily in less than two months, with a possibility of prolonging the timeline by one month in more complex cases.正如新冠疫情危机所表明的那样，在公共卫生领域拥有法定职权的欧盟各机构、部门、办事处和 agencies，特别是欧盟委员会，需要长期且定期地获取健康数据。这不仅可能出现在危机时期欧盟或国家法律规定的特定情况下，也可能用于为欧盟政策定期提供科学依据和技术支持。获取此类数据的需求可能存在于特定成员国，也可能覆盖整个欧盟领土。这些欧盟机构、部门、办事处和 agencies 应当能够受益于加速程序来获取数据，通常应在两个月内完成，对于更复杂的情况，有可能将时间延长一个月。

(76)Member States should be able to designate trusted health data holders for which the data permit issuing procedure can be performed in a simplified manner, in order to alleviate the administrative burden for health data access bodies of managing requests for the data processed by them. Trusted health data holders should be allowed to assess the health data access applications submitted under this simplified procedure, based on their expertise in

dealing with the type of health data they are processing, and issue a recommendation regarding a data permit. The health data access body should remain responsible for issuing the final data permit and should not be bound by the recommendation provided by the trusted health data holder. Health data intermediation entities should not be designated as trusted health data holders.成员国应当能够指定受信任的健康数据持有者，对于这些持有者，可以以简化方式执行数据许可的发放程序，以减轻健康数据访问机构在处理由这些持有者处理的数据的请求时所承担的行政负担。受信任的健康数据持有者应被允许根据其在处理自身所处理的健康数据类型方面的专业知识，对通过这一简化程序提交的健康数据访问申请进行评估，并就数据许可出具建议。健康数据访问机构仍应负责发放最终的数据许可，且不受受信任的健康数据持有者所提供建议的约束。健康数据中介实体不应被指定为受信任的健康数据持有者。

(77)Given the sensitivity of electronic health data, health data users should not have unrestricted access to such data. All secondary use access to the requested electronic health data should be done through a secure processing environment. In order to ensure there are strong technical and security safeguards in place for the electronic health data, the health data access body or, where relevant, the trusted health data holder should provide access to such data in a secure processing environment, complying with the high technical and security standards set out pursuant to this Regulation. The processing of personal data in such a secure processing environment should comply with Regulation (EU) 2016/679, including, where the secure processing environment is managed by a third party, the requirements of Article 28 of that Regulation and, where applicable, Chapter V thereof. Such secure processing environment should reduce the privacy risks related to such processing activities and prevent the electronic health data from being transmitted directly to the health data users. The health data access body or the health data holder providing that service should remain at all times in control of the access to the electronic health data, and the access granted to the health data users should be determined by the conditions of the issued data permit. Only non-personal electronic health data which do not contain any personal electronic health data should be downloaded by the health data users from such secure processing environment. Thus, such a secure processing environment is an essential safeguard to preserve the rights and freedoms of natural persons in relation to the processing of their electronic health data for secondary use. The Commission should assist the Member States in developing common security standards in order to promote the security and interoperability of the various secure processing environments.鉴于电子健康数据的敏感性，健康数据使用者不应不受限制地访问此类数据。所有对所请求电子健康数据的二次使用访问都应通过安全处理环境进行。为确保为电子健康数据设置强有力的技术和安全保障措施，健康数据访问机构或相关情况下的受信任健康数据持有者应通过安全处理环境提供对此类数据的访问，并遵守根据本条例制定的高技术性和安全性标准。在这种安全处理环境中对个人数据的处理应符合《欧盟条例》（EU）2016/679，包括当安全处理环境由第三方管理时，应符合该条例第 28 条的要求以及适用情况下该条例第五章的要求。此类安全处理环境应降低与此类处理活动相关的隐私风险，并防止电子健康数据直接传输给健康数据使用者。提供该服务的健康数据访问机构或健康数据持有者应始终控制对电子健康数据的访问，授予健康数据使用者的访问权限应由所颁发的数据许可条件决定。健康数据使用者仅可从该安全处理环境下载不包含任何个人电子健康数据的非个人电子健康数据。因此，这种安全处理环境是维护自然人在其电子健康数据被

用于二次处理方面的权利和自由的重要保障。欧盟委员会应协助成员国制定通用安全标准，以促进各种安全处理环境的安全性和互操作性。

(78)Regulation (EU) 2022/868 sets out the general rules for the management of data altruism. Given that the health sector manages sensitive data, additional criteria should be established through the rulebook referred to in that Regulation. Where such rules provide for the use of a secure processing environment for that sector, such secure processing environment should comply with the criteria established in this Regulation. The health data access bodies should cooperate with the competent authorities designated under Regulation (EU) 2022/868 to supervise the activity of data altruism organisations in the health or care sector.《欧盟条例（EU）2022/868》规定了数据利他主义管理的一般规则。鉴于卫生部门管理敏感数据，应通过该条例所提及的规则手册制定额外标准。若此类规则规定该部门使用安全处理环境，则该安全处理环境应符合本条例确立的标准。卫生数据访问机构应与根据《欧盟条例（EU）2022/868》指定的主管当局合作，监督卫生或护理领域数据利他主义组织的活动。

(79)For the processing of electronic health data in the scope of a data permit or a health data request, health data holders, including trusted health data holders, health data access bodies and health data users should be deemed each of them, in turn, controllers for a specific part of the process and according to their respective roles therein. Health data holders should be deemed controllers for the disclosure of the requested personal electronic health data to the health data access bodies, while the health data access bodies should in turn be deemed controllers for the processing of the personal electronic health data when preparing the data and making them available to the health data users. Health data users should be deemed controllers for the processing of personal electronic health data in pseudonymised form in the secure processing environment pursuant to their data permits. Health data access bodies should be deemed processors on behalf of the health data user for the processing carried out by the health data user pursuant to a data permit in the secure processing environment as well as for the processing to generate a response to a health data request. Similarly, trusted health data holders should be deemed controllers for their processing of personal electronic health data related to the provision of electronic health data to the health data user pursuant to a data permit or a health data request. The trusted health data holders should be deemed processors for the health data user when providing data through a secure processing environment.在数据许可或健康数据请求范围内处理电子健康数据时，健康数据持有者（包括可信健康数据持有者、健康数据访问机构和健康数据使用者）应根据其在流程中各自的角色，依次被视为流程特定部分的控制者。健康数据持有者应被视为向健康数据访问机构披露所请求的个人电子健康数据的控制者，而健康数据访问机构在整理数据并将其提供给健康数据使用者时，应相应地被视为个人电子健康数据处理的控制者。健康数据使用者应被视为依据其数据许可，在安全处理环境中处理去标识化形式的个人电子健康数据的控制者。对于健康数据使用者依据数据许可在安全处理环境中进行的处理，以及为响应健康数据请求而进行的处理，健康数据访问机构应被视为代表健康数据使用者的处理者。同样，可信健康数据持有者在依据数据许可或健康数据请求向健康数据使用者提供电子健康数据时，对相关个人电子健康数据的处理应被视为控制者。可信健康数据持有者通过安全处理环境提供数据时，应被视为健康数据使用者的处理者。

(80)In order to achieve an inclusive and sustainable framework for multi-country secondary use,

a cross-border infrastructure should be established ('HealthData@EU'). HealthData@EU should accelerate secondary use while increasing legal certainty, respecting the privacy of natural persons and being interoperable. Due to the sensitivity of health data, principles such as 'privacy by design' and 'privacy by default' and the concept of bringing questions to data instead of moving those data should be respected whenever possible. Member States should designate national contact points for secondary use, as organisational and technical gateways for health data access bodies, and connect those contact points to HealthData@EU. The Union health data access service should also be connected to HealthData@EU. In addition, authorised participants in HealthData@EU could be research infrastructures established as a European Research Infrastructure Consortium (ERIC) under Council Regulation (EC) No 723/2009 [19], as a European digital infrastructure consortium (EDIC) under Decision (EU) 2022/2481 or similar infrastructures established under other Union legal acts, as well as other types of entities, including infrastructures under the European Strategy Forum on Research Infrastructures (ESFRI) or infrastructures federated under the European Open Science Cloud (EOSC). Third countries and international organisations could also become authorised participants in HealthData@EU, provided that they are compliant with the requirements in this Regulation. The Commission communication of 19 February 2020 entitled 'A European strategy for data' promoted the linking of the various common European data spaces. HealthData@EU should therefore enable the secondary use of different categories of electronic health data, including linking of the health data with data from other data spaces such as those relating to the environment, agriculture and social sector. Such interoperability between the health sector and other sectors such as the environmental, agricultural or social sectors could be relevant for obtaining additional insights on health determinants. The Commission could provide a number of services within HealthData@EU, including supporting the exchange of information amongst health data access bodies and authorised participants in HealthData@EU for the handling of cross-border access requests, maintaining catalogues of electronic health data available through the infrastructure, network discoverability and metadata queries, connectivity and compliance services. The Commission could also set up a secure processing environment, allowing data from different national infrastructures to be transmitted and analysed, at the request of the controllers. For the sake of IT efficiency, rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, such as those being built for the exchange of evidence under the 'once-only' technical system of Regulation (EU) 2018/1724 of the European Parliament and of the Council [20].为了构建一个具有包容性且可持续的多国二次使用框架，应当建立一个跨境基础设施（"HealthData@EU"）。HealthData@EU 应在加快二次使用的同时，增强法律确定性，尊重自然人的隐私，并具备互操作性。由于健康数据的敏感性，应尽可能遵循"设计即隐私""默认即隐私"等原则，以及"让问题对接数据而非移动数据"的理念。成员国应指定二次使用的国家联络点，作为健康数据访问机构的组织和技术网关，并将这些联络点与 HealthData@EU 相连。欧盟健康数据访问服务也应接入 HealthData@EU。此外，HealthData@EU 的授权参与者可以是根据理事会条例（EC）第 723/2009 号成立的欧洲研究基础设施联盟（ERIC）、根据（EU）2022/2481 号决定成立的欧洲数字基础设施联盟（EDIC），或根据其他欧盟法律成立的类似基础设施，以及其他类型的实体，包括欧洲研究基础设施战略论坛（ESFRI）下属的基础设施或欧洲开放科学云（EOSC）下属的联合基础设施。第三国和国际组织若符合本

条例的要求，也可成为 HealthData@EU 的授权参与者。2020 年 2 月 19 日欧盟委员会题为《欧洲数据战略》的通讯推动了各种欧洲共同数据空间的互联。因此，HealthData@EU 应支持不同类别的电子健康数据的二次使用，包括将健康数据与来自其他数据空间（如环境、农业和社会领域的数据空间）的数据相连。健康领域与环境、农业或社会等其他领域之间的这种互操作性，可能有助于深入了解健康决定因素。欧盟委员会可在 HealthData@EU 内提供多项服务，包括支持健康数据访问机构与 HealthData@EU 的授权参与者之间就跨境访问请求的处理进行信息交流，维护可通过该基础设施获取的电子健康数据目录，实现网络可发现性和元数据查询，以及提供连接和合规服务。欧盟委员会还可建立一个安全处理环境，应控制者的请求，允许传输和分析来自不同国家基础设施的数据。为了提高信息技术效率、实现数据交换的合理化和互操作性，应尽可能复用现有的数据共享系统，例如为执行欧洲议会和理事会（EU）2018/1724 号条例的“一次提交”技术系统下的证据交换而构建的系统。

(81)In addition, given that the connection to HealthData@EU could entail transfers of personal data related to the applicant or the health data user to third countries, relevant transfer instruments under Chapter V of Regulation (EU) 2016/679 need to be in place for such transfers.此外，鉴于与 HealthData@EU 的连接可能需要将与申请人或健康数据用户相关的个人数据传输到第三国，因此需要依据《欧盟条例（EU）2016/679》第五章的相关传输工具来进行此类传输。

(82)In the case of cross-border registries or databases, such as the registries of European Reference Networks for Rare Diseases, which receive data from different healthcare providers in several Member States, the health data access body of the Member State where the coordinator of the registry is located should be responsible for providing access to data.对于跨境登记处或数据库，例如接收多个成员国不同医疗服务提供者数据的欧洲罕见病参考网络登记处，登记处协调机构所在成员国的健康数据访问机构应负责提供数据访问服务。

(83)The authorisation process to gain access to personal electronic health data in different Member States can be repetitive and cumbersome for health data users. Whenever possible, synergies should be established to reduce the burden and barriers for health data users. One way to achieve that aim is to adhere to the ‘single application’ principle whereby, with one application, the health data user can obtain authorisation from multiple health data access bodies in different Member States or authorised participants in HealthData@EU.在不同成员国，获取个人电子健康数据的授权流程对健康数据使用者而言可能既重复又繁琐。只要有可能，就应建立协同机制，以减轻健康数据使用者的负担并减少障碍。实现这一目标的一种方法是遵循“单一申请”原则，即通过一次申请，健康数据使用者就能从不同成员国的多个健康数据访问机构或 HealthData@EU 的授权参与者那里获得授权。

(84)The health data access bodies should provide information about the available datasets and their characteristics so that health data users can be informed of elementary facts about the dataset and assess the possible relevance of those facts to those users. For this reason, each dataset should include, at least, information concerning the source and nature of the data and the conditions for making the data available. The health data holder should, at least every year, check that its dataset description in the national dataset catalogue is accurate and up to date. Therefore, an EU dataset catalogue should be established to: facilitate the discoverability of datasets available in the EHDS; help health data holders to publish their

datasets; provide all stakeholders, including the general public, taking into account the specific needs of people with disabilities, with information about datasets placed on the EHDS, such as quality and utility labels and dataset information sheets; and provide health data users with up-to-date data quality and utility information about datasets.健康数据访问机构应提供有关可用数据集及其特征的信息，以便健康数据用户能够了解数据集的基本情况，并评估这些情况与自身可能存在的相关性。为此，每个数据集至少应包含有关数据来源、数据性质以及数据提供条件的信息。健康数据持有者至少应每年检查其在国家数据集目录中的数据集描述是否准确且为最新版本。因此，应建立一个欧盟数据集目录，以实现以下目的：提高欧洲健康数据空间（EHDS）中可用数据集的可发现性；帮助健康数据持有者发布其数据集；向所有利益相关者（包括公众，同时考虑到残疾人的特殊需求）提供有关欧洲健康数据空间（EHDS）中数据集的信息，如质量和效用标签以及数据集信息表；并向健康数据用户提供有关数据集的最新数据质量和效用信息。

(85)Information on the quality and utility of datasets increases the value of outcomes from data-intensive research and innovation significantly while, at the same time, promoting evidence-based regulatory and policy decision-making. Improving the quality and utility of datasets through informed customer choice and harmonising related requirements at Union level, taking into account existing Union and international standards, guidelines and recommendations for data collection and data exchange, such as FAIR principles, also benefits health data holders, health professionals, natural persons and the Union economy overall. A data quality and utility label for datasets would inform health data users about the quality and utility characteristics of a dataset and enable them to choose the datasets that best fit their needs. The data quality and utility label should not prevent datasets from being made available through the EHDS, but provide a transparency mechanism between health data holders and health data users. For example, a dataset that does not fulfil any requirement of data quality and utility should be labelled with the class representing the poorest quality and utility, but should still be made available. Expectations set by frameworks created pursuant to Article 10 of Regulation (EU) 2024/1689 and the relevant technical documentation specified in Annex IV to that Regulation should be taken into account when developing the data quality and utility framework. Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support those activities. The use of datasets could be prioritised by their users according to their usefulness and quality.关于数据集质量和实用性的信息能显著提升数据密集型研究与创新成果的价值，同时也能促进基于证据的监管和政策决策。通过让用户做出知情选择来提高数据集的质量和实用性，并在欧盟层面协调相关要求，同时考虑到现有的欧盟及国际数据收集和数据交换标准、指南与建议（如 FAIR 原则），这也将使健康数据持有者、医疗专业人员、自然人以及整个欧盟经济受益。数据集的质量和实用性标签能让健康数据用户了解数据集的质量和实用性特征，使他们能够选择最符合自身需求的数据集。数据质量和实用性标签不应阻碍数据集通过欧洲健康数据空间（EHDS）提供，而应在健康数据持有者和健康数据用户之间建立一种透明度机制。例如，一个不满足任何数据质量和实用性要求的数据集，应被贴上代表最差质量和实用性的类别标签，但仍应予以提供。在制定数据质量和实用性框架时，应考虑到依据《欧盟条例（2024/1689）》第 10 条创建的框架以及该条例附件四所规定的相关技术文件提出的期望。成员国应通过宣传活动提高对数据质量和实用性标签的认识。欧盟委员会可对这些活动提供支持。用户可根据数据集的实用性和质量来确定其使用优先级。

(86)The EU dataset catalogue should minimise the administrative burden for the health data holders and other database users, be user-friendly, accessible and cost-effective, connect national dataset catalogues and avoid redundant registration of datasets. Without prejudice to the requirements set out in Regulation (EU) 2022/868, the EU dataset catalogue could be aligned with the data.europa.eu initiative. Interoperability should be ensured between the EU dataset catalogue, the national dataset catalogues and the dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.欧盟数据集目录应最大限度地减轻健康数据持有者和其他数据库用户的行政负担，做到用户友好、易于访问且具成本效益，连接各国数据集目录，并避免数据集的重复注册。在不影响《欧盟条例（2022/868）》规定要求的前提下，欧盟数据集目录可与 data.europa.eu 计划保持一致。欧盟数据集目录、各国数据集目录以及来自欧洲研究基础设施和其他相关数据共享基础设施的数据集目录之间应确保互操作性。

(87)Cooperation and work are ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets, for instance registries. That work is more advanced in areas such as cancer, rare diseases, cardiovascular and metabolic diseases, risk factor assessment and statistics, and should be taken into account when defining new standards and disease-specific harmonised templates for structured data elements. However, many datasets are not harmonised, raising comparability issues and making cross-border research difficult. Therefore, more detailed rules should be set out in implementing acts to ensure a harmonised coding and registration of electronic health data to enable the supply of such data for secondary use in a consistent way. Such datasets could include data from registries of rare diseases, orphan drugs databases, cancer registries and registries of highly relevant infectious diseases. Member States should work towards ensuring that European electronic health systems and services and interoperable applications deliver sustainable economic and social benefits, with a view to achieving a high level of trust and security, enhancing continuity of healthcare and ensuring access to safe and high-quality healthcare. Existing health data infrastructures and registries can provide models that are useful for defining and implementing data standards and interoperability and should be leveraged to enable continuity and to build on existing expertise.不同专业组织、委员会及其他机构之间正在开展合作与工作，以设定不同数据集（例如登记册）的最小数据字段和其他特征。在癌症、罕见病、心血管和代谢疾病、风险因素评估及统计等领域，这项工作更为深入，在为结构化数据元素制定新标准和特定疾病统一模板时，应考虑到这一点。然而，许多数据集尚未统一，这带来了可比性问题，并使跨境研究变得困难。因此，应在实施法案中制定更详细的规则，确保电子健康数据的统一编码和登记，以便以一致的方式为二次使用提供此类数据。此类数据集可包括罕见病登记册、孤儿药数据库、癌症登记册以及高度相关传染病登记册中的数据。成员国应致力于确保欧洲电子健康系统和服务以及互操作应用程序能带来可持续的经济和社会效益，以期实现高度的信任和安全性，加强医疗保健的连续性，并确保获得安全高质量的医疗保健。现有的健康数据基础设施和登记册可以提供有助于定义和实施数据标准及互操作性的模型，应加以利用以确保连续性并借助现有专业知识。

(88)The Commission should support Member States in building capacity and enhancing effectiveness in the area of digital health systems for primary use and secondary use.

Member States should be supported to strengthen their capacity. Activities at Union level, such as benchmarking and exchange of best practices, are relevant measures in that respect. Those activities should take into account the specific circumstances of different categories of stakeholders, such as representatives of civil society, researchers, medical societies and SMEs. 委员会应支持成员国在数字健康系统的主要使用和次要使用领域建设能力并提高效率。应支持成员国加强自身能力。欧盟层面的活动，如基准测试和最佳实践交流，是这方面的相关措施。这些活动应考虑到不同类别利益相关者的具体情况，例如民间社会代表、研究人员、医学学会和中小企业。

(89)Improving digital health literacy for both natural persons and health professionals is essential to trust and safety and appropriate use of health data and thus is essential to achieving a successful implementation of this Regulation. Health professionals are faced with profound changes in the context of digitalisation and will be offered further digital tools as part of the implementation of the EHDS. Consequently, health professionals need to develop their digital health literacy and digital skills and Member States should provide access for health professionals to digital literacy courses so that they can prepare to work with EHR systems. Such courses should allow health professionals and IT operators to receive sufficient training in working with new digital infrastructures to ensure cybersecurity and ethical management of health data. The training courses should be developed and reviewed, and kept up to date, on a regular basis in consultation and cooperation with relevant experts. Improving digital health literacy is fundamental in order to empower natural persons to have true control over their health data, actively manage their health and care, and understand the implications of the management of such data for both primary use and secondary use. Different demographic groups have varying degrees of digital literacy, which can affect natural persons' ability to exercise their rights to control their electronic health data. Member States, including regional and local authorities, should therefore support digital health literacy and public awareness, while ensuring that the implementation of this Regulation contributes to reducing inequalities and does not discriminate against people lacking digital skills. Particular attention should be given to persons with disabilities and vulnerable groups including migrants and the elderly. Member States should create targeted national digital literacy programmes, including programmes to maximise social inclusion and to ensure all natural persons can effectively exercise their rights under this Regulation. Member States should also provide patient-centric guidance to natural persons in relation to the use of electronic health records and primary use of their personal electronic health data. Guidance should be tailored to the patient's level of digital health literacy, with specific attention to be given to the needs of vulnerable groups.提高自然人与卫生专业人员的数字健康素养，对于健康数据的信任、安全及合理使用至关重要，因此也是本条例成功实施的关键。在数字化背景下，卫生专业人员面临着深刻变革，而作为电子健康数据系统（EHDS）实施的一部分，他们还将获得更多数字工具。因此，卫生专业人员需要提升自身的数字健康素养和数字技能，成员国应让卫生专业人员有机会参加数字素养课程，以便他们做好使用电子健康记录（EHR）系统的准备。这类课程应能让卫生专业人员和信息技术操作人员接受充分培训，掌握新数字基础设施的使用方法，从而确保健康数据的网络安全和合乎伦理的管理。培训课程的制定、审查和更新应定期进行，并与相关专家开展咨询与合作。 提高数字健康素养的根本目的是增强自然人对自身健康数据的实际控制权，让他们能积极管理自身健康与医疗护理，同时理解健康数据在主要用途和次要用途方面的管理所带来的影响。不同人

群的数字素养水平存在差异，这可能会影响自然人行使对其电子健康数据的控制权。因此，成员国（包括地区和地方当局）应支持数字健康素养的提升和公众意识的培养，同时确保本条例的实施有助于减少不平等现象，且不会歧视缺乏数字技能的人群。应特别关注残疾人以及包括移民和老年人在内的弱势群体。成员国应制定有针对性的国家数字素养计划，包括最大限度促进社会包容的计划，确保所有自然人都能有效行使本条例赋予他们的权利。成员国还应为自然人提供以患者为中心的指导，内容涉及电子健康记录的使用以及个人电子健康数据的主要用途。指导应根据患者的数字健康素养水平量身定制，并特别关注弱势群体的需求。

(90)The use of funds should also contribute to attaining the objectives of the EHDS. Public procurers, national competent authorities in the Member States, including digital health authorities and health data access bodies, and the Commission should make references to applicable technical specifications, standards and profiles on interoperability, security and data quality, as well as other requirements developed under this Regulation, when defining the conditions for public procurement, calls for proposals and allocation of Union funds, including structural and cohesion funds. Union funds need to be distributed transparently among the Member States, taking into account the different levels of health system digitalisation. Making data available for secondary use requires additional resources for healthcare systems, in particular public healthcare systems. That additional burden should be addressed and minimised during the implementation phase of the EHDS.资金的使用还应有助于实现电子健康数据空间（EHDS）的目标。公共采购方、成员国的国家主管部门（包括数字健康主管部门和健康数据访问机构）以及欧盟委员会在确定公共采购条件、招标提案和欧盟资金（包括结构基金和凝聚力基金）分配时，应参考适用的关于互操作性、安全性和数据质量的技术规范、标准和概况，以及根据本条例制定的其他要求。欧盟资金需要在成员国之间透明分配，同时考虑到各国卫生系统数字化的不同水平。为二次使用提供数据需要为医疗系统，特别是公共医疗系统投入额外资源。在电子健康数据空间（EHDS）的实施阶段，应解决并尽量减轻这一额外负担。

(91)The implementation of the EHDS requires appropriate investment in capacity-building and training and a well-funded commitment to public consultation and engagement both at Union and national level. The economic costs of implementing this Regulation will need to be borne at both Union and national level, and a fair sharing of that burden between Union and national funds will need to be found.电子健康数据空间（EHDS）的实施需要在能力建设和培训方面进行适当投资，并且需要在欧盟和国家层面为公众咨询与参与提供充足的资金支持。实施本条例的经济成本需要由欧盟和国家层面共同承担，同时需要找到欧盟资金与国家资金之间公平分担这一负担的方式。

(92)Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically provided for in Regulation (EU) 2022/868. Even where state-of-the-art anonymisation techniques are used, there remains a residual risk that the capacity to re-identify could be or become available, beyond the means reasonably likely to be used. Such residual risk is present in relation to rare diseases, that is to say a life-threatening or chronically debilitating condition affecting not more than 5 in 10 000 persons in the Union, where the limited numbers of cases reduce the possibility of fully aggregating the published data in order to preserve the privacy of natural persons while also maintaining an appropriate level of granularity in order to remain

meaningful. Such residual risk can affect different categories of health data and can lead to the re-identification of the data subjects using means that are beyond those reasonably likely to be used. Such risk depends on the level of granularity, on the description of the characteristics of data subjects, on the number of people affected, for instance in cases of data included in electronic health records, disease registries, biobanks and person-generated data, where the range of identification characteristics is broader, and on the possible combination with other information, for example in very small geographical areas, or through the technological evolution of methods which had not been available at the moment of anonymisation. Such re-identification of natural persons would present a major concern and would be likely to put the acceptance of the rules on secondary use provided for in this Regulation at risk. Furthermore, aggregation techniques are less tested for non-personal data containing for example trade secrets, as is the case in the reporting on clinical trials and clinical investigations, and enforcement of breaches of trade secrets outside the Union is more difficult in the absence of a sufficient international protection standard. Therefore, for those categories of health data, there remains a risk of re-identification after the anonymisation or aggregation, which cannot be reasonably mitigated initially. This falls within the criteria indicated in Article 5(13) of Regulation (EU) 2022/868. Those types of health data would thus fall within the empowerment set out in Article 5(13) of that Regulation for transfer to third countries. The special conditions provided for under the empowerment set out in Article 5(13) of Regulation (EU) 2022/868 will be detailed in the context of the delegated act adopted under that empowerment, and need to be proportional to the risk of re-identification and to take into account the specificities of different data categories or of different anonymisation or aggregation techniques.某些类别的电子健康数据即使经过匿名化处理而不涉及个人信息，仍可能具有特别的敏感性，这一点在《欧盟条例（EU）2022/868》中已有明确规定。即便采用最先进的匿名化技术，仍存在一种残余风险，即可能出现或获得重新识别的能力，而这种能力超出了合理可能被使用的手段范畴。 这种残余风险在罕见病领域尤为突出，所谓罕见病是指在欧盟范围内每万人中患病不超过 5 人的危及生命或慢性致残性疾病。由于病例数量有限，既难以通过充分汇总已发布数据来保护自然人隐私，同时又要保持适当的 granularity 以确保数据有意义，这两者之间难以兼顾。 此类残余风险可能影响不同类别的健康数据，并可能导致通过超出合理可能使用的手段重新识别数据主体。这种风险取决于以下因素：数据的 granularity 水平、对数据主体特征的描述、受影响的人数（例如，电子健康记录、疾病登记册、生物样本库和个人生成的数据中所包含的数据，其识别特征范围更广），以及与其他信息的可能组合（例如在非常小的地理区域内），或者匿名化时所不具备的方法在技术上的发展。对自然人进行此类重新识别将引发重大关切，并可能危及本条例所规定的二次使用规则的可接受性。此外，对于包含商业秘密的非个人数据（如临床试验和临床调查报告中的数据），聚合技术的测试较少；而且在缺乏足够的国际保护标准的情况下，在欧盟以外地区对商业秘密泄露行为的执法难度更大。 因此，对于这些类别的健康数据，在匿名化或聚合后仍存在重新识别的风险，且这种风险最初无法得到合理缓解。这符合《欧盟条例（EU）2022/868》第 5 条第 13 款规定的标准。因此，这类健康数据属于该条例第 5 条第 13 款规定的可向第三国传输的授权范围。 《欧盟条例（EU）2022/868》第 5 条第 13 款授权项下规定的特殊条件，将在根据该授权通过的 delegated act 中详细说明，且这些条件需与重新识别的风险成比例，并考虑到不同数据类别或不同匿名化、聚合技术的特殊性。

(93)The processing of large amounts of personal electronic health data for the purposes of the EHDS, as part of data processing activities in the context of handling health data access applications, data permits and health data requests entails higher risks of unauthorised access to such personal data, as well as the possibility of cybersecurity incidents. Personal electronic health data are particularly sensitive as they often contain information covered by medical secrecy, the disclosure of which to unauthorised third parties can cause significant distress. Taking fully into consideration the principles outlined in the case law of the Court of Justice of the European Union, this Regulation ensures full respect for fundamental rights, for the right to privacy and for the principle of proportionality. In order to ensure the full integrity and confidentiality of personal electronic health data under this Regulation, to guarantee a particularly high level of protection and security, and to reduce the risk of unlawful access to those personal electronic health data, this Regulation allows Member States to require that personal electronic health data be stored and processed solely within the Union for the purpose of carrying out the tasks provided for in this Regulation, unless an adequacy decision adopted pursuant to Article 45 of Regulation (EU) 2016/679 applies.为实现电子健康数据系统（EHDS）的目的，在处理健康数据访问申请、数据许可和健康数据请求相关的数据处理活动中，对大量个人电子健康数据进行处理，这会带来更高的未经授权访问此类个人数据的风险，也可能引发网络安全事件。个人电子健康数据尤其敏感，因为它们往往包含受医疗保密原则保护的信息，向未经授权的第三方披露这类信息可能会造成极大的困扰。本条例充分考虑到欧盟法院判例法中阐述的原则，确保充分尊重基本权利、隐私权和比例原则。为确保本条例所涵盖的个人电子健康数据的完全完整性和保密性，保证其得到极高水平的保护和安全，并降低非法访问这些个人电子健康数据的风险，本条例允许成员国要求，仅在欧盟境内存储和处理用于执行本条例所规定任务的个人电子健康数据，除非适用根据《欧盟条例（2016/679）》第 45 条通过的充分性决定。

(94)Access to electronic health data for health data users established in third countries or for international organisations should take place only on the basis of the reciprocity principle. Making electronic health data available to a third country should be allowed to take place only where the Commission has established, by means of an implementing act, that the third country concerned allows access to electronic health data originating from that third country by Union entities under the same conditions and with the same safeguards as would be the case if they were accessing electronic health data within the Union. The Commission should monitor and carry out a periodic review of the situation in those third countries and for international organisations and list those implementing acts. Where the Commission finds that a third country no longer ensures access on the same terms, it should revoke the corresponding implementing act.对于在第三国设立的健康数据使用者或国际组织获取电子健康数据，应仅基于互惠原则进行。只有在欧盟委员会通过实施法案确定相关第三国允许欧盟实体按照与在欧盟境内获取电子健康数据相同的条件和保障措施，获取源自该第三国的电子健康数据的情况下，才应允许向该第三国提供电子健康数据。欧盟委员会应监测并定期审查这些第三国和国际组织的情况，并列出这些实施法案。如果欧盟委员会发现某一第三国不再确保按相同条件提供数据访问，应撤销相应的实施法案。

(95)In order to promote the consistent application of this Regulation, including as regards cross-border interoperability of electronic health data, a European Health Data Space Board

should be set up. The Commission should participate in its activities and co-chair it. The EHDS Board should be able to issue written contributions related to the consistent application of this Regulation throughout the Union, including by helping Member States to coordinate the use of electronic health data for healthcare and certification, but also concerning secondary use, and the funding for those activities. This could also include sharing information on risks and incidents in the secure processing environments. The sharing of that kind of information does not affect obligations under other legal acts, such as data breach notifications under Regulation (EU) 2016/679. More generally, the activities of the EHDS Board are without prejudice to the powers of the supervisory authorities pursuant to Regulation (EU) 2016/679. Given that, at national level, digital health authorities dealing with primary use may be different from the health data access bodies dealing with secondary use, the functions are different and there is a need for distinct cooperation in each of those areas, the EHDS Board should be able to set up subgroups dealing with those two functions, as well as other subgroups, as needed. In order for there to be an efficient working method, the digital health authorities and health data access bodies should create networks and links at national level with other bodies and authorities, but also at Union level. Such bodies could comprise data protection authorities, cybersecurity, eID and standardisation bodies, as well as bodies and expert groups under Regulations (EU) 2022/868, (EU) 2023/2854 and (EU) 2024/1689 and Regulation (EU) 2019/881 of the European Parliament and of the Council [21]. The EHDS Board should operate independently, in the public interest and in line with its code of conduct.为促进本条例的统一适用，包括在电子健康数据的跨境互操作性方面，应设立欧洲健康数据空间委员会（European Health Data Space Board）。欧盟委员会应参与其活动并共同主持该委员会。欧洲健康数据空间委员会应能够就本条例在整个欧盟范围内的统一适用发表书面意见，包括帮助成员国协调电子健康数据在医疗保健和认证方面的使用，以及在二次使用和这些活动的资金方面提供协助。这还可包括在安全处理环境中共享有关风险和事件的信息。此类信息的共享不影响其他法律文件规定的义务，例如《(欧盟) 2016/679 号条例》规定的数据泄露通知义务。更广泛地说，欧洲健康数据空间委员会的活动不影响根据《(欧盟) 2016/679 号条例》赋予监管机构的权力。考虑到在国家层面，处理一次使用的数字健康机构可能与处理二次使用的健康数据访问机构不同，其职能各异，且在这些领域的每个领域都需要开展不同的合作，因此欧洲健康数据空间委员会应能够根据需要设立处理这两项职能的 subgroups 以及其他 subgroups。为实现高效的工作方法，数字健康机构和健康数据访问机构应在国家层面与其他机构和主管部门建立网络和联系，并在欧盟层面开展此类合作。这些机构可包括数据保护机构、网络安全机构、电子身份机构和标准化机构，以及根据《(欧盟) 2022/868 号条例》、《(欧盟) 2023/2854 号条例》、《(欧盟) 2024/1689 号条例》和欧洲议会及理事会《(欧盟) 2019/881 号条例》设立的机构和专家小组(21)。欧洲健康数据空间委员会应本着公共利益并按照其行为准则独立运作。

(96) Where issues that are considered by the EHDS Board to be of specific relevance are discussed, it should be able to invite observers, for instance the EDPS, representatives of Union institutions, including of the European Parliament, and other stakeholders.当讨论被 EHDS 委员会视为具有特定相关性的问题时，该委员会应能够邀请观察员，例如 EDPS、包括欧洲议会在内的欧盟机构代表以及其他利益相关者。

(97) A stakeholder forum should be set up to advise the EHDS Board in the fulfilment of its tasks

by providing stakeholder input on matters pertaining to this Regulation. The stakeholder forum should be composed, inter alia, of representatives of patient and consumer organisations, health professionals, industry, scientific researchers and academia. It should have a balanced composition and represent the views of different relevant stakeholders. Both commercial and non-commercial interests should be represented.应设立一个利益相关者论坛，通过就本条例相关事宜提供利益相关者的意见，为 EHDS 委员会履行其职责提供建议。该利益相关者论坛的组成人员应包括但不限于患者和消费者组织、卫生专业人员、行业、科研人员和学术界的代表。论坛的组成应保持平衡，并代表不同相关利益相关者的观点。商业和非商业利益都应得到代表。

(98)In order to ensure proper day-to-day management of the cross-border infrastructures for primary use and secondary use, it is necessary to create steering groups consisting of Member State representatives. These steering groups should take operational decisions on the technical day-to-day management of the cross-border infrastructures and their technical development, including on technical changes to the infrastructures, improving functionalities or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. Their activities should not include contributing to the development of implementing acts affecting those infrastructures. The steering groups should also be able to invite representatives of other authorised participants in HealthData@EU as observers to their meetings and should consult relevant experts when carrying out their tasks.为确保跨境基础设施在主要用途和次要用途方面的日常妥善管理，有必要成立由成员国代表组成的指导小组。这些指导小组应就跨境基础设施的日常技术管理及其技术发展做出运营决策，包括关于基础设施的技术变更、功能或服务的改进，以及确保与其他基础设施、数字系统或数据空间的互操作性。其活动不应包括为制定影响这些基础设施的实施法案提供帮助。指导小组还应有权邀请 HealthData@EU 的其他授权参与者的代表作为观察员参加其会议，并应在执行任务时咨询相关专家。

(99)Without prejudice to any other administrative, judicial or non-judicial remedy, any natural or legal person should have the right to lodge a complaint with a digital health authority or with a health data access body, if the natural or legal person considers that his or her rights or interests under this Regulation have been affected. The investigation following a complaint should be carried out, subject to judicial review, to the extent appropriate in the specific case. The digital health authority or health data access body should inform the natural or legal person of the progress and the outcome of the complaint within a reasonable period. If the case requires further investigation or coordination with another digital health authority or health data access body, information on the progress made in dealing with the complaint should be given to the natural or legal person. In order to facilitate the submission of complaints, each digital health authority and health data access body should take measures such as providing a complaint submission form which can also be completed electronically, without excluding the possibility of using other means of communication. Where the complaint concerns the rights of natural persons related to the protection of their personal data, the digital health authority or health data access body should transmit the complaint to the supervisory authorities under Regulation (EU) 2016/679. Digital health authorities or health data access bodies should cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.在不损害任何

其他行政、司法或非司法补救措施的前提下，任何自然人或法人如认为其在本条例下的权利或利益受到影响，应有权向数字健康主管部门或健康数据访问机构提出投诉。投诉后的调查应在司法审查的约束下，根据具体情况进行适当程度的开展。数字健康主管部门或健康数据访问机构应在合理期限内将投诉的进展和结果告知该自然人或法人。如果案件需要进一步调查或与其他数字健康主管部门或健康数据访问机构协调，应向该自然人或法人提供有关处理投诉进展的信息。为便利投诉的提交，每个数字健康主管部门和健康数据访问机构应采取措施，例如提供可电子填写的投诉提交表格，同时不排除使用其他通信方式的可能性。如果投诉涉及自然人与个人数据保护相关的权利，数字健康主管部门或健康数据访问机构应将投诉转交至《(欧盟)2016/679 号条例》规定的监管机构。数字健康主管部门或健康数据访问机构应开展合作以处理和解决投诉，包括通过电子方式毫不拖延地交换所有相关信息。

(100)Where a natural person considers that his or her rights under this Regulation have been infringed, he or she should have the right to mandate a not-for-profit body, organisation or association constituted in accordance with national law, having statutory public interest objectives and active in the field of the protection of personal data, to lodge a complaint on his or her behalf.当自然人认为其在本条例下的权利受到侵犯时，应有权委托根据国家法律成立、具有法定公共利益目标且在个人数据保护领域积极活动的非营利性机构、组织或协会代表自己提出投诉。

(101)The digital health authority, health data access body, health data holder or health data user should compensate any damage which a natural or legal person suffers as a result of an infringement of this Regulation. The concept of damage should be broadly interpreted in the light of the case law of the Court of Justice of the European Union, in a manner which fully reflects the objectives of this Regulation. This is without prejudice to any claims for damage deriving from the violation of other provisions in Union or national law. Natural persons should receive full and effective compensation for the damage they have suffered. 数字健康主管机构、健康数据访问机构、健康数据持有方或健康数据使用方应当对自然人或法人因违反本条例而遭受的任何损害进行赔偿。损害的概念应参照欧洲联盟法院的判例法进行广义解释，其方式应充分体现本条例的目标。这不妨碍因违反欧盟或国家法律的其他规定而产生的任何损害赔偿请求。自然人应当因其遭受的损害获得充分有效的赔偿。

(102)In order to strengthen the enforcement of the rules of this Regulation, penalties, including administrative fines, should be imposed for any infringement of this Regulation, in addition to, or instead of, appropriate measures imposed by health data access bodies pursuant to this Regulation. The imposition of penalties, including administrative fines, should be subject to appropriate procedural safeguards in accordance with the general principles of Union law and the Charter of Fundamental Rights of the European Union, including effective judicial protection and due process.为加强本条例各项规定的执行力度，除由健康数据访问机构依据本条例采取适当措施外，或在不采取这些措施的情况下，应对任何违反本条例的行为处以包括行政罚款在内的处罚。包括行政罚款在内的处罚的施加，应遵循欧盟法律的一般原则以及《欧盟基本权利宪章》的规定，具备适当的程序保障，其中包括有效的司法保护和正当法律程序。

(103)It is appropriate to lay down provisions enabling health data access bodies to apply administrative fines for certain infringements of this Regulation which should be considered

under this Regulation to be serious infringements, such as the re-identification of natural persons, downloading personal electronic health data outside of the secure processing environment or processing of data for prohibited uses or uses not covered by a data permit. This Regulation should specify those infringements and the upper limit and criteria for setting the related administrative fines, which should be determined by the competent health data access body in each individual case, taking into account all the relevant circumstances of the specific situation, having due regard in particular to the nature, gravity and duration of the infringement and its consequences and the measures taken to ensure compliance with the obligations under this Regulation and to prevent or mitigate the consequences of the infringement. For the purposes of the imposition of administrative fines under this Regulation, the concept of undertaking should be understood in accordance with Articles 101 and 102 TFEU. It should be for the Member States to determine whether and to what extent public authorities should be subject to administrative fines. Imposing an administrative fine or giving a warning should not affect the enforcement of other powers of the health data access bodies or of other penalties under this Regulation.制定相关规定，使健康数据访问机构能够对本条例下被视为严重侵权的某些违规行为处以行政罚款，是恰当的。这些严重侵权行为包括自然人的重新识别、在安全处理环境之外下载个人电子健康数据，或者为禁止用途或数据许可未涵盖的用途处理数据。本条例应明确这些侵权行为，以及设定相关行政罚款的上限和标准。主管健康数据访问机构应根据具体情况，在考虑到特定情形的所有相关因素后，针对每个个案确定罚款金额，尤其应适当考虑侵权行为的性质、严重程度、持续时间及其后果，以及为确保遵守本条例规定的义务、防止或减轻侵权后果而采取的措施。就本条例规定的行政罚款的征收而言，“企业”这一概念应依照《欧盟运行条约》第 101 条和第 102 条进行理解。应由成员国确定公共当局是否以及在何种程度上应受到行政罚款的约束。处以行政罚款或发出警告不应影响健康数据访问机构其他权力的行使，也不应影响本条例规定的其他处罚的执行。

(104) In order to ensure that the EHDS fulfils its objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the modification, addition or removal in Annex I of the main characteristics of the priority categories of personal electronic health data, the list of required data to be entered by the manufacturers of EHR systems and wellness applications into the EU database for registration of EHR systems and wellness applications as well as the modification, addition or removal of elements to be covered by the data quality and utility label. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making [22]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.为确保电子健康数据空间（EHDS）实现其目标，应授权欧盟委员会根据《欧盟运行条约》第 290 条采取相关行动，具体涉及对附件一中个人电子健康数据优先类别的主要特征进行修改、增补或删除，对电子健康记录系统和健康应用程序制造商需录入欧盟电子健康记录系统及健康应用程序注册数据库的数据清单进行修改、增补或删除，以及对数据质量和效用标签应涵盖的要素进行修改、增补或删除。尤为重要的是，欧盟委员会在筹备工

作中应开展适当磋商，包括专家层面的磋商，且这些磋商需遵循 2016 年 4 月 13 日《关于更好制定法律的机构间协议》(22)中规定的原则。特别是，为确保在授权法案的筹备过程中各方参与平等，欧洲议会和理事会应与成员国专家同时收到所有文件，且其专家应有系统地参与欧盟委员会专家小组关于授权法案筹备工作的会议。

(105)In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards:为确保本条例的统一实施，应赋予委员会以下方面的执行权：

— -technical specifications for the interoperability of the proxy services of the Member States,成员国代理服务互操作性的技术规范

— -data quality requirements for the registration of personal electronic health data in an EHR system,电子健康记录系统中个人电子健康数据注册的数据质量要求

— -cross-border specifications for priority categories of personal electronic health data,个人电子健康数据优先类别的跨境规范，

— -technical specifications for the categories of personal electronic health data, setting out the European electronic health record exchange format,个人电子健康数据类别的技术规范，其中规定了欧洲电子健康记录交换格式，

— -updates of the European electronic health record exchange format to integrate relevant revisions of the healthcare coding systems and nomenclatures,欧洲电子健康记录交换格式的更新，以整合医疗编码系统和术语的相关修订

— -technical specifications to extend the European electronic health record exchange format to additional categories of personal electronic health data,将欧洲电子健康记录交换格式扩展到更多类别的个人电子健康数据的技术规范，

— -requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No 910/2014,根据欧盟第 910/2014 号条例，关于自然人及卫生专业人员的互操作性跨境识别与认证机制的要求

— -requirements for the technical implementation of the rights of natural persons in relation to the primary use of their personal electronic health data,自然人就其个人电子健康数据的主要使用所享权利的技术实施要求

— -necessary measures for the technical development of MyHealth@EU, detailed rules concerning the security, confidentiality and protection of personal electronic health data and the conditions for compliance checks necessary to join and remain connected to MyHealth@EU,MyHealth@EU 技术开发的必要措施、有关个人电子健康数据的安全、保密和保护的详细规则，以及加入和保持与 MyHealth@EU 连接所需的合规检查条件，

— -rules regarding the requirements of cybersecurity, technical interoperability, semantic interoperability, operations and service management in relation to the processing by the Commission and its responsibilities towards the controllers,关于欧盟委员会处理过程中涉及网络安全、技术互操作性、语义互操作性、运营和服务管理要求的规则，以及其对控制者的责任

— -technical aspects of supplementary services provided through MyHealth@EU, 通过 MyHealth@EU 提供的补充服务的技术方面，

— -technical aspects of exchanges of personal electronic health data between MyHealth@EU and other services or infrastructures,MyHealth@EU 与其他服务或基础设施之间个人电子健康数据交换的技术方面，

— -connection and disconnection of other infrastructures, of national contact points for digital health of third countries or of systems established at international level by international organisations to or from the central interoperability platform of MyHealth@EU,其他基础设施、第三国数字健康国家联络点或国际组织在国际层面建立的系统与 MyHealth@EU 中央互操作性平台的连接和断开连接

— -common specifications in respect of the essential requirements laid down in Annex II,关于附件 II 中规定的基本要求的通用规范，

— -common specifications for the European digital testing environment,欧洲数字测试环境的通用规范，

— -justifications of national measures taken by market surveillance authorities in the case of non-compliance by EHR systems,市场监管机构在电子健康记录系统不达标情况下所采取国家措施的正当理由，

— -format and content of the label of wellness applications,健康应用程序标签的格式和内容，

— -principles for the fee policies and fee structures regarding the fees that health data access bodies and trusted health data holders can charge for making electronic health data available for secondary use,关于健康数据访问机构和受信任的健康数据持有者为提供电子健康数据供二次使用可收取费用的收费政策和收费结构原则，

— -the architecture of an IT tool aimed at supporting and making transparent to health data access bodies enforcement measures,一种旨在支持健康数据访问机构并使其执法措施透明化的 IT 工具的架构，

— -the logo for acknowledging the contribution of the EHDS,用于认可 EHDS 贡献的标识

— -templates for the health data access application, the data permit and the health data request,健康数据访问申请、数据许可和健康数据请求的模板，

— -technical, organisational, information security, confidentiality, data protection and interoperability requirements for the secure processing environments,安全处理环境的技术、组织、信息安全、保密性、数据保护和互操作性要求，

— -templates for agreements between controllers and processors,控制者与处理者之间的协议模板，

— -decisions on the compliance of a national contact point for secondary use of a third country or a system established at international level by international organisations with the requirements of HealthData@EU for the purposes of secondary use of health data, on the compliance with Chapter IV and on whether that national contact point for secondary use or that system provides equivalent access for health data users located in

the Union to the electronic health data it has access to,关于第三国二次使用国家联络点或国际组织在国际层面建立的系统是否符合 HealthData@EU 关于健康数据二次使用的要求、是否符合第四章规定，以及该二次使用国家联络点或系统是否为位于欧盟的健康数据用户提供其可访问的电子健康数据的同等访问权的决定，

— -HealthData@EU's requirements, technical specifications and IT architecture; conditions and compliance checks to join and remain connected to HealthData@EU; minimum criteria to be met by national contact points for secondary use and the authorised participants in HealthData@EU; responsibilities of the controllers and processors which participate in HealthData@EU; responsibilities of the controllers and processors for the secure processing environment managed by the Commission; and common specifications for the architecture of HealthData@EU and for its interoperability with other common European data spaces,HealthData@EU 的要求、技术规范和 IT 架构；加入并保持与 HealthData@EU 连接的条件和合规性检查；国家次级使用联络点以及 HealthData@EU 授权参与者需满足的最低标准；参与 HealthData@EU 的控制者和处理者的责任；控制者和处理者在欧盟委员会管理的安全处理环境方面的责任；以及 HealthData@EU 的架构及其与其他欧洲共同数据空间的互操作性的通用规范。

— -decisions to connect individual authorised participants to HealthData@EU,将个别授权参与者接入 HealthData@EU 的决定，

— -minimum elements for datasets and the characteristics of those elements to be provided by health data holders,健康数据持有者需提供的数据集的最小元素及其特征，

— -visual characteristics and technical specifications of the data quality and utility label,数据质量和效用标签的视觉特征和技术规格，

— -minimum specifications for datasets of high impact for secondary use,供二次使用的高影响力数据集的最低规格

— -decisions on whether a third country allows Union health data applicants to access electronic health data in that third country under conditions that are not more restrictive than those provided for in this Regulation,关于第三国是否允许欧盟健康数据申请者在该国访问电子健康数据，且其条件不比对本条例所规定的条件更具限制性的决定，

— -necessary measures for the establishment and operation of the EHDS Board.为 EHDS 委员会的设立和运作所采取的必要措施。

Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council [23].这些权力的行使应符合欧洲议会和理事会第 182/2011 号条例（欧盟）(23)。

(106) Member States should take all measures necessary to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. When deciding on the amount of the penalty for each individual case, Member States should take into account the limits and criteria set out in this Regulation. Re-identification of natural persons should be considered a serious breach of this Regulation.成员国应采取一切必要措施确保本条例的规定得到实施，包括

对违反规定的行为制定有效、适当且具有威慑力的处罚。在确定每个具体案件的处罚金额时，成员国应考虑本条例规定的限制和标准。对自然人的重新识别应被视为严重违反本条例的行为。

(107)Implementing the EHDS will require significant development work across Member States and central services. To track the progress made in that regard, the Commission should, until the full application of this Regulation, report annually on that progress, taking into account information provided by the Member States. Those reports could include recommendations for remedial measures, as well as an assessment of the progress made.实施电子健康数据空间（EHDS）需要各成员国和中央部门开展大量开发工作。为跟踪在这方面取得的进展，在本条例全面适用之前，委员会应每年就相关进展提交报告，同时考虑到各成员国提供的信息。这些报告可包括补救措施建议以及对所取得进展的评估。

(108)In order to assess whether this Regulation reaches its objectives effectively and efficiently, is coherent and still relevant and provides added value at Union level, the Commission should carry out an evaluation of this Regulation. The Commission should carry out a targeted evaluation of this Regulation within eight years of its entry into force, and an overall evaluation within 10 years of its entry into force. The Commission should submit reports on its main findings following each evaluation to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions.为评估本条例是否能有效且高效地实现其目标、是否连贯且仍具相关性，以及是否在欧盟层面具有附加价值，欧盟委员会应对本条例进行评估。欧盟委员会应在本条例生效后 8 年内对其进行有针对性的评估，并在生效后 10 年内进行全面评估。欧盟委员会应在每次评估后，向欧洲议会、欧盟理事会、欧洲经济和社会委员会以及地区委员会提交关于主要评估结果的报告。

(109)For a successful cross-border implementation of the EHDS, the European Interoperability Framework, the scope of which was updated and extended by the Commission communication of 23 March 2017 entitled ‘European Interoperability Framework – Implementation Strategy’ to take on board new or revised interoperability requirements, should be considered as a common reference to ensure legal, organisational, semantic and technical interoperability.为成功实现电子健康数据空间（EHDS）的跨境实施，应将《欧洲互操作性框架》视为确保法律、组织、语义和技术互操作性的共同参考。欧盟委员会在 2017 年 3 月 23 日题为《欧洲互操作性框架——实施战略》的通讯中对该框架的范围进行了更新和扩展，以纳入新的或经修订的互操作性要求。

(110)Since the objectives of this Regulation, namely to empower natural persons by providing them with increased control over their personal electronic health data and supporting their freedom of movement by ensuring that their health data follow them, to foster a genuine internal market for digital health services and products and to ensure a consistent and efficient framework for the reuse of natural persons’ health data for research, innovation, policymaking and regulatory activities, cannot be sufficiently achieved by the Member States through coordination measures alone, as shown by the evaluation of the digital aspects of Directive 2011/24/EU, but can rather, by reason of harmonising measures for rights of natural persons in relation to their electronic health data, interoperability of electronic health data and a common framework and safeguards for the primary use and

secondary use, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.本条例的目标是通过增强自然人对其个人电子健康数据的控制权、确保其健康数据可随其移动以支持其迁徙自由、培育真正的数字健康服务和产品内部市场，以及为自然人健康数据在研究、创新、政策制定和监管活动中的再利用提供一致且高效的框架。正如对《2011/24/EU 号指令》数字方面的评估所示，成员国仅通过协调措施无法充分实现这些目标。而通过协调与自然人电子健康数据相关的权利措施、实现电子健康数据的互操作性，并建立关于数据主要用途和次要用途的通用框架及保障措施，在欧盟层面能够更好地实现这些目标。因此，欧盟可根据《欧洲联盟条约》第 5 条规定的辅助性原则采取相关措施。根据该条规定的比例原则，本条例的内容不超出实现上述目标所必需的范围。

(111)The evaluation of the digital aspects of Directive 2011/24/EU shows that the effectiveness of the eHealth Network is limited, but also that there is strong potential for work at Union level in the area of digital health, as demonstrated by the work carried out during the COVID-19 pandemic. Directive 2011/24/EU should therefore be amended accordingly.对《2011/24/EU 号指令》数字化方面的评估显示，电子健康网络的成效有限，但正如新冠疫情期间开展的工作所表明的那样，在欧盟层面开展数字健康领域的工作具有巨大潜力。因此，应相应修订《2011/24/EU 号指令》。

(112)This Regulation complements the essential cybersecurity requirements laid down in Regulation (EU) 2024/2847. EHR systems which are products with digital elements within the meaning of Regulation (EU) 2024/2847 should therefore also comply with the essential cybersecurity requirements set out in that Regulation. The manufacturers of those EHR systems should demonstrate conformity as required by this Regulation. To facilitate that conformity, manufacturers should be allowed to draw up a single set of technical documents containing the elements required by both legal acts. It should be possible to demonstrate conformity of EHR systems with essential cybersecurity requirements laid down in Regulation (EU) 2024/2847 through the assessment framework under this Regulation. However, the parts of the conformity assessment procedure under this Regulation which relate to the use of testing environments should not be applied, since those testing environments do not allow for an assessment of conformity with the essential cybersecurity requirements. As Regulation (EU) 2024/2847 does not cover Software as a Service (SaaS) directly as such, EHR systems offered through the SaaS licensing and delivery model do not fall within the scope of that Regulation. Similarly, EHR systems that are developed and used in-house do not fall within the scope of that Regulation, as they are not placed on the market.本条例补充了《(欧盟)2024/2847 号条例》中规定的基本网络安全要求。因此，属于《(欧盟)2024/2847 号条例》所指的带有数字元素的产品的电子健康记录系统，还应符合该条例规定的基本网络安全要求。这些电子健康记录系统的制造商应按照本条例的要求证明其合规性。为便于合规，应允许制造商编制一套包含这两项法律文件所要求内容的技术文件。应能够通过本条例规定的评估框架，证明电子健康记录系统符合《(欧盟)2024/2847 号条例》中规定的基本网络安全要求。然而，本条例规定的合格评定程序中与测试环境使用相关的部分不应适用，因为这些测试环境

无法对是否符合基本网络安全要求进行评估。由于《(欧盟)2024/2847 号条例》本身并未直接涵盖软件即服务（SaaS），通过软件即服务许可和交付模式提供的电子健康记录系统不在该条例的适用范围内。同样，内部开发和使用的电子健康记录系统也不在该条例的适用范围内，因为它们未投放市场。

(113)The EDPS and the EDPB were consulted in accordance with Article 42(1) and (2) of Regulation (EU) 2018/1725 and delivered their joint opinion on 12 July 2022.已根据《欧盟条例》（EU）2018/1725 第 42 条第（1）和（2）款咨询了欧洲数据保护监督员（EDPS）和欧洲数据保护委员会（EDPB），它们于 2022 年 7 月 12 日发表了联合意见。

(114)This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 TFEU. The measures provided for in this Regulation should not be used to restrict competition in a manner contrary to the TFEU.本条例不应影响竞争规则的适用，特别是《欧盟运行条约》第 101 条和第 102 条的适用。本条例规定的措施不得用于以违反《欧盟运行条约》的方式限制竞争。

(115)Given the need for technical preparation, this Regulation should apply from 26 March 2027. In order to support the successful implementation of the EHDS and the creation of effective conditions for European health data cooperation, the implementation should take place in stages,鉴于技术准备的必要性，本条例应自 2027 年 3 月 26 日起生效。为支持电子健康数据空间（EHDS）的成功实施，并为欧洲健康数据合作创造有效条件，其实施应分阶段进行。

HAVE ADOPTED THIS REGULATION: 兹通过本条例：

CHAPTER I 第一章
GENERAL PROVISIONS 总则

Article 1 第一条
Subject matter and scope 主题与范围

1. This Regulation establishes the European Health Data Space (EHDS) by providing for common rules, standards and infrastructures and a governance framework, with a view to facilitating access to electronic health data for the purposes of primary use of electronic health data and secondary use of those data.1. 本条例通过制定共同规则、标准、基础设施和治理框架，建立了欧洲健康数据空间（EHDS），旨在为电子健康数据的主要使用和二次使用目的促进对电子健康数据的访问。

2. This Regulation: 2. 本条例：

(a) （a）specifies and complements the rights laid down in Regulation (EU) 2016/679 of natural persons in relation to the primary use and secondary use of their personal electronic health data;规定并补充了《欧盟条例（EU）2016/679》中规定的自然人在其个人电子健康数据的主要使用和二次使用方面的权利；

(b) (b) 规定了电子健康记录系统（“EHR 系lays down common rules for electronic health 统”）关于两个强制性统一软件组件的通用record systems (‘EHR systems’) in relation to two 规则，即分别在第 2 条第（2）款（n）项mandatory harmonised software components,

和（o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志软件组件；同时也规定了声称能与 EHR 系统在这两个统一软件组件方面实现互操作的健康应用程序在电子健康数据的主要使用方面的通用规则；

namely the European interoperability software component for EHR systems and the European logging software component for EHR systems, as defined in Article 2(2), points (n) and (o), respectively, and for wellness applications which are claimed to be interoperable with EHR systems in relation to those two harmonised software components, as regards primary use of electronic health data;针对电子健康数据的主要使用，本条例规定了电子健康记录系统（“EHR 系统”）关于两个强制性统一软件组件的通用规则，这两个组件分别是第 2 条第（2）款（n）项和（o）项所定义的欧洲 EHR 系统互操作性软件组件和欧洲 EHR 系统日志软件组件；同时，本条例也规定了声称可与 EHR 系统在上述两个统一软件组件方面实现互操作的健康应用程序的通用规则。

(c)lays down common rules and mechanisms for primary use of electronic health data and secondary use of electronic health data;制定了电子健康数据的主要使用和次要使用的通用规则和机制；

(d) （d）establishes a cross-border infrastructure enabling the primary use of personal electronic health data across the Union;建立一个跨境基础设施，使个人电子健康数据能够在欧盟范围内得到主要使用；

(e)establishes a cross-border infrastructure for secondary use of electronic health data;建立电子健康数据二次使用的跨境基础设施；

(f)establishes governance and coordination mechanisms at Union and national level for both primary use of electronic health data and secondary use of electronic health data.在欧盟和国家层面建立了电子健康数据的主要使用和次要使用的治理与协调机制。

3. This Regulation shall be without prejudice to other Union legal acts regarding access to, and sharing of or secondary use of, electronic health data, or Union requirements related to the processing of data in relation to electronic health data, in particular Regulations (EC) No 223/2009 (24), (EU) No 536/2014 (25), (EU) 2016/679, (EU) 2018/1725, (EU) 2022/868 and (EU) 2023/2854 of the European Parliament and of the Council and Directives 2002/58/EC (26) and (EU) 2016/943 (27) of the European Parliament and of the Council.3. 本条例不影响欧盟其他关于电子健康数据的获取、共享或二次使用的法律文件，也不影响欧盟关于电子健康数据处理的相关要求，特别是欧洲议会和理事会的（EC）第 223/2009 号条例(24)、（EU）第 536/2014 号条例(25)、（EU）2016/679 号条例、（EU）2018/1725 号条例、（EU）2022/868 号条例、（EU）2023/2854 号条例，以及欧洲议会和理事会的 2002/58/EC 号指令(26)和（EU）2016/943 号指令(27)。

4. References in this Regulation to the provisions of Regulation (EU) 2016/679 shall be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725, where relevant, as regards Union institutions, bodies, offices and

agencies.4. 本条例中提及《(欧盟)2016/679 号条例》条款之处，就欧盟各机构、团体、办事处及代理机构而言，在相关情况下，也应理解为提及《(欧盟)2018/1725 号条例》的相应条款。

5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, (EU) 2017/746 and (EU) 2024/1689, as regards the security of medical devices, *in vitro* diagnostic medical devices and artificial intelligence (AI) systems that interact with EHR systems.5. 就与电子健康记录系统交互的医疗器械、体外诊断医疗器械和人工智能（AI）系统的安全性而言，本条例不影响（欧盟）2017/745 号条例、（欧盟）2017/746 号条例和（欧盟）2024/1689 号条例。

6. This Regulation shall be without prejudice to Union or national law regarding electronic health data processing for the purposes of reporting, complying with access to information requests or demonstrating or verifying compliance with legal obligations, or to Union or national law regarding the granting of access to and disclosure of official documents.6. 本条例不影响欧盟或成员国关于为报告、响应信息获取请求、证明或核实法定义务遵守情况而进行电子健康数据处理的法律，也不影响欧盟或成员国关于官方文件获取与披露的法律。

7. This Regulation shall be without prejudice to specific provisions in Union or national law providing for access to electronic health data for further processing by Member States' public sector bodies, by Union institutions, bodies, offices and agencies, or by private entities entrusted under Union or national law with a task of public interest, for the purpose of carrying out such task.7. 本条例不影响欧盟或国家法律中的具体规定，这些规定允许成员国公共部门机构、欧盟机构、团体、办事处和代理机构，或根据欧盟或国家法律受委托执行公共利益任务的私人实体获取电子健康数据以进行进一步处理，从而完成此类任务。

8. This Regulation shall not affect access to electronic health data for secondary use agreed in the framework of contractual or administrative arrangements between public or private entities.8. 本条例不影响公共或私人实体之间在合同或行政安排框架内商定的电子健康数据用于二次使用的访问。

9. This Regulation does not apply to the processing of personal data in the following cases:9. 本条例不适用于以下情况下的个人数据处理：

(a) （a）where the processing is carried out in the course of an activity which falls outside the scope of Union law;在属于欧盟法律范围之外的活动过程中进行处理的情况；

(b) (b) 规定了电子健康记录系统（"EHR 系where the processing is carried out by competent 统"）关于两个强制性统一软件组件的通用authorities for the purposes of the prevention, 规则，即分别在第 2 条第（2）款（n）项和investigation, detection or prosecution of criminal （o）项中定义的 EHR 系统欧洲互操作性软offences or the execution of criminal penalties, 件组件和 EHR 系统欧洲日志软件组件；同时including the safeguarding against and the 也规定了声称能与 EHR 系统在这两个统一prevention of threats to public security.由主管机 软件组件方面实现互操作的健康应用程序关为预防、调查、侦查或起诉刑事犯罪或执行刑 在电子健康数据的主要使用方面的通用规事处罚（包括保障和预防对公共安全的威胁）而 则； 进行处理的情况。

Article 2 第 2 条

Definitions 定义

1. For the purposes of this Regulation, the following definitions apply:1. 就本条例而言，适用下列定义：

(a) （a）the definitions of ‘personal data’, ‘processing’, ‘pseudonymisation’, ‘controller’, ‘processor’, ‘third party’, ‘consent’, ‘genetic data’, ‘data concerning health’ and ‘international organisation’ laid down in Article 4, points (1), (2), (5), (7), (8), (10), (11), (13), (15) and (26), respectively, of Regulation (EU) 2016/679;《欧盟条例》（EU）2016/679 第 4 条第（1）、（2）、（5）、（7）、（8）、（10）、（11）、（13）、（15）和（26）点分别规定的“个人数据”、“处理”、“假名化”、“控制者”、“处理者”、“第三方”、“同意”、“基因数据”、“健康数据”和“国际组织”的定义；

(b) (b) 规定了电子健康记录系统（“EHR 系the definitions of ‘healthcare’, ‘Member State of 统”）关于两个强制性统一软件组件的通用affiliation’, ‘Member State of treatment’, ‘health 规则，即分别在第 2 条第（2）款（n）项professional’, ‘healthcare provider’, ‘medicinal 和（o）项中定义的 EHR 系统欧洲互操作性product’ and ‘prescription’ laid down in Article 3, 软件组件和 EHR 系统欧洲日志软件组件； points (a), (c), (d), (f), (g), (i) and (k), respectively, of 同时也规定了声称能与 EHR 系统在这两个Directive 2011/24/EU;《2011/24/EU 号指令》第 3 统一软件组件方面实现互操作的健康应用条(a)、(c)、(d)、(f)、(g)、(i)和(k)点分别规定的“医程序在电子健康数据的主要使用方面的通疗保健”、“参保成员国”、“治疗成员国”、“医疗专用规则； 业人员”、“医疗服务提供者”、“药品”和“处方”的定义；

(c)the definitions of ‘data’, ‘access’, ‘data altruism’, ‘public sector body’ and ‘secure processing environment’ laid down in Article 2, points (1), (13), (16), (17) and (20), respectively, of Regulation (EU) 2022/868;《欧盟条例》（EU）2022/868 第 2 条第（1）、（13）、（16）、（17）和（20）点分别规定的“数据”、“访问”、“数据利他主义”、“公共部门机构”和“安全处理环境”的定义；

(d) （d）the definitions of ‘making available on the market’, ‘placing on the market’, ‘market surveillance’, ‘market surveillance authority’, ‘non-compliance’, ‘manufacturer’, ‘importer’, ‘distributor’, ‘economic operator’, ‘corrective action’, ‘recall’ and ‘withdrawal’ laid down in Article 3, points (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (22) and (23), respectively, of Regulation (EU) 2019/1020;欧盟法规（EU）2019/1020 第 3 条第（1）、（2）、（3）、（4）、（7）、（8）、（9）、（10）、（13）、（16）、（22）和（23）点分别规定的“投放市场”、“上市”、“市场监督”、“市场监督机构”、“不合规”、“制造商”、“进口商”、“分销商”、“经济经营者”、“纠正措施”、“召回”和“撤回”的定义；

(e)the definitions of ‘medical device’, ‘intended purpose’, ‘instructions for use’, ‘performance’, ‘health institution’ and ‘common specifications’ laid down in Article 2, points (1), (12), (14), (22), (36) and (71), respectively, of Regulation (EU) 2017/745;《欧盟条例》（EU）2017/745 第 2 条第（1）、（12）、（14）、（22）、（36）和（71）点分别规定的“医疗器械”、“预期用途”、“使用说明”、“性能”、“医疗机构”和“通用规范”的定义；

(f)the definitions of ‘electronic identification’ and ‘electronic identification means’ laid down in

Article 3, points (1) and (2), respectively, of Regulation (EU) No 910/2014;《欧盟条例》（EU）第 910/2014 号第 3 条第（1）点和第（2）点分别规定的“电子身份”和“电子身份手段”的定义；

(g) （g）the definition of ‘contracting authorities’ laid down in Article 2(1), point (1), of Directive 2014/24/EU of the European Parliament and of the Council [28];欧洲议会和理事会第 2014/24/EU 号指令第 2 条第（1）款第（1）项规定的“缔约当局”定义（28）；

(h)the definition of ‘public health’ laid down in Article 3, point (c), of Regulation (EC) No 1338/2008 of the European Parliament and of the Council [29].欧洲议会和理事会第 1338/2008 号条例（EC）第 3 条（c）点所规定的“公共卫生”定义(29)。

2. In addition, for the purposes of this Regulation the following definitions apply:2. 此外，就本条例而言，适用下列定义：

(a) （a）‘personal electronic health data’ means data concerning health and genetic data, processed in an electronic form;“个人电子健康数据”指以电子形式处理的有关健康和基因的数据；

(b) (b) 规定了电子健康记录系统（“EHR 系‘non-personal electronic health data’ means 统”）关于两个强制性统一软件组件的通用electronic health data other than personal 规则，即分别在第 2 条第（2）款（n）项和electronic health data, including both data that （o）项中定义的 EHR 系统欧洲互操作性软have been anonymised so that they no longer 件组件和 EHR 系统欧洲日志软件组件；同relate to an identified or identifiable natural person 时也规定了声称能与 EHR 系统在这两个统(the ‘data subject’) and data that have never 一软件组件方面实现互操作的健康应用程related to a data subject;“非个人电子健康数据”指序在电子健康数据的主要使用方面的通用的是个人电子健康数据以外的电子健康数据，既规则；包括已匿名化处理、不再与已识别或可识别的自然人（“数据主体”）相关联的数据，也包括从未与数据主体相关联的数据。

(c)‘electronic health data’ means personal or non-personal electronic health data;“电子健康数据”是指个人或非个人电子健康数据；

(d) （d）‘primary use’ means the processing of electronic health data for the provision of healthcare, in order to assess, maintain or restore the state of health of the natural person to whom those data relate, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social, administrative or reimbursement services;“主要用途”是指为提供医疗服务而处理电子健康数据，以评估、维持或恢复这些数据所涉及的自然人的健康状况，包括药品和医疗设备的处方、配药和提供，以及相关的社会、行政或报销服务；

(e)‘secondary use’ means the processing of electronic health data for the purposes set out in Chapter IV of this Regulation, other than the initial purposes for which they were collected or produced;“二次使用”是指为实现本条例第四章规定的目的而对电子健康数据进行的处理，但不包括为最初收集或生成这些数据的目的而进行的处理；

(f)‘interoperability’ means the ability of organisations, as well as of software applications or devices from the same manufacturer or different manufacturers, to interact through the processes they support, involving the exchange of information and knowledge, without

changing the content of the data, between those organisations, software applications or devices;“互操作性”指的是组织以及同一制造商或不同制造商的软件应用程序或设备，能够通过它们所支持的流程进行交互，包括在这些组织、软件应用程序或设备之间交换信息和知识，且不改变数据内容的能力。

(g) （g）‘registration of electronic health data’ means the recording of health data in an electronic format, through the manual entry of such data, through the collection of such data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application;“电子健康数据注册”是指通过手动输入、设备收集或非电子健康数据转换为电子格式的方式，将健康数据以电子形式记录，以便在电子健康记录系统或健康应用程序中进行处理；

(h)‘electronic health data access service’ means an online service, such as a portal or an application for mobile devices, that enables natural persons not acting in a professional capacity to access their own electronic health data or the electronic health data of those natural persons whose electronic health data they are legally authorised to access;“电子健康数据访问服务”是指一种在线服务，例如门户网站或移动设备应用程序，它使不以专业身份行事的自然人能够访问自己的电子健康数据，或访问其依法有权访问的其他自然人的电子健康数据；

(i) （一）‘health professional access service’ means a service, supported by an EHR system, that enables health professionals to access data of natural persons under their treatment;“医疗专业人员访问服务”是指由电子健康记录系统支持、使医疗专业人员能够访问其治疗的自然人数据的服务；

(j) （j）‘electronic health record’ or ‘EHR’ means a collection of electronic health data related to a natural person and collected in the health system, processed for the purpose of the provision of healthcare;“电子健康记录”或“EHR”指在卫生系统中收集的、与自然人相关的电子健康数据集合，其处理目的是提供医疗服务。

(k) (k) “电子健康记录系统”或“EHR 系统”‘electronic health record system’ or ‘EHR system’ means any system whereby the software, or a combination of the hardware and the software of that system, allows personal electronic health data that belong to the priority categories of personal electronic health data established under this Regulation to be stored, intermediated, exported, imported, converted, edited or viewed, and intended by the manufacturer to be used by healthcare providers when providing patient care or by patients when accessing their electronic health data;“电子健康记录系统”或“EHR 系统”指的是任何这样的系统，即该系统的软件，或硬件与软件的组合，能够对根据本条例确立的个人电子健康数据优先类别中的个人电子健康数据进行存储、中转、导出、导入、转换、编辑或查看，且其制造商旨在供医疗服务提供

指任何这样的系统，其软件，或该系统的硬件与软件的组合，能够对本条例所确立的属于优先类别的个人电子健康数据进行存储、中转、导出、导入、转换、编辑或查看，且其制造商意图供医疗服务提供者在提供患者护理时使用，或供患者在访问其电子健康数据时使用；

者在提供患者护理时使用，或供患者在访问其电子健康数据时使用。

(l) “投入使用”是指本条例所涵盖的电子健康记录系统在欧盟内首次按其预定用途使用。
‘putting into service’ means the first use, for its intended purpose, in the Union of an EHR system covered by this Regulation;“投入使用”是指本条例所涵盖的电子健康记录系统在欧盟首次按其预定用途使用；

(m)‘software component’ means a discrete part of software which provides a specific functionality or performs specific functions or procedures and which can operate independently or in conjunction with other components;“软件组件”指软件中具有特定功能、执行特定操作或程序的独立部分，它可以独立运行，也可以与其他组件协同运行。

(n) （n） “欧洲电子健康记录系统互操作性软件组件”是指电子健康记录系统的一个软件组件，该组件以本条例规定的欧洲电子健康记录交换格式，提供和接收根据本条例确立的主要用途优先类别下的个人电子健康数据，且独立于欧洲电子健康记录系统日志软件组件；
‘European interoperability software component for EHR systems’ means a software component of the EHR system which provides and receives personal electronic health data under a priority category for primary use established under this Regulation in the European electronic health record exchange format provided for in this Regulation and which is independent of the European logging software component for EHR systems;“电子健康记录系统的欧洲互操作性软件组件”指的是电子健康记录系统的一个软件组件，该组件以本条例规定的欧洲电子健康记录交换格式提供和接收本条例所确立的主要用途优先类别下的个人电子健康数据，且独立于电子健康记录系统的欧洲日志软件组件。

(o) ‘电子健康记录系统欧洲互操作性软件组件’指的是电子健康记录系统的一种软件组件，它以本条例规定的欧洲电子健康记录交换格式，根据本条例确立的主要用途优先类别，提供和接收个人电子健康数据，且独立于电子健康记录系统欧洲日志软件组件；
‘European logging software component for EHR systems’ means a software component of the EHR system which provides logging information related to access by health professionals or other individuals to priority categories of personal electronic health data established under this Regulation, in the format defined in point 3.2. of Annex II thereto, and which is independent of the European interoperability software component for EHR systems;“电子健康记录系统的欧洲日志软件组件”指的是电子健康记录系统的一个软件组件，该组件以附件二第 3.2 点规定的格式，提供与医疗专业人员或其他个人访问本条例所确立的个人电子健康数据优先类别相关的日志信息，且独立于电子健康记录系统的欧洲互操作性软件组件。

(p) （p） ‘CE marking of conformity’ means a marking by which the manufacturer indicates that the EHR system is in conformity with the applicable requirements set out in this Regulation and other applicable Union law providing for its affixing pursuant to Regulation (EC) No 765/2008 of the European Parliament and of the Council [30];“合格性 CE 标志”是指制造商通过该标志表明电子健康记录系统符合本条例及根据欧洲

议会和理事会第 765/2008 号条例（EC）规定可加贴该标志的其他适用欧盟法律中规定的适用要求(30)；

(q) “风险”是指危害发生并‘risk’ means the combination of the probability of an occurrence of 对健康、安全或信息安全造a hazard causing harm to health, safety or information security and 成损害的可能性与该损害the degree of severity of such harm;“风险”是指危害对健康、安全的严重程度的组合；　　或信息安全造成损害的发生概率与该损害的严重程度的组合；

(r) “严重事件”是指投放市场的‘serious incident’ means any malfunction or deterioration in the 电子健康记录系统出现的任何characteristics or performance of an EHR system made available 故障或特性、性能下降，直接on the market that directly or indirectly leads, might have led or 或间接导致、可能已导致或可might lead to any of the following:“严重事件”是指市售电子健能导致以下任何一种情况：自康记录系统出现的任何故障或特性、性能退化，这些故障或然人死亡或自然人健康受到严退化直接或间接导致、可能已导致或可能导致以下任何一种重损害；　　情况：

(i) （一）the death of a natural person or serious harm to a natural person’s health;自然人死亡或对自然人健康造成严重损害；

(ii)serious prejudice to a natural person’s rights;对自然人权利的严重损害；

(iii)serious disruption of the management and operation of critical infrastructure in the health sector;对卫生部门关键基础设施的管理和运营造成严重干扰；

(s)‘care’ means a professional service the purpose of which is to address the specific needs of a natural person who, on account of impairment or other physical or mental conditions, requires assistance, including preventive and supportive measures, to carry out essential activities of daily living in order to support his or her personal autonomy;“照护”指的是一种专业服务，其目的是满足自然人的特定需求。该自然人由于存在障碍或其他身体、精神状况，需要获得包括预防和支持性措施在内的协助，以开展日常生活的基本活动，从而支持其个人自主性。

(t) （t）‘health data holder’ means any natural or legal person, public authority, agency or other body in the healthcare or the care sectors, including reimbursement services where necessary, as well as any natural or legal person developing products or services intended for the health, healthcare or care sectors, developing or manufacturing wellness applications, performing research in relation to the healthcare or care sectors or acting as a mortality registry, as well as any Union institution, body, office or agency, that has either:“健康数据持有者”指的是医疗或护理领域的任何自然人、法人、公共机构、代理机构或其他组织（必要时包括报销服务机构），以及任何开发用于健康、医疗或护理领域的产品或服务、开发或制造健康应用程序、从事医疗或护理领域相关研究、作为死亡登记机构的自然人或法人，还包括任何欧盟机构、团体、办公室或代理机构，且该等主体需满足以下任一条件：

(i) （一）the right or obligation, in accordance with applicable Union or national law and in its capacity as a controller or joint controller, to process personal

electronic health data for the provision of healthcare or care or for the purposes of public health, reimbursement, research, innovation, policymaking, official statistics or patient safety or for regulatory purposes; or 根据适用的欧盟或国家法律，并以控制者或联合控制者的身份，为提供医疗保健或护理，或为公共卫生、报销、研究、创新、政策制定、官方统计、患者安全或监管目的而处理个人电子健康数据的权利或义务；或

(ii)the ability to make available non-personal electronic health data through the control of the technical design of a product and related services, including by registering, providing, restricting access to or exchanging such data;通过对产品及相关服务的技术设计进行控制（包括注册、提供、限制访问或交换此类数据），使非个人电子健康数据可用的能力；

(u) （u）'health data user' means a natural or legal person, including Union institutions, bodies, offices or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, a health data request approval or an access approval by an authorised participant in HealthData@EU;"健康数据使用者"是指根据数据许可、健康数据请求批准或 HealthData@EU 中授权参与者的访问批准，获得合法访问电子健康数据以进行二次使用的自然人或法人，包括欧盟的机构、团体、办公室或机构。

(v) （v）'data permit' means an administrative decision issued to a health data user by a health data access body to process certain electronic health data specified in the data permit for specific secondary use purposes, based on conditions laid down in Chapter IV of this Regulation;"数据许可"是指健康数据访问机构向健康数据使用者作出的行政决定，允许其根据本条例第四章规定的条件，为特定的二次使用目的处理数据许可中指定的某些电子健康数据；

(w) "数据集"是指结构化的电'dataset' means a structured collection of electronic health 子健康数据集合； data;"数据集"是指结构化的电子健康数据集合；

(x) "对二次使用具有高影响'dataset of high impact for secondary use' means a dataset the 的数据集"是指因其与健康re-use of which is associated with significant benefits due to its 研究的相关性而在再利用时relevance for health research;"'具有高影响力的二次使用数据集'能带来重大益处的数据集；指的是因其与健康研究的相关性，其再利用能带来显著益处的数据集；"

(y)'dataset catalogue' means a collection of dataset descriptions, arranged in a systematic manner and including a user-oriented public part, in which information concerning individual dataset parameters is accessible by electronic means through an online portal;"数据集目录"指的是数据集描述的集合，这些描述以系统的方式排列，并包含面向用户的公共部分，其中有关各个数据集参数的信息可通过在线门户以电子方式获取。

(z)（z） "数据质量"指电子健'data quality' means the degree to which the elements of 康数据的各项要素适用于其electronic health data are suitable for their intended primary use 预期的主要用途和次要用途and secondary use;"数据质量"指的是电子健康数据的各项要素的程度； 与其预期的主要用途和次要用途相适配的程度；

(aa)（aa） "数据质量和实用性'data quality and utility label' means a graphic diagram,

标签”指一种包含量表的图表，including a scale, describing the data quality and conditions of 用于描述数据集的数据质量和use of a dataset;“数据质量和实用性标签”指的是一种图形图使用条件； 表，包括一个量表，用于描述数据集的数据质量和使用条件。

(ab) “健康应用程序”是指制造商‘wellness application’ means any software, or any 意图供自然人使用的任何软件，combination of hardware and software, intended by the 或任何硬件与软件的组合，用于manufacturer to be used by a natural person, for the 处理电子健康数据，专门用于提processing of electronic health data, specifically for providing 供有关自然人健康的信息，或出information on the health of natural persons, or the delivery 于提供医疗服务以外的目的提供of care for purposes other than the provision of 护理。 healthcare.“健康应用程序”指制造商意图供自然人使用的任何软件，或任何软硬件组合，用于处理电子健康数据，专门用于提供有关自然人健康的信息，或提供除医疗保健以外目的的护理服务。

CHAPTER II 第二章

PRIMARY USE 主要用途

SECTION 1 第一节

Rights of natural persons in relation to the primary use of their personal electronic health data, and related provisions 自然人在其个人电子健康数据的主要使用方面的权利及相关规定

Article 3 第 3 条

Right of natural persons to access their personal electronic health data 自然人访问其个人电子健康数据的权利

1. Natural persons shall have the right to access at least personal electronic health data relating to them that belong to the priority categories referred to in Article 14 and are processed for the provision of healthcare through the electronic health data access services referred to in Article 4. Access shall be provided immediately after the personal electronic health data have been registered in an EHR system, while respecting the need for technological practicability, and shall be provided free of charge and in an easily readable, consolidated and accessible format.1. 自然人有权通过第 4 条所述的电子健康数据访问服务，获取至少与其相关、属于第 14 条所述优先类别的、为提供医疗服务而处理的个人电子健康数据。在考虑技术可行性的前提下，个人电子健康数据在电子健康记录系统中登记后，应立即提供访问，且访问应免费，并以易于读取、整合且可获取的格式提供。

2. Natural persons, or their representatives referred to in Article 4(2), shall have the right to download free of charge an electronic copy of at least the personal electronic health data in the priority categories referred to in Article 14 related to those natural persons, through the electronic health data access services referred to in Article 4, in the European electronic health record exchange format referred to in Article 15.2. 自

然人或其第 4 条第 2 款所述的代表，应有权通过第 4 条所述的电子健康数据访问服务，以第 15 条所述的欧洲电子健康记录交换格式，免费下载至少与该自然人相关的第 14 条所述优先类别中的个人电子健康数据的电子副本。

3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of rights provided for in paragraphs 1 and 2 of this Article, in particular whenever those restrictions are necessary to protect natural persons, on the basis of patient safety and ethical considerations by delaying access to their personal electronic health data for a limited period of time until a health professional is able to properly communicate and explain to the natural persons concerned information that can have a significant impact on their health.3. 根据《欧盟条例》（EU）2016/679 第 23 条，成员国可限制本条第 1 款和第 2 款所规定权利的范围，特别是在以下情况下：基于患者安全和伦理考量，为保护自然人，可在有限时间内延迟其获取个人电子健康数据，直至卫生专业人员能够向相关自然人妥善传达并解释可能对其健康产生重大影响的信息。

Article 4 第 4 条

Electronic health data access services for natural persons and their representatives 自然人及其代表的电子健康数据访问服务

1. Member States shall ensure that one or more electronic health data access services at national, regional or local level are established, thereby enabling natural persons to access their personal electronic health data and exercise their rights provided for in Articles 3 and 5 to 10. Such electronic health data access services shall be free of charge for the natural persons and their representatives referred to in paragraph 2 of this Article.1. 成员国应确保在国家、地区或地方层面建立一个或多个电子健康数据访问服务，从而使自然人能够访问其个人电子健康数据，并行使第 3 条及第 5 至 10 条所规定的权利。此类电子健康数据访问服务对本条第 2 款所述的自然人及其代表应免费提供。

2. Member States shall ensure that one or more proxy services are established as a functionality of electronic health data access services which enables:2. 成员国应确保建立一个或多个代理服务，作为电子健康数据访问服务的一项功能，该功能应能：

(a) （a）natural persons to authorise other natural persons of their choice to access their personal electronic health data, or part thereof, on their behalf for a limited or unlimited period and, if needed, for a specific purpose only, and to manage those authorisations; and 自然人授权其选择的其他自然人代表自己访问其个人电子健康数据或其中的部分数据，授权期限可长可短，必要时也可仅为特定目的，并对这些授权进行管理；以及

(b) (b) 规定了电子健康记录系统（“EHR 系统”）legal representatives of natural persons to 关于两个强制性统一软件组件的通用规则，即分access personal electronic health data of 别在第 2 条第（2）款（n）项和（o）项中定义的those natural persons whose affairs they EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲administer, in accordance with national law. 日志软件组件；同时也规定了声称能与 EHR 系统自然人的法定代表人依照国家法律规定，

在这两个统一软件组件方面实现互操作的健康应访问其管理的自然人的个人电子健康数用程序在电子健康数据的主要使用方面的通用规据。
则；

Member States shall establish rules regarding the authorisations referred to in point (a) of the first subparagraph and actions of guardians and other legal representatives.成员国应制定关于第一款第（a）项所述授权以及监护人及其他法定代表人行为的规则。

3. The proxy services referred to in paragraph 2 shall provide authorisations in a transparent and easily understandable way, free of charge, and electronically or on paper. Natural persons and their representatives shall be informed about their authorisation rights, including about how to exercise those rights, and about the authorisation process.3. 第 2 款所指的代理服务应以透明且易于理解的方式提供授权，且不收取费用，形式可为电子或纸质。自然人及其代表应被告知其授权权利，包括如何行使这些权利以及授权流程。

The proxy services shall provide an easy complaint mechanism for natural persons.代理服务应为自然人提供便捷的投诉机制。

4. The proxy services referred to in paragraph 2 of this Article shall be interoperable among Member States. The Commission shall, by means of implementing acts, lay down the technical specifications for the interoperability of the proxy services of the Member States. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).4. 本条第 2 款所述的代理服务应能在成员国之间实现互操作。欧盟委员会应通过实施法案，制定成员国代理服务互操作性的技术规范。此类实施法案应依照第 98 条第 2 款所述的审查程序通过。

5. The electronic health data access services and the proxy services shall be easily accessible for persons with disabilities, vulnerable groups and persons with low digital literacy.5. 电子健康数据访问服务和代理服务应当便于残疾人、弱势群体以及数字素养较低的人使用。

Article 5 第 5 条

Right of natural persons to insert information in their own EHR 自然人在其自己的电子健康记录中插入信息的权利

Natural persons, or their representatives referred to in Article 4(2), shall have the right to insert information in the EHR of those natural persons through electronic health data access services or applications linked to those services as referred to in that Article. That information shall be clearly distinguishable as having been inserted by the natural person or by his or her representative. Natural persons, or their representatives referred to in Article 4(2), shall not be able to directly alter the electronic health data and related information inserted by health professionals.自然人或其第 4 条第（2）款所述的代表，有权通过电子健康数据访问服务或该条所述与这些服务相关联的应用程序，在该自然人的电子健康记录中插入信息。该信息

应能被清晰区分，表明是由自然人本人或其代表插入的。自然人或其第 4 条第（2）款所述的代表，不得直接更改由医疗专业人员插入的电子健康数据及相关信息。

Article 6 第 6 条

Right of natural persons to rectification 自然人的更正权

Electronic health data access services referred to in Article 4 shall enable natural persons to easily request online the rectification of their personal electronic health data in accordance with Article 16 of Regulation (EU) 2016/679. Where appropriate, the controller shall verify with a relevant health professional the accuracy of the information provided in the request.第 4 条所指的电子健康数据访问服务应使自然人能够根据《欧盟条例》（EU）2016/679 第 16 条，轻松在线请求更正其个人电子健康数据。在适当情况下，控制者应与相关医疗专业人员核实请求中所提供信息的准确性。

Member States may also enable natural persons to exercise online other rights pursuant to Chapter III of Regulation (EU) 2016/679 through electronic health data access services.成员国还可允许自然人通过电子健康数据访问服务，依据《欧盟条例（2016/679）》第三章行使其他在线权利。

Article 7 第 7 条

Right to data portability for natural persons 自然人的数据可携带权

1. Natural persons shall have the right to give access to, or to request a healthcare provider to transmit, all or part of their personal electronic health data to another healthcare provider of their choice immediately, free of charge and without hindrance from the healthcare provider or from the manufacturers of the systems used by that healthcare provider.1. 自然人有权允许其个人电子健康数据的全部或部分被访问，或要求医疗服务提供者立即、免费且不受该医疗服务提供者或其使用的系统制造商阻碍地，将其个人电子健康数据的全部或部分传输给其选择的另一位医疗服务提供者。

2. Natural persons shall have the right, where the healthcare providers are located in different Member States, to request the transmission of their personal electronic health data in the European electronic health record exchange format referred to in Article 15 through the cross-border infrastructure referred to in Article 23. The receiving healthcare provider shall accept such data and shall be able to read them.2. 当医疗服务提供者位于不同成员国时，自然人有权要求通过第 23 条所述的跨境基础设施，以第 15 条所述的欧洲电子健康记录交换格式传输其个人电子健康数据。接收方医疗服务提供者应当接收此类数据，并能够读取这些数据。

3. Natural persons shall have the right to request a healthcare provider to transmit a part of their personal electronic health data to a clearly identified recipient in the social security or reimbursement services sector. Such transmission shall be carried out immediately, free of charge and without hindrance from the healthcare provider or from the manufacturers of the systems used by that healthcare provider, and shall be

one-way only.3. 自然人有权要求医疗服务提供者将其部分个人电子健康数据传输给社会保障或报销服务领域中明确确定的接收者。此类传输应立即进行，且免费、不受医疗服务提供者或该医疗服务提供者所使用系统的制造商的阻碍，并且只能是单向的。

4. Where natural persons have downloaded an electronic copy of their priority categories of personal electronic health data in accordance with Article 3(2), they shall be able to transmit those data to healthcare providers of their choice in the European electronic health record exchange format referred to in Article 15. The receiving healthcare provider shall accept such data and be able to read them, as applicable.4. 自然人依照第 3 条第 2 款下载了其个人电子健康数据中优先类别的电子副本后，应当能够将这些数据以第 15 条所述的欧洲电子健康记录交换格式传输给其选择的医疗服务提供者。接收数据的医疗服务提供者应当按规定接收并能够读取这些数据。

Article 8 第 8 条

Right to restrict access 限制访问权

Natural persons shall have the right to restrict the access of health professionals and healthcare providers to all or parts of their personal electronic health data as referred to in Article 3.自然人有权限制卫生专业人员和医疗服务提供者访问其第 3 条所述的全部或部分个人电子健康数据。

When exercising the right referred to in the first paragraph, natural persons shall be made aware that restricting access might impact the provision of healthcare to them.在行使第一段所述权利时，应当让自然人知晓，限制访问可能会影响为其提供的医疗服务。

The fact that a natural person has restricted access under the first paragraph shall not be visible to healthcare providers.自然人根据第一款受到访问限制这一情况，不应被医疗服务提供者知晓。

Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.成员国应制定关于此类限制机制的规则和具体保障措施。

Article 9 第 9 条

Right to obtain information on accessing data 获取数据访问信息的权利

1. Natural persons shall have the right to obtain information, including through automatic notifications, on any access to their personal electronic health data through the health professional access service obtained in the context of healthcare, including access provided in accordance with Article 11(5).1. 自然人有权获取相关信息，包括通过自动通知的方式，了解通过在医疗保健领域获得的医疗专业人员访问服务对其个人电子健康数据的任何访问情况，包括根据第 11 条第 5 款提供的访问。

2. The information referred to in paragraph 1 shall be provided, free of charge and without delay, through electronic health data access services and shall be available for at least three years from each date of access to the data. That information shall include

at least the following:2. 第 1 款所指的信息应通过电子健康数据访问服务免费且无延迟地提供，并且自每次数据访问之日起至少三年内可获取。该信息应至少包括以下内容：

(a) （a）information on the healthcare provider or other individuals who accessed the personal electronic health data;关于访问个人电子健康数据的医疗服务提供者或其他个人的信息；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制性统一软件the date and time 组件的通用规则，即分别在第 2 条第（2）款（n）项和（o）项中定义的of access; 访问的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志软件组件；同时也规日期和时间；
定了声称能与 EHR 系统在这两个统一软件组件方面实现互操作的健康应用
程序在电子健康数据的主要使用方面的通用规则；

(c) which personal electronic health data were accessed.访问了哪些个人电子健康数据。

3. Member States may provide for restrictions to the right referred to in paragraph 1 in exceptional circumstances, where there are factual indications that disclosure would endanger the vital interests or rights of the health professional or the care of the natural person.3. 在特殊情况下，若有事实表明披露会危及卫生专业人员的重大利益或权利，或危及自然人的护理，成员国可对第 1 款所述权利作出限制规定。

Article 10 第 10 条

Right of natural persons to opt out in primary use 自然人在主要使用中的退出权

1. Member States' laws may provide that natural persons have the right to opt out from the access to their personal electronic health data registered in an EHR system through the electronic health data access services referred to in Articles 4 and 12. In such cases, Member States shall ensure that the exercise of that right is reversible.1. 成员国法律可规定，自然人有权选择不通过第 4 条和第 12 条所述的电子健康数据访问服务获取其在电子健康记录系统中登记的个人电子健康数据。在这种情况下，成员国应确保该权利的行使是可撤销的。

2. If a Member State provides for a right referred to in paragraph 1 of this Article, it shall establish the rules and specific safeguards regarding the opt-out mechanism. In particular, Member States may provide for a healthcare provider or health professional to be able to get access to the personal electronic health data in cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person as referred to in Article 9(2), point (c), of Regulation (EU) 2016/679, even if the patient has exercised the right to opt out in primary use.2. 如成员国规定了本条第 1 款所述的权利，则其应制定关于退出机制的规则和具体保障措施。特别是，成员国可规定，在为保护数据主体或《欧盟条例（2016/679）》第 9 条第 2 款（c）项所述的其他自然人的重大利益而有必要进行处理的情况下，即便患者已行使在主要用途中的退出权，医疗服务提供者或卫生专业人员仍可访问个人电子健康数据。

Article 11 第 11 条

Access by health professionals to personal electronic health data 医疗专业人员对个人电子健康数据的访问

1. Where health professionals process data in an electronic format, they shall have access to the relevant and necessary personal electronic health data of natural persons under their treatment through the health professional access services referred to in Article 12, irrespective of the Member State of affiliation and the Member State of treatment.1. 当医疗专业人员以电子格式处理数据时，他们应能通过第 12 条所述的医疗专业人员访问服务，获取其治疗的自然人的相关且必要的个人电子健康数据，无论其所属成员国和治疗所在成员国为何。

2. Where the Member State of affiliation of the natural person under treatment and the Member State of treatment of such natural person differ, cross-border access to the personal electronic health data of the natural person under treatment shall be provided through the cross-border infrastructure referred to in Article 23.2. 当接受治疗的自然人的参保成员国与该自然人的治疗成员国不同时，应通过第 23 条所述的跨境基础设施提供对接受治疗的自然人的个人电子健康数据的跨境访问。

3. The access referred to in paragraphs 1 and 2 of this Article shall include at least the priority categories of personal electronic health data referred to in Article 14.3. 本条第 1 款和第 2 款所指的访问权应至少包括第 14 条所指的个人电子健康数据的优先类别。

In line with the principles provided for in Article 5 of Regulation (EU) 2016/679, Member States shall establish rules providing for the categories of personal electronic health data accessible by different categories of health professionals or for different healthcare tasks. Such rules shall take into account the possibility of restrictions imposed under Article 8 of this Regulation.根据《欧盟条例（EU）2016/679》第 5 条规定的原则，成员国应制定相关规则，明确不同类别医疗专业人员可访问的个人电子健康数据类别，或针对不同医疗任务可访问的个人电子健康数据类别。此类规则应考虑根据本条例第 8 条施加限制的可能性。

4. In the case of treatment in a Member State other than the Member State of affiliation, the rules referred to in paragraph 3 shall be those of the Member State of treatment.4. 若在参保成员国以外的其他成员国接受治疗，则第 3 款所指规则应适用治疗所在成员国的规则。

5. Where access to personal electronic health data has been restricted by a natural person pursuant to Article 8, the healthcare provider or health professional shall not be informed of the restricted content of those data.5. 若自然人依据第 8 条限制了对其个人电子健康数据的访问权限，则医疗服务提供者或卫生专业人员不应被告知这些数据中受限制的内容。

By way of derogation from the first paragraph of Article 8, where necessary in order to protect the vital interests of the data subject, the healthcare provider or health professional may be granted access to the restricted electronic health data. Such cases shall be logged in a clear and understandable format and shall be easily accessible for the data subject.作为对第 8 条第一段的背离，在为保护数据主体的重大利益有必

要的情况下，可允许医疗服务提供者或医疗专业人员访问受限的电子健康数据。此类情况应以清晰易懂的格式记录，并应便于数据主体查阅。

Member States may provide for additional safeguards.成员国可规定额外的保障措施。

Article 12 第 12 条

Health professional access services 医疗专业人员访问服务

For the provision of healthcare, Member States shall ensure that health professionals are able to access free of charge the priority categories of personal electronic health data referred to in Article 14, including for cross-border care, through health professional access services.在提供医疗服务方面，成员国应确保医疗专业人员能够通过医疗专业人员访问服务，免费获取第 14 条所述的优先类别的个人电子健康数据，包括用于跨境医疗。

The services referred to in the first paragraph of this Article shall be accessible only to health professionals who are in possession of electronic identification means which are recognised pursuant to Article 6 of Regulation (EU) No 910/2014 or other electronic identification means compliant with common specifications referred to in Article 36 of this Regulation.本条第一款所述服务仅向持有根据《欧盟条例第 910/2014 号》第 6 条认可的电子识别工具，或符合本条例第 36 条所述通用规范的其他电子识别工具的卫生专业人员开放。

Personal electronic health data shall be presented in a user-friendly manner in the electronic health records to allow for easy use by health professionals.个人电子健康数据应在电子健康记录中以用户友好的方式呈现，以便医疗专业人员轻松使用。

Article 13 第 13 条

Registration of personal electronic health data 个人电子健康数据的注册

1. Member States shall ensure that, where electronic health data are processed for the provision of healthcare, healthcare providers register the relevant personal electronic health data falling fully or partially under at least the priority categories of personal electronic health data referred to in Article 14 in an electronic format in an EHR system.1. 成员国应确保，在为提供医疗服务而处理电子健康数据的情况下，医疗服务提供者将至少完全或部分属于第 14 条所述的个人电子健康数据优先类别的相关个人电子健康数据以电子格式登记在电子健康记录系统中。

2. When processing data in an electronic format, healthcare providers shall ensure that the personal electronic health data of the natural persons under their treatment are updated with information related to the healthcare.2. 在处理电子格式的数据时，医疗服务提供者应确保其治疗的自然人的个人电子健康数据及时更新与医疗相关的信息。

3. Where personal electronic health data are registered in a Member State of treatment that differs from the Member State of affiliation of the natural person concerned, the Member State of treatment shall ensure that the registration is

performed under the identification data of the natural person in the Member State of affiliation.3. 当个人电子健康数据在与相关自然人所属成员国不同的治疗成员国进行登记时，治疗成员国应确保登记是根据该自然人在所属成员国的身份识别数据进行的。

4. By 26 March 2027, the Commission shall, by means of implementing acts, determine data quality requirements, including in relation to semantics, uniformity, consistency, accuracy and completeness, for the registration of personal electronic health data in an EHR system as relevant. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).4. 到 2027 年 3 月 26 日，委员会应通过实施法案，确定与电子健康记录系统中个人电子健康数据注册相关的数据质量要求，包括语义、统一性、一致性、准确性和完整性方面的要求。这些实施法案应依照第 98 条第（2）款所述的审查程序通过。

When personal electronic health data are registered or updated, the electronic health records shall identify the health professional and healthcare provider that carried out such registration or update, and the time at which such registration or update was carried out. Member States may require other aspects of data registration to be recorded.当个人电子健康数据被登记或更新时，电子健康记录应明确进行该登记或更新操作的健康专业人员和医疗服务提供者，以及进行该登记或更新的时间。成员国可要求记录数据登记的其他方面信息。

Article 14 第 14 条

Priority categories of personal electronic health data for primary use 主要用途的个人电子健康数据优先类别

1. For the purposes of this Chapter, where data are processed in electronic format the priority categories of personal electronic health data shall be the following:1. 就本章而言，当数据以电子格式处理时，个人电子健康数据的优先类别如下：

(a) （a） patient summaries; 患者摘要；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制性统一软electronic 件组件的通用规则，即分别在第 2 条第（2）款（n）项和（o）项中定义prescriptions; 电子的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志软件组件；同时处方；也规定了声称能与 EHR 系统在这两个统一软件组件方面实现互操作的健康应用程序在电子健康数据的主要使用方面的通用规则；

(c) electronic dispensations; 电子配药；

(d) （d）medical imaging studies and related imaging reports;医学影像研究及相关影像报告；

(e)medical test results, including laboratory and other diagnostic results and related reports; and 医疗检测结果，包括实验室检测结果、其他诊断结果及相关报告；以及

(f) discharge reports. 出院报告。

The main characteristics of the priority categories of personal electronic health data for primary use shall be as set out in Annex I.主要使用的个人电子健康数据优先类别的主要特征应如附件一所述。

Member States may provide in their national law for additional categories of personal electronic health data to be accessed and exchanged for primary use pursuant to this Chapter.成员国可以在其国内法中规定，根据本章，可额外增加几类个人电子健康数据用于访问和交换，以满足主要用途。

The Commission may, by means of implementing acts, lay down cross-border specifications for the categories of personal electronic health data referred to in the third subparagraph of this paragraph pursuant to Article 15(3) and Article 23(8). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).委员会可通过实施法案，依据第 15 条第 3 款和第 23 条第 8 款，为本款第三项所指的个人电子健康数据类别制定跨境规范。此类实施法案应按照第 98 条第 2 款所述的审查程序通过。

2. The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend this Regulation by amending Annex I through the addition, modification or removal of the main characteristics of the priority categories of personal electronic health data as referred to in paragraph 1, provided that the amendments are aimed at adapting the priority categories of personal electronic health data to technical developments and international standards. Moreover, additions and modifications of those characteristics shall satisfy both of the following criteria:2. 委员会有权根据第 97 条通过授权法案，通过增加、修改或删除第 1 款所述个人电子健康数据优先类别的主要特征来修订本条例，但前提是这些修订旨在使个人电子健康数据的优先类别适应技术发展和国际标准。此外，这些特征的增加和修改应满足以下两项标准：

(a) （a）the characteristic is relevant for healthcare provided to natural persons;该特征与向自然人提供的医疗服务相关；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个the characteristic is used in the 强制性统一软件组件的通用规则，即分别在第 2 条第（2）majority of Member States 款（n）项和（o）项中定义的 EHR 系统欧洲互操作性软件according to the most recent 组件和 EHR 系统欧洲日志软件组件；同时也规定了声称能information.根据最新信息，这一与 EHR 系统在这两个统一软件组件方面实现互操作的健康特征在大多数成员国中得到应应用程序在电子健康数据的主要使用方面的通用规则； 用。

Article 15 第 15 条

European electronic health record exchange format 欧洲电子健康记录交换格式

1. By 26 March 2027, the Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 14(1), setting out the European electronic health record exchange format. Such format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. Such format shall support transmission of structured and unstructured health data and shall include the following elements:1. 到 2027 年 3 月 26 日，委员会应通过实施法案，为第 14 条第（1）款所述的个人电子健康数据优先类别制定技术规范，确定欧洲电子健康记录交换格式。该格式

应具有通用性和机器可读性，并允许在不同软件应用程序、设备和医疗服务提供者之间传输个人电子健康数据。此格式应支持结构化和非结构化健康数据的传输，并应包含以下要素：

(a) （a）harmonised datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;包含电子健康数据并定义结构的协调数据集，例如用于表示临床内容和电子健康数据其他部分的数据字段和数据组；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制coding systems and values to 性统一软件组件的通用规则，即分别在第 2 条第（2）款（n）be used in datasets containing 项和（o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHRelectronic health data;电子健系统欧洲日志软件组件；同时也规定了声称能与 EHR 系统在这康数据数据集所使用的编码两个统一软件组件方面实现互操作的健康应用程序在电子健康系统和值；
数据的主要使用方面的通用规则；

(c)technical interoperability specifications for the exchange of electronic health data, including its content representation, standards and profiles.电子健康数据交换的技术互操作性规范，包括其内容表示、标准和概要。

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 98(2).本款第一项所指的实施法案应根据第 98 条第（2）款所述的审查程序通过。

2. The Commission shall, by means of implementing acts, provide regular updates of the European electronic health record exchange format to integrate relevant revisions of the healthcare coding systems and nomenclatures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).2. 委员会应通过实施法案，定期更新欧洲电子健康记录交换格式，以整合医疗编码系统和命名法的相关修订。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

3. The Commission may, by means of implementing acts, lay down technical specifications to extend the European electronic health record exchange format to additional categories of personal electronic health data referred to in Article 14(1), third subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).3. 委员会可通过实施法案，制定技术规范，将欧洲电子健康记录交换格式扩展至第 14 条第（1）款第三项所指的其他类别的个人电子健康数据。此类实施法案应依照第 98 条第（2）款提及的审查程序通过。

4. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 14 are issued in the European electronic health record exchange format referred to in paragraph 1 of this Article. Where such data are transmitted by automated means for primary use, the receiving provider shall accept the format of the data and be able to read them.4. 成员国应确保第 14 条所述的个人电子健康数据优先类别以本条第 1 款所述的欧洲电子健康记录交换格式发布。当此类数据通过自动化方式传输用于主要用途时，接收方应接受该数据格式并能够读取这些数据。

Article 16 第16 条

Identification management 身份管理

1. Where natural persons use electronic health data access services referred to in Article 4, those natural persons shall have the right to identify themselves electronically using any electronic identification means which are recognised pursuant to Article 6 of Regulation (EU) No 910/2014. Member States may provide complementary mechanisms to ensure appropriate identity matching in cross-border situations.1. 当自然人使用第 4 条所述的电子健康数据访问服务时，这些自然人有权使用根据《欧盟条例》第 910/2014 号第 6 条认可的任何电子身份识别方式进行电子身份验证。成员国可提供补充机制，以确保在跨境情况下实现适当的身份匹配。

2. The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No 910/2014. That mechanism shall facilitate the transferability of personal electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).2. 委员会应根据第(EU)910/2014 号条例，通过实施法案确定自然人与卫生专业人员的可互操作跨境识别和认证机制的要求。该机制应促进个人电子健康数据在跨境环境中的可转移性。这些实施法案应依照第 98 条第(2)款所述的审查程序通过。

3. The Commission, in cooperation with Member States, shall implement services required by the interoperable, cross-border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border infrastructure referred to in Article 23.3. 委员会应与成员国合作，在欧盟层面实施本条第 2 款所述的互操作性跨境身份识别和认证机制所需的服务，作为第 23 条所述跨境基础设施的一部分。

4. The Member States' competent authorities and the Commission shall implement the interoperable, cross-border identification and authentication mechanism at Member State and Union level, respectively.4. 成员国的主管当局和委员会应分别在成员国层面和欧盟层面实施可互操作的跨境识别与认证机制。

Article 17 第17 条

Requirements for technical implementation 技术实施要求

The Commission shall, by means of implementing acts, determine the requirements for the technical implementation of the rights set out in this Section.委员会应通过实施法案，确定本节所规定权利的技术实施要求。

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).这些实施法案应依照第 98 条第（2）款所述的审查程序予以通过。

Article 18 第 18 条

Compensation for making personal electronic health data available 提供个人电子健康数据的补偿

Providers receiving data under this Chapter shall not be required to compensate the healthcare provider for making personal electronic health data available. A healthcare provider or a third party shall not directly or indirectly charge data subjects a fee or costs, or require compensation, for sharing or accessing data.根据本章接收数据的提供者无需因医疗服务提供者提供个人电子健康数据而向其支付报酬。医疗服务提供者或第三方不得直接或间接就数据的共享或访问向数据主体收取费用、成本或要求补偿。

SECTION 2 第 2 节

Governance for primary use 主要用途治理

Article 19 第 19 条

Digital health authorities 数字健康主管部门

1. Each Member State shall designate one or more digital health authorities responsible for the implementation and enforcement of this Chapter at national level. The Member States shall inform the Commission of the identity of the digital health authorities by 26 March 2027. Where a Member State designates more than one digital health authority or where the digital health authority consists of multiple organisations, the Member State concerned shall communicate to the Commission a description of the distribution of tasks between those various authorities or organisations. Where a Member State designates several digital health authorities, it shall designate one digital health authority to act as coordinator. The Commission shall make that information publicly available.1. 每个成员国应指定一个或多个数字健康主管部门，负责在国家层面实施和执行本章规定。成员国应在 2027 年 3 月 26 日前将数字健康主管部门的身份告知委员会。如果成员国指定了多个数字健康主管部门，或者数字健康主管部门由多个组织组成，相关成员国应向委员会说明这些不同主管部门或组织之间的任务分配情况。如果成员国指定了多个数字健康主管部门，应指定其中一个作为协调机构。委员会应将该信息公之于众。

2. Each digital health authority shall be entrusted with the following tasks and powers:2. 每个数字健康主管部门应被赋予以下任务和权力：

(a) （a）ensuring the implementation of the rights and obligations provided for in this Chapter and Chapter III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;通过采取必要的国家、区域或地方技术解决方案，并建立相关规则和机制，确保本章及第三章规定的权利和义务得到履行；

(b) (b) 规定了电子健康记录系统（“EHR 系ensuring that complete and up-to-date information 统”）关于两个强制性统一软件组件的通用about the implementation of rights and obligations 规则，即分别在第 2 条第（2）款（n）项provided for in this Chapter and Chapter III is made 和（o）项中定义的 EHR 系统欧洲互操作性readily available to natural persons, health

软件组件和 EHR 系统欧洲日志软件组件；professionals and healthcare providers; 确保自然同时也规定了声称能与 EHR 系统在这两个人、卫生专业人员和医疗服务提供者能够随时获统一软件组件方面实现互操作的健康应用取关于本章和第三章所规定的权利与义务的实施程序在电子健康数据的主要使用方面的通情况的完整且最新的信息；
用规则；

(c)in the implementation of technical solutions referred to in point (a) of this paragraph, ensuring that such technical solutions comply with this Chapter, Chapter III and Annex II;在执行本款（a）项所述技术解决方案时，确保此类技术解决方案符合本章、第三章及附件二的规定；

(d) （d）contributing at Union level to the development of technical solutions enabling natural persons and health professionals to exercise their rights and comply with their obligations set out in this Chapter;在欧盟层面助力技术解决方案的开发，使自然人及卫生专业人员能够行使其权利，并履行本章规定的义务；

(e)facilitating persons with disabilities to exercise their rights under this Chapter in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council (31);根据欧洲议会和理事会第(EU)2019/882 号指令(31)，为残疾人行使本章规定的权利提供便利；

(f)supervising the national contact points for digital health and cooperating with other digital health authorities and the Commission on further development of MyHealth@EU;监督国家数字健康联络点，并与其他数字健康主管部门及委员会合作，以进一步发展 MyHealth@EU；

(g) （g）ensuring the implementation at national level of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;与国家主管部门和利益相关者合作，确保欧洲电子健康记录交换格式在国家层面的实施；

(h)contributing at Union level to the development of the European electronic health record exchange format, to the elaboration of common specifications, in accordance with Article 36, which address quality, interoperability, security, safety, ease of use, accessibility, non-discrimination or fundamental right concerns, and to the elaboration of the specifications of the EU database for registration of EHR systems and wellness applications referred to in Article 49;在欧盟层面为以下工作做出贡献：制定欧洲电子健康记录交换格式；根据第 36 条拟定涉及质量、互操作性、安全性、易用性、可及性、非歧视或基本权利相关问题的通用规范；以及拟定第 49 条所述的欧盟电子健康记录系统和健康应用注册数据库的规范。

(i) （一）where applicable, performing market surveillance activities in accordance with Article 43, while ensuring that any conflicts of interest are avoided;在适用情况下，根据第 43 条开展市场监督活动，同时确保避免任何利益冲突；

(j) （j）building national capacity for implementing requirements concerning interoperability and security of electronic health data for primary use and participating in information exchanges and capacity building activities at Union level;建设国家能力，以落实有关电子健康数据在主要用途中的互操作性和安全性要求，并参与欧盟层面的信息交流和能力建设活动；

(k) (k) “电子健康记录系统”或“EHR 系统”cooperating with market surveillance authorities, 指任何这样的系统，其软件，或该系统participating in the activities related to handling of 的硬件与软件的组合，能够对本条例所risks posed by EHR systems and of serious incidents 确立的属于优先类别的个人电子健康数and supervising the implementation of corrective

据进行存储、中转、导出、导入、转换、action in accordance with Article 44;与市场监督机构编辑或查看，且其制造商意图供医疗服合作，参与处理电子健康记录系统带来的风险和严务提供者在提供患者护理时使用，或供重事件相关的活动，并根据第 44 条监督纠正措施的患者在访问其电子健康数据时使用； 实施；

(l) “投入使用”是指本cooperating with other relevant entities and bodies at local, regional, 条例所涵盖的电子健national or Union level, to ensure interoperability, portability and 康记录系统在欧盟内security of electronic health data;与地方、区域、国家或欧盟层面的其首次按其预定用途使他相关实体和机构合作，以确保电子健康数据的互操作性、可移植性用。 和安全性；

(m)cooperating with supervisory authorities in accordance with Regulations (EU) No 910/2014 and (EU) 2016/679 and Directive (EU) 2022/2555 of the European Parliament and of the Council (32) and with other relevant authorities, including those competent for cybersecurity and electronic identification.根据《(欧盟)第 910/2014 号条例》《(欧盟)2016/679 号条例》以及欧洲议会和理事会《(欧盟)2022/2555 号指令》(32)，与监管机构合作，并与其他相关机构合作，包括负责网络安全和电子身份识别的机构。

3. Each Member State shall ensure that each digital health authority is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers.3. 每个成员国应确保为每个数字健康机构配备有效履行其任务和行使其权力所必需的人力、技术和财政资源、场所及基础设施。

4. In the performance of its tasks, each digital health authority shall avoid any conflicts of interest. Each member of staff of the digital health authority shall act in the public interest and in an independent manner.4. 在履行其职责时，每个数字健康机构都应避免任何利益冲突。数字健康机构的每位工作人员都应以公共利益为重，独立行事。

5. In the performance of their tasks, the relevant digital health authorities shall actively cooperate and consult with relevant stakeholders’ representatives, including patients’ representatives, healthcare providers and health professionals’ representatives, including health professional associations, as well as consumer organisations and industry associations.5. 在执行其任务时，相关数字健康主管部门应积极与相关利益相关者代表合作并进行磋商，包括患者代表、医疗服务提供者和卫生专业人员代表（包括卫生专业协会），以及消费者组织和行业协会。

Article 20 第 20 条

Reporting by digital health authorities 数字健康机构的报告义务

Digital health authorities designated pursuant to Article 19 shall publish an activity report every two years, which shall contain a comprehensive overview of their activities. If a Member State designates more than one digital health authority, one of them shall be responsible for the drawing up of the report and, in doing so, it shall request the necessary information from the other digital health authorities. That activity report shall follow a structure agreed at Union level within the European

Health Data Space Board (the 'EHDS Board') referred to in Article 92. That activity report shall contain at least information concerning:根据第 19 条指定的数字健康主管部门应每两年发布一份活动报告，其中应包含其活动的全面概述。如果某一成员国指定了不止一个数字健康主管部门，则其中一个部门应负责起草报告，并在此过程中向其他数字健康主管部门索取必要信息。该活动报告应遵循第 92 条所指的欧洲健康数据空间委员会（以下简称"EHDS 委员会"）在欧盟层面商定的结构。该活动报告至少应包含以下方面的信息：

(a) （a） the measures taken to implement this Regulation;为实施本条例而采取的措施；

(b) (b) 规定了电子健康记录系统（"EHR 系统"）关于两个强the percentage of natural persons 制性统一软件组件的通用规则，即分别在第 2 条第（2）款having access to the various data （n）项和（o）项中定义的 EHR 系统欧洲互操作性软件组categories of their electronic 件和 EHR 系统欧洲日志软件组件；同时也规定了声称能与 health records;能够访问其电子健 EHR 系统在这两个统一软件组件方面实现互操作的健康应康记录中各类数据的自然人比用程序在电子健康数据的主要使用方面的通用规则； 例；

(c)the handling of requests from natural persons regarding the exercise of their rights pursuant to this Regulation;自然人依据本条例行使其权利时所提出请求的处理

(d) （d）the number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated: 计算了连接到 MyHealth@EU 的不同类型医疗服务提供者的数量，包括药店、医院和其他医疗点：

(i) （一） in absolute terms; 从绝对数量上看；

(ii)as a share of all healthcare providers of the same type; and 占同类型所有医疗服务提供者的比例；以及

(iii)as a share of natural persons that are able to use the services;占能够使用这些服务的自然人的比例；

(e)the volumes of electronic health data of different categories shared across borders through MyHealth@EU;通过 MyHealth@EU 跨境共享的各类电子健康数据的体量；

(f)the number of cases of non-compliance with mandatory requirements.违反强制性要求的案例数量。

Article 21 第 21 条

Right to lodge a complaint with a digital health authority 向数字健康机构投诉的权利

1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint in relation to the provisions laid down in this Chapter, individually or, where relevant, collectively, with the competent digital health authority, provided that their rights or interests are negatively affected.1. 在不损害任何其他行政或司法补救措施的前提下，自然人及法人在其权利或利益受到不利影响时，有权就本章规定单独或在相关情况下集体向主管数字健康机构提出申诉。

2. Where the complaint concerns the rights of natural persons pursuant to Articles 3 and 5 to 10 of this Regulation, the digital health authority shall transmit the complaint to the competent supervisory authorities under Regulation (EU) 2016/679. The digital health authority shall provide the necessary information at its disposal to the competent supervisory authority under Regulation (EU) 2016/679 in order to facilitate the assessment and investigation of the complaint.2. 若投诉涉及自然人依据本条例第 3 条及第 5 至 10 条所享有的权利，数字健康机构应将该投诉转交给《欧盟条例》（EU）2016/679 规定的主管监管机构。数字健康机构应向《欧盟条例》（EU）2016/679 规定的主管监管机构提供其掌握的必要信息，以便利对该投诉的评估和调查。

3. The competent digital health authority with which the complaint has been lodged shall inform, in accordance with national law, the complainant of the progress made in dealing with the complaint, of the decision taken on the complaint, of any referral of the complaint to the competent supervisory authority under Regulation (EU) 2016/679 and, in cases of such a referral, that that supervisory authority is, from that moment on, to be the sole point of contact for the complainant in that matter.3. 受理投诉的主管数字健康机构应依照国家法律，将投诉处理进展、就投诉作出的决定、根据《欧盟条例（EU）2016/679》将投诉移交至主管监管机构的情况，以及在发生此类移交时该监管机构自此成为投诉人在该事项上的唯一联络点等信息通知投诉人。

4. Digital health authorities in the Member States concerned shall cooperate to handle and resolve complaints related to cross-border exchange of and access to personal electronic health data, including by exchanging all relevant information by electronic means, without undue delay.4. 相关成员国的数字卫生主管部门应开展合作，处理和解决与个人电子健康数据跨境交换及访问相关的投诉，包括通过电子方式及时交换所有相关信息，不得有不当拖延。

5. Digital health authorities shall facilitate the submission of complaints and provide easily accessible tools for the submission of complaints.5. 数字健康监管机构应简化投诉提交流程，并提供易于使用的投诉提交工具。

Article 22 第 22 条

Relationship with supervisory authorities under Regulation (EU) 2016/679 与《欧盟条例》（EU）2016/679 项下监管机构的关系

The supervisory authority or supervisory authorities responsible for monitoring and enforcing the application of Regulation (EU) 2016/679 shall also be competent for monitoring and enforcing the application of Articles 3 and 5 to 10 of this Regulation. The relevant provisions of Regulation (EU) 2016/679 shall apply *mutatis mutandis*. Supervisory authorities shall be empowered to impose administrative fines up to the amount referred to in Article 83(5) of Regulation (EU) 2016/679.负责监督和执行《欧盟条例（EU）2016/679》实施的监管机构也有权监督和执行本条例第 3 条以及第 5 至 10 条的实施。《欧盟条例（EU）2016/679》的相关规定经必要修改后适用。监管机构有权处以不超过《欧盟条例（EU）2016/679》第 83 条第 5 款所述金额的行政罚款。

The supervisory authorities referred to in the first paragraph of this Article and digital health authorities referred to in Article 19 shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.本条第一款所述的监管机构和第 19 条所述的数字健康机构应在各自职权范围内，在相关情况下合作执行本条例。

SECTION 3 第 3 节

Cross-border infrastructure for primary use of personal electronic health data 个人电子健康数据主要用途的跨境基础设施

Article 23 第 23 条

MyHealth@EU 欧盟健康平台

1. The Commission shall establish a central interoperability platform for digital health ('MyHealth@EU') to provide services to support and facilitate the exchange of personal electronic health data between the national contact points for digital health of the Member States.1. 委员会应建立一个数字健康中央互操作性平台（"MyHealth@EU"），以提供服务，支持和促进成员国数字健康国家联络点之间个人电子健康数据的交换。

2. Each Member State shall designate one national contact point for digital health, as an organisational and technical gateway for the provision of services linked to the cross-border exchange of personal electronic health data in the context of primary use. Each national contact point for digital health shall be connected to all other national contact points for digital health in other Member States and to the central interoperability platform for digital health in the cross-border infrastructure MyHealth@EU. Where a national contact point for digital health is an entity consisting of multiple organisations responsible for implementing different services, the Member State concerned shall communicate to the Commission a description of the distribution of tasks between the organisations. Each Member State shall inform the Commission of the identity of its national contact point for digital health by 26 March 2027. The national contact point for digital health may be designated within the digital health authority referred to in Article 19. Member States shall inform the Commission of any subsequent modification of the identity of those national contact points for digital health. The Commission and the Member States shall make that information publicly available.2. 每个成员国应指定一个国家数字健康联络点，作为在主要用途范围内提供与个人电子健康数据跨境交换相关服务的组织和技术门户。每个国家数字健康联络点应与其他成员国的所有其他国家数字健康联络点以及跨境基础设施 MyHealth@EU 中的数字健康中央互操作性平台相连。如果国家数字健康联络点是由多个负责提供不同服务的组织组成的实体，相关成员国应向委员会通报这些组织之间的任务分配情况。每个成员国应在 2027 年 3 月 26 日前将其国家数字健康联络点的身份告知委员会。国家数字健康联络点可在第 19 条所述的数字健康机构内指定。成员国如对这些国家数字健康联络点的身份有任何后续变更，应告知委员会。委员会和成员国应将该信息公之于众。

3. Each national contact point for digital health shall enable the exchange of the personal electronic health data referred to in Article 14(1) with national contact points for digital health in other Member States through MyHealth@EU. That exchange shall be based on the European electronic health record exchange format.3. 每个国家数字健康联络点应能够通过 MyHealth@EU 与其他成员国的国家数字健康联络点交换第 14 条第（1）款所述的个人电子健康数据。此类交换应基于欧洲电子健康记录交换格式。

Where Member States provide for additional categories of personal electronic health data under Article 14(1), third subparagraph, the national contact point for digital health shall enable the exchange of the additional categories of personal electronic health data referred to in Article 14(1), third subparagraph, insofar as the Member State concerned has provided for those additional categories of personal electronic health data to be accessed and exchanged in accordance with Article 14(1), third subparagraph.如果成员国根据第 14 条第（1）款第三项规定了个人电子健康数据的额外类别，那么数字健康国家联络点应允许交换第 14 条第（1）款第三项所述的个人电子健康数据额外类别，前提是相关成员国已根据第 14 条第（1）款第三项规定这些个人电子健康数据额外类别可被访问和交换。

4. By 26 March 2027, the Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of MyHealth@EU, detailed rules concerning the security, confidentiality and protection of personal electronic health data and the conditions for compliance checks necessary to join and remain connected to MyHealth@EU. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).4. 到 2027 年 3 月 26 日，委员会应通过实施法案，为 MyHealth@EU 的技术开发、有关个人电子健康数据的安全、保密和保护的详细规则，以及加入并保持与 MyHealth@EU 连接所需的合规检查条件，采取必要措施。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

5. Member States shall ensure the connection of all healthcare providers to their national contact points for digital health. Member States shall ensure that connected healthcare providers are able to perform two-way exchanges of electronic health data with the national contact point for digital health.5. 成员国应确保所有医疗服务提供者均与本国数字健康联络点相连。成员国应确保已接入的医疗服务提供者能够与本国数字健康联络点进行电子健康数据的双向交换。

6. Member States shall ensure that pharmacies operating on their territories, including online pharmacies, are able to dispense electronic prescriptions issued in other Member States, under the conditions laid down in Article 11 of Directive 2011/24/EU.6. 成员国应确保其领土上运营的药房（包括网上药房）能够按照 2011/24/EU 号指令第 11 条规定的条件，调配其他成员国开具的电子处方。

Pharmacies shall access and accept electronic prescriptions transmitted to them from other Member States through MyHealth@EU, provided that the conditions laid down in Article 11 of Directive 2011/24/EU are fulfilled.只要符合《2011/24/EU 号指令》

第 11 条规定的条件，药房就应当访问并接收通过 MyHealth@EU 从其他成员国传输给它们的电子处方。

Following the dispensation of medicinal products based on an electronic prescription from another Member State, the pharmacy concerned shall report through MyHealth@EU such dispensation to the national contact point for digital health of the Member State in which that prescription was issued.根据来自另一成员国的电子处方调配药品后，相关药房应通过 MyHealth@EU 向开具该处方的成员国的数字健康国家联络点报告此次调配情况。

7. The national contact points for digital health shall act as joint controllers of the personal electronic health data communicated through MyHealth@EU for the processing operations in which they are involved. The Commission shall act as processor.7. 数字健康国家联络点应作为通过 MyHealth@EU 传输的个人电子健康数据在其参与的处理操作中的联合控制者。委员会应作为处理者。

8. The Commission shall, by means of implementing acts, lay down the rules regarding the requirements of cybersecurity, technical interoperability, semantic interoperability, operations and service management in relation to the processing by the processor referred to in paragraph 7 of this Article and its responsibilities towards the controllers, in accordance with Chapter IV of Regulation (EU) 2016/679. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).8. 委员会应依据《欧盟条例》（EU）2016/679 第四章，通过实施法案，制定关于第 7 款所指的处理者进行数据处理时在网络安全、技术互操作性、语义互操作性、运营及服务管理方面的要求，以及其对控制者所负责任的相关规则。此类实施法案应按照第 98 条第（2）款所述的审查程序予以通过。

9. The national contact points for digital health shall fulfil the conditions to join and to remain connected to MyHealth@EU as laid down in the implementing acts referred to in paragraph 4. The compliance of the national contact points for digital health with those conditions shall be verified by the Commission through compliance checks.9. 数字健康国家联络点应满足加入并持续接入“我的健康@欧盟”的条件，这些条件由第 4 款提及的实施法案规定。欧盟委员会应通过合规检查，核实数字健康国家联络点是否符合这些条件。

Article 24 第 24 条

Supplementary cross-border digital health services and infrastructures 补充性跨境数字健康服务和基础设施

1. Member States may provide through MyHealth@EU supplementary services that facilitate telemedicine, mobile health, access by natural persons to existing translations of their health data, exchange or verification of health-related certificates, including vaccination card services supporting public health and public health monitoring or digital health systems, services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare. The Commission shall, by means of implementing acts, set out the technical aspects of such supplementary services.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).1. 成员国可通过“MyHealth@EU”提供补充服务，以促进远程医疗、移动医疗、自然人获取其健康数据的现有翻译版本、健康相关证书的交换或验证，包括支持公共卫生和公共卫生监测的疫苗接种卡服务，或数字健康系统、服务及互操作应用，旨在实现高度的信任与安全，加强医疗连续性，并确保获得安全、高质量的医疗服务。欧盟委员会应通过实施法案，规定此类补充服务的技术方面。这些实施法案应依照第 98 条第（2）款所述的审查程序通过。

2. The Commission and Member States may facilitate the exchange of personal electronic health data with other infrastructures, such as the Clinical Patient Management System or other services or infrastructures in the health, care or social security fields which may become authorised participants in MyHealth@EU. The Commission shall, by means of implementing acts, set out the technical aspects of such exchanges. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).2. 委员会和成员国可促进个人电子健康数据与其他基础设施的交换，例如临床患者管理系统或健康、护理或社会保障领域内可能成为 MyHealth@EU 授权参与者的其他服务或基础设施。委员会应通过实施法案，规定此类交换的技术方面。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

The connection and disconnection of another infrastructure to or from the central platform for digital health shall be subject to a decision of the Commission adopted by means of an implementing act, based on the result of compliance checks of the technical aspects of exchanges as referred to in the first subparagraph of this paragraph. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).另一项基础设施与数字健康中央平台的连接和断开，应根据委员会依据本段第一分句所述的交流技术方面合规性检查结果，通过执行法案作出的决定而定。该执行法案应依照第 98 条第（2）款所述的审查程序通过。

3. A national contact point for digital health of a third country or a system established at international level by an international organisation may become an authorised participant in MyHealth@EU, provided that it fulfils the requirements of MyHealth@EU for the purposes of the personal electronic health data exchange as referred to in Article 23, that the transfer stemming from the connection to MyHealth@EU complies with the rules in Chapter V of Regulation (EU) 2016/679, and that the requirements concerning legal, organisational, operational, semantic, technical and cybersecurity measures are equivalent to those applicable to Member States in the operation of MyHealth@EU services. Those requirements shall be verified by the Commission through compliance checks.3. 第三国的国家数字健康联络点或国际组织在国际层面建立的系统，若满足《我的健康@欧盟》中关于第 23 条所述个人电子健康数据交换的要求，且因接入《我的健康@欧盟》而产生的传输符合《欧盟条例（2016/679）》第五章的规定，同时其在法律、组织、运营、语义、技术及网络安全措施方面的要求与成员国在《我的健康@欧盟》服务

运营中适用的要求相当，则可成为《我的健康@欧盟》的授权参与者。这些要求应由欧盟委员会通过合规检查进行核实。

Based on the outcome of the compliance checks referred to in the first subparagraph of this paragraph, the Commission may, by means of implementing acts, decide to connect or disconnect the national contact point for digital health of the third country or the system established at international level by an international organisation, as applicable, to or from MyHealth@EU. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).根据本款第一项所述合规检查的结果，欧盟委员会可通过实施法案，决定将第三国的数字健康国家联络点或国际组织在国际层面建立的系统（视情况而定）接入"我的健康@欧盟"平台或从中断开连接。此类实施法案应依照第 98 条第（2）款所述的审查程序通过。

The Commission shall establish and maintain a list of national contact points for digital health of third countries or of systems established at international level by international organisations which are connected to MyHealth@EU pursuant to this paragraph and shall make that list publicly available.委员会应建立并维护一份国家联络点清单，这些联络点属于根据本款与 MyHealth@EU 相连的第三国数字健康领域，或由国际组织在国际层面建立的系统，并应将该清单公之于众。

CHAPTER III 第三章

EHR SYSTEMS AND WELLNESS APPLICATIONS 电子健康记录系统和健康应用程序

SECTION 1 第一节

Scope and general provisions for EHR systems 电子健康记录系统的范围和一般规定

Article 25 第 25 条

Harmonised software components of EHR systems 电子健康记录系统的统一软件组件

1. EHR systems shall include a European interoperability software component for EHR systems and a European logging software component for EHR systems (the 'harmonised software components of EHR systems'), in accordance with the provisions laid down in this Chapter.1. 电子健康记录系统应包含一个用于电子健康记录系统的欧洲互操作性软件组件和一个用于电子健康记录系统的欧洲日志软件组件（即"电子健康记录系统的统一软件组件"），具体应符合本章规定。

2. This Chapter shall not apply to general purpose software used in a healthcare environment.2. 本章不适用于医疗环境中使用的通用软件。

Article 26 第 26 条

Placing on the market and putting into service 投放市场和投入使用

1. EHR systems shall be placed on the market or put into service only if they comply with the provisions laid down in this Chapter.1. 只有符合本章规定，电子健康记录系统方可上市或投入使用。

2. EHR systems that are manufactured and used within health institutions established in the Union, as well as EHR systems offered as a service as defined in Article 1(1), point (b), of Directive (EU) 2015/1535 of the European Parliament and of the Council [33] to a natural or legal person established in the Union, shall be considered as having been put into service.2. 在欧盟境内设立的医疗机构内制造和使用的电子健康记录系统，以及根据欧洲议会和理事会第(EU)2015/1535 号指令第 1(1)条(b)点定义的、向欧盟境内设立的自然人或法人提供的服务型电子健康记录系统，应被视为已投入使用。(33)

3. Member States shall not prohibit or restrict the placing on the market of EHR systems which comply with this Regulation, on account of considerations relating to aspects concerning the harmonised software components of EHR systems regulated by this Regulation.3. 成员国不得基于与本条例所规范的电子健康记录系统的统一软件组件相关方面的考虑，禁止或限制符合本条例的电子健康记录系统上市。

Article 27 第 27 条

Relation to Union law governing medical devices, in vitro diagnostic medical devices and AI systems 与管辖医疗器械、体外诊断医疗器械和人工智能系统的欧盟法律的关系

1. Manufacturers of medical devices or *in vitro* diagnostic medical devices, as defined in Article 2, point (1), of Regulation (EU) 2017/745 and Article 2, point (2), of Regulation (EU) 2017/746, respectively, that claim interoperability of those medical devices or *in vitro* diagnostic medical devices with the harmonised software components of EHR systems shall prove compliance with the essential requirements on the European interoperability software component for EHR systems and the European logging software component for EHR systems, laid down in Section 2 of Annex II to this Regulation. Article 36 of this Regulation shall apply to those medical devices and *in vitro* diagnostic medical devices.1. 分别符合《欧盟条例》（EU）2017/745 第 2 条第（1）点和《欧盟条例》（EU）2017/746 第 2 条第（2）点定义的医疗器械或体外诊断医疗器械制造商，若声称其医疗器械或体外诊断医疗器械与电子健康记录系统的统一软件组件具有互操作性，则应证明其符合本条例附件二第 2 节规定的电子健康记录系统欧洲互操作性软件组件和电子健康记录系统欧洲日志软件组件的基本要求。本条例第 36 条适用于这些医疗器械和体外诊断医疗器械。

2. Providers of AI systems considered to be high-risk in accordance with Article 6 of Regulation (EU) 2024/1689 (the ‘high-risk AI system’) and which do not fall within the scope of Regulation (EU) 2017/745 or (EU) 2017/746, that claim interoperability of those high-risk AI systems with the harmonised software components of EHR systems, shall prove compliance with the essential requirements on the European

interoperability software component for EHR systems and the European logging software component for EHR systems, as laid down in Section 2 of Annex II to this Regulation. Article 36 of this Regulation shall apply to those high-risk AI systems.2. 根据《欧盟条例（EU）2024/1689》第 6 条被认定为高风险的人工智能系统（以下简称“高风险人工智能系统”）的提供商，若该系统不属于《欧盟条例（EU）2017/745》或《欧盟条例（EU）2017/746》的适用范围，且声称其高风险人工智能系统可与电子健康记录系统的统一软件组件实现互操作性，则应证明其符合本条例附件二第 2 节规定的电子健康记录系统欧洲互操作性软件组件和电子健康记录系统欧洲日志软件组件的基本要求。本条例第 36 条适用于此类高风险人工智能系统。

Article 28 第 28 条

Claims 声明

In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the professional user as defined in Article 3, point (8), of Regulation (EU) 2018/1807 of the European Parliament and of the Council (34) with regard to their intended purpose, interoperability and security by:在电子健康记录系统所附的信息表、使用说明或其他信息中，以及在电子健康记录系统的广告中，禁止使用可能误导欧盟议会和理事会第 2018/1807 号条例第 3 条第（8）点所定义的专业用户的文本、名称、商标、图片以及图形或其他标志，这些标志在以下方面可能产生误导：其预期用途、互操作性和安全性。

(a) （a）ascribing functions and properties to the EHR system which it does not have;将电子健康记录系统不具备的功能和特性归属于该系统；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）failing to inform the professional user of likely 关于两个强制性统一软件组件的通用规则，即分limitations related to interoperability or 别在第 2 条第（2）款（n）项和（o）项中定义security features of the EHR system in relation 的 EHR 系统欧洲互操作性软件组件和 EHR 系统to its intended purpose;未向专业用户告知电欧洲日志软件组件；同时也规定了声称能与 EHR子健康记录系统在其预期用途方面可能存系统在这两个统一软件组件方面实现互操作的在的与互操作性或安全功能相关的局限性；健康应用程序在电子健康数据的主要使用方面
的通用规则；

(c)suggesting uses for the EHR system other than those stated to form part of the intended purpose in the technical documentation.提出电子健康记录系统的其他用途，而非技术文档中所述的构成预期用途一部分的用途。

Article 29 第 29 条

Procurement, reimbursement and financing 采购、报销和融资

Member States may maintain or define specific rules for the procurement or financing of, or reimbursement for, EHR systems in the context of the organisation, delivery or

financing of healthcare services, provided that such rules are compliant with Union law and do not affect the functioning or compliance of the harmonised software components of EHR systems.成员国可在医疗服务的组织、提供或融资方面，对电子健康记录系统的采购、融资或报销制定或保留具体规则，前提是这些规则符合欧盟法律，且不影响电子健康记录系统中已协调软件组件的功能或合规性。

SECTION 2 第 2 节

Obligations of economic operators with regard to EHR systems 经济运营商在电子健康记录系统方面的义务

Article 30 第 30 条

Obligations of manufacturers of EHR systems 电子健康记录系统制造商的义务

1. Manufacturers of EHR systems shall:1. 电子健康记录系统制造商应：

(a) （a）ensure that the harmonised software components of their EHR systems and the EHR systems themselves, to the extent that this Chapter establishes requirements for them, are in conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 36;确保其电子健康记录系统的统一软件组件以及电子健康记录系统本身（在本章对其规定要求的范围内）符合附件二规定的基本要求以及根据第 36 条制定的通用规范；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关ensure that the harmonised software components of their EHR systems are not adversely affected by other software components of the same EHR system;于两个强制性统一软件组件的通用规则，即分别在第 2 条第（2）款（n）项和（o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志确保软件组件；同时也规定了声称能与 EHR 系统在这其电子健康记录系统中经过协调的软件组两个统一软件组件方面实现互操作的健康应用程件不会受到同一电子健康记录系统中其他序在电子健康数据的主要使用方面的通用规则； 软件组件的不利影响；

(c)draw up the technical documentation of their EHR systems in accordance with Article 37 before placing those EHR systems on the market, and subsequently keep it up to date;在将其电子健康记录系统投放市场前，根据第 37 条起草该系统的技术文档，并在之后保持文档的更新。

(d) （d）ensure that their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 38 and clear and complete instructions for use;确保其电子健康记录系统随附第 38 条规定的信息表以及清晰完整的使用说明，且用户可免费获取这些内容；

(e)draw up the EU declaration of conformity in accordance with Article 39;根据第 39 条拟定欧盟合格声明；

(f)affix the CE marking of conformity in accordance with Article 41;根据第 41 条的规定粘贴 CE 合格标志；

(g) （g）indicate the name, registered trade name or registered trade mark, the postal address, and the website, email address or other digital contact details through which they can

be contacted, in the EHR system; indicate in the contact details a single point at which the manufacturer can be contacted; the contact details shall be in a language that is easily understood by users and market surveillance authorities;在电子健康记录系统中注明其名称、注册商号或注册商标、邮政地址，以及可用于联系的网站、电子邮件地址或其他数字联系方式；在联系方式中注明一个可联系制造商的单一渠道；联系方式应使用用户和市场监督机构易于理解的语言。

(h) comply with the registration obligations in Article 49;遵守第 49 条规定的注册义务；

(i) （一）take without undue delay any necessary corrective action in respect of their EHR systems, where they consider or have reason to believe that such systems are not or are no longer in conformity with the essential requirements laid down in Annex II, or recall or withdraw such systems; the manufacturers of EHR systems shall subsequently inform the national authorities of the Member States in which they made their EHR systems available on the market or put them into service of the non-conformity, of any corrective action taken, including the timetable for implementation, and of the date at which the harmonised software components of their EHR systems have been brought into conformity or been recalled or withdrawn;如果认为其电子健康记录系统不符合或不再符合附件二规定的基本要求，应立即采取任何必要的纠正措施，或召回、撤回此类系统；电子健康记录系统制造商随后应将不符合情况、所采取的任何纠正措施（包括实施时间表）以及其电子健康记录系统的统一软件组件已符合要求或已被召回、撤回的日期，通知其电子健康记录系统在市场上销售或投入使用所在的成员国国家主管部门。

(j) （j）inform the distributors of their EHR systems and, where applicable, the authorised representative, importers and users of the non-conformity and of any corrective action, recall or withdrawal of those EHR systems;告知其电子健康记录系统的分销商，以及（如适用）授权代表、进口商和用户有关不符合项的情况，以及这些电子健康记录系统的任何纠正措施、召回或撤回信息。

(k) (k) “电子健康记录系统”或“EHR 系统”inform the distributors of their EHR systems and, 指任何这样的系统，其软件，或该系统的where applicable, the authorised representative, 硬件与软件的组合，能够对本条例所确立importers and users of any mandatory preventive 的属于优先类别的个人电子健康数据进maintenance of the EHR systems and its frequency; 行存储、中转、导出、导入、转换、编辑告知其电子健康记录系统的分销商，以及（如适用）或查看，且其制造商意图供医疗服务提供授权代表、进口商和用户关于电子健康记录系统的者在提供患者护理时使用，或供患者在访任何强制性预防性维护及其频率；
问其电子健康数据时使用；

(l) “投入使用”是指upon request, provide, in an official language of the Member State 本条例所涵盖的电concerned, market surveillance authorities in that Member State with all 子健康记录系统在the information and documentation necessary to demonstrate the 欧盟内首次按其预conformity of the EHR systems which they have placed on the market or put 定用途使用。 into service with the essential requirements laid down in Annex II;应要求，以相关成员国的官方语言向该成员国的市场监督机构提供所有必要的信息和文件，以证明其投放市场或投入使用的电子健康记录系统符合附件二规定的基本要求；

(m)cooperate with market surveillance authorities, at their request, on any action taken to bring the EHR systems which they have placed on the market or put into service into conformity with the essential requirements laid down in Annex II and with any requirements adopted pursuant to Article 42 in an official language of the Member State concerned;应市场监管机构的要求，配合其采取任何行动，使自己投放市场或投入使用的电子健康记录系统符合附件二规定的基本要求，以及根据第 42 条以相关成员国官方语言通过的任何要求。

(n) （n） “欧洲电子健康记录系统互操作性软件组件”是指电establish channels of complaint 子健康记录系统的一个软件组件，该组件以本条例规定的欧and keep distributors informed 洲电子健康记录交换格式，提供和接收根据本条例确立的主thereof;建立投诉渠道，并将相要用途优先类别下的个人电子健康数据，且独立于欧洲电子关情况告知经销商；
健康记录系统日志软件组件；

(o) ‘电子健康记录系统欧洲互操作性软件组件’keep a register of complaints and a register of 指的是电子健康记录系统的一种软件组件，它non-conforming EHR systems and keep 以本条例规定的欧洲电子健康记录交换格式，distributors informed thereof.对投诉情况和不根据本条例确立的主要用途优先类别，提供和符合要求的电子健康记录系统进行登记，并接收个人电子健康数据，且独立于电子健康记将相关情况告知经销商。
录系统欧洲日志软件组件；

2. Manufacturers of EHR systems shall ensure that procedures are in place to ensure that the design, development and deployment of the harmonised software components of an EHR system continue to comply with the essential requirements laid down in Annex II and the common specifications referred to in Article 36. Changes in EHR system design or characteristics with regard to the harmonised software components of an EHR system shall be adequately taken into account and reflected in the technical documentation.2. 电子健康记录系统制造商应确保制定相关程序，以保证电子健康记录系统中经协调的软件组件的设计、开发和部署持续符合附件二规定的基本要求以及第 36 条提及的通用规范。电子健康记录系统设计或特性中与经协调的软件组件相关的变更，应在技术文件中得到充分考虑和体现。

3. Manufacturers of EHR systems shall keep the technical documentation referred to in Article 37 and the EU declaration of conformity referred to in Article 39 for 10 years after the EHR system covered by the EU declaration of conformity has been placed on the market.3. 电子健康记录系统制造商应在符合欧盟符合性声明的电子健康记录系统投放市场后，将第 37 条所述的技术文件和第 39 条所述的欧盟符合性声明保存 10 年。

Manufacturers of EHR systems shall make available the source code or the programming logic included in the technical documentation, upon a reasoned request, to the relevant authorities, if that source code or programming logic is necessary in order for those authorities to be able to check compliance with the essential requirements laid down in Annex II.电子健康记录系统制造商应在相关主管部门提出合理请求时，提供技术文档中包含的源代码或编程逻辑，前提是该源代码或编程逻辑是这些主管部门能够检查是否符合附件 II 规定的基本要求所必需的。

4. A manufacturer of EHR systems established outside the Union shall ensure that its authorised representative has the necessary documentation readily available in order

to fulfil the tasks referred to in Article 31(2).4. 在联盟外设立的电子健康记录系统制造商应确保其授权代表拥有随时可用的必要文件，以履行第 31 条第（2）款所述的任务。

5. Manufacturers of EHR systems shall, upon a reasoned request from a market surveillance authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EHR system with the essential requirements laid down in Annex II and the common specifications referred to in Article 36, in a language which can be easily understood by that market surveillance authority. The manufacturers of EHR systems shall cooperate with the market surveillance authority, at its request, on any measures taken to eliminate the risks posed by an EHR system which they have placed on the market or put into service.5. 电子健康记录系统制造商应市场监督机构的合理要求，以该机构易于理解的语言，提供所有必要的信息和文件（纸质或电子形式），以证明其电子健康记录系统符合附件二规定的基本要求以及第 36 条所述的通用规范。电子健康记录系统制造商应应市场监督机构的要求，配合其为消除其投放市场或投入使用的电子健康记录系统所带来的风险而采取的任何措施。

Article 31 第 31 条

Authorised representatives 授权代表

1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.1. 在将电子健康记录系统投放欧盟市场之前，欧盟境外的电子健康记录系统制造商应通过书面授权，指定一家设立在欧盟境内的授权代表。

2. An authorised representative shall perform the tasks specified in the mandate agreed with the manufacturer. The mandate shall allow the authorised representative to do at least the following:2. 授权代表应履行与制造商商定的授权范围内规定的任务。该授权应至少允许授权代表从事以下工作：

(a) （a）keep the EU declaration of conformity and the technical documentation referred to in Article 37 at the disposal of market surveillance authorities for the period referred to in Article 30(3);在第 30 条第 3 款所述期间内，应将欧盟符合性声明以及第 37 条所提及的技术文件留存，供市场监督机构查阅。

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制性统一软件组件的通用规则，即分别在第 2 条第（2）款（n）项和（o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志软件组件；同时也规定了声称能与 EHR 系统在这两个统一软件组件方面实现互操作的健康应用程序在电子健康数据的主要使用方面的通用规则；

further to a reasoned request from a market surveillance authority, provide authorities of the Member State concerned with a copy of the mandate and all the information and documentation necessary to demonstrate the conformity of an EHR system with the essential requirements laid down in Annex II as well as the common specifications referred to in Article 36; 应市场监督机构的合理要求，向相关成员国的主管部门提供授权委托书副本，以及证明电子健康记

录系统符合附件二规定的基本要求和第 36 条所述通用规范所需的所有信息和文件；

(c)inform without undue delay the manufacturer if the authorised representative has reason to believe that an EHR system is no longer in conformity with the essential requirements laid down in Annex II;如果授权代表有理由相信电子健康记录系统不再符合附件二规定的基本要求，应毫不延迟地通知制造商。

(d) （d）inform without undue delay the manufacturer about any complaint received from consumers or professional users;毫不拖延地将从消费者或专业用户那里收到的任何投诉通知制造商；

(e)cooperate with the market surveillance authorities, at their request, on any corrective action taken in relation to the EHR systems covered by their mandate;应市场监管部门的要求，就其职权范围内的电子健康记录系统所采取的任何纠正措施进行配合；

(f)terminate the mandate if the manufacturer does not comply with its obligations under this Regulation;如果制造商不遵守本法规规定的义务，应终止其授权；

(g) （g）ensure that the technical documentation referred to in Article 37 can be made available to relevant authorities, upon request.确保第 37 条所提及的技术文件可应要求向相关当局提供。

3. In the event of a change of the authorised representative, the detailed arrangements for such change shall address at least the following:3. 若授权代表发生变更，此类变更的详细安排至少应涉及以下内容：

(a) （a）the date of termination of the mandate of the outgoing authorised representative and the date of the beginning of the mandate of the incoming authorised representative;离任授权代表的任务终止日期以及新任授权代表的任务开始日期；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制the transfer of documents, 性统一软件组件的通用规则，即分别在第 2 条第（2）款（n）including confidentiality 项和（o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHRaspects and property rights. 文系统欧洲日志软件组件；同时也规定了声称能与 EHR 系统在件的转让，包括保密方面和知这两个统一软件组件方面实现互操作的健康应用程序在电子识产权。
健康数据的主要使用方面的通用规则；

4. Where the manufacturer is established outside the Union and has not complied with the obligations laid down in Article 30, the authorised representative shall be jointly and severally liable for non-compliance with this Regulation on the same basis as the manufacturer.4. 若制造商位于欧盟境外且未履行第 30 条规定的义务，则授权代表应与制造商在同等基础上对违反本条例的行为承担连带责任。

Article 32 第 32 条

Obligations of importers 进口商的义务

1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements laid down in Annex II as well as the

common specifications referred to in Article 36.1. 进口商仅可将符合附件二规定的基本要求以及第 36 条所述通用规范的电子健康记录系统投放欧盟市场。

2. Before making an EHR system available on the market, importers shall ensure that:2. 在将电子健康记录系统投放市场之前，进口商应确保：

(a) （a）the manufacturer has drawn up the technical documentation referred to in Article 37 and the EU declaration of conformity;制造商已拟定第 37 条所指的技术文件和欧盟合格声明。

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个the manufacturer is identified and an
强制性统一软件组件的通用规则，即分别在第 2 条第（2）authorised representative has been
款（n）项和（o）项中定义的 EHR 系统欧洲互操作性软appointed in accordance with
件组件和 EHR 系统欧洲日志软件组件；同时也规定了声Article 31;制造商已被确认，且已根
称能与 EHR 系统在这两个统一软件组件方面实现互操作据第 31 条任命了授权代表；
的健康应用程序在电子健康数据的主要使用方面的通用
规则；

(c)the EHR system bears the CE marking of conformity referred to in Article 41 after the conformity assessment procedure has been completed;在合格评定程序完成后，电子健康记录系统带有第 41 条所述的 CE 合格标志；

(d) （d）the EHR system is accompanied by the information sheet referred to in Article 38 with clear and complete instructions for use, including for its maintenance, in accessible formats.电子健康记录系统需附带第 38 条所提及的信息表，其中包含清晰完整的使用说明（包括维护说明），且信息表需采用易于获取的格式。

3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address, website, email address or other digital contact details through which they can be contacted in a document accompanying the EHR system. The contact details shall indicate a single point at which the manufacturer can be contacted and shall be in a language which can be easily understood by users and market surveillance authorities. Importers shall ensure that any additional label does not conceal or obscure any of the information provided by the manufacturer that appears on any original label which is provided for the EHR system.3. 进口商应在随附电子健康记录系统的文件中注明其名称、已注册商号或注册商标、邮政地址、网站、电子邮件地址或其他可用于联系他们的数字联系方式。这些联系方式应指向一个可联系到制造商的单一地点，且所用语言应便于用户和市场监督机构理解。进口商应确保任何附加标签不会掩盖或遮挡制造商在电子健康记录系统原有标签上提供的任何信息。

4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements laid down in Annex II and with any requirements adopted pursuant to Article 42 is jeopardised.4. 进口商应确保，在电子健康记录系统由其负责期间，该系统的变更方式不得危及它对附件二所规定的基本要求以及根据第 42 条通过的任何要求的符合性。

5. Where an importer considers or has reason to believe that an EHR system is not or is no longer in conformity with the essential requirements laid down in Annex II and with any requirements adopted pursuant to Article 42, it shall not make that EHR system available on the market, or, if that EHR system was already placed on the market, shall recall or withdraw it, until the EHR system has been brought into conformity. In the event of such recall or withdrawal, the importer shall inform without undue delay the manufacturer of such EHR system, the users and the market surveillance authorities of the Member State in which it made the EHR system available on the market of such recall or withdrawal, giving details, in particular, of the non-conformity and of any corrective measures taken.5. 当进口商认为或有理由相信某一电子健康记录系统不符合或不再符合附件二规定的基本要求以及根据第 42 条通过的任何要求时，不得将该电子健康记录系统投放市场；如果该电子健康记录系统已投放市场，则应将其召回或撤回，直至该系统符合要求为止。在发生此类召回或撤回情况时，进口商应毫不拖延地将该召回或撤回事宜通知该电子健康记录系统的制造商、用户以及其投放该系统的成员国的市场监督机构，并详细说明不符合项以及所采取的任何纠正措施。

Where an importer considers or has reason to believe that an EHR system presents a risk to the health or safety of natural persons, it shall without undue delay inform the market surveillance authorities of the Member State in which it is established, as well as the manufacturer and, where applicable, the authorised representative.如果进口商认为或有理由相信电子健康记录系统对自然人的健康或安全构成风险，应立即通知其所在成员国的市场监督机构，以及制造商，如适用，还应通知授权代表。

6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in Article 30(3) and ensure that the technical documentation referred to in Article 37 can be made available to those authorities, upon request.6. 进口商应在第 30 条第 3 款所述期间内，将欧盟符合性声明的副本留存，供市场监督机构查阅，并确保应要求能向这些机构提供第 37 条所述的技术文件。

7. Importers shall, further to a reasoned request from market surveillance authorities of the Member States concerned, provide them with all the information and documentation necessary to demonstrate the conformity of an EHR system. Importers shall cooperate with those authorities, at their request, and with the manufacturer and, where applicable, with the authorised representative in an official language of the Member State where the market surveillance authority is located. Importers shall cooperate with those authorities, at their request, on any action taken to bring their EHR systems into conformity with the essential requirements in relation to the harmonised software components as laid down in Annex II or to ensure that the EHR systems which are not in conformity with those essential requirements are recalled or withdrawn.7. 应相关成员国市场监督机构的合理要求，进口商还应向其提供证明电子健康记录系统合规所需的所有信息和文件。应上述机构的要求，进口商应与其合作，并与制造商合作；如适用，还应使用市场监督机构所在成员国的官方语言与授权代表合作。应上述机构的要求，进口商应就为使电子健康记录系统符合

附件二规定的统一软件组件相关基本要求而采取的任何行动，或为确保召回或撤回不符合这些基本要求的电子健康记录系统而采取的任何行动，与上述机构合作。

8. Importers shall establish reporting channels and ensure that they are accessible to allow users to submit complaints, and shall keep a register of complaints, of non-conforming EHR systems and EHR system recalls and withdrawals. Importers shall verify whether the channels of complaint established pursuant to Article 30(1), point (n), are publicly available, allowing users to submit complaints and to receive any communication concerning any risk related to their health and safety or to other aspects of public interest protection and allowing users to be informed of any serious incident involving an EHR system. Where such channels of complaint were not established, the importers shall establish them and take into account the accessibility needs of vulnerable groups and persons with disabilities.8. 进口商应建立报告渠道，并确保这些渠道便于用户提交投诉，同时应保留投诉、不合格电子健康记录系统以及电子健康记录系统召回和撤回的登记册。进口商应核实依据第 30 条第（1）款（n）项建立的投诉渠道是否公开可用，以便用户提交投诉、接收与自身健康安全或公共利益保护其他方面相关的任何风险的信息，以及了解涉及电子健康记录系统的任何严重事件。若未建立此类投诉渠道，进口商应予以建立，并考虑弱势群体和残疾人的无障碍需求。

9. Importers shall investigate complaints and follow up on information received on incidents involving an EHR system they made available on the market. Importers shall register those complaints, any recalls or withdrawals of EHR systems and any corrective measure taken to bring the EHR system into conformity, in the register referred to in Article 30(1), point (o), or in their own internal register. Importers shall keep the manufacturer, distributors and, where relevant, authorised representatives informed in a timely manner of the investigation and follow-up carried out and of the results of the investigation and follow-up.9. 进口商应调查投诉，并对所收到的、涉及其投放市场的电子健康记录系统相关事件的信息采取后续行动。进口商应在第 30 条第（1）款（o）项所述的登记册中，或在其自身的内部登记册中，记录这些投诉、电子健康记录系统的任何召回或撤回情况，以及为使电子健康记录系统符合要求而采取的任何纠正措施。进口商应及时将所开展的调查和后续行动及其结果通知制造商、分销商，以及相关情况下的授权代表。

Article 33 第 33 条

Obligations of distributors 经销商的义务

1. Before making an EHR system available on the market, distributors shall verify that:1. 在将电子健康记录系统投放市场前，经销商应确认：

(a) （a）the manufacturer has drawn up the EU declaration of conformity;制造商已起草欧盟符合性声明；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制性统the EHR system bears the 一软件组件的通用规则，即分别在第 2 条第（2）款（n）项和（o）CE marking of conformity; 项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志软该电子健康记录系统带件组件；同时也规定了声称能与 EHR 系统在这两个统一软件组件方有 CE 合格标志；

面实现互操作的健康应用程序在电子健康数据的主要使用方面的
通用规则；

(c)the EHR system is accompanied by the information sheet referred to in Article 38 with clear and complete instructions for use in accessible formats;电子健康记录系统应附有第 38 条所提及的信息表，其中包含以易获取格式呈现的清晰完整的使用说明；

(d) （d）where applicable, the importer has complied with the requirements set out in Article 32(3).在适用情况下，进口商已遵守第 32 条第（3）款规定的要求。

2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements laid down in Annex II and with any requirements adopted pursuant to Article 42 is jeopardised.2. 经销商应确保，在电子健康记录系统由其负责期间，该系统的改动方式不得危及它对附件二所载基本要求以及根据第 42 条通过的任何要求的符合性。

3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II and with any requirements adopted pursuant to Article 42, it shall not make that EHR system available on the market until it has been brought into conformity. The distributor shall inform without undue delay the manufacturer or the importer, as well as the market surveillance authorities of the Member States where the EHR system has been or is to be made available on the market, to that effect. Where a distributor considers or has reason to believe that an EHR system presents a risk to the health or safety of natural persons, it shall inform the market surveillance authorities of the Member State in which the distributor is established, as well as the manufacturer and the importer.3. 若经销商认为或有理由相信某电子健康记录系统不符合附件二规定的基本要求以及根据第 42 条通过的任何要求，则在该系统达到合规状态前，不得将其投放市场。经销商应毫不拖延地将此情况通知制造商或进口商，以及该电子健康记录系统已投放或拟投放市场的成员国的市场监督机构。若经销商认为或有理由相信某电子健康记录系统对自然人的健康或安全构成风险，则应通知其所在成员国的市场监督机构，以及制造商和进口商。

4. Distributors shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EHR system. They shall cooperate with that authority, at its request, and with the manufacturer, the importer and, where applicable, with the manufacturer’s authorised representative on any action taken to bring an EHR system into conformity with the essential requirements laid down in Annex II and with any requirements adopted pursuant to Article 42 or to recall or withdraw it.4. 应市场监督机构的合理要求，经销商还应向其提供证明电子健康记录系统合规性所需的所有信息和文件。经市场监督机构要求，经销商应与该机构、制造商、进口商以及（如适用）制造商的授权代表合作，采取一切必要措施，使电子健康记录系统符合附件二规定的基本要求以及根据第 42 条通过的任何要求，或对其进行召回或撤回。

Article 34 第34 条

Cases in which obligations of manufacturers of an EHR system apply to other entities or individuals 电子健康记录系统制造商的义务适用于其他实体或个人的情况

An importer, distributor or user shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations laid down in Article 30 where they:就本条例而言，进口商、分销商或用户在以下情况下应被视为制造商，并应履行第 30 条规定的义务：

(a) （a）make an EHR system available on the market under their own name or trademark;以自己的名称或商标在市场上提供电子健康记录系统；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于modify an EHR system already placed on 两个强制性统一软件组件的通用规则，即分别在第 2the market in such a way that conformity 条第（2）款（n）项和（o）项中定义的 EHR 系统欧with the applicable requirements might 洲互操作性软件组件和 EHR 系统欧洲日志软件组件；be affected; or 以可能影响其符合适用同时也规定了声称能与 EHR 系统在这两个统一软件要求的方式修改已投放市场的电子健组件方面实现互操作的健康应用程序在电子健康数康记录系统；或
据的主要使用方面的通用规则；

(c)modify an EHR system in such a way that it leads to changes in the intended purpose declared by the manufacturer.以某种方式修改电子健康记录系统，使其导致制造商声明的预期用途发生变化。

Article 35 第35 条

Identification of economic operators 经济运营商的识别

Economic operators shall, on request, identify the following to the market surveillance authorities, for 10 years from the date when the last EHR system covered by the EU declaration of conformity has been placed on the market:自符合欧盟合格声明的最后一个电子健康记录系统投放市场之日起十年内，经济运营商应市场监督机构的要求，须向其提供以下信息。

(a) （a）any economic operator that has supplied them with an EHR system; and 向其提供电子健康记录系统的任何经济运营商；以及

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制性any economic operator to 统一软件组件的通用规则，即分别在第 2 条第（2）款（n）项和which they have supplied an （o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧EHR system. 他们曾向其供洲日志软件组件；同时也规定了声称能与 EHR 系统在这两个统一应电子健康记录系统的任软件组件方面实现互操作的健康应用程序在电子健康数据的主何经济运营商。
要使用方面的通用规则；

SECTION 3 第3 节

Conformity of the harmonised software components of EHR systems 电子健康记录系统协调软件组件的合规性

Article 36 第36 条

Common specifications 通用规范

1. By 26 March 2027, the Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements laid down in Annex II, including a common template and a time limit for implementing those common specifications. Where relevant, those common specifications shall take into account the specificities of medical devices and high-risk AI systems referred to in Article 27(1) and (2), respectively, including the state-of-the-art standards for health informatics and the European electronic health record exchange format. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).1. 到 2027 年 3 月 26 日，委员会应通过实施法案，针对附件二规定的基本要求采用通用规范，包括通用模板以及实施这些通用规范的时限。在相关情况下，这些通用规范应分别考虑第 27 条第（1）款和第（2）款所述的医疗设备和高风险人工智能系统的特殊性，包括健康信息学的最新标准和欧洲电子健康记录交换格式。这些实施法案应依照第 98 条第（2）款所述的审查程序通过。

2. The common specifications referred to in paragraph 1 shall include the following information and elements:2. 第 1 款所提及的通用规范应包含以下信息和要素：

(a) （a） their scope; 其适用范围；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强their applicability to different 制性统一软件组件的通用规则，即分别在第 2 条第（2）款categories of EHR systems or （n）项和（o）项中定义的 EHR 系统欧洲互操作性软件组functions included in them; 它们件和 EHR 系统欧洲日志软件组件；同时也规定了声称能与对不同类别的电子健康记录系 EHR 系统在这两个统一软件组件方面实现互操作的健康应统或其中包含的功能的适用性；用程序在电子健康数据的主要使用方面的通用规则；

(c) their version; 其版本；

(d) （d） their validity period; 它们的有效期；

(e) a normative part; 一个规范性部分；

(f)an explanatory part, including any relevant implementation guidelines.一个解释部分，包括任何相关的实施指南。

3. The common specifications referred to in paragraph 1 may include elements related to the following:3. 第 1 款所提及的通用规范可包含与以下内容相关的要素：

(a) （a）datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;包含电子健康数据并定义结构的数据集，例如用于表示临床内容和电子健康数据其他部分的数据字段和数据组；

(b) (b) 规定了电子健康记录系统（“EHR 系coding systems and values to be used in datasets 统”）关于两个强制性统一软件组件的通用规containing electronic health data, taking due 则，即分别在第 2 条第（2）款（n）项和（o）account of both potential future harmonisation of

项中定义的 EHR 系统欧洲互操作性软件组件terminologies and their compatibility with existing 和 EHR 系统欧洲日志软件组件；同时也规定national terminologies;用于包含电子健康数据的了声称能与 EHR 系统在这两个统一软件组件数据集中的编码系统和值，同时适当考虑术语未方面实现互操作的健康应用程序在电子健康来可能的统一及其与现有国家术语的兼容性；数据的主要使用方面的通用规则；

(c)other requirements related to data quality, such as the completeness and accuracy of electronic health data;其他与数据质量相关的要求，例如电子健康数据的完整性和准确性；

(d) （d）technical specifications, standards and profiles for the exchange of electronic health data;电子健康数据交换的技术规范、标准和概要；

(e)requirements and principles related to patient safety and the security, confidentiality, integrity and protection of electronic health data;与患者安全以及电子健康数据的安全性、保密性、完整性和保护性相关的要求和原则；

(f)specifications and requirements related to identification management and the use of electronic identification.与身份管理和电子身份使用相关的规范和要求。

4. EHR systems, medical devices, *in vitro* diagnostic medical devices and high-risk AI systems referred to in Articles 25 and 27 that are in conformity with the common specifications referred to in paragraph 1 of this Article shall be considered to be in conformity with the essential requirements covered by those common specifications or parts thereof, laid down in Annex II, and covered by those common specifications or the relevant parts thereof.4. 符合本条第 1 款所述通用规范的电子健康记录系统、医疗设备、体外诊断医疗设备以及第 25 条和第 27 条所述的高风险人工智能系统，应被视为符合附件 II 规定的、且由这些通用规范或其相关部分所涵盖的基本要求，或这些通用规范所涵盖的基本要求的相关部分。

5. Where common specifications covering interoperability and security requirements of EHR systems affect medical devices, *in vitro* diagnostic medical devices or high-risk AI systems falling under other legal acts, such as Regulation (EU) 2017/745, (EU) 2017/746 or (EU) 2024/1689, the adoption of those common specifications may be preceded by a consultation with the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745 or the European Artificial Intelligence Board established by Article 65 of Regulation (EU) 2024/1689 and the European Data Protection Board (EDPB), as applicable.5. 若涵盖电子健康记录系统互操作性和安全要求的通用规范涉及受其他法律条例（如《欧盟条例（EU）2017/745》《欧盟条例（EU）2017/746》或《欧盟条例（EU）2024/1689》）管辖的医疗设备、体外诊断医疗设备或高风险人工智能系统，在通过这些通用规范之前，可酌情与《欧盟条例（EU）2017/745》第 103 条设立的医疗设备协调小组（MDCG）、《欧盟条例（EU）2024/1689》第 65 条设立的欧洲人工智能委员会以及欧洲数据保护委员会（EDPB）进行磋商。

6. Where common specifications covering interoperability and security requirements of medical devices, *in vitro* diagnostic medical devices or high-risk AI systems falling under other legal acts, such as Regulation (EU) 2017/745, (EU) 2017/746 or (EU) 2024/1689, affect EHR systems, the Commission shall ensure that the adoption of those common specifications is preceded by a consultation with the EHDS Board and

the EDPB, as applicable.6. 若涵盖医疗器械、体外诊断医疗器械或属于其他法律文件（如欧盟法规 2017/745、2017/746 或 2024/1689）管辖范围的高风险人工智能系统的互操作性和安全要求的通用规范对电子健康记录系统产生影响，欧盟委员会应确保在通过这些通用规范之前，酌情与电子健康档案系统委员会和欧洲数据保护委员会进行磋商。

Article 37 第 37 条

Technical documentation 技术文档

1. Manufacturers shall draw up technical documentation before the EHR system is placed on the market or put into service, and shall keep that documentation up to date.1. 制造商应在电子健康记录系统上市或投入使用前编制技术文档，并应及时更新该文档。

2. The technical documentation referred to in paragraph 1 of this Article shall demonstrate that the EHR system complies with the essential requirements laid down in Annex II and provide market surveillance authorities with all the necessary information to assess the conformity of the EHR system with those requirements. That technical documentation shall contain, as a minimum, the elements set out in Annex III and a reference to the results obtained from a European digital testing environment referred to in Article 40.2. 本条第 1 款所述的技术文件应证明电子健康记录系统符合附件 II 规定的基本要求，并向市场监督机构提供评估该系统是否符合这些要求所需的全部必要信息。该技术文件至少应包含附件 III 所列要素，以及提及从第 40 条所述的欧洲数字测试环境中获得的结果。

3. The technical documentation referred to in paragraph 1 shall be drawn up in an official language of the Member State concerned or a language that is easily understandable in that Member State. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into an official language of that Member State.3. 第 1 款所指的技术文件应以相关成员国的官方语言或在该成员国易于理解的语言编制。应某一成员国市场监督机构的合理请求，制造商应将技术文件的相关部分翻译成该成员国的一种官方语言。

4. When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, the manufacturer shall provide such technical documentation or translation within 30 days of the date of the request, unless a shorter deadline is justified because of a serious and immediate risk. If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3 of this Article, the market surveillance authority may require it to have a test performed by an independent body at its own expense within a specified period in order to verify the conformity with the essential requirements laid down in Annex II and the common specifications referred to in Article 36.4. 当市场监督机构要求制造商提供技术文件或其部分内容的翻译件时，制造商应在收到请求之日起 30 天内提供此类技术文件或翻译件，除非因存在严重且紧迫的风险而有正当理由设定更短的期限。如果制造商未遵守本条第 1、2 和 3 款的要求，市场监督机构可要求其在指定期限

内由独立机构自费进行测试，以验证其是否符合附件 II 规定的基本要求以及第 36 条提及的通用规范。

Article 38 第 38 条

Information sheet accompanying the EHR system 伴随电子健康记录系统的信息表

1. EHR systems shall be accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to professional users.1. 电子健康记录系统应附带一份信息表，其中包含简洁、完整、准确且清晰的信息，这些信息需与专业用户相关、易于获取且易于理解。

2. The information sheet referred to in paragraph 1 shall specify:2. 第 1 款所指的信息表应明确：

(a) （a）the identity, registered trade name or registered trademark, and contact details of the manufacturer and, where applicable, of its authorised representative;制造商及其（如适用）授权代表的身份、注册商号或注册商标，以及联系方式；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制性统the name and version of 一软件组件的通用规则，即分别在第 2 条第（2）款（n）项和（o）the EHR system and date 项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志of its release;电子健康记软件组件；同时也规定了声称能与 EHR 系统在这两个统一软件组件录系统的名称、版本及其方面实现互操作的健康应用程序在电子健康数据的主要使用方面发布日期；
的通用规则；

(c) the intended purpose of the EHR system;电子健康记录系统的预期用途；

(d) （d）the categories of electronic health data that the EHR system has been designed to process;电子健康记录系统设计用于处理的电子健康数据类别；

(e)the standards, formats and specifications supported by the EHR system and versions of those standards, formats and specifications.电子健康记录系统支持的标准、格式和规范，以及这些标准、格式和规范的版本。

3. As an alternative to supplying the information sheet referred to in paragraph 1 of this Article with the EHR system, manufacturers may enter the information referred to in paragraph 2 of this Article into the EU database for registration of EHR systems and wellness applications referred to in Article 49.3. 作为向电子健康记录系统提供本条第 1 款所述信息表的替代方案，制造商可将本条第 2 款所述信息录入第 49 条所述的欧盟电子健康记录系统和健康应用注册数据库。

Article 39 第 39 条

EU declaration of conformity 欧盟符合性声明

1. The EU declaration of conformity referred to in Article 30(1), point (e), shall state that the manufacturer of an EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.1. 第 30 条第（1）款（e）项

所提及的欧盟符合性声明应表明，电子健康记录系统的制造商已证明其符合附件 II 中规定的基本要求。

2. Where an EHR system is subject to other Union legal acts in respect of aspects not covered by this Regulation, which also require an EU declaration of conformity by the manufacturer in which it is stated that the fulfilment of the requirements of those legal acts has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union legal acts applicable to the EHR system. That EU declaration of conformity shall contain all the information required for the identification of the Union legal acts to which it relates.2. 若电子健康记录系统在本条例未涵盖的方面受其他欧盟法律行为约束，且这些法律行为也要求制造商出具欧盟合格声明，声明已证明符合这些法律行为的要求，则应就适用于该电子健康记录系统的所有欧盟法律行为拟定一份单一的欧盟合格声明。该欧盟合格声明应包含识别其所涉及的欧盟法律行为所需的全部信息。

3. The EU declaration of conformity shall contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member States in which the EHR system is made available.3. 欧盟符合性声明应包含附件四所列信息，并应翻译成提供电子健康记录系统的成员国所确定的一种或多种欧盟官方语言。

4. Where an EU declaration of conformity is drawn up in a digital format, it shall be made accessible online for the expected lifetime of the EHR system and, in any event, for at least 10 years from the placing on the market or the putting into service of the EHR system.4. 当欧盟符合性声明以数字形式编制时，应在电子健康记录系统的预期使用寿命内在线提供，且无论如何，自该电子健康记录系统投放市场或投入使用之日起，至少需提供 10 年。

5. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the harmonised software components of the EHR system with the requirements laid down in this Regulation when it is placed on the market or put into service.5. 制造商通过起草欧盟符合性声明，应承担电子健康记录系统中已协调软件组件在投放市场或投入使用时符合本法规规定要求的责任。

6. The Commission shall publish a standard uniform template for the EU declaration of conformity and make it available in a digital format in all official languages of the Union.6. 委员会应发布欧盟符合性声明的标准统一模板，并以数字格式提供欧盟所有官方语言的版本。

Article 40 第 40 条

European digital testing environment 欧洲数字测试环境

1. The Commission shall develop a European digital testing environment for the assessment of harmonised software components of EHR systems. The Commission shall make the software supporting the European digital testing environment available as open-source.1. 委员会应开发一个欧洲数字测试环境，用于评估电子健康记录

系统的统一软件组件。委员会应将支持该欧洲数字测试环境的软件作为开源软件提供。

2. Member States shall operate digital testing environments for the assessment of harmonised software components of EHR systems. Such digital testing environments shall comply with the common specifications for the European digital testing environment laid down pursuant to paragraph 4. Member States shall inform the Commission about their digital testing environments.2. 成员国应运行数字测试环境，以评估电子健康记录系统的统一软件组件。此类数字测试环境应符合根据第 4 款制定的欧洲数字测试环境通用规范。成员国应向委员会通报其数字测试环境的相关情况。

3. Before placing EHR systems on the market, manufacturers shall use the digital testing environments referred to in paragraphs 1 and 2 of this Article for the assessment of harmonised software components of EHR systems. The results of that assessment shall be included in the technical documentation referred to in Article 37. The elements in relation to which the results of the assessment are positive shall be presumed to be in conformity with this Regulation.3. 在将电子健康记录系统投放市场前，制造商应使用本条第 1 款和第 2 款所述的数字测试环境，对电子健康记录系统的统一软件组件进行评估。评估结果应纳入第 37 条所述的技术文件中。评估结果为阳性的相关要素，应推定符合本条例。

4. The Commission shall, by means of implementing acts, lay down the common specifications for the European digital testing environment. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).4. 委员会应通过实施法案，制定欧洲数字测试环境的通用规范。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

Article 41 第 41 条

CE marking of conformity CE 合格标志

1. The CE marking of conformity shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the packaging of the EHR system.1. 合格的 CE 标志应清晰、易读且不可磨灭地粘贴在电子健康记录系统的随附文件上，如适用，还应粘贴在电子健康记录系统的包装上。

2. The CE marking of conformity shall be affixed before placing the EHR system on the market.2. 合格 CE 标志应在电子健康记录系统投放市场前粘贴。

3. The CE marking of conformity shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.3. 合格性 CE 标志应遵循（EC）第 765/2008 号条例第 30 条规定的一般原则。

Article 42 第 42 条

National requirements and reporting to the Commission 国家要求及向委员会报告

1. Member States may adopt national requirements for EHR systems and provisions on their conformity assessment in relation to aspects other than the harmonised software components of EHR systems.1. 成员国可针对电子健康记录系统的国家要求以及与其合格评定相关的规定进行制定，但这些要求和规定不适用于电子健康记录系统中已协调统一的软件组件方面。

2. The national requirements or provisions referred to in paragraph 1 shall not adversely affect the harmonised software components of EHR systems.2. 第 1 款所指的国家要求或规定不得对电子健康记录系统的统一软件组件产生不利影响。

3. When Member States adopt requirements or provisions in accordance with paragraph 1, they shall inform the Commission thereof.3. 成员国根据第 1 款通过要求或规定时，应将此事通知委员会。

SECTION 4 第 4 节

Market surveillance of EHR systems 电子健康记录系统的市场监督

Article 43 第 43 条

Market surveillance authorities 市场监管机构

1. Regulation (EU) 2019/1020 shall apply to EHR systems in relation to the requirements applicable to, and risks posed by, EHR systems covered by this Chapter.1. 欧盟法规（EU）2019/1020 应适用于电子健康记录系统，涉及本章所涵盖的电子健康记录系统适用的要求及其带来的风险。

2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. Member States shall entrust their market surveillance authorities with the necessary powers and shall provide them with the human, financial and technical resources, the equipment and the knowledge necessary for the proper performance of their tasks pursuant to this Regulation. Market surveillance authorities shall be empowered to take the market surveillance measures referred to in Article 16 of Regulation (EU) 2019/1020 to enforce the obligations laid down in this Chapter. Member States shall communicate the identity of the market surveillance authorities they designate to the Commission. The Commission and the Member States shall make that information publicly available.2. 成员国应指定一个或多个市场监督机构负责本章的实施。成员国应赋予其市场监督机构必要的权力，并为其提供根据本条例妥善履行任务所需的人力、财力、技术资源、设备和知识。市场监督机构应有权采取《欧盟条例（EU）2019/1020》第 16 条所述的市场监督措施，以执行本章规定的义务。成员国应将其指定的市场监督机构的身份告知欧盟委员会。欧盟委员会和成员国应将该信息公之于众。

3. Market surveillance authorities designated pursuant to paragraph 2 of this Article may be the same authorities as the digital health authorities designated pursuant to Article 19. Where a digital health authority carries out tasks of a market surveillance authority, Member States shall ensure that any conflicts of interest are avoided.3. 根据本条第 2 款指定的市场监督机构可以与根据第 19 条指定的数字健康机构为同

一机构。当数字健康机构履行市场监督机构的职责时，成员国应确保避免任何利益冲突。

4. Market surveillance authorities shall report to the Commission on a yearly basis the outcomes of relevant market surveillance activities.4. 市场监管机构应每年向委员会报告相关市场监管活动的结果。

5. Where a manufacturer or another economic operator fails to cooperate with a market surveillance authority or where the information and documentation they have provided is incomplete or incorrect, the market surveillance authority may take all appropriate measures to prohibit or restrict the relevant EHR system from being made available on the market until the manufacturer or the economic operator concerned cooperates or provides complete and correct information, or to recall or withdraw such EHR system from the market.5. 若制造商或其他经济运营商不配合市场监督机构，或其提供的信息和文件不完整、不正确，市场监督机构可采取一切适当措施，禁止或限制相关电子健康记录系统投放市场，直至该制造商或相关经济运营商配合或提供完整、正确的信息，或责令其从市场召回或撤回该电子健康记录系统。

6. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall enable the organisation of exchanges of information necessary for such cooperation.6. 成员国的市场监管机构应相互合作，并与欧盟委员会合作。欧盟委员会应促成开展此类合作所需的信息交流。

7. For medical devices, *in vitro* diagnostic medical devices or high-risk AI systems referred to in Article 27(1) and (2), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745, Article 88 of Regulation (EU) 2017/746 or Article 70 of Regulation (EU) 2024/1689, as applicable.7. 对于医疗设备、体外诊断医疗设备或第 27 条第（1）款和第（2）款所述的高风险人工智能系统，市场监督的主管部门应是（欧盟）2017/745 号条例第 93 条、（欧盟）2017/746 号条例第 88 条或（欧盟）2024/1689 号条例第 70 条中所述的部门，具体适用情况依实际而定。

Article 44 第 44 条

Handling of risks posed by EHR systems and of serious incidents 电子健康记录系统所带来的风险及严重事件的处理

1. Where a market surveillance authority of one Member State has reason to believe that an EHR system poses a risk to the health, safety or rights of natural persons or to the protection of personal data, that market surveillance authority shall carry out an evaluation in relation to the EHR system concerned covering all relevant requirements laid down in this Regulation. The manufacturer, the manufacturer's authorised representative and all other relevant economic operators shall cooperate as necessary with the market surveillance authority for that purpose and take all appropriate measures to ensure that the EHR system concerned no longer poses that risk when placed on the market or to recall or withdraw the EHR system from the market within

a reasonable period.1. 当某一成员国的市场监督机构有理由相信某一电子健康记录系统对自然人的健康、安全、权利或个人数据保护构成风险时，该市场监督机构应针对相关电子健康记录系统开展评估，评估范围涵盖本条例规定的所有相关要求。为此，制造商、制造商的授权代表及所有其他相关经济运营商应与市场监督机构进行必要合作，并采取一切适当措施，确保相关电子健康记录系统在投放市场时不再构成上述风险，或在合理期限内将该电子健康记录系统从市场召回或撤回。

2. Where the market surveillance authorities of a Member State consider that the non-compliance of the EHR system is not limited to their national territory, they shall inform the Commission and the other Member States' market surveillance authorities of the results of the evaluation referred to in paragraph 1 of this Article and of the corrective action which they have required the economic operator to take pursuant to Article 16(2) of Regulation (EU) 2019/1020.2. 当某成员国的市场监督机构认为电子健康记录系统的不合规问题不仅限于其本国领土时，该机构应将本条第 1 款所述的评估结果以及其根据《欧盟条例（EU）2019/1020》第 16 条第 2 款要求经济运营商采取的纠正措施通知欧盟委员会及其他成员国的市场监督机构。

3. Where a market surveillance authority finds that an EHR system has caused harm to the health or safety of natural persons or to certain aspects of public interest protection, the manufacturer shall immediately provide information and documentation, as applicable, to the affected natural person or user and, where applicable, other third parties affected by that harm, without prejudice to data protection rules.3. 当市场监督机构发现电子健康记录系统已对自然人的健康或安全，或对公共利益保护的某些方面造成损害时，制造商应立即向受影响的自然人或用户，并在适用情况下向受该损害影响的其他第三方，提供相关信息和文件（如适用），且不得违反数据保护规则。

4. The economic operator concerned referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems concerned that it has placed on the market throughout the Union.4. 第 1 款所述的相关经济运营商应确保对其在整个欧盟市场上投放的所有相关电子健康记录系统采取纠正措施。

5. The market surveillance authority shall without undue delay inform the Commission and the market surveillance authorities, or, if applicable, the supervisory authorities under Regulation (EU) 2016/679, of other Member States of the corrective action referred to in paragraph 2. That information shall include all available details, in particular the data necessary for the identification of the EHR system concerned, the origin and the supply chain of the EHR system, the nature of the risk involved and the nature and duration of the national measures taken.5. 市场监督机构应毫不拖延地将第 2 款所述的纠正措施通知欧盟委员会以及其他成员国的市场监督机构，或者在适用情况下，通知《欧盟条例（EU）2016/679》规定的监管机构。该信息应包含所有可获得的细节，特别是用于识别相关电子健康记录系统所需的数据、该系统的来源和供应链、所涉及风险的性质以及所采取国家措施的性质和持续时间。

6. Where a finding of a market surveillance authority, or a serious incident it is informed of, concerns personal data protection, that market surveillance authority shall without undue delay inform the relevant supervisory authorities under Regulation (EU) 2016/679 and cooperate with them.6. 当市场监督机构的调查结果或其获悉的严重事件涉及个人数据保护时，该市场监督机构应毫不拖延地通知依据《欧盟条例（EU）2016/679》设立的相关监管机构，并与它们开展合作。

7. Manufacturers of EHR systems placed on the market or put into service shall report any serious incident involving an EHR system to the market surveillance authorities of the Member States where such serious incident occurred and of the Member States where such EHR systems are placed on the market or put into service. That reporting shall also include a description of the corrective action taken or envisaged by the manufacturer. Member States may provide for users of EHR systems placed on the market or put into service to be able to report such incidents.7. 投放市场或投入使用的电子健康记录系统制造商，应向发生严重事件的成员国以及该电子健康记录系统投放市场或投入使用的成员国的市场监督机构报告涉及该系统的任何严重事件。报告还应包括制造商已采取或计划采取的纠正措施的说明。成员国可规定，投放市场或投入使用的电子健康记录系统的用户能够报告此类事件。

The reporting required pursuant to the first subparagraph of this paragraph shall be carried out, without prejudice to incident notification requirements under Directive (EU) 2022/2555, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of such a link and, in any event, not later than three days after the manufacturer becomes aware of the serious incident involving the EHR system.根据本款第一项要求进行的报告，在不影响《欧盟指令（EU）2022/2555》规定的事件通知要求的前提下，应在制造商确定电子健康记录系统与严重事件之间存在因果关系或存在此类关联的合理可能性后立即进行，且无论如何，不得迟于制造商知晓涉及该电子健康记录系统的严重事件后三天。

8. The market surveillance authorities referred to in paragraph 7 shall inform the other market surveillance authorities, without delay, of the serious incident and the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident.8. 第 7 款所指的市场监督机构应立即将严重事件以及制造商已采取、拟采取或被要求采取的旨在最大限度降低严重事件再次发生风险的纠正措施通知其他市场监督机构。

9. Where its tasks are not performed by the digital health authority, the market surveillance authority shall cooperate with the digital health authority. The market surveillance authority shall inform the digital health authority of any serious incidents, of EHR systems presenting a risk, including risks related to interoperability, security and patient safety, of any corrective action and of any recall or withdrawal of such EHR systems.9. 若数字健康主管部门未执行其任务，市场监督主管部门应与数字健康主管部门开展合作。市场监督主管部门应向数字健康主管部门通报任何严重事件、存在风险（包括与互操作性、安全性和患者安全相关的风险）的电子健康记录系统、任何纠正措施以及此类电子健康记录系统的任何召回或撤回情况。

10. In the event of incidents putting at risk patient safety or information security, the market surveillance authorities may take immediate action and require the manufacturer of the EHR system concerned, its authorised representative and other economic operators, if applicable, to take immediate corrective action.10. 若发生危及患者安全或信息安全的事件，市场监督机构可立即采取行动，并要求相关电子健康记录系统的制造商、其授权代表以及其他适用的经济运营商立即采取纠正措施。

Article 45 第 45 条

Handling of non-compliance 违规处理

1. Where a market surveillance authority makes a finding of non-compliance, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to take, by a specific deadline, adequate corrective action to bring the EHR system into conformity. Such findings of non-compliance include, but are not limited to, the following:1. 市场监督机构如认定存在不合规情况，应要求相关电子健康记录系统的制造商、其授权代表及所有其他相关经济运营商在特定期限内采取充分的纠正措施，使该电子健康记录系统符合要求。此类不合规认定包括但不限于以下情况：

(a) （a）the EHR system is not in conformity with essential requirements laid down in Annex II or with the common specifications referred to in Article 36;电子健康记录系统不符合附件二规定的基本要求，也不符合第 36 条提及的通用规范；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个the technical documentation is not 强制性统一软件组件的通用规则，即分别在第 2 条第（2）available, not complete or not in 款（n）项和（o）项中定义的 EHR 系统欧洲互操作性软件accordance with Article 37;技术文组件和 EHR 系统欧洲日志软件组件；同时也规定了声称能档不可用、不完整或不符合第 37 与 EHR 系统在这两个统一软件组件方面实现互操作的健康条规定；
应用程序在电子健康数据的主要使用方面的通用规则；

(c)the EU declaration of conformity has not been drawn up or has not been drawn up correctly in accordance with Article 39;未起草欧盟合格声明，或未按照第 39 条正确起草该声明；

(d) （d）the CE marking of conformity has been affixed in breach of Article 41 or has not been affixed;违反第 41 条加贴或未加贴 CE 合格标志；

(e)the registration obligations of Article 49 have not been fulfilled.第 49 条规定的注册义务未得到履行。

2. Where the manufacturer of the EHR system concerned, its authorised representative or any other relevant economic operator does not take adequate corrective action within a reasonable period, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the EHR system from being made available on the market of their Member States, or to recall or withdraw the EHR system from that market.2. 若相关电子健康记录系统的制造商、其授权代表或任何其他相关经济运营商未在合理期限内采取充分的纠正措施，市场监督机

构应采取一切适当的临时措施，禁止或限制该电子健康记录系统在其成员国市场上投放，或从该市场召回或撤回该电子健康记录系统。

The market surveillance authorities shall inform the Commission and the other Member States' market surveillance authorities, without delay, of those provisional measures. That information shall include all available details, in particular the data necessary for the identification of the non-compliant EHR system, the origin of that EHR system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the measures taken by the market surveillance authorities and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:市场监督机构应立即将这些临时措施通知委员会和其他成员国的市场监督机构。该信息应包含所有可用的细节，特别是用于识别不合规电子健康记录系统的必要数据、该电子健康记录系统的来源、所指控的不合规性质及所涉及的风险、市场监督机构所采取措施的性质和期限，以及相关经济运营商提出的论据。特别是，市场监督机构应指出不合规是否由以下任何一种原因造成：

(a) （a）failure of the EHR system to meet the essential requirements set out in Annex II;电子健康记录系统未能满足附件二规定的基本要求；

(b) (b) 规定了电子健康记录系统（"EHR 系统"）关于两个强制shortcomings regarding the 性统一软件组件的通用规则，即分别在第 2 条第（2）款（n）common specifications 项和（o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHR referred to in Article 36. 关于系统欧洲日志软件组件；同时也规定了声称能与 EHR 系统在这第 36 条所提及的通用规范存两个统一软件组件方面实现互操作的健康应用程序在电子健在的缺陷。
康数据的主要使用方面的通用规则；

3. Market surveillance authorities other than the market surveillance authorities initiating the procedure under this Article shall inform without delay the Commission and the other Member States' market surveillance authorities of any measures adopted, of any additional information at their disposal relating to the non-compliance of the EHR system concerned and, in the event of disagreement with the adopted national measure, of their objections.3. 除根据本条启动程序的市场监督机构外，其他市场监督机构应立即将所采取的任何措施、其掌握的与相关电子健康记录系统不合规有关的任何补充信息，以及在对所采取的国家措施有异议的情况下，将其异议通知委员会和其他成员国的市场监督机构。

4. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 2, no objection has been raised by either a market surveillance authority from another Member State or the Commission in respect of a provisional measure taken by a market surveillance authority, that measure shall be deemed justified.4. 若在收到第 2 款第二分段所述信息后的三个月内，其他成员国的市场监督机构或欧盟委员会均未对某一市场监督机构采取的临时措施提出异议，则该措施应被视为合理。

5. Where the non-compliance referred to in paragraph 1 persists, the market surveillance authority concerned shall take all appropriate measures to prohibit or restrict the EHR system from being made available on the market or ensure that it is

recalled or withdrawn from the market.5. 若第 1 款所述的不合规情况持续存在，相关市场监督机构应采取一切适当措施，禁止或限制该电子健康记录系统投放市场，或确保其被召回或撤出市场。

Article 46 第 46 条

Union safeguard procedure 欧盟保障程序

1. Where, under Article 44(2) and Article 45(3), objections are raised against a national measure taken by a market surveillance authority, or where the Commission considers a national measure to be contrary to Union law, the Commission shall without delay enter into consultations with that market surveillance authority and the relevant economic operators and shall evaluate the national measure concerned. On the basis of the results of that evaluation, the Commission shall adopt an implementing decision determining whether the national measure is justified. That implementing decision shall be adopted in accordance with the examination procedure referred to in Article 98(2). The Commission shall address its implementing decision to all Member States and shall immediately communicate it to them and to the relevant economic operators.1. 根据第 44 条第 2 款和第 45 条第 3 款，如果对市场监督机构采取的国家措施提出异议，或者委员会认为某项国家措施违反欧盟法律，委员会应立即与该市场监督机构及相关经济经营者进行磋商，并对所涉国家措施进行评估。基于评估结果，委员会应通过一项实施决定，确定该国家措施是否合理。该实施决定应按照第 98 条第 2 款所述的审查程序通过。委员会应将其实施决定送达所有成员国，并立即向它们及相关经济经营者通报。

2. If the national measure referred to in paragraph 1 is considered justified by the Commission, all Member States concerned shall take the necessary measures to ensure that the non-compliant EHR system is withdrawn from their market, and shall inform the Commission accordingly.2. 若委员会认为第 1 款所述的国家措施具有正当性，所有相关成员国均应采取必要措施，确保不合规的电子健康记录系统退出其市场，并相应地通知委员会。

If the national measure referred to in paragraph 1 is considered unjustified by the Commission, the Member State concerned shall revoke that measure.如果委员会认为第 1 款所述的国家措施不合理，有关成员国应撤销该措施。

SECTION 5 第 5 节

Other provisions on interoperability 关于互操作性的其他规定

Article 47 第 47 条

Labelling of wellness applications 健康应用程序的标签标注

1. Where a manufacturer of a wellness application claims interoperability with an EHR system in relation to the harmonised software components of EHR systems and therefore compliance with the common specifications referred to in Article 36 and essential requirements laid down in Annex II, such wellness application shall be

accompanied by a label, clearly indicating its compliance with those specifications and requirements. That label shall be issued by the manufacturer of the wellness application.1. 当健康应用程序的制造商声称其产品在电子健康记录系统的统一软件组件方面与电子健康记录系统具有互操作性，并因此符合第 36 条所述的通用规范以及附件 II 规定的基本要求时，该健康应用程序应附有标签，明确表明其符合这些规范和要求。该标签应由健康应用程序的制造商出具。

2. The label referred to in paragraph 1 shall indicate the following information:2. 第 1 款所述标签应标明以下信息：

(a) （a）the categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;已确认符合附件二规定的基本要求的电子健康数据类别；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关于两个强制性a reference to common 统一软件组件的通用规则，即分别在第 2 条第（2）款（n）项和specifications to （o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧demonstrate compliance;提洲日志软件组件；同时也规定了声称能与 EHR 系统在这两个统一及通用规范以证明合规软件组件方面实现互操作的健康应用程序在电子健康数据的主要性；
使用方面的通用规则；

(c) the validity period of the label. 标签的有效期。

3. The Commission shall, by means of implementing acts, determine the format and content of the label referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).3. 委员会应通过实施法案，确定第 1 款所述标签的格式和内容。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

4. The label shall be drawn-up in one or more official languages of the Union or in an easily understandable language determined by the Member State in which the wellness application is placed on the market or put into service.4. 标签应以欧盟的一种或多种官方语言拟定，或使用健康应用投放市场或投入使用所在成员国规定的易于理解的语言拟定。

5. The validity of the label shall not exceed three years.5. 标签的有效期不得超过三年。

6. If the wellness application is an integral part of a device or is embedded in a device after it has been put into service, the accompanying label shall be shown in the application itself or placed on that device. Where the wellness application consists only of software, the label shall have a digital format and shall be shown in the application itself. Two-dimensional (2D) barcodes may also be used to display the label.6. 如果健康应用程序是设备的组成部分，或者在设备投入使用后嵌入设备中，则随附标签应显示在应用程序本身中或贴在该设备上。如果健康应用程序仅由软件组成，则标签应采用数字格式，并显示在应用程序本身中。也可以使用二维（2D）条形码来显示标签。

7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II.7. 市场监管机构应检查健康应用程序是否符合附件二规定的基本要求。

8. Each supplier of a wellness application for which a label has been issued shall ensure that the wellness application that is placed on the market or put into service is accompanied by the label for each individual unit, free of charge.8. 每个已获发标签的健康应用程序供应商应确保，投放市场或投入使用的健康应用程序的每个单独单元都随附该标签，且不收取任何费用。

9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at the point of sale in electronic form.9. 每个已获发标签的健康应用程序分销商，均应在销售点以电子形式向客户提供该标签。

Article 48 第 48 条

Interoperability of wellness applications with EHR systems 健康应用程序与电子健康记录系统的互操作性

1. Manufacturers of wellness applications may claim interoperability with an EHR system, provided that the relevant common specifications and essential requirements referred to in Article 36 and Annex II, respectively, are met. In the event of such claim, those manufacturers shall duly inform users of the interoperability of such wellness applications and the effects of such interoperability.1. 健康应用程序的制造商可以声称其与电子健康记录系统具有互操作性，前提是分别满足第 36 条和附件 II 中提及的相关通用规范和基本要求。如果做出此类声明，这些制造商应适当地向用户告知此类健康应用程序的互操作性及其效果。

2. The interoperability of wellness applications with EHR systems shall not entail the automatic sharing of all or part of the health data from the wellness application with, or automatic transmission of all or part of such data to, the EHR system. The sharing or transmission of such data shall only be possible if it is in accordance with Article 5 and after consent is given by the natural person concerned and interoperability shall be limited exclusively to those purposes. The manufacturers of wellness applications claiming interoperability with an EHR system shall ensure that the natural person concerned is able to choose which categories of health data from the wellness application are to be inserted in the EHR system and the circumstances for the sharing or transmission of those categories of data.2. 健康应用程序与电子健康记录系统的互操作性不得意味着自动共享健康应用程序中的全部或部分健康数据，也不得意味着自动将该等数据的全部或部分传输至电子健康记录系统。只有符合第 5 条规定且经相关自然人同意后，方可共享或传输该等数据，且互操作性应仅限于这些目的。声称可与电子健康记录系统互操作的健康应用程序制造商，应确保相关自然人能够选择将健康应用程序中的哪些类别的健康数据录入电子健康记录系统，以及共享或传输这些类别的数据的具体情形。

SECTION 6 第 6 节

Registration of EHR systems and wellness applications 电子健康记录系统和健康应用程序的注册

Article 49 第 49 条

EU database for registration of EHR systems and wellness applications 欧盟电子健康记录系统和健康应用注册数据库

1. The Commission shall establish and maintain a publicly available EU database with data on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 39 and wellness applications for which a label has been issued pursuant to Article 47 (the 'EU database for registration of EHR systems and wellness applications').1. 委员会应建立并维护一个可公开访问的欧盟数据库，其中包含已根据第 39 条出具欧盟合格声明的电子健康记录系统以及已根据第 47 条获得标签的健康应用程序的数据（即"欧盟电子健康记录系统和健康应用程序注册数据库"）。

2. Before placing on the market or putting into service an EHR system referred to in Article 26 or a wellness application referred to in Article 47, the manufacturer of such EHR system or wellness application or, where applicable, its authorised representative shall enter the required data as referred to in paragraph 4 of this Article into the EU database for registration of EHR systems and wellness applications, including, in the case of EHR systems, the results of the assessment referred to in Article 40.2. 在将第 26 条所述的电子健康记录系统或第 47 条所述的健康应用程序投放市场或投入使用之前，该电子健康记录系统或健康应用程序的制造商，或在适用情况下其授权代表，应将本条第 4 款所述的必要数据录入欧盟电子健康记录系统和健康应用程序注册数据库，其中对于电子健康记录系统，还应包括第 40 条所述的评估结果。

3. Medical devices, *in vitro* diagnostic medical devices or high-risk AI systems referred to in Article 27(1) and (2) of this Regulation shall also be registered in the databases established pursuant to Regulation (EU) 2017/745, (EU) 2017/746 or (EU) 2024/1689, as applicable. In such cases, the data to be entered shall also be forwarded to the EU database for registration of EHR systems and wellness applications.3. 本条例第 27 条第（1）款和第（2）款所述的医疗器械、体外诊断医疗器械或高风险人工智能系统，还应在根据《欧盟条例》（EU）2017/745、（EU）2017/746 或（EU）2024/1689（如适用）建立的数据库中注册。在这种情况下，将要录入的数据还应转发至用于电子健康记录系统和健康应用程序注册的欧盟数据库。

4. The Commission is empowered to adopt delegated acts in accordance with Article 97 to supplement this Regulation by determining the list of required data to be entered into the EU database for registration of EHR systems and wellness applications by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2 of this Article.4. 根据第 97 条，委员会有权通过授权法案，以补充本条例，确定电子健康记录系统和健康应用程序制造商根据本条第 2 款需录入欧盟电子健康记录系统和健康应用程序注册数据库的必填数据清单。

CHAPTER IV 第四章

SECONDARY USE 二次使用

SECTION 1 第一节

General conditions with regard to secondary use 关于二次使用的一般条件

Article 50 第 50 条

Applicability to health data holders 对健康数据持有者的适用性

1. The following categories of health data holders shall be exempt from the obligations on health data holders laid down in this Chapter:1. 以下几类健康数据持有者不受本章规定的健康数据持有者义务的约束：

(a) （a） natural persons, including individual researchers;自然人，包括个体研究人员；

(b) (b) 规定了电子健康记录系统（“EHR 系统”）关legal persons that qualify as microenterprises as defined in Article 2(3) of the Annex to Commission Recommendation 2003/361/EC.于两个强制性统一软件组件的通用规则，即分别在符合欧盟第 2 条第（2）款（n）项和（o）项中定义的 EHR 系统欧洲互操作性软件组件和 EHR 系统欧洲日志软件组件；同时也规定了声称能与 EHR 系统在这两委员会 2003/361/EC 号建议附件第 2 条第 3 款所定义的微型企业的法人。
在电子健康数据的主要使用方面的通用规则；

2. Member States may provide in their national law that the obligations of health data holders laid down in this Chapter apply to the health data holders referred to in paragraph 1 which fall under their jurisdiction.2. 成员国可在其国内法中规定，本章规定的健康数据持有人的义务适用于第 1 款所述且属于其管辖范围的健康数据持有人。

3. Member States may provide in their national law that the duties of certain categories of health data holders are to be fulfilled by health data intermediation entities. In that case, the data shall nevertheless be considered as being made available by several health data holders.3. 成员国可在其国内法中规定，某些类别的健康数据持有者的义务由健康数据中介实体履行。在这种情况下，该数据仍应被视为由多个健康数据持有者提供。

4. Member States shall notify to the Commission the national law referred to in paragraphs 2 and 3 by 26 March 2029. Any subsequent law or amendment affecting such law shall be notified to the Commission without delay.4. 成员国应在 2029 年 3 月 26 日前将第 2 款和第 3 款所指的国家法律通知委员会。任何随后影响此类法律的法律或修正案应立即通知委员会。

Article 51 第 51 条

Minimum categories of electronic health data for secondary use 用于二次使用的电子健康数据的最低类别

1. Health data holders shall make the following categories of electronic health data available for secondary use in accordance with this Chapter:1. 健康数据持有者应依照本章规定，提供以下类别的电子健康数据用于二次使用：

(a) （a） electronic health data from EHRs; 来自电子健康记录的电子健康数据；

(b) （乙）data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;关于影响健康的因素的数据，包括健康的社会经济、环境和行为决定因素；

(c) 电子健康记录之外的其他aggregated data on healthcare needs, resources allocated to 电子健康数据，包括来自移动healthcare, the provision of and access to healthcare, healthcare 健康应用程序、可穿戴设备和expenditure and financing;关于医疗需求、分配给医疗保健的资远程患者监测设备的数据； 源、医疗保健的提供与获取、医疗保健支出及资金筹措的汇总数据；

(d) （d） data on pathogens that impact human health;影响人类健康的病原体相关数据；

(e)healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;与医疗相关的行政数据，包括配药、报销申请和报销方面的数据；

(f) （f）human genetic, epigenomic and genomic data;人类遗传、表观基因组和基因组数据；

(g) （g）other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;其他人类分子数据，如蛋白质组学、转录组学、代谢组学、脂质组学和其他组学数据；

(h)personal electronic health data automatically generated through medical devices;通过医疗设备自动生成的个人电子健康数据；

(i) （一） data from wellness applications; 健康类应用程序的数据；

(j) （j）data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;关于专业身份，以及参与自然人治疗的卫生专业人员的专业领域和所属机构的数据；

(k) (k) “电子健康记录系统”或“EHR 系统”指任何这样的data from population-based health 系统，其软件，或该系统的硬件与软件的组合，能够对data registries such as public health 本条例所确立的属于优先类别的个人电子健康数据进registries;来自基于人群的健康数据行存储、中转、导出、导入、转换、编辑或查看，且其登记处（如公共卫生登记处）的数据；制造商意图供医疗服务提供者在提供患者护理时使用，
或供患者在访问其电子健康数据时使用；

(l) “投入使用”是指本条例所涵盖的电子健康data from medical registries and mortality 记录系统在欧盟内首次按其预定用途使用。registries;来自医疗登记处和死亡率登记处的数据；

(m)data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;受《欧盟法规》第536/2014 号、欧洲议会和理事会《欧盟法规》2024/1938 号(35)、《欧盟法规》2017/745 号以及《欧盟法规》2017/746 号约束的临床试验、临床研究、临床调查和性能研究的数

据；

(n) （n） “欧洲电子健康记录系统互操作性软件组件”是指电子健康记other health data 录系统的一个软件组件，该组件以本条例规定的欧洲电子健康记录交from medical devices; 换格式，提供和接收根据本条例确立的主要用途优先类别下的个人电医疗设备的其他健康 子健康数据，且独立于欧洲电子健康记录系统日志软件组件； 数据；

(o) ‘电子健康记录系统欧洲互操作性软件组件’指的是电子健康data from registries for 记录系统的一种软件组件，它以本条例规定的欧洲电子健康记medicinal products and 录交换格式，根据本条例确立的主要用途优先类别，提供和接medical devices; 药品和医疗 收个人电子健康数据，且独立于电子健康记录系统欧洲日志软器械注册数据库中的数据； 件组件；

(p) （p）data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;相关结果首次发表后，来自与健康相关的研究队列、问卷和调查的数据；

(q) “风险”是指危害发生并对健康、安全或信息health data from biobanks and associated 安全造成损害的可能性与该损害的严重程度的databases.生物样本库及相关数据库中的健康 组合； 数据。

2. Member States may provide in their national law that additional categories of electronic health data are to be made available for secondary use pursuant to this Regulation.2. 成员国可在其国内法中规定，根据本条例，更多类别的电子健康数据可用于二次使用。

3. Member States may establish rules for the processing and use of electronic health data containing improvements related to the processing of those data, such as correction, annotation or enrichment, based on a data permit pursuant to Article 68.3. 成员国可依据第 68 条规定的 data permit，针对包含与数据处理相关改进（如更正、注释或充实）的电子健康数据，制定其处理和使用规则。

4. Member States may introduce stricter measures and additional safeguards at national level aimed at safeguarding the sensitivity and value of the data that fall under paragraph 1, points (f), (g), (i) and (q). Member States shall notify the Commission of those measures and safeguards and, without delay, of any subsequent amendment affecting them.4. 成员国可在国家层面采取更严格的措施和额外的保障措施，以保护第 1 款(f)、(g)、(i)和(q)项所涵盖数据的敏感性和价值。成员国应将这些措施和保障措施通知委员会，并立即通知影响它们的任何后续修订。

Article 52 第 52 条

Intellectual property rights and trade secrets 知识产权和商业秘密

1. Electronic health data protected by intellectual property rights, trade secrets or covered by the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC of the European Parliament and of the Council (36) or Article 14(11) of Regulation (EC) No 726/2004 of the European Parliament and of the Council (37) shall be made available for secondary use in accordance with the rules laid down in this Regulation.1. 受知识产权、商业秘密保护的电子健康数据，或受欧洲议会和理事

会第 2001/83/EC 号指令第 10(1)条(36)或欧洲议会和理事会第 726/2004 号条例(EC)第 14(11)条(37)规定的监管数据保护权涵盖的电子健康数据，应根据本条例规定的规则用于二次使用。

2. Health data holders shall inform the health data access body of any electronic health data containing content or information protected by intellectual property rights, trade secrets or covered by the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC or Article 14(11) of Regulation (EC) No 726/2004. Health data holders shall identify which parts of the datasets are concerned and justify the need for the specific protection of the data. Health data holders shall provide that information when communicating to the health data access body the description of the dataset they hold pursuant to Article 60(3) of this Regulation or, at the latest, following a request received from the health data access body.2. 健康数据持有方应向健康数据访问机构告知任何包含受知识产权、商业秘密保护的内容或信息的电子健康数据，或受 2001/83/EC 号指令第 10 条第 1 款或（EC）第 726/2004 号条例第 14 条第 11 款规定的监管数据保护权涵盖的内容或信息的电子健康数据。健康数据持有方应明确数据集中涉及的部分，并说明对这些数据进行特定保护的必要性。健康数据持有方应在根据本条例第 60 条第 3 款向健康数据访问机构提供其持有的数据集描述时，或最迟在收到健康数据访问机构的请求后，提供上述信息。

3. Health data access bodies shall take all specific appropriate and proportionate measures, including of a legal, organisational and technical nature, they deem necessary to protect the intellectual property rights, trade secrets or the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC or Article 14(11) of Regulation (EC) No 726/2004. Health data access bodies shall remain responsible for determining whether such measures are necessary and appropriate.3. 健康数据访问机构应采取所有其认为必要的、具体的、适当的且成比例的措施，包括法律、组织和技术层面的措施，以保护知识产权、商业秘密或《2001/83/EC 号指令》第 10 条第 1 款或《(EC)第 726/2004 号条例》第 14 条第 11 款规定的监管数据保护权。健康数据访问机构应对此类措施是否必要且适当的判定承担责任。

4. When issuing data permits in accordance with Article 68, health data access bodies may make the access to certain electronic health data conditional on legal, organisational and technical measures, which may include contractual arrangements between health data holders and health data users for the sharing of data containing information or content protected by intellectual property rights or trade secrets. The Commission shall develop and recommend non-binding models of contractual terms for such arrangements.4. 根据第 68 条发放数据许可时，健康数据访问机构可将对某些电子健康数据的访问权限与法律、组织和技术措施挂钩，这些措施可包括健康数据持有者与健康数据使用者之间就共享包含受知识产权或商业秘密保护的信息或内容的数据所达成的合同安排。欧盟委员会应制定并推荐此类安排的非约束性合同条款范本。

5. Where the granting of access to electronic health data for secondary use entails a serious risk of infringing intellectual property rights, trade secrets or the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC or

Article 14(11) of Regulation (EC) No 726/2004 which cannot be addressed in a satisfactory manner, the health data access body shall refuse access to the health data applicant to such data. The health data access body shall inform the health data applicant of, and provide to the health data applicant a justification for, that refusal. Health data holders and health data applicants shall have the right to lodge a complaint in accordance with Article 81 of this Regulation.5. 当为二次使用而授予电子健康数据访问权可能会严重侵犯知识产权、商业秘密或《2001/83/EC 号指令》第 10 条第 1 款或《(EC)第 726/2004 号条例》第 14 条第 11 款规定的监管数据保护权，且该风险无法以令人满意的方式解决时，健康数据访问机构应拒绝健康数据申请人访问此类数据。健康数据访问机构应将拒绝事宜告知健康数据申请人，并向其提供拒绝的理由。健康数据持有者和健康数据申请人有权依照本条例第 81 条提出申诉。

Article 53 第 53 条

Purposes for which electronic health data can be processed for secondary use 可对电子健康数据进行二次使用处理的目的

1. Health data access bodies shall only grant access to electronic health data referred to in Article 51 for secondary use to a health data user where the processing of the data by that health data user is necessary for one of the following purposes:1. 健康数据访问机构仅应在健康数据用户对数据的处理是出于以下目的之一所必需的情况下，向该健康数据用户授予对第 51 条所述电子健康数据的二次使用访问权限：

(a) （a）the public interest in the areas of public or occupational health, such as activities to protect against serious cross-border threats to health, public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;公共或职业健康领域的公共利益，例如防范严重跨境健康威胁的活动、公共卫生监测，或确保高水平医疗质量与安全（包括患者安全）以及药品或医疗器械质量与安全的活动；

(b) （乙）policymaking and regulatory activities to support public sector bodies or Union institutions, bodies, offices or agencies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;支持公共部门机构或欧盟机构、团体、办事处或 agencies（包括卫生或医疗领域的监管机构）执行其职权范围内规定任务的政策制定和监管活动；

(c) 电子健康记录之外的statistics as defined in Article 3, point (1), of Regulation (EC) 其他电子健康数据，包括No 223/2009, such as national, multi-national and Union-level official 来自移动健康应用程序、statistics, related to health or care sectors;《欧洲共同体条例》（EC）可穿戴设备和远程患者第 223/2009 号第 3 条第（1）点所定义的统计数据，例如与卫生或监测设备的数据； 护理部门相关的国家、跨国及欧盟层面的官方统计数据；

(d) （d）education or teaching activities in health or care sectors at vocational or higher education level;职业教育或高等教育层面的卫生或护理领域的教育或教学活动；

(e)scientific research related to health or care sectors that contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of

medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators, including:与健康或护理领域相关的科学研究，这类研究有助于公共卫生或健康技术评估，或确保医疗保健、医药产品或医疗设备的高质量和高安全性，其目的是使终端用户受益，例如患者、卫生专业人员和卫生管理人员，包括：

(i) （一）development and innovation activities for products or services;产品或服务的开发与创新活动；

(ii)training, testing and evaluation of algorithms, including in medical devices, *in vitro* diagnostic medical devices, AI systems and digital health applications;算法的训练、测试和评估，包括在医疗设备、体外诊断医疗设备、人工智能系统和数字健康应用中的算法

(f) （f）improvement of the delivery of care, of the optimisation of treatment and of the provision of healthcare, based on the electronic health data of other natural persons.基于其他自然人的电子健康数据，改善护理服务的提供、优化治疗以及改进医疗服务的供给。

2. Access to electronic health data for the purposes referred to in paragraph 1, points (a), (b) and (c), shall be reserved for public sector bodies and Union institutions, bodies, offices and agencies exercising the tasks conferred on them by Union or national law, including where processing of data for carrying out those tasks is done by a third party on behalf of those public sector bodies or of Union institutions, bodies, offices and agencies.2. 为实现第 1 款(a)、(b)和(c)项所述目的而获取电子健康数据，应仅限公共部门机构以及根据联盟或国家法律被赋予相关任务的联盟各机构、团体、办事处和部门，包括由第三方代表这些公共部门机构或联盟各机构、团体、办事处和部门为执行这些任务而进行数据处理的情况。

Article 54 第 54 条

Prohibited secondary use 禁止二次使用

Health data users shall only process electronic health data for secondary use on the basis of and in accordance with the purposes contained in a data permit issued pursuant to Article 68, health data requests approved pursuant to Article 69 or, in situations referred to in Article 67(3), an access approval from the relevant authorised participant in HealthData@EU referred to in Article 75.健康数据使用者仅可在依据第 68 条发放的数据许可、依据第 69 条批准的健康数据请求所包含的目的范围内，或者在第 67 条第 3 款所述情形下，根据第 75 条所述的 HealthData@EU 相关授权参与方的访问批准，对电子健康数据进行二次使用处理。

In particular, seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 68 or a health data request approved pursuant to Article 69 for the following uses shall be prohibited:特别是，禁止为以下用途获取和处理通过依据第 68 条颁发的数据许可或依据第 69 条批准的健康数据请求所获得的电子健康数据：

(a) （a）taking decisions detrimental to a natural person or a group of natural persons based on

their electronic health data; in order to qualify as 'decisions' for the purposes of this point, they have to produce legal, social or economic effects or similarly significantly affect those natural persons;基于自然人或一群自然人的电子健康数据做出对其不利的决定；就本点而言，要符合"决定"的定义，这些决定必须产生法律、社会或经济影响，或对这些自然人产生类似的重大影响；

(b) （乙）taking decisions in relation to a natural person or a group of natural persons in relation to job offers, offering less favourable terms in the provision of goods or services, including exclusion of such persons or groups from the benefit of an insurance or credit contract, the modification of their contributions and insurance premiums or conditions of loans, or taking any other decisions in relation to a natural person or a group of natural persons which result in discriminating against them on the basis of the health data obtained;就自然人或一群自然人做出与工作机会相关的决定，在提供商品或服务时给出较不利的条款（包括将此类个人或群体排除在保险合同或信贷合同的权益之外、修改其缴费金额和保险费或贷款条件），或做出任何其他与自然人或一群自然人相关且基于所获取的健康数据而导致歧视他们的决定；

(c) 电子健康记录之外的其他电子健康数据，包括来自移carrying out advertising or marketing 动健康应用程序、可穿戴设备和远程患者监测设备的数activities;开展广告或营销活动；
据；

(d) （d）developing products or services that may harm individuals, public health or society at large, such as illicit drugs, alcoholic beverages, tobacco and nicotine products, weaponry or products or services which are designed or modified in such a way that they create addiction, contravene public order or cause a risk for human health;开发可能危害个人、公共健康或整个社会的产品或服务，例如非法药物、酒精饮料、烟草和尼古丁产品、武器，或以会使人成瘾、违反公共秩序或对人类健康造成风险的方式设计或改造的产品或服务；

(e)carrying out activities in conflict with ethical provisions laid down in national law.从事与国家法律规定的道德条款相冲突的活动。

SECTION 2 第 2 节

Governance and mechanisms for secondary use 二次使用的治理与机制

Article 55 第 55 条

Health data access bodies 健康数据访问机构

1. Member States shall designate one or more health data access bodies responsible for carrying out the tasks and obligations set out in Articles 57, 58 and 59. Member States may either establish one or more new public sector bodies or rely on existing public sector bodies or on internal services of public sector bodies that fulfil the conditions set out in this Article. The tasks set out in Article 57 may be distributed between different health data access bodies. Where a Member State designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for coordinating tasks with the other health data

access bodies both within the territory of that Member State and in other Member States.1. 成员国应指定一个或多个健康数据访问机构，负责执行第 57 条、第 58 条和第 59 条规定的任务和义务。成员国可以设立一个或多个新的公共部门机构，也可以依靠现有的公共部门机构或满足本条规定条件的公共部门机构内部服务。第 57 条规定的任务可在不同的健康数据访问机构之间分配。若某一成员国指定了多个健康数据访问机构，则应指定其中一个健康数据访问机构作为协调者，负责协调该成员国境内以及其他成员国的其他健康数据访问机构的任务。

Each health data access body shall contribute to the consistent application of this Regulation throughout the Union. For that purpose, health data access bodies shall cooperate with each other, with the Commission and, for concerns regarding data protection, with the relevant supervisory authorities.每个健康数据访问机构应促进本条例在整个欧盟范围内的统一适用。为此，健康数据访问机构应相互合作，并与欧盟委员会合作；对于涉及数据保护的问题，还应与相关监管机构合作。

2. In order to support the effective performance of the tasks and the exercise of the powers of the health data access bodies, Member States shall ensure that each health data access body is provided with the following elements:2. 为支持健康数据访问机构有效执行任务和行使权力，成员国应确保为每个健康数据访问机构提供以下要素：

(a) （a）the necessary human, financial and technical resources;必要的人力、财力和技术资源；

(b) （乙） the necessary expertise; and 必要的专业知识；以及

(c) 电子健康记录之外的其他电子健康数据，包括来自the necessary premises and 移动健康应用程序、可穿戴设备和远程患者监测设备的infrastructure.必要的场所和基础设 数据； 施。

Where an assessment by ethics bodies is required under national law, those bodies shall make expertise available to the health data access body. As an alternative, Member States may provide for ethics bodies to form part of the health data access body.在国家法律要求由伦理机构进行评估的情况下，这些机构应向健康数据访问机构提供专业知识。作为替代方案，成员国可规定伦理机构成为健康数据访问机构的组成部分。

3. Member States shall ensure that any conflicts of interest between the organisational parts of health data access bodies performing the different tasks of such bodies is avoided by, for example, providing for organisational safeguards such as segregation between health data access bodies' different functions, including assessing applications, the reception and preparation of datasets, for example pseudonymisation and anonymisation of datasets, and the provision of data in secure processing environments.3. 成员国应确保避免健康数据访问机构中执行不同任务的组织部门之间出现任何利益冲突，例如通过规定组织保障措施，如将健康数据访问机构的不同职能分开，包括评估申请、接收和准备数据集（例如对数据集进行假名化和匿名化）以及在安全处理环境中提供数据。

4. In the performance of their tasks, health data access bodies shall actively cooperate with relevant stakeholders' representatives, especially with representatives

of patients, health data holders and health data users and shall avoid any conflicts of interest.4. 在执行其任务时，健康数据访问机构应积极与相关利益相关者的代表合作，特别是与患者、健康数据持有者和健康数据使用者的代表合作，并应避免任何利益冲突。

5. In the performance of their tasks and exercise of their powers, health data access bodies shall avoid any conflicts of interest. Health data access bodies' staff shall act in the public interest and in an independent manner.5. 在履行职责和行使权力时，健康数据访问机构应避免任何利益冲突。健康数据访问机构的工作人员应以公共利益为重，独立行事。

6. Member States shall inform the Commission of the identity of the health data access bodies designated pursuant to paragraph 1 by 26 March 2027. They shall also inform the Commission of any subsequent modification of the identity of those bodies. The Commission and the Member States shall make that information publicly available.6. 成员国应在 2027 年 3 月 26 日前将根据第 1 款指定的健康数据访问机构的身份告知委员会。它们还应将这些机构身份的任何后续变更告知委员会。委员会和成员国应公开这些信息。

Article 56 第 56 条

Union health data access service 欧盟健康数据访问服务

1. The Commission shall perform the tasks set out in Articles 57 and 59 where the health data holders are Union institutions, bodies, offices or agencies.1. 当健康数据持有者为欧盟机构、团体、办事处或代理机构时，委员会应执行第 57 条和第 59 条规定的任务。

2. The Commission shall ensure that the necessary human, technical and financial resources, premises and infrastructure are allocated for the effective performance of the tasks set out in Articles 57 and 59 and the exercise of its duties.2. 委员会应确保分配必要的人力、技术和财政资源、场地及基础设施，以有效履行第 57 条和第 59 条规定的任务并行使其职责。

3. Unless otherwise explicitly excluded, references to health data access bodies in this Regulation in relation to the performance of tasks and exercise of duties shall be understood to also apply to the Commission, where the health data holders are Union institutions, bodies, offices or agencies.3. 除非另有明确排除，本条例中提及的与履行任务和行使职责相关的健康数据访问机构，在健康数据持有者为欧盟机构、团体、办事处或机构的情况下，应理解为也适用于委员会。

Article 57 第 57 条

Tasks of health data access bodies 健康数据访问机构的任务

1. Health data access bodies shall carry out the following tasks:1. 健康数据访问机构应执行以下任务：

(a) （a）deciding on health data access applications pursuant to Article 67 of this Regulation,

authorising and issuing data permits pursuant to Article 68 of this Regulation to access electronic health data falling within their remit for secondary use and deciding on health data requests submitted pursuant to Article 69 of this Regulation in accordance with this Chapter and Chapter II of Regulation (EU) 2022/868, including with regard to:根据本条例第 67 条对健康数据访问申请作出决定，根据本条例第 68 条批准并发放数据许可，以允许访问其职权范围内可供二次使用的电子健康数据，并根据本章以及《欧盟条例（2022/868）》第二章，对依据本条例第 69 条提交的健康数据请求作出决定，包括以下方面：

(i) （一）providing access to electronic health data to health data users pursuant to a data permit in a secure processing environment in accordance with Article 73;根据第 73 条的规定，在安全的处理环境中，依据数据许可向健康数据使用者提供电子健康数据的访问权限；

(ii) （二）monitoring and supervising compliance by health data users and health data holders with the requirements laid down in this Regulation;监测和监督健康数据使用者及健康数据持有者遵守本条例规定的要求；

(iii) （三）requesting electronic health data referred to in Article 51 from relevant health data holders pursuant to a data permit issued or a health data request approved;根据已签发的数据许可或已批准的健康数据请求，向相关健康数据持有者索取第 51 条所述的电子健康数据；

(b) （乙）processing electronic health data referred to in Article 51 such as by receiving, combining, preparing and compiling such data when requested from health data holders and the pseudonymisation or anonymisation of those data;处理第 51 条所述的电子健康数据，例如应健康数据持有者的请求接收、合并、准备和汇编此类数据，以及对此类数据进行假名化或匿名化处理；

(c) 电子健康记录之外的其他电子健康数据，包括来自移动健康应用程序、可穿戴设备和远程患者监测设备的数据；taking all measures necessary to preserve the confidentiality of intellectual property rights, for regulatory data protection and to preserve the confidentiality of trade secrets as provided for in Article 52, taking into account the relevant rights of both the health data holder and health data user;采取一切必要措施，按照第 52 条的规定，维护知识产权的保密性、监管数据保护以及商业秘密的保密性，同时考虑到健康数据持有者和健康数据使用者双方的相关权利；

(d) （d）cooperating with and supervising health data holders to ensure the consistent and accurate implementation of the provisions on data quality and utility label in Article 78;与健康数据持有者合作并对其进行监督，以确保第 78 条中关于数据质量和实用标签的规定得到一致且准确的实施；

(e)maintaining a management system to record and process health data access applications, health data requests, decisions on those applications and requests and the data permits issued and health data requests handled, providing at least information on the name of the health data applicant, the purpose of access, the date of issuance, the duration of the data permit and a description of the health data access application or the health data request;维护一个管理系统，用于记录和处理健康数据访问申请、健康数据请求、对这些申请和请求的决定、所发放的数据许可以及所处理的健康数据请求，并至少提供健康数据申请人姓名、访问

目的、发放日期、数据许可期限以及健康数据访问申请或健康数据请求的描述等信息；

(f) （f）maintaining a public information system to comply with the obligations laid down in Article 58;维护一个公共信息系统，以遵守第 58 条规定的义务；

(g) （g）cooperating at Union and national level to lay down common standards, technical requirements and appropriate measures for accessing electronic health data in a secure processing environment;在联盟和国家层面开展合作，为在安全处理环境中访问电子健康数据制定共同标准、技术要求和适当措施；

(h) (h) 在欧盟和国家层面开展合作，并就电子cooperating at Union and national level and 健康数据的二次使用和管理技术及最佳实践向providing advice to the Commission on 委员会提供建议； 通过第 75 条所述的techniques and best practices for secondary HealthData@EU，为跨境访问其他成员国托管的use and the management of electronic health 用于二次使用的电子健康数据提供便利，并彼data;在欧盟层面和国家层面开展合作，并就此之间以及与委员会密切合作； 电子健康数据的二次使用及管理的技术和最佳实践向委员会提供建议；

(i) （一）facilitating cross-border access to electronic health data for secondary use hosted in other Member States through HealthData@EU referred to in Article 75 and cooperating closely with each other and with the Commission;通过第 75 条所述的 HealthData@EU 促进跨境获取其他成员国托管的用于二次使用的电子健康数据，并彼此之间以及与委员会密切合作；

(j) (j) 通过电子方式公开： 一份国家making public, through electronic means:通过电子方式数据集目录，其中应根据第 77 条、公开：
第 78 条和第 80 条的规定，包含电子健康数据的来源、性质详情以及提供电子健康数据的条件； 所有健康数据访问申请和健康数据请求，在初步接收后应立即公开，不得有不当延迟； 所有已签发的数据许可、已批准的健康数据请求以及拒绝决定（包括其理由），应在签发、批准或拒绝后的 30 个工作日内公开；

(i) （一）a national dataset catalogue that includes details about the source and nature of electronic health data, in accordance with Articles 77, 78 and 80, and the conditions for making electronic health data available;一个国家数据集目录，其中包含根据第 77、78 和 80 条规定的电子健康数据的来源和性质详情，以及提供电子健康数据的条件；

(ii) （二）any health data access application and health data request without undue delay after initial reception;任何健康数据访问应用程序和健康数据请求，在初步接收后不得有不当延迟；

(iii) （三）all data permits issued or health data requests approved as well as refusal decisions, including their justification, within 30 working days of the issuance, approval or refusal;所有已签发的数据许可、已批准的健康数据请求以及拒绝决定（包括其理由），均应在签发、批准或拒绝后的 30 个工作日内（公布）。 注：根据语境补充了“公布”一词，使句子完整，

符合此类规定的常见表述逻辑，若无需补充可删除括号内内容。

(iv) （四）measures related to non-compliance pursuant to Article 63;依据第 63 条针对不遵守情况所采取的措施；

(v) （五）results communicated by health data users pursuant to Article 61(4);卫生数据用户根据第 61 条第 4 款传达的结果；

(vi) (六)an information system to comply with the obligations laid down in Article 58;一个用于履行第 58 条规定义务的信息系统；

(vii) （七）information, at a minimum on an easily accessible website or web portal, on the connection to HealthData@EU of national contact points for secondary use of a third country, or of a system established at international level by an international organisation, as soon as the third country or the international organisation becomes an authorised participant in HealthData@EU; 至少应在一个易于访问的网站或网络门户上提供关于第三国二次使用国家联络点或国际组织在国际层面建立的系统与 HealthData@EU 连接的信息，且应在该第三国或国际组织成为 HealthData@EU 的授权参与者后立即提供；

(k)fulfilling obligations towards natural persons pursuant to Article 58;履行根据第 58 条对自然人承担的义务；

(l) （l）fulfilling any other tasks related to making possible the secondary use of electronic health data in the context of this Regulation.履行与在本条例范围内使电子健康数据的二次使用成为可能相关的任何其他任务。

The national dataset catalogue referred to in point (j)(i) of this paragraph shall also be made available to single information points under Article 8 of Regulation (EU) 2022/868.本款第(j)(i)点所提及的国家数据集目录，也应根据《欧盟条例》（2022/868）第 8 条向单一信息点开放。

2. In the exercise of their tasks, health data access bodies shall:2. 在履行其职责时，健康数据访问机构应：

(a) （a）cooperate with supervisory authorities under Regulation (EU) 2016/679 in relation to personal electronic health data and the EHDS Board;根据《欧盟条例》（EU）2016/679，就个人电子健康数据及电子健康数据委员会（EHDS Board）事宜与监管机构合作；

(b) （乙）cooperate with all relevant stakeholders, including patient organisations, representatives of natural persons, health professionals, researchers, and ethics committees, where applicable in accordance with Union or national law;与所有相关利益相关者合作，包括患者组织、自然人代表、卫生专业人员、研究人员和伦理委员会，在适用的情况下，应符合欧盟或国家法律；

(c) 电子健康记录之外的其他电子健康数据，包括来自移动健康应用程序、可穿戴设备和远程患者监测设备的数据；cooperate with other national competent bodies, including the national competent authorities supervising data altruism organisations under Regulation (EU) 2022/868, the competent authorities under Regulation (EU) 2023/2854 and the national competent authorities under Regulations (EU) 2017/745, (EU) 2017/746 and (EU) 2024/1689, where relevant.与其他国家主管机构合作，包括根据《欧盟条例（EU）2022/868》监管数据利他主义组织的国家主管部门、根据《欧盟条例（EU）2023/2854》设立的主管部门，以及在相关情况下根据《欧盟条例（EU）2017/745》《欧盟条例（EU）2017/746》和《欧盟条例（EU）2024/1689》设立的国家主管部门。

3. Health data access bodies may provide assistance to public sector bodies where those public sector bodies access electronic health data in accordance with Article 14 of Regulation (EU) 2023/2854.3. 健康数据访问机构可向公共部门机构提供协助，前提是这些公共部门机构根据《欧盟条例（2023/2854）》第 14 条访问电子健康数据。

4. Health data access bodies may provide support to a public sector body where it obtains data in the circumstances referred to in Article 15, point (a) or (b), of Regulation (EU) 2023/2854, in accordance with the rules laid down in that Regulation, by providing technical support to process those data or combining them with other data for joint analysis.4. 健康数据访问机构可依据《欧盟条例（EU）2023/2854》规定的规则，在公共部门机构根据该条例第 15 条（a）项或（b）项所述情形获取数据时，通过提供技术支持以处理这些数据，或将其与其他数据结合进行联合分析，为公共部门机构提供支持。

Article 58 第 58 条

Obligations of health data access bodies towards natural persons 健康数据访问机构对自然人的义务

1. Health data access bodies shall make information on the conditions under which electronic health data are made available for secondary use publicly available, easily searchable through electronic means and accessible for natural persons. That information shall cover the following:1. 健康数据访问机构应公开电子健康数据用于二次使用的条件相关信息，这些信息应能通过电子方式轻松检索，且便于自然人获取。该信息应涵盖以下内容：

(a) （a）the legal basis under which access to electronic health data is granted to the health data user;向健康数据使用者授予电子健康数据访问权限所依据的法律基础；

(b) （乙）the technical and organisational measures taken to protect the rights of natural

persons;为保护自然人权利而采取的技术和组织措施；

(c) 电子健康记录之外的其他电子健康数据，包括来自移动健康应用程序、可穿戴设备和远程患者监测设备的数据；

the applicable rights of natural persons in relation to secondary use;自然人在二次使用方面的适用权利；

(d) （d）the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;自然人根据《欧盟条例（2016/679）》第三章行使其权利的安排；

(e)the identity and the contact details of the health data access body;健康数据访问机构的身份和联系方式；

(f) （f）who has been granted access to datasets of electronic health data and to which datasets they were granted access and details of the data permit regarding the purposes for processing such data as referred to in Article 53(1);已获授权访问电子健康数据数据集的人员、他们被授权访问的数据集，以及第 53 条第 1 款所指的关于此类数据处理目的的数据许可详情；

(g) （g）the results or outcomes of the projects for which the electronic health data were used.使用电子健康数据的项目所产生的结果或成果。

2. If a Member State has provided for the right to opt out pursuant to Article 71 to be exercised through the health data access bodies, the relevant health data access bodies shall provide public information about the procedure to opt out and facilitate the exercise of that right.2. 若成员国规定可通过健康数据访问机构行使根据第 71 条享有的退出权，则相关健康数据访问机构应提供有关退出程序的公开信息，并为行使该权利提供便利。

3. Where a health data access body is informed by a health data user of a significant finding related to the health of a natural person, as referred to in Article 61(5), the health data access body shall inform the health data holder about that finding. The health data holder shall, under the conditions laid down by national law, inform the natural person or health professional treating the natural person concerned. Natural persons shall have the right to request not to be informed of such findings.3. 当健康数据访问机构收到健康数据使用者告知的、与第 61 条第 5 款所述自然人健康相关的重大发现时，该健康数据访问机构应将此发现告知健康数据持有者。健康数据持有者应根据国家法律规定的条件，通知相关自然人或为其治疗的健康专业人员。自然人有权请求不被告知此类发现。

4. Member States shall inform the public at large about the role and benefits of health data access bodies.4. 成员国应向广大公众宣传健康数据访问机构的作用和益处。

Article 59 第 59 条

Reporting by health data access bodies 健康数据访问机构的报告义务

1. Each health data access body shall publish an activity report every two years and make it publicly available on its website. If a Member State designates more than one

health data access body, the coordinating body referred to in Article 55(1) shall be responsible for the activity report and request the necessary information from the other health data access bodies. That activity report shall follow a structure agreed by the EHDS Board pursuant to Article 94(2), point (d), and contain at least the following categories of information:1. 每个健康数据访问机构应每两年发布一份活动报告，并在其网站上公开。如果某成员国指定了多个健康数据访问机构，则第 55 条第（1）款所述的协调机构应负责该活动报告，并向其他健康数据访问机构索取必要信息。该活动报告应遵循欧洲健康数据空间委员会根据第 94 条第（2）款（d）项商定的结构，并至少包含以下类别的信息：

(a) （a）information relating to the health data access applications and health data requests submitted, such as the types of health data applicants, number of data permits issued or refused, categories of purposes of access and categories of electronic health data accessed, and a summary of the results of the electronic health data uses, where applicable;与已提交的健康数据访问申请和健康数据请求相关的信息，例如健康数据申请者的类型、已发放或拒绝的数据许可数量、访问目的类别、所访问的电子健康数据类别，以及适用情况下电子健康数据使用结果的摘要；

(b) （乙）information on the fulfilment of regulatory and contractual commitments by health data users and health data holders, as well as the number and amount of administrative fines imposed by health data access bodies;关于健康数据使用者和健康数据持有者履行监管及合同承诺的信息，以及健康数据访问机构施加的行政罚款的数量和金额；

(c) 电子健康记录之外的其information on audits carried out on health data users to ensure 他电子健康数据，包括来compliance of the processing they carry out in the secure processing 自移动健康应用程序、可environment pursuant to Article 73(1), point (e);关于对健康数据使穿戴设备和远程患者监测用者进行审计的信息，以确保其依据第 73 条第（1）款（e）项在设备的数据； 安全处理环境中开展的处理活动合规。

(d) （d）information on internal and third-party audits on compliance of secure processing environments with the defined standards, specifications and requirements, as referred to in Article 73(3);关于安全处理环境是否符合第 73 条第 3 款所述的既定标准、规范和要求的内部及第三方审计信息；

(e)information on the handling of requests from natural persons relating to the exercise of their data protection rights;关于自然人行使其数据保护权利相关请求的处理信息；

(f) （f）a description of the health data access body's activities carried out in relation to engagement with and consultation of relevant stakeholders;关于健康数据访问机构在与相关利益相关者互动和咨询方面所开展活动的描述；

(g) （g）revenues from data permits and health data requests;数据许可和健康数据请求的收入；

(h) (h) 在欧盟和国家层面开展合作，并就电子健康数据the average number of days between 的二次使用和管理技术及最佳实践向委员会提供建议；health data access applications or 通过第 75 条所述的 HealthData@EU，为跨境访问其他成health data requests and access to 员国托管的用于二次使用的电子健康数据提供便利，并data;健康数据访问申请或健康数据

彼此之间以及与委员会密切合作；　　请求与数据访问之间的平均天数；

(i) （一）the number of data quality labels issued by health data holders, disaggregated per quality category;健康数据持有者发布的数据质量标签数量，按质量类别分列；

(j) (j) 通过电子方式公开： 一份国家数据集目录，the number of peer-reviewed research 其中应根据第 77 条、第 78 条和第 80 条的规定，publications, policy documents and 包含电子健康数据的来源、性质详情以及提供电子regulatory procedures using data accessed 健康数据的条件； 所有健康数据访问申请和健康via the EHDS;通过欧洲健康数据空间数据请求，在初步接收后应立即公开，不得有不当（EHDS）获取的数据所涉及的同行评审研延迟； 所有已签发的数据许可、已批准的健康数究出版物、政策文件和监管程序的数量；据请求以及拒绝决定（包括其理由），应在签发、
批准或拒绝后的 30 个工作日内公开；

(k)the number of digital health products and services, including AI applications, developed using data accessed via the EHDS.使用通过电子健康数据空间（EHDS）获取的数据开发的数字健康产品和服务（包括人工智能应用）的数量。

2. The activity report referred to in paragraph 1 shall be submitted to the Commission and the EHDS Board within six months of the end of the second year of the relevant reporting period. The activity report shall be accessible via the Commission's website.2. 第 1 款所述的活动报告应在相关报告期第二年结束后的六个月内提交给委员会和 EHDS 委员会。该活动报告应可通过委员会网站查阅。

Article 60 第 60 条

Duties of health data holders 健康数据持有者的义务

1. Health data holders shall make relevant electronic health data referred to in Article 51 available upon request to the health data access body, in accordance with a data permit issued pursuant to Article 68, or upon a health data request approved pursuant to Article 69.1. 健康数据持有者应根据第 68 条颁发的数据许可，或根据第 69 条批准的健康数据请求，应健康数据访问机构的要求，提供第 51 条所述的相关电子健康数据。

2. Health data holders shall put the requested electronic health data referred to in paragraph 1 at the disposal of the health data access body within a reasonable time and no later than three months from the receipt of the request by the health data access body. In justified cases, the health data access body may extend that period by a maximum of three months.2. 健康数据持有方应在合理时间内，且不晚于健康数据访问机构收到请求后的三个月内，向该机构提供第 1 款所述的请求的电子健康数据。在有正当理由的情况下，健康数据访问机构可将该期限最多延长三个月。

3. The health data holder shall communicate to the health data access body a description of the dataset it holds in accordance with Article 77. The health data holder shall, at a minimum on an annual basis, check that its dataset description in the national dataset catalogue is accurate and up to date.3. 健康数据持有方应根据第 77 条，向健康数据访问机构传达其持有的数据集说明。健康数据持有方至少应每年检查一次其在国家数据集目录中的数据集说明是否准确且最新。

4. Where a data quality and utility label accompanies the dataset pursuant to Article 78, the health data holder shall provide sufficient documentation to the health data access body for that body to verify the accuracy of the label.4. 若数据集根据第 78 条附有数据质量和效用标签，健康数据持有人应向健康数据访问机构提供足够的文件，以便该机构核实标签的准确性。

5. Health data holders of non-personal electronic health data shall provide access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place robust, transparent and sustainable governance and a transparent model of user access.5. 非个人电子健康数据的健康数据持有者应通过可信开放数据库提供数据访问权限，以确保所有用户能够不受限制地访问数据，并保障数据的存储和保存。可信开放公共数据库应建立健全、透明且可持续的治理机制，以及透明的用户访问模式。

Article 61 第 61 条

Duties of health data users 健康数据使用者的职责

1. Health data users may access and process the electronic health data referred to in Article 51 for secondary use only in accordance with a data permit issued pursuant to Article 68, a health data request approved pursuant to Article 69 or, in situations referred to in Article 67(3), an access approval from the relevant authorised participant in HealthData@EU referred to in Article 75.1. 健康数据使用者仅可依据第 68 条颁发的数据许可、第 69 条批准的健康数据请求，或在第 67 条第 3 款所述情形下，依据第 75 条所述的 HealthData@EU 相关授权参与方的访问批准，访问和处理第 51 条所述的电子健康数据，用于二次使用。

2. When processing electronic health data within the secure processing environments referred to in Article 73, health data users shall not provide access to the electronic health data, or make those data available, to third parties not mentioned in the data permit.2. 在第 73 条所述的安全处理环境中处理电子健康数据时，健康数据使用者不得向数据许可中未提及的第三方提供电子健康数据的访问权限，也不得向其提供这些数据。

3. Health data users shall not re-identify or attempt to re-identify the natural persons to whom the electronic health data obtained by the health data users on the basis of a data permit, a health data request or an access approval by an authorised participant in HealthData@EU relate.3. 健康数据使用者不得重新识别或试图重新识别其依据数据许可、健康数据请求或 HealthData@EU 中授权参与者的访问批准所获取的电子健康数据所涉及的自然人。

4. Health data users shall make public the results or output of secondary use, including information relevant for the provision of healthcare, within 18 months of the completion of the processing of the electronic health data in the secure processing environment or of having received the response to the health data request referred to in Article 69.4. 健康数据使用者应在安全处理环境中完成电子健康数据处理后，或在收到第 69 条所述健康数据请求的回复后 18 个月内，公开二次使用的结果或产出，包括与医疗服务提供相关的信息。

In justified cases related to the permitted purposes of the processing of electronic health data, the period referred to in the first subparagraph may be extended by the health data access body, in particular in cases where the result is published in a scientific journal or other scientific publication.在与电子健康数据处理的许可目的相关的合理情况下，第一段所述期限可由健康数据访问机构延长，特别是在结果发表于科学期刊或其他科学出版物的情况下。

The results or output of secondary use shall contain only anonymous data.二次使用的结果或输出应仅包含匿名数据。

Health data users shall inform the health data access bodies from which a data permit was obtained about the results or output of secondary use and assist them to make that information public on health data access bodies' websites. Such publication shall be without prejudice to publication rights in scientific journals or other scientific publications.健康数据使用者应将二次使用的结果或产出告知其获取数据许可的健康数据访问机构，并协助这些机构在其网站上公开该信息。此类公开不应损害在科学期刊或其他科学出版物上的发表权。

When health data users use electronic health data in accordance with this Chapter, they shall acknowledge the sources of the electronic health data and the fact that the electronic health data have been obtained in the framework of the EHDS.当健康数据使用者依照本章规定使用电子健康数据时，应当声明电子健康数据的来源以及该电子健康数据是在电子健康数据系统（EHDS）框架下获取的这一事实。

5. Without prejudice to paragraph 2, health data users shall inform the health data access body of any significant finding related to the health of the natural person whose data are included in the dataset.5. 在不影响第 2 款规定的前提下，健康数据使用者应将与数据集中所包含数据的自然人健康相关的任何重大发现告知健康数据访问机构。

6. Health data users shall cooperate with health data access bodies in those bodies' performance of their tasks.6. 健康数据使用者应配合健康数据访问机构履行其职责。

Article 62 第 62 条

Fees 费用

1. Health data access bodies, including the Union health data access service, or trusted health data holders referred to in Article 72 may charge fees for making electronic health data available for secondary use.1. 健康数据访问机构，包括联盟健康数据访问服务机构或第 72 条所述的可信健康数据持有者，可为提供电子健康数据供二次使用收取费用。

The fees shall be in proportion to the cost of making the data available and they shall not restrict competition.费用应与提供数据的成本成比例，且不得限制竞争。

The fees shall cover all or part of the costs related to the procedure for assessing a health data access application or a health data request, for issuing, refusing or amending a data permit pursuant to Articles 67 and 68 or for providing a response to

a health data request submitted pursuant to Article 69, including costs related to the consolidation, preparation, pseudonymisation, anonymisation and provision of the electronic health data.这些费用应涵盖与评估健康数据访问申请或健康数据请求的程序、根据第 67 条和第 68 条签发、拒绝或修改数据许可，或对根据第 69 条提交的健康数据请求作出回应相关的全部或部分成本，包括与电子健康数据的整合、准备、假名化、匿名化和提供相关的成本。

Member States may establish reduced fees for certain types of health data users located in the Union, such as public sector bodies or Union institutions, bodies, offices and agencies with a legal mandate in the field of public health, university researchers or microenterprises.成员国可对位于欧盟境内的特定类型健康数据使用者设定降低的费用，例如公共部门机构或在公共卫生领域拥有法定职权的欧盟机构、团体、办事处和代理机构、大学研究人员或微型企业。

2. The fees referred to in paragraph 1 of this Article may include compensation for the costs incurred by the health data holder for compiling and preparing the electronic health data to be made available for secondary use. In such cases, the health data holder shall provide an estimate of such costs to the health data access body. Where the health data holder is a public sector body, Article 6 of Regulation (EU) 2022/868 shall not apply. The part of the fees linked to the health data holder's costs shall be paid to the health data holder.2. 本条第 1 款所指的费用可包括对健康数据持有人为汇编和准备可供二次使用的电子健康数据所产生成本的补偿。在这种情况下，健康数据持有人应向健康数据访问机构提供此类成本的估算。若健康数据持有人是公共部门机构，则《欧盟条例（EU）2022/868》第 6 条不适用。与健康数据持有人成本相关的那部分费用应支付给健康数据持有人。

3. Any fees charged to health data users pursuant to this Article shall be transparent and non-discriminatory.3. 根据本条向健康数据使用者收取的任何费用均应透明且非歧视性。

4. Where health data holders and health data users do not agree on the level of the fees within one month of the data permit being issued, the health data access body may set the fees in proportion to the cost of making electronic health data available for secondary use. Where health data holders or health data users disagree with the fee set by the health data access body, they shall have access to dispute settlement bodies in accordance with Article 10 of Regulation (EU) 2023/2854.4. 若健康数据持有者与健康数据使用者在数据许可发放后一个月内未能就费用水平达成一致，健康数据访问机构可根据提供电子健康数据供二次使用的成本按比例设定费用。若健康数据持有者或健康数据使用者对健康数据访问机构设定的费用有异议，他们可依据《欧盟条例》（EU）2023/2854 第 10 条向争议解决机构寻求解决。

5. Before issuing a data permit pursuant to Article 68 or providing a response to a health data request submitted pursuant to Article 69, the health data access body shall inform the health data applicant of the estimated fees. The health data applicant shall be informed about the option to withdraw the health data access application or health data request. If the health data applicant withdraws its application or request, the health data applicant shall only be charged the costs that have already been

incurred.5. 在依据第 68 条签发数据许可或针对依据第 69 条提交的健康数据请求作出回应之前，健康数据访问机构应向健康数据申请人告知预估费用。还应告知健康数据申请人有权撤回健康数据访问申请或健康数据请求。若健康数据申请人撤回其申请或请求，仅需支付已产生的费用。

6. The Commission shall, by means of implementing acts, lay down principles for the fee policies and fee structures, including deductions for the entities referred to in paragraph 1, fourth subparagraph, of this Article in order to support consistency and transparency between Member States regarding such fee policies and fee structures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).6. 委员会应通过实施法案，制定费用政策和费用结构的原则，包括对本条第 1 款第四项所指实体的减免，以促进成员国之间在此类费用政策和费用结构方面的一致性和透明度。该实施法案应根据第 98 条第（2）款所述的审查程序通过。

Article 63 第 63 条

Enforcement by health data access bodies 健康数据访问机构的执法

1. When carrying out their monitoring and supervisory tasks, as referred to in Article 57(1), point (a)(ii), health data access bodies shall have the right to request and receive all the necessary information from health data users and health data holders to verify compliance with this Chapter.1. 健康数据访问机构在执行第 57 条第（1）款（a）项（ii）目所述的监测和监督任务时，有权要求健康数据使用者和健康数据持有者提供所有必要信息，以核实其是否遵守本章规定。

2. Where health data access bodies find that a health data user or health data holder does not comply with the requirements of this Chapter, they shall immediately notify the health data user or health data holder of those findings and take appropriate measures. The health data access body concerned shall give the health data user or health data holder concerned the opportunity to state their views within a reasonable period that shall not exceed four weeks.2. 当健康数据访问机构发现健康数据使用者或健康数据持有者未遵守本章要求时，应立即将这些发现通知该健康数据使用者或健康数据持有者，并采取适当措施。相关健康数据访问机构应给予相关健康数据使用者或健康数据持有者陈述其观点的机会，期限应在合理范围内且不超过四周。

Where the finding of non-compliance concerns a possible breach of Regulation (EU) 2016/679, the health data access body concerned shall immediately inform the supervisory authorities under that Regulation and provide them with all relevant information concerning that finding.如果不遵守的调查结果涉及可能违反《(欧盟)2016/679 号条例》，相关健康数据访问机构应立即通知该条例规定的监管机构，并向其提供与该调查结果相关的所有信息。

3. With regard to non-compliance by health data users, health data access bodies shall have the power to revoke the data permit issued pursuant to Article 68 and stop without undue delay the affected electronic health data processing operation carried out by the health data user, and shall take appropriate and proportionate measures

aimed at ensuring compliant processing by the health data user.3. 对于健康数据使用者的不合规行为，健康数据访问机构有权撤销根据第 68 条颁发的数据许可，并毫不拖延地停止健康数据使用者开展的相关电子健康数据处理操作，同时应采取适当且相称的措施，确保健康数据使用者合规处理数据。

As part of such enforcement measures, the health data access bodies may also, where appropriate, exclude, or initiate proceedings to exclude, in accordance with national law, the health data user concerned from any access to electronic health data within the EHDS in the context of secondary use for a period of up to five years.作为此类执行措施的一部分，健康数据访问机构在适当情况下，还可依照国家法律，将相关健康数据使用者排除在电子健康数据空间（EHDS）内二次使用电子健康数据的权限之外，或启动相关程序将其排除，期限最长可达五年。

4. With regard to non-compliance by health data holders, where a health data holder withholds the electronic health data from health data access bodies with the manifest intention of obstructing the use of electronic health data, or does not respect the deadlines set out in Article 60(2), the health data access body shall have the power to fine the health data holder for each day of delay with a periodic penalty payment, which shall be transparent and proportionate. The amount of the fines shall be established by the health data access body in accordance with national law. In the event of repeated breaches by the health data holder of the obligation of cooperation with the health data access body, that body may exclude or initiate proceedings to exclude, in accordance with national law, the health data holder concerned from submitting health data access applications pursuant to this Chapter for a period of up to five years. During the period of that exclusion, the health data holder shall remain obliged to make data accessible under this Chapter, where applicable.4. 关于健康数据持有者的不遵守行为，若健康数据持有者以明显阻碍电子健康数据使用的意图向健康数据访问机构隐瞒电子健康数据，或不遵守第 60 条第（2）款规定的期限，健康数据访问机构有权对健康数据持有者按延迟天数处以定期罚款，罚款应具有透明度且适度。罚款金额由健康数据访问机构根据国家法律确定。若健康数据持有者多次违反与健康数据访问机构合作的义务，该机构可根据国家法律，将相关健康数据持有者排除在外，或启动程序将其排除在根据本章提交健康数据访问申请的范围之外，期限最长可达五年。在被排除期间，健康数据持有者在适用情况下，仍有义务根据本章规定提供可访问的数据。

5. The health data access body shall communicate the enforcement measures taken pursuant to paragraphs 3 and 4, and the reasons on which they are based, to the health data user or health data holder concerned, without delay, and shall lay down a reasonable period for the health data user or health data holder to comply with those measures.5. 健康数据访问机构应立即将根据第 3 款和第 4 款采取的执行措施及其依据的理由告知相关健康数据使用者或健康数据持有者，并应为健康数据使用者或健康数据持有者设定一个合理的期限以遵守这些措施。

6. Any enforcement measures taken by the health data access body pursuant to paragraph 3 shall be notified to other health data access bodies through the IT tool referred to in paragraph 7. Health data access bodies may make that information publicly available on their websites.6. 健康数据访问机构根据第 3 款采取的任何执

行措施，均应通过第 7 款所述的信息技术工具通知其他健康数据访问机构。健康数据访问机构可在其网站上公开该信息。

7. The Commission shall, by means of implementing acts, set out the architecture of an IT tool, as part of the infrastructure of HealthData@EU referred to in Article 75, aimed at supporting and making transparent to other health data access bodies the enforcement measures referred to in this Article, especially periodic penalty payments, the revoking of data permits and exclusions. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).7. 委员会应通过实施法案，制定一个信息技术工具的架构。该工具作为第 75 条所述 HealthData@EU 基础设施的一部分，旨在为其他健康数据访问机构提供支持，并使本条所述的执行措施（特别是定期罚款、撤销数据许可和排除在外）透明化。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

8. The Commission shall issue guidelines, by 26 March 2032, in close cooperation with the EHDS Board, on enforcement measures including periodic penalty payments and other measures to be taken by the health data access bodies.8. 委员会应在 2032 年 3 月 26 日前，与 EHDS 委员会密切合作，发布关于执法措施的指南，包括定期罚款以及健康数据访问机构应采取的其他措施。

Article 64 第 64 条

General conditions for the imposition of administrative fines by health data access bodies 健康数据访问机构处以行政罚款的一般条件

1. Each health data access body shall ensure that the imposition of administrative fines pursuant to this Article in respect of infringements referred to in paragraphs 4 and 5 is effective, proportionate and dissuasive in each individual case.1. 每个健康数据访问机构应确保，根据本条对第 4 款和第 5 款所述侵权行为处以的行政罚款，在每一个别案件中都是有效、适当且具有威慑力的。

2. Administrative fines shall, depending on the circumstances of each individual case, be imposed in addition to, or instead of, enforcement measures referred to in Article 63(3) and (4). Health data access bodies shall decide whether to impose an administrative fine and the amount of the administrative fine in each individual case by giving due regard to the following circumstances:2. 行政罚款应根据每个案件的具体情况，在第 63 条第（3）款和第（4）款所述的执行措施之外附加施加，或替代这些执行措施施加。健康数据访问机构在每个案件中决定是否施加行政罚款以及罚款金额时，应充分考虑以下情况：

(a) （a）the nature, gravity and duration of the infringement;侵权行为的性质、严重程度和持续时间；

(b) （乙）whether any penalties or administrative fines have already been imposed by other competent authorities for the same infringement;其他主管机关是否已就同一侵权行为处以任何处罚或行政罚款；

(c) 电子健康记录之外的其他电子健康数据，包括the intentional or negligent character of the 来自移动健康应用程序、可穿戴设备和远程患者监infringement;侵权行为的故意或过失性

测设备的数据；　　质；

(d) （d）any action taken by the health data holder or health data user to mitigate the damage caused;健康数据持有者或健康数据使用者为减轻所造成的损害而采取的任何行动；

(e)the degree of responsibility of the health data user, taking into account technical and organisational measures implemented by that health data user pursuant to Article 67(2), point (g), and Article 67(4);健康数据使用者的责任程度，同时考虑到该健康数据使用者依据第 67 条第（2）款（g）项和第 67 条第（4）款所实施的技术和组织措施；

(f) （f）any relevant previous infringements by the health data holder or health data user;健康数据持有者或健康数据使用者以往任何相关的侵权行为；

(g) （g）the degree of cooperation of the health data holder or health data user with the health data access body as regards remedying the infringement and mitigating its possible adverse effects;健康数据持有者或健康数据使用者在纠正侵权行为及减轻其可能产生的不利影响方面与健康数据访问机构的合作程度；

(h) (h) 在欧盟和国家层面开展合作，并就电子the manner in which the health data access 健康数据的二次使用和管理技术及最佳实践向body became aware of the infringement, in 委员会提供建议； 通过第 75 条所述的particular whether, and to what extent, the HealthData@EU，为跨境访问其他成员国托管的health data user notified it of the infringement; 用于二次使用的电子健康数据提供便利，并彼健康数据访问机构知晓侵权行为的方式，特此之间以及与委员会密切合作；　　别是健康数据使用者是否以及在何种程度上向其通报了该侵权行为；

(i) （一）compliance with any enforcement measures referred to in Article 63(3) and (4) which have been ordered previously against the controller or processor concerned with regard to the same subject matter;遵守先前针对相关控制者或处理者就同一标的下达的第 63 条第（3）款和第（4）款所述的任何执行措施；

(j) (j) 通过电子方式公开： 一份国家数据集目any other aggravating or mitigating factor 录，其中应根据第 77 条、第 78 条和第 80 条的applicable to the circumstances of the case, 规定，包含电子健康数据的来源、性质详情以such as financial benefits gained or losses 及提供电子健康数据的条件；所有健康数据访avoided, directly or indirectly, through the 问申请和健康数据请求，在初步接收后应立即infringement.案件情节中适用的任何其他加公开，不得有不当延迟； 所有已签发的数据许重或减轻处罚的因素，例如通过侵权行为直可、已批准的健康数据请求以及拒绝决定（包接或间接获得的经济利益或避免的损失。括其理由），应在签发、批准或拒绝后的 30
个工作日内公开；

3. If a health data holder or a health data user intentionally or negligently infringes several provisions of this Regulation for the same or a linked data permit or health data request, the total amount of the administrative fine shall not exceed the amount specified for the most serious infringement.3. 若健康数据持有方或健康数据使用方在同一或关联的数据许可或健康数据请求中，故意或过失违反本条例的多项规定，行政罚款的总额不得超过针对最严重违规行为所规定的金额。

4. In accordance with paragraph 2 of this Article, infringements of the duties of the health data holder or health data user pursuant to Article 60 and Article 61(1), (5) and

(6) shall be subject to administrative fines of a maximum of EUR 10 000 000 or, in the case of an undertaking, of a maximum of 2 % of its total worldwide annual turnover in the preceding financial year, whichever is higher.4. 根据本条第 2 款，违反第 60 条以及第 61 条第（1）、（5）和（6）款规定的健康数据持有人或健康数据使用者义务的，应处以最高 1000 万欧元的行政罚款；如系企业，最高罚款为其上一财政年度全球年营业额的 2%，以两者中较高者为准。

5. In accordance with paragraph 2, the following infringements shall be subject to administrative fines of a maximum of EUR 20 000 000 or, in the case of an undertaking, of a maximum of 4 % of its total worldwide annual turnover in the preceding financial year, whichever is higher:5. 根据第 2 款，下列侵权行为应处以最高 2000 万欧元的行政罚款；如果是企业，最高罚款为其上一财政年度全球总营业额的 4%，以较高者为准：

(a) （a）health data users processing electronic health data obtained via a data permit issued pursuant to Article 68 for the uses referred to in Article 54;健康数据用户处理通过依据第 68 条发放的数据许可获取的电子健康数据，用于第 54 条所述用途；

(b) （乙）health data users extracting personal electronic health data from secure processing environments;健康数据使用者从安全处理环境中提取个人电子健康数据；

(c) 电子健康记录之外的re-identifying or attempting to re-identify the natural persons to whom 其他电子健康数据，包the electronic health data obtained by the health data users on the 括来自移动健康应用程basis of a data permit or a health data request pursuant to Article 61(3) 序、可穿戴设备和远程relate;重新识别或试图重新识别健康数据使用者依据第 61 条第 3 款 患者监测设备的数据； 规定的的数据许可或健康数据请求所获取的电子健康数据所涉及的自然人。

(d) （d）non-compliance with enforcement measures taken by the health data access body pursuant to Article 63(3) and (4).不遵守健康数据访问机构根据第 63 条第（3）和（4）款采取的执行措施。

6. Without prejudice to the powers of health data access bodies pursuant to Article 63, each Member State may lay down rules on whether and to what extent administrative fines may be imposed on public authorities and public sector bodies established in that Member State.6. 在不损害第 63 条规定的健康数据访问机构权力的前提下，各成员国可制定规则，规定是否以及在何种程度上可对设在该成员国的公共当局和公共部门机构处以行政罚款。

7. The exercise by a health data access body of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and national law, including effective judicial remedies and due process.7. 健康数据访问机构根据本条行使其权力时，应遵守符合欧盟及国家法律的适当程序保障措施，包括有效的司法救济和正当程序。

8. Where the legal system of a Member State does not provide for administrative fines, this Article may be applied in a manner that, in accordance with its national legal framework, ensures that those legal remedies are effective and have an equivalent effect to the administrative fines imposed by health data access bodies. In

any event, the fines imposed shall be effective, proportionate and dissuasive. The Member State concerned shall notify the Commission of the provisions of the laws which it adopts pursuant to this paragraph by 26 March 2029 and, without delay, of any subsequent law amending such provisions or amendments affecting such provisions.8. 若某成员国的法律体系未规定行政罚款，则可依据其国内法律框架，以确保相关法律救济措施有效且与健康数据访问机构所施加的行政罚款具有同等效力的方式适用本条。在任何情况下，所施加的罚款都应有效、适当且具有威慑力。相关成员国应在 2029 年 3 月 26 日前将其根据本款通过的法律规定通知委员会，并且应立即将任何后续修订此类规定的法律或影响此类规定的修正案通知委员会。

Article 65 第 65 条

Relationship with supervisory authorities under Regulation (EU) 2016/679 与《欧盟条例》（EU）2016/679 项下监管机构的关系

The supervisory authority or authorities responsible for monitoring and enforcing the application of Regulation (EU) 2016/679 shall also be competent for monitoring and enforcing the application of the right to opt out from the processing of personal electronic health data for secondary use pursuant to Article 71. Those supervisory authorities shall be empowered to impose administrative fines up to the amount referred to in Article 83 of Regulation (EU) 2016/679.负责监督和执行《欧盟条例》（EU）2016/679 实施情况的一个或多个监管机构，也应有权监督和执行根据第 71 条规定的、对出于二次使用目的处理个人电子健康数据的退出权的实施情况。这些监管机构应有权处以不超过《欧盟条例》（EU）2016/679 第 83 条所述金额的行政罚款。

The supervisory authorities referred to in the first paragraph of this Article and the health data access bodies referred to in Article 55 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences. The relevant provisions of Regulation (EU) 2016/679 shall apply *mutatis mutandis*.本条第一款所述的监管机构与本条例第 55 条所述的健康数据访问机构应在相关情况下，在各自职权范围内合作执行本条例。（欧盟）2016/679 号条例的相关规定经适当修改后适用。

SECTION 3 第 3 节

Access to electronic health data for secondary use 电子健康数据的二次使用权限

Article 66 第六十六条

Data minimisation and purpose limitation 数据最小化和目的限制

1. Where health data access bodies receive a health data access application, they shall ensure that access is only provided to electronic health data that are adequate, relevant and limited to what is necessary in relation to the purpose of processing indicated in the health data access application by the health data user and in line with

the data permit issued pursuant to Article 68.1. 健康数据访问机构收到健康数据访问申请后，应确保仅提供那些充分、相关且限于健康数据使用者在申请中表明的处理目的所必需，并符合根据第 68 条颁发的数据许可的电子健康数据。

2. Health data access bodies shall provide electronic health data in an anonymised format, where the purpose of processing by the health data user can be achieved with such data, taking into account the information provided by the health data user.2. 健康数据访问机构应提供匿名格式的电子健康数据，前提是健康数据使用者的处理目的可通过此类数据实现，同时需考虑健康数据使用者提供的信息。

3. Where the health data user has sufficiently demonstrated that the purpose of processing cannot be achieved with anonymised data in accordance with Article 68(1), point (c), health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary to reverse the pseudonymisation shall be available only to the health data access body or an entity that acts as a trusted third party in accordance with national law.3. 若健康数据使用者充分证明，按照第 68 条第（1）款（c）项的规定，使用匿名化数据无法实现处理目的，健康数据访问机构应提供经假名化处理的电子健康数据的访问权限。用于撤销假名化处理的必要信息，仅应由健康数据访问机构或依据国家法律充当可信第三方的实体掌握。

Article 67 第 67 条

Health data access applications 健康数据访问申请

1. A natural or legal person may submit a health data access application for the purposes referred to in Article 53(1) to a health data access body.1. 自然人或法人可出于第 53 条第（1）款所述目的，向健康数据访问机构提交健康数据访问申请。

2. The health data access application shall include:2. 健康数据访问申请应包括：

(a) （a）the health data applicant's identity, a description of that health data applicant's professional functions and activities, including the identity of the natural persons who would have access to the electronic health data if a data permit were issued; the health data applicant shall notify the health data access body of any update of the list of natural persons;健康数据申请者的身份、对该健康数据申请者的专业职能和活动的描述（包括若数据许可获批将有权访问电子健康数据的自然人的身份）；健康数据申请者应将自然人名单的任何更新通知健康数据访问机构。

(b) （乙）the purposes referred to in Article 53(1) for which access to data is applied for;申请数据访问所依据的第 53 条第（1）款所述目的；

(c) 电子健康记录之外的a detailed explanation of the intended use of the electronic health 其他电子健康数据，包括data and expected benefit related to that use and how that benefit 来自移动健康应用程序、would contribute to the purposes referred to in Article 53(1);对电子可穿戴设备和远程患者健康数据的预期用途、与该用途相关的预期收益，以及该收益将如监测设备的数据； 何有助于实现第 53 条第（1）款所述目的的详细解释；

(d) （d）a description of the requested electronic health data, including their scope, time range, format, sources and, where possible, the geographical coverage where such data are

requested from health data holders in several Member States or from authorised participants in HealthData@EU referred to in Article 75;对所请求的电子健康数据的描述，包括其范围、时间范围、格式、来源，以及在可能的情况下，当此类数据是向若干成员国的健康数据持有者或第 75 条所述的 HealthData@EU 授权参与者请求时的地理覆盖范围；

(e)a description explaining whether the electronic health data need to be made available in a pseudonymised or anonymised format; in the case of a pseudonymised format, a justification as to why the processing cannot be carried out using anonymised data;一份说明，解释电子健康数据是否需要以假名化或匿名化的格式提供；如果采用假名化格式，需说明为何无法使用匿名化数据进行处理。

(f) （f）where the health data applicant intends to bring datasets already held by that health data applicant into the secure processing environment, a description of those datasets; 如果健康数据申请者打算将其已持有的数据集带入安全处理环境，则需提供这些数据集的说明；

(g) （g）a description of the safeguards, which are to be proportionate to the risks, planned to prevent any misuse of the electronic health data, as well as to protect the rights and interests of the health data holder and of the natural persons concerned, including to prevent any re-identification of natural persons in the dataset;关于保障措施的说明，这些措施应与风险相匹配，旨在防止电子健康数据的任何滥用，并保护健康数据持有人及相关自然人的权益，包括防止数据集中自然人的任何重新识别。

(h) (h) 在欧盟和国家层面开展合作，并就电子健康数a justified indication of the period during 据的二次使用和管理技术及最佳实践向委员会提供which the electronic health data are 建议； 通过第 75 条所述的 HealthData@EU，为跨境needed for processing in a secure 访问其他成员国托管的用于二次使用的电子健康数processing environment;在安全处理环 据提供便利，并彼此之间以及与委员会密切合作； 境中处理电子健康数据所需期限的合理说明；

(i) （一）a description of the tools and computing resources needed for a secure processing environment;对安全处理环境所需工具和计算资源的描述；

(j) (j) 通过电子方式公开：一份国家数据集目where applicable, information on any 录，其中应根据第 77 条、第 78 条和第 80 条assessment of ethical aspects of the processing, 的规定，包含电子健康数据的来源、性质详情required under national law, which may serve to 以及提供电子健康数据的条件； 所有健康数replace the health data applicant’s own ethics 据访问申请和健康数据请求，在初步接收后应assessment;在适用情况下，根据国家法律要求 立即公开，不得有不当延迟； 所有已签发的对处理的伦理方面进行的任何评估的相关信 数据许可、已批准的健康数据请求以及拒绝决息，这些信息可用于替代健康数据申请人自身 定（包括其理由），应在签发、批准或拒绝后的伦理评估；
的 30 个工作日内公开；

(k)where the health data applicant intends to make use of an exception under Article 71(4), the justification required by national law pursuant to that Article.若健康数据申请人打算依据第 71 条第 4 款适用例外规定，则需提供国内法根据该条款要求的正当理由。

3. When seeking access to electronic health data held by health data holders established in more than one Member State or from the relevant authorised participants in HealthData@EU referred to in Article 75, the health data applicant shall submit a single health data access application through the health data access body of the Member State where the main establishment of the health data applicant is located, through the health data access body of the Member State in which one of those health data holders is established or through the services provided by the Commission in HealthData@EU referred to in Article 75. The health data access application shall be automatically forwarded to the relevant authorised participants in HealthData@EU and to the health data access bodies of the Member States where the health data holders identified in the health data access application are established.3. 当寻求访问由在一个以上成员国设立的健康数据持有者持有的电子健康数据，或访问第 75 条所述的 HealthData@EU 中相关授权参与者的数据时，健康数据申请者应通过其主要机构所在成员国的健康数据访问机构、其中一个健康数据持有者所在成员国的健康数据访问机构，或通过第 75 条所述的欧盟委员会在 HealthData@EU 中提供的服务，提交一份单一的健康数据访问申请。该健康数据访问申请应自动转发给 HealthData@EU 中的相关授权参与者，以及申请中所指明的健康数据持有者所在成员国的健康数据访问机构。

4. When seeking access to the personal electronic health data in a pseudonymised format, the health data applicant shall provide, together with the health data access application, a description of how the processing would comply with applicable Union and national law on data protection and privacy, in particular with Regulation (EU) 2016/679 and, more specifically, with Article 6(1) thereof.4. 当寻求以假名化格式获取个人电子健康数据时，健康数据申请人在提交健康数据访问申请的同时，应说明相关处理将如何遵守欧盟及成员国适用的数据保护和隐私法律，特别是《欧盟条例（EU）2016/679》，更具体地说，是该条例第 6 条第 1 款的规定。

5. Public sector bodies and Union institutions, bodies, offices and agencies shall provide the same information as required under paragraphs 2 and 4, except for paragraph 2, point (h), in which case they shall submit instead information concerning the period for which the electronic health data can be accessed, the frequency of that access or the frequency of the data updates.5. 公共部门机构以及欧盟的各机构、团体、办公室和代理机构应提供第 2 款和第 4 款所要求的相同信息，但第 2 款(h)项除外，在这种情况下，它们应提交有关电子健康数据可访问期限、访问频率或数据更新频率的信息。

Article 68 第 68 条

Data permit 数据许可

1. For the purposes of granting access to electronic health data, the health data access bodies shall assess whether all the following criteria are fulfilled:1. 为授予电子健康数据的访问权限，健康数据访问机构应评估是否满足以下所有标准：

(a) （a）the purposes described in the health data access application correspond to one or more of the purposes listed in Article 53(1);健康数据访问申请中所述的目的对应于第 53 条

第 1 款所列的一项或多项目的；

(b) （乙）the requested data are necessary, adequate and proportionate for the purposes described in the health data access application, taking into account data minimisation and purpose limitation requirements provided for in Article 66;所请求的数据对于健康数据访问申请中描述的目的而言是必要、充分且适当的，同时考虑到第 66 条规定的数据最小化和目的限制要求；

(c) 电子健康记录之外的the processing complies with Article 6(1) of Regulation (EU) 2016/679 其他电子健康数据，包and, in the case of pseudonymised data, there is sufficient justification 括来自移动健康应用程that the purpose cannot be achieved with anonymised data;该处理符序、可穿戴设备和远程合《欧盟条例》（EU）2016/679 第 6 条第 1 款的规定，且对于假名患者监测设备的数据； 化数据，有充分理由表明无法通过匿名化数据实现该目的。

(d) （d）the health data applicant is qualified in relation to the intended purposes of data use and has appropriate expertise, including professional qualifications in the areas of healthcare, care, public health or research, consistent with ethical practice and applicable laws and regulations;健康数据申请人具备与数据使用预期目的相关的资质，并拥有适当的专业知识，包括医疗、护理、公共卫生或研究领域的专业资格，且符合道德规范及适用法律法规。

(e)the health data applicant demonstrates sufficient technical and organisational measures to prevent the misuse of the electronic health data and to protect the rights and interests of the health data holder and of the natural persons concerned;健康数据申请者证明其已采取足够的技术和组织措施，以防止电子健康数据被滥用，并保护健康数据持有者及相关自然人的权益。

(f) （f）the information on the assessment of ethical aspects of the processing, referred to in Article 67(2), point (j), where applicable, complies with national law;第 67 条第（2）款第（j）项所述的关于处理的伦理方面评估的信息（如适用）符合国家法律；

(g) （g）where the health data applicant intends to make use of an exception under Article 71(4), the justification required by national law adopted pursuant to that Article has been provided;如果健康数据申请人打算利用第 71 条第 4 款规定的例外情况，则已提供根据该条通过的国内法所要求的理由；

(h) (h) 在欧盟和国家层面开展合作，并就电子健康数据的二all other requirements in this 次使用和管理技术及最佳实践向委员会提供建议； 通过第 Chapter are fulfilled by the health 75 条所述的 HealthData@EU，为跨境访问其他成员国托管的data applicant. 本章中的所有其用于二次使用的电子健康数据提供便利，并彼此之间以及与他要求均由健康数据申请人满委员会密切合作； 足。

2. The health data access body shall also take into account the following:2. 健康数据访问机构还应考虑以下因素：

(a) （a）risks for national defence, security, public security and public order;国防、安全、公共安全和公共秩序风险；

(b) （乙）the risk of undermining the confidentiality of data in governmental databases of regulatory authorities.破坏监管机构政府数据库中数据保密性的风险。

3. Where the health data access body concludes that the requirements in paragraph 1 are fulfilled and the risks referred to in paragraph 2 are sufficiently mitigated, the health data access body shall grant access to electronic health data by issuing a data permit. Health data access bodies shall refuse all health data access applications where the requirements in this Chapter are not fulfilled.3. 当健康数据访问机构认定第 1 款中的要求已得到满足，且第 2 款所述风险已得到充分缓解时，该机构应通过发放数据许可的方式授予电子健康数据的访问权限。对于未满足本章要求的所有健康数据访问申请，健康数据访问机构应予以拒绝。

Where the requirements for issuing a data permit are not met, but the requirements to provide a response in an anonymised statistical format under Article 69 are, the health data access body may decide to provide such response, on condition that providing that response would mitigate the risks and, if the purpose of the health data access application can be fulfilled in this manner, that the health data applicant agrees to receiving a response in an anonymised statistical format under Article 69.若不符合发放数据许可的要求，但符合第 69 条规定的以匿名统计格式提供回应的要求，健康数据访问机构可决定提供此类回应，条件是提供该回应能降低风险，且若健康数据访问申请的目的可通过这种方式实现，健康数据申请人同意接收第 69 条规定的匿名统计格式的回应。

4. By way of derogation from Regulation (EU) 2022/868, the health data access body shall issue or refuse a data permit within three months of receiving a complete health data access application. If the health data access body finds that the health data access application is incomplete, it shall notify the health data applicant, which shall be given the possibility of completing that application. If the health data applicant does not complete the health data access application within four weeks, the data permit shall not be issued.4. 作为对《欧盟条例》（EU）2022/868 的背离，健康数据访问机构应在收到完整的健康数据访问申请后三个月内签发或拒绝数据许可。如果健康数据访问机构发现健康数据访问申请不完整，应通知健康数据申请人，申请人应有机会补全申请。如果健康数据申请人未在四周内补全健康数据访问申请，则不予签发数据许可。

The health data access body may extend the period for responding to a health data access application by three additional months where necessary, taking into account the urgency and complexity of the health data access application and the volume of health data access applications submitted for decision. In such cases, the health data access body shall notify the health data applicant as soon as possible that more time is needed for examining the health data access application, together with the reasons for the delay.健康数据访问机构在必要时，可综合考虑健康数据访问申请的紧迫性、复杂性以及待决策的健康数据访问申请数量，将回应健康数据访问申请的期限再延长三个月。在此情况下，健康数据访问机构应尽快通知健康数据申请人，说明审查该申请需要更多时间，并告知延迟的原因。

5. When handling a health data access application for cross-border access to electronic health data referred to in Article 67(3), health data access bodies and relevant authorised participants in HealthData@EU referred to in Article 75 shall remain responsible for adopting decisions to grant or refuse access to electronic health

data within their remit in accordance with this Chapter.5. 在处理第 67 条第 3 款所述的跨境获取电子健康数据的健康数据访问申请时，健康数据访问机构以及第 75 条所述的 HealthData@EU 中的相关授权参与者，应继续负责根据本章规定，在其职权范围内就批准或拒绝访问电子健康数据作出决定。

The health data access bodies and authorised participants in HealthData@EU concerned shall inform each other of their decisions. They may take that information into consideration when deciding on granting or refusing access to electronic health data.HealthData@EU 中相关的健康数据访问机构和授权参与者应相互告知各自的决定。他们在决定批准或拒绝电子健康数据访问时，可以考虑这些信息。

A data permit issued by one health data access body may benefit from mutual recognition by the other health data access bodies.一个健康数据访问机构颁发的数据许可可能会得到其他健康数据访问机构的相互认可。

6. Member States shall provide for an accelerated health data access application procedure for public sector bodies and Union institutions, bodies, offices and agencies with a legal mandate in the field of public health if the processing of electronic health data is to be carried out for the purposes established in Article 53(1), points (a), (b) and (c).6. 若为第 53 条第（1）款（a）、（b）和（c）项所规定的目的而处理电子健康数据，成员国应为准许公共部门机构以及在公共卫生领域拥有法定职权的欧盟各机构、团体、办事处和部门使用一种加速的健康数据访问申请程序。

When such accelerated procedure applies, the health data access body shall issue or refuse a data permit within two months of receiving a complete health data access application. The health data access body may extend the period for responding to a health data access application by one additional month where necessary.当适用此类加急程序时，健康数据访问机构应在收到完整的健康数据访问申请后两个月内签发或拒绝数据许可。必要时，健康数据访问机构可将回应健康数据访问申请的期限再延长一个月。

7. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the health data holder. The health data access body shall make available the electronic health data to the health data user within two months of receiving them from the health data holders, unless the health data access body specifies that the data are to be provided within a longer specified timeframe.7. 数据许可发放后，健康数据获取机构应立即向健康数据持有方请求电子健康数据。健康数据获取机构应在从健康数据持有方收到电子健康数据后的两个月内，向健康数据使用者提供这些数据，除非健康数据获取机构明确规定数据将在更长的特定时间范围内提供。

8. In cases referred to in paragraph 5, first subparagraph, of this Article, the health data access bodies and authorised participants in HealthData@EU which issued a data permit or access approval, respectively, may decide to provide access to the electronic health data in the secure processing environment provided by the Commission as referred to in Article 75(9).8. 在本条第 5 款第一分段所述情形中，分别签发了数据许可或访问批准的健康数据访问机构及 HealthData@EU 的授权参与者，可决定

在第 75 条第 9 款所述的由委员会提供的安全处理环境中提供对电子健康数据的访问权限。

9. Where the health data access body refuses to issue a data permit, it shall provide a justification for that refusal to the health data applicant.9. 当健康数据访问机构拒绝发放数据许可时，应当向健康数据申请人提供拒绝的理由。

10. When issuing a data permit, the health data access body shall set out in that data permit the general conditions applicable to the health data user. The data permit shall contain the following:10. 健康数据访问机构在签发数据许可时，应在该许可中列明适用于健康数据使用者的一般条件。数据许可应包含以下内容：

(a) （a）the categories, specification and format of the electronic health data to be accessed, which are covered by the data permit, including their sources and an indication of whether the electronic health data are to be accessed in a pseudonymised format in the secure processing environment;数据许可所涵盖的、拟访问的电子健康数据的类别、规格和格式，包括其来源以及关于电子健康数据是否将在安全处理环境中以假名化格式被访问的说明；

(b) （乙）a detailed description of the purpose for which the electronic health data are made available;对电子健康数据可用目的的详细说明；

(c) 电子健康记录之外的其where a mechanism to implement an exception is provided for and 他电子健康数据，包括来自applicable under Article 71(4), information on whether it has been 移动健康应用程序、可穿戴applied and the reason for the related decision;在第 71 条第 4 款规设备和远程患者监测设备定并适用例外实施机制的情况下，关于该机制是否已被适用以及的数据； 相关决定理由的信息；

(d) （d）the identity of authorised persons, in particular the identity of the principal investigator, with access rights to the electronic health data in the secure processing environment;有权访问安全处理环境中电子健康数据的授权人员的身份，特别是主要研究者的身份；

(e) the duration of the data permit; 数据许可的期限；

(f) （f）information about the technical characteristics and tools available to the health data user within the secure processing environment;关于健康数据用户在安全处理环境中可使用的技术特征和工具的信息；

(g) （g） the fees to be paid by the health data user;健康数据使用者需支付的费用；

(h) (h) 在欧盟和国家层面开展合作，并就电子健康数据的二次使用和管any specific 理技术及最佳实践向委员会提供建议； 通过第 75 条所述的conditions. 任何特 HealthData@EU，为跨境访问其他成员国托管的用于二次使用的电子健康定条件。
数据提供便利，并彼此之间以及与委员会密切合作；

11. Health data users shall have the right to access and process the electronic health data in a secure processing environment in accordance with the data permit issued to them on the basis of this Regulation.11. 健康数据使用者有权依据本条例向其颁发的数据许可，在安全的处理环境中访问和处理电子健康数据。

12. A data permit shall be issued for the duration necessary to fulfil the requested purposes and that duration shall not exceed 10 years. That duration may be extended once, for a period which does not exceed 10 years, at the request of the health data user, based on arguments and documents to justify that extension which shall be provided one month before the expiry of the data permit. The health data access body may charge fees which increase to reflect the costs and risks of storing electronic health data for a period exceeding the initial period. In order to reduce such costs and fees, the health data access body may also propose to the health data user to store the dataset in a storage system with reduced capabilities. Such reduced capabilities shall not affect the security of the processed dataset. The electronic health data within the secure processing environment shall be deleted within six months of the expiry of the data permit. At the request of the health data user, the formula for the creation of the requested dataset may be stored by the health data access body.12. 数据许可的有效期应为实现请求目的所必需的时间，且该有效期不得超过 10 年。经健康数据使用者请求，并在数据许可到期前一个月提供证明延期合理性的论据和文件，该有效期可延长一次，延长期限不超过 10 年。健康数据访问机构可收取费用，且该费用会有所增加，以反映电子健康数据存储超过初始期限所产生的成本和风险。为降低此类成本和费用，健康数据访问机构也可向健康数据使用者提议，将数据集存储在功能有所缩减的存储系统中。此类缩减的功能不得影响所处理数据集的安全性。安全处理环境中的电子健康数据应在数据许可到期后的六个月内删除。经健康数据使用者请求，健康数据访问机构可存储用于生成所请求数据集的公式。

13. If the data permit needs to be updated, the health data user shall submit a request for an amendment of the data permit.13. 若数据许可需要更新，健康数据使用者应提交数据许可修改申请。

14. The Commission may, by means of an implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).14. 委员会可通过一项实施法案，设计一个标志以表彰电子健康数据空间（EHDS）的贡献。该实施法案应根据第 98 条第（2）款所述的审查程序通过。

Article 69 第 69 条

Health data request 健康数据请求

1. The health data applicant may submit a health data request for the purposes referred to in Article 53 with the aim of obtaining a response only in an anonymised statistical format. A health data access body shall not provide a response to a health data request in any other format and the health data user shall have no access to the electronic health data used to provide that response.1. 健康数据申请人可出于第 53 条所述目的提交健康数据请求，旨在仅获取匿名统计格式的回复。健康数据访问机构不得以外任何其他格式对健康数据请求作出回复，且健康数据使用者不得访问用于提供该回复的电子健康数据。

2. A health data request as referred to in paragraph 1 shall include the following information:2. 第 1 款所指的健康数据请求应包含以下信息：

(a) （a）the identity of the health data applicant and a description of that health data applicant's professional functions and activities;健康数据申请者的身份以及该健康数据申请者的专业职能和活动描述；

(b) （乙）a detailed explanation of the intended use of the electronic health data, including the purposes referred to in Article 53(1) for which the health data request is submitted;对电子健康数据预期用途的详细说明，包括第 53 条第 1 款中提及的提交健康数据请求的目的；

(c) 电子健康记录之外的其他电子健a description of the requested electronic health data, their 康数据，包括来自移动健康应用程format and the sources of those data, where possible;对所序、可穿戴设备和远程患者监测设请求的电子健康数据的描述，包括其格式和数据来源（如备的数据； 可能）；

(d) （d） a description of the statistical content;对统计内容的描述；

(e)a description of the safeguards planned to prevent any misuse of the requested electronic health data;一份关于为防止所请求的电子健康数据被滥用而计划采取的保障措施的说明；

(f) （f）a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 or Article 5(1) and Article 10(2) of Regulation (EU) 2018/1725;关于该处理方式如何符合《欧盟条例（2016/679）》第 6 条第 1 款或《欧盟条例（2018/1725）》第 5 条第 1 款及第 10 条第 2 款的说明；

(g) （g）where the health data applicant intends to make use of an exception under Article 71(4), the justification required in that regard by national law pursuant to that Article.如果健康数据申请人打算适用第 71 条第 4 款规定的例外情形，则需提供成员国法律根据该条要求的相关正当理由。

3. The health data access body shall assess if the health data request is complete and take into account the risks referred to in Article 68(2).3. 健康数据访问机构应评估健康数据请求是否完整，并考虑第 68 条第（2）款所述的风险。

4. The health data access body shall assess the health data request within three months of receipt of the request and, where possible, subsequently provide the response to the health data user within a further three months.4. 健康数据访问机构应在收到请求后的三个月内对健康数据请求进行评估，并在可能的情况下，在接下来的三个月内将回复提供给健康数据使用者。

Article 70 第 70 条

Templates to support access to electronic health data for secondary use 支持电子健康数据二次使用访问的模板

By 26 March 2027, the Commission shall, by means of implementing acts, set out the templates for the health data access application, the data permit and the health data request referred to in Articles 67, 68 and 69, respectively. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).截至 2027 年 3 月 26 日，委员会应通过实施法案，分别制定第 67 条、

第68条和第69条所提及的健康数据访问申请、数据许可和健康数据请求的模板。这些实施法案应根据第98条第（2）款所述的审查程序通过。

Article 71 第71条

Right to opt out from the processing of personal electronic health data for secondary use 拒绝将个人电子健康数据用于二次处理的权利

1. Natural persons shall have the right to opt out at any time, and without providing any reason, from the processing of personal electronic health data relating to them for secondary use under this Regulation. The exercise of that right shall be reversible.1. 自然人有权随时且无需提供任何理由，选择退出本条例规定的、与其相关的个人电子健康数据用于二次使用的处理活动。该权利的行使应具有可撤销性。

2. Member States shall provide for an accessible and easily understandable opt-out mechanism to exercise the right established in paragraph 1, whereby natural persons may explicitly state that they do not wish to have their personal electronic health data processed for secondary use.2. 成员国应规定一种易于获取且易于理解的退出机制，以行使第1款所确立的权利，据此，自然人可明确表示不希望其个人电子健康数据被用于二次处理。

3. Once natural persons have exercised the right to opt out, and where personal electronic health data relating to them can be identified in a dataset, personal electronic health data relating to those natural persons shall not be made available or otherwise processed pursuant to data permits issued under Article 68 or health data requests under Article 69 approved after the natural person has exercised the right to opt out.3. 一旦自然人行使了退出权，且在数据集中可识别出与其相关的个人电子健康数据，则不得根据该自然人行使退出权后依据第68条发放的数据许可或根据第69条批准的健康数据请求，提供或通过其他方式处理这些自然人的个人电子健康数据。

The first subparagraph of this paragraph shall not affect the processing for secondary use of personal electronic health data relating to those natural persons pursuant to data permits or health data requests that were issued or approved before the natural persons exercised their right to opt out.本款第一项不应影响根据自然人行使退出权之前已签发或批准的数据许可或健康数据请求，对涉及这些自然人的个人电子健康数据进行二次使用的处理。

4. By way of exception from the right to opt out provided for in paragraph 1, a Member State may provide in its national law for a mechanism to make data for which a right to opt out has been exercised available, provided that all the following conditions are fulfilled:4. 作为对第1款规定的退出权的例外，成员国可在其国内法中规定一种机制，使已行使退出权的数据能够被使用，前提是满足以下所有条件：

(a) （a）the health data access application or health data request is submitted by a public sector body or a Union institution, body, office or agency with a mandate to carry out tasks in the area of public health, or by another entity entrusted with carrying out public tasks

in the area of public health, or acting on behalf of or commissioned by a public authority, and the processing of those data is necessary for any of the following purposes:健康数据访问申请或健康数据请求由以下机构或实体提交：具有在公共卫生领域执行任务授权的公共部门机构、欧盟机构、团体、办公室或代理机构，或受委托在公共卫生领域执行公共任务的其他实体，或代表公共当局行事或受公共当局委托的实体，且对这些数据的处理对于以下任何目的而言都是必要的：

(i) （一）the purposes referred to in Article 53(1), points (a), (b) and (c);第 53 条第（1）款（a）、（b）和（c）项所述目的；

(ii) （二）scientific research for important reasons of public interest;出于重大公共利益原因的科学研究；

(b) （乙）those data cannot be obtained by alternative means in a timely and effective manner under equivalent conditions;在同等条件下，这些数据无法通过其他方式及时有效地获取；

(c) 电子健康记录之外的其他电the health data applicant has provided the justification 子健康数据，包括来自移动健康referred to in Article 68(1), point (g), or in Article 69(2), point 应用程序、可穿戴设备和远程患(g).健康数据申请人已提供第 68 条第（1）款（g）项或第 69 者监测设备的数据； 条第（2）款（g）项所述的理由。

The national law providing for such a mechanism shall provide for specific and suitable measures in order to protect the fundamental rights and the personal data of natural persons.规定此类机制的国家法律应规定具体且适当的措施，以保护自然人的基本权利和个人数据。

Where a Member State has provided in its national law for the possibility to request access to data for which a right to opt out has been exercised and the conditions referred to in the first subparagraph of this paragraph are fulfilled, those data may be included when carrying out the tasks under Article 57(1), points (a)(i), (a)(iii) and (b).如果某成员国在其国内法中规定，对于已行使退出权的数据，可以申请访问，且本款第一项所述条件得到满足，则在执行第 57 条第（1）款（a）项（i）目、（a）项（iii）目和（b）项规定的任务时，可纳入这些数据。

5. The rules on any mechanism to implement exceptions provided for under paragraph 4 by way of exception from paragraph 1 shall respect the essence of the fundamental rights and freedoms and shall be a necessary and proportionate measure in a democratic society to fulfil purposes of public interest in the area of legitimate scientific and societal objectives.5. 对于通过第 1 款的例外情形来实施第 4 款所规定例外的任何机制，其规则应尊重基本权利和自由的本质，且在民主社会中，为实现在合法的科学和社会目标领域内的公共利益目的，应是一项必要且相称的措施。

6. Any processing carried out in accordance with a mechanism to implement exceptions provided for under paragraph 4 of this Article shall comply with the requirements of this Chapter, in particular the prohibition on re-identifying or attempting to re-identify natural persons in accordance with Article 61(3). Any legislative measure providing for a mechanism in national law as referred to in

paragraph 4 of this Article shall include specific provisions for the safety, and the protection of the rights, of natural persons.6. 根据本条第 4 款规定的例外情形实施机制所进行的任何处理，均应符合本章的要求，特别是应遵守第 61 条第 3 款关于禁止对自然人进行重新识别或试图重新识别的规定。各国法律中就本条第 4 款所述机制作出规定的任何立法措施，均应包含关于自然人安全及权利保护的具体条款。

7. Member States shall notify without delay the Commission of the provisions of their national law which they adopt pursuant to paragraph 4 and of any subsequent amendment affecting them.7. 成员国应立即将其根据第 4 款通过的国内法规定以及影响这些规定的任何后续修订通知委员会。

8. When the purposes of the processing of personal electronic health data by a health data holder do not or no longer require the identification of a data subject by the controller, that health data holder shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with the right to opt out under this Article.8. 当健康数据持有者处理个人电子健康数据的目的不需要或不再需要控制者识别数据主体时，该健康数据持有者无义务为仅履行本条规定的退出权而保留、获取或处理额外信息以识别数据主体。

Article 72 第 72 条

Simplified procedure for access to electronic health data from a trusted health data holder 从可信健康数据持有者处获取电子健康数据的简化程序

1. Where a health data access body receives a health data access application pursuant to Article 67 or a health data request pursuant to Article 69 that only covers electronic health data held by a trusted health data holder designated in accordance with paragraph 2 of this Article, the procedure set out in paragraphs 4 to 6 of this Article shall apply.1. 当健康数据访问机构收到依据第 67 条提出的健康数据访问申请，或依据第 69 条提出的仅涉及根据本条第 2 款指定的可信健康数据持有者所持有的电子健康数据的健康数据请求时，应适用本条第 4 至 6 款规定的程序。

2. Member States may establish a procedure whereby health data holders can apply to be designated as trusted health data holders, provided the health data holders meet the following conditions:2. 成员国可设立一种程序，据此，健康数据持有者可申请被指定为可信健康数据持有者，前提是该健康数据持有者满足以下条件：

(a) （a）they are able to provide access to health data through a secure processing environment that complies with Article 73;它们能够通过符合第 73 条规定的安全处理环境提供健康数据的访问权限；

(b) （乙）they have the necessary expertise to assess health data access applications and health data requests;他们拥有评估健康数据访问申请和健康数据请求所需的专业知识；

(c) 电子健康记录之外的其他电子健康数they provide the necessary guarantees to ensure compliance with this Regulation.它们提供必要的据，包括来自移动健康应用程序、可穿戴设备和远程患者监测设备的数据；保障，以确保符合本条例。

Member States shall designate trusted health data holders following an assessment of the fulfilment of those conditions by the relevant health data access body.成员国应在相关健康数据访问机构对这些条件的满足情况进行评估后，指定受信任的健康数据持有者。

Member States shall establish a procedure to regularly review whether the trusted health data holder continues to fulfil those conditions.成员国应建立程序，定期审查受信任的健康数据持有者是否继续满足这些条件。

Health data access bodies shall indicate the trusted health data holders in the dataset catalogue referred to in Article 77.健康数据访问机构应在第 77 条所述的数据目录中指明受信任的健康数据持有者。

3. Health data access applications and health data requests referred to in paragraph 1 shall be submitted to the health data access body, which may forward them to the relevant trusted health data holder.3. 第 1 款所述的健康数据访问申请和健康数据请求应提交给健康数据访问机构，该机构可将其转发给相关的可信健康数据持有者。

4. Following receipt of a health data access application or health data request pursuant to paragraph 3 of this Article, the trusted health data holder shall assess the health data access application or health data request against the criteria listed in Article 68(1) and (2) or Article 69(2) and (3), as applicable.4. 在收到根据本条第 3 款提交的健康数据访问申请或健康数据请求后，可信健康数据持有人应根据适用情况，对照第 68 条第(1)款和第(2)款或第 69 条第(2)款和第(3)款所列标准，对该健康数据访问申请或健康数据请求进行评估。

5. The trusted health data holder shall submit the assessment it carries out pursuant to paragraph 4, accompanied by a proposal for decision, to the health data access body within two months of receipt of the health data access application or health data request from the health data access body. Within two months of receipt of the assessment, the health data access body shall issue a decision on the health data access application or health data request. The health data access body shall not be bound by the proposal submitted by the trusted health data holder.5. 可信健康数据持有方应在收到健康数据访问机构的健康数据访问申请或健康数据请求后的两个月内，将其根据第 4 款开展的评估以及附带的决策建议提交给该机构。健康数据访问机构应在收到评估后的两个月内，就健康数据访问申请或健康数据请求作出决定。健康数据访问机构不受可信健康数据持有方所提交建议的约束。

6. Following the health data access body’s decision to issue the data permit or to approve the health data request, the trusted health data holder shall carry out the tasks referred to in Article 57(1), points (a)(i) and (b).6. 在健康数据访问机构决定颁发数据许可或批准健康数据请求后，受信任的健康数据持有者应执行第 57 条第（1）款（a）项（i）目和（b）项所述的任务。

7. The Union health data access service referred to in Article 56 may designate health data holders that are Union institutions, bodies, offices or agencies which comply with the conditions laid down in paragraph 2, first subparagraph, points (a), (b) and (c), of this Article as trusted health data holders. Where it does so, paragraph 2,

third and fourth subparagraphs, and paragraphs 3 to 6 of this Article shall apply *mutatis mutandis*.7. 第 56 条所指的欧盟健康数据访问服务可指定符合本条第 2 款第一分段(a)、(b)和(c)项规定条件的欧盟机构、团体、办事处或代理机构作为健康数据持有人，将其认定为可信健康数据持有人。在这种情况下，本条第 2 款第三和第四分段以及第 3 至第 6 款应参照适用。

Article 73 第 73 条

Secure processing environment 安全处理环境

1. Health data access bodies shall provide access to electronic health data pursuant to a data permit only through a secure processing environment which is subject to technical and organisational measures and security and interoperability requirements. In particular, the secure processing environment shall comply with the following security measures:1. 健康数据访问机构仅可通过符合技术和组织措施以及安全与互操作性要求的安全处理环境，依据数据许可提供电子健康数据的访问权限。特别是，该安全处理环境应遵守以下安全措施：

(a) （a）the restriction of access to the secure processing environment to authorised natural persons listed in the data permit issued pursuant to Article 68;仅允许根据第 68 条颁发的数据许可中所列的获授权自然人进入安全处理环境。

(b) （乙）the minimisation of the risk of the unauthorised reading, copying, modification or removal of electronic health data hosted in the secure processing environment through state-of-the-art technical and organisational measures;通过最先进的技术和组织措施，将在安全处理环境中存储的电子健康数据被未经授权读取、复制、修改或删除的风险降至最低；

(c) 电子健康记录之外的the limitation of the input of electronic health data and the inspection, 其他电子健康数据，包modification or deletion of electronic health data hosted in the secure 括来自移动健康应用程processing environment to a limited number of authorised identifiable 序、可穿戴设备和远程individuals;电子健康数据输入的限制，以及由有限数量的经授权可识 患者监测设备的数据； 别个人对安全处理环境中托管的电子健康数据进行检查、修改或删除；

(d) （d）ensuring that health data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;通过唯一的个人用户身份和保密访问模式，确保健康数据使用者仅能访问其数据许可所涵盖的电子健康数据；

(e)the keeping of identifiable logs of access to and activities in the secure processing environment for the period necessary to verify and audit all processing operations in that environment; logs of access shall be kept for at least one year;在必要的时期内，保存对安全处理环境的访问和其中活动的可识别日志，以验证和审计该环境中的所有处理操作；访问日志应至少保存一年；

(f) （f）ensuring compliance and monitoring the security measures referred to in this paragraph to mitigate potential security threats.确保合规，并监控本段落中提及的安全措施，以缓解潜在的安全威胁。

2. Health data access bodies shall ensure that electronic health data from health data holders in the format specified in the data permit can be uploaded by those health data holders and can be accessed by the health data user in a secure processing environment.2. 健康数据访问机构应确保，健康数据持有者能够以上述数据许可中规定的格式上传其电子健康数据，且健康数据使用者能够在安全的处理环境中访问这些数据。

Health data access bodies shall review the electronic health data included in a download request to ensure that health data users are only able to download non-personal electronic health data, including electronic health data in an anonymised statistical format, from the secure processing environment.健康数据访问机构应当对下载请求中包含的电子健康数据进行审查，以确保健康数据使用者只能从安全处理环境中下载非个人电子健康数据，包括匿名统计格式的电子健康数据。

3. Health data access bodies shall ensure that audits of the secure processing environments are carried out on a regular basis, including by third parties, and shall take corrective action for any shortcomings, risks or vulnerabilities identified by those audits in the secure processing environments.3. 健康数据访问机构应确保定期对安全处理环境进行审计，包括由第三方进行审计，并应对安全处理环境中这些审计所发现的任何缺陷、风险或漏洞采取纠正措施。

4. Where recognised data altruism organisations under Chapter IV of Regulation (EU) 2022/868 process personal electronic health data using a secure processing environment, those environments shall also comply with the security measures set out in paragraph 1, points (a) to (f), of this Article.4. 根据《欧盟条例（EU）2022/868》第四章认定的数据利他主义组织在安全处理环境中处理个人电子健康数据时，这些环境还应遵守本条第 1 款（a）至（f）项规定的安全措施。

5. By 26 March 2027, the Commission shall, by means of implementing acts, lay down the technical, organisational, information security, confidentiality, data protection and interoperability requirements for the secure processing environments, including with regard to the technical characteristics and tools available to the health data user within the secure processing environments. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).5. 到 2027 年 3 月 26 日，委员会应通过实施法案，制定安全处理环境的技术、组织、信息安全、保密性、数据保护和互操作性要求，包括健康数据用户在安全处理环境中可使用的技术特征和工具方面的要求。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

Article 74 第 74 条 控制权限

Controllership 控制权

1. The health data holder shall be deemed controller for the making available of personal electronic health data requested pursuant to Article 60(1) to the health data access body.1. 根据第 60 条第 1 款的规定，健康数据持有方向健康数据访问机构提供所请求的个人电子健康数据时，该健康数据持有方应被视为控制者。

The health data access body shall be deemed controller for the processing of the personal electronic health data when fulfilling its tasks pursuant to this Regulation.健康数据访问机构在依照本条例履行其任务时，应被视为个人电子健康数据处理的控制者。

Notwithstanding the second subparagraph of this paragraph, the health data access body shall be deemed to act as a processor on behalf of the health data user acting as a controller for the processing of the personal electronic health data pursuant to a data permit issued under Article 68 in the secure processing environment when providing data through such environment or for the processing of such data pursuant to a health data request approved under Article 69 for a response to be generated.尽管有本款第二项的规定，健康数据访问机构在通过安全处理环境提供数据时，根据第 68 条颁发的数据许可对个人电子健康数据进行处理，或者为生成响应而根据第 69 条批准的健康数据请求对该类数据进行处理的，应被视为代表作为控制者的健康数据使用者充当处理者。

2. In situations referred to in Article 72(6), the trusted health data holder shall be deemed controller for its processing of personal electronic health data related to the provision of electronic health data to the health data user pursuant to a data permit or a health data request. The trusted health data holder shall be deemed to act as a processor on behalf of the health data user when providing data through a secure processing environment.2. 在第 72 条第 6 款所述情形中，可信健康数据持有人在根据数据许可或健康数据请求向健康数据使用者提供电子健康数据的过程中，对相关个人电子健康数据的处理应被视为控制者。当可信健康数据持有人通过安全处理环境提供数据时，应被视为代表健康数据使用者以处理者身份行事。

3. The Commission may, by means of implementing acts, establish a template for agreements between controllers and processors under paragraphs (1) and (2) of this Article. Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 98(2).3. 委员会可通过实施法案，为依据本条第（1）款和第（2）款签订的控制者与处理者之间的协议制定模板。此类实施法案应根据第 98 条第（2）款规定的审查程序通过。

SECTION 4 第 4 节

Cross-border infrastructure for secondary use 跨境二次使用基础设施

Article 75 第 75 条

HealthData@EU 欧盟健康数据平台

1. Each Member State shall designate one national contact point for secondary use. That national contact point for secondary use shall be an organisational and technical gateway, enabling and responsible for the making available of electronic health data for secondary use in a cross-border context. The national contact point for secondary use may be the coordinator health data access body referred to in Article 55(1). Each Member State shall inform the Commission of the name and contact details of the

national contact point for secondary use by 26 March 2027. The Commission and the Member States shall make that information publicly available.1. 每个成员国应指定一个二次使用国家联络点。该二次使用国家联络点应作为组织和技术网关，负责在跨境情况下提供电子健康数据以供二次使用，并为此提供支持。二次使用国家联络点可以是第 55 条第（1）款所述的健康数据访问协调机构。每个成员国应在 2027 年 3 月 26 日前将二次使用国家联络点的名称和联系方式告知委员会。委员会和成员国应将该信息公之于众。

2. The Union health data access service shall act as the contact point of the Union's institutions, bodies, offices and agencies for secondary use and shall be responsible for making electronic health data available for secondary use.2. 欧盟健康数据访问服务应作为欧盟各机构、团体、办公室和机构在二次使用方面的联络点，并负责提供可供二次使用的电子健康数据。

3. The national contact points for secondary use referred to in paragraph 1 and the Union health data access service referred to in paragraph 2 shall connect to the cross-border infrastructure for secondary use, namely HealthData@EU. The national contact points for secondary use and the Union health data access service shall facilitate the cross-border access to electronic health data for secondary use for different authorised participants in HealthData@EU. The national contact points for secondary use shall cooperate closely with each other and with the Commission.3. 第 1 款提及的二次使用国家联络点和第 2 款提及的欧盟健康数据访问服务应接入二次使用跨境基础设施，即 HealthData@EU。二次使用国家联络点和欧盟健康数据访问服务应为 HealthData@EU 中不同的授权参与者跨境访问用于二次使用的电子健康数据提供便利。二次使用国家联络点应彼此密切合作，并与欧盟委员会密切合作。

4. Health-related research infrastructures or similar infrastructures whose functioning is based on Union law and which provide support for the use of electronic health data for research, policymaking, statistical, patient safety or regulatory purposes may become authorised participants in HealthData@EU and connect to it.4. 与健康相关的研究基础设施或类似基础设施，其运作基于欧盟法律，并为将电子健康数据用于研究、政策制定、统计、患者安全或监管目的提供支持，可成为 HealthData@EU 的授权参与者并与之连接。

5. Third countries or international organisations may become authorised participants in HealthData@EU where they comply with the rules of this Chapter and provide access to health data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies, subject to compliance with Chapter V of Regulation (EU) 2016/679.5. 第三国或国际组织若遵守本章规定，并根据同等条款和条件，向位于欧盟的健康数据用户提供其健康数据访问机构可获取的电子健康数据，且符合《(欧盟)2016/679 号条例》第五章的规定，则可成为 HealthData@EU 的授权参与者。

The Commission may, by means of implementing acts, determine that a national contact point for secondary use of a third country or a system established at international level by an international organisation is compliant with the requirements

of HealthData@EU for the purposes of secondary use of health data, is compliant with this Chapter and provides access to health data users located in the Union to the electronic health data it has access to on terms and conditions equivalent to those of HealthData@EU. Compliance with those legal, organisational, technical and security requirements, including with the requirements for secure processing environments provided for in Article 73, shall be checked under the control of the Commission. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.委员会可以通过实施法案，认定第三国的二次使用国家联络点或国际组织在国际层面建立的系统符合 HealthData@EU 关于健康数据二次使用的要求、符合本章规定，并且能让位于欧盟的健康数据用户以与 HealthData@EU 同等的条款和条件访问其可获取的电子健康数据。在委员会的监督下，应对是否符合这些法律、组织、技术和安全要求（包括第 73 条规定的安全处理环境要求）进行核查。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。委员会应将依据本款通过的实施法案清单公之于众。

6. Each national contact point for secondary use and each authorised participant in HealthData@EU shall acquire the required technical capability to connect to and participate in HealthData@EU. They shall comply with the requirements and technical specifications needed to operate HealthData@EU and to allow them to connect to it.6. 每个二次使用国家联络点以及 HealthData@EU 的每个授权参与者都应具备连接并参与 HealthData@EU 所需的技术能力。他们应遵守运营 HealthData@EU 以及实现与该平台连接所需的要求和技术规范。

7. The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-border access to electronic health data for secondary use, connecting the national contact points for secondary use and authorised participants in HealthData@EU and the central platform referred to in paragraph 8.7. 成员国和委员会应建立 HealthData@EU，以支持和促进跨境获取电子健康数据用于二次使用，将二次使用的国家联络点、HealthData@EU 的授权参与者以及第 8 款所述的中央平台连接起来。

8. The Commission shall develop, deploy and operate a central platform for HealthData@EU by providing information technology services needed to support and facilitate the exchange of information between health data access bodies as part of HealthData@EU. The Commission shall only process electronic health data on behalf of the controllers as a processor.8. 委员会应通过提供支持和促进健康数据访问机构之间信息交换所需的信息技术服务，开发、部署和运营 HealthData@EU 中央平台，作为 HealthData@EU 的一部分。委员会仅作为处理者代表控制者处理电子健康数据。

9. Where requested by two or more national contact points for secondary use, the Commission may provide a secure processing environment which is compliant with the requirements of Article 73 for data from more than one Member State. Where two or more national contact points for secondary use or authorised participants in HealthData@EU put electronic health data in the secure processing environment

managed by the Commission, they shall be joint controllers and the Commission shall be processor for the purpose of processing data in that environment.9. 当两个或多个二次使用国家联络点提出请求时，欧盟委员会可提供一个符合第 73 条要求的安全处理环境，用于处理来自一个以上成员国的数据。当两个或多个二次使用国家联络点或“健康数据@欧盟”的授权参与者将电子健康数据放入由欧盟委员会管理的安全处理环境中时，他们应作为共同控制者，而欧盟委员会则应作为该环境中数据处理的处理者。

10. The national contact points for secondary use shall act as joint controllers of the processing operations carried out in HealthData@EU in which they are involved and the Commission shall act as processor on behalf of those national contact points for secondary use, without affecting the tasks of health data access bodies prior to and following those processing operations.10. 二次使用的国家联络点应作为其参与的 HealthData@EU 中所开展处理操作的联合控制者，而委员会应作为代表这些二次使用国家联络点的处理者，且不影响健康数据访问机构在这些处理操作前后的任务。

11. Member States and the Commission shall seek to ensure that HealthData@EU is interoperable with other relevant common European data spaces as referred to in Regulations (EU) 2022/868 and (EU) 2023/2854.11. 成员国和委员会应努力确保 HealthData@EU 与《欧盟条例》（EU）2022/868 和（EU）2023/2854 中提及的其他相关欧洲共同数据空间具备互操作性。

12. By 26 March 2027, the Commission shall, by means of implementing acts, set out:12. 到 2027 年 3 月 26 日，委员会应通过实施法案，制定以下内容：

(a) （a）requirements, technical specifications and the IT architecture of HealthData@EU, which shall ensure state-of-the-art data security, confidentiality, and protection of electronic health data in HealthData@EU;HealthData@EU 的要求、技术规范和 IT 架构，这些内容应确保 HealthData@EU 中电子健康数据达到最先进的数据安全性、保密性和保护性；

(b) （乙）conditions and compliance checks required to be able to join and remain connected to HealthData@EU and conditions for temporary disconnection or definitive exclusion from HealthData@EU, including specific provisions for cases of serious misconduct or repeated infringements;加入并保持与 HealthData@EU 的连接所需的条件和合规性检查，以及暂时断开连接或被永久排除出 HealthData@EU 的条件，包括针对严重不当行为或屡次违规情况的具体规定；

(c) 电子健康记录之外的其他电the minimum criteria that need to be met by the national 子健康数据，包括来自移动健contact points for secondary use and the authorised participants 康应用程序、可穿戴设备和远in HealthData@EU;国家二级使用联络点以及 HealthData@EU 程患者监测设备的数据； 授权参与者需要满足的最低标准；

(d) （d）the responsibilities of the controllers and processors participating in HealthData@EU;参与 HealthData@EU 的控制者和处理者的责任；

(e)the responsibilities of the controllers and processors for the secure processing environment managed by the Commission;委员会管理的安全处理环境中控制者和处理者的责任；

(f) （f）common specifications for the architecture of HealthData@EU and for its interoperability with other common European data spaces.HealthData@EU 架构的通用规范及其与其他欧洲通用数据空间的互操作性。

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 98(2).本款第一项所指的实施法案应根据第 98 条第（2）款所述的审查程序通过。

13. Where there is a positive outcome of the compliance check referred to in paragraph 5 of this Article, the Commission may, by means of implementing acts, take decisions to connect individual authorised participants to HealthData@EU. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).13. 若本条第 5 款所述的合规性检查结果为阳性，委员会可通过实施法案，决定将个别获授权参与者接入 HealthData@EU。此类实施法案应依照第 98 条第 2 款所述的审查程序通过。

Article 76 第 76 条

Access to cross-border registries or databases of electronic health data for secondary use 获取用于二次使用的跨境电子健康数据登记处或数据库的访问权限

1. In the case of cross-border registries and databases, the health data access body with which the health data holder for the specific registry or database is registered shall be competent to decide on health data access applications to provide access to electronic health data pursuant to a data permit. Where such registries or databases have joint controllers, the health data access body that decides on the health data access applications to be used to provide access to electronic health data shall be the health data access body of the Member State where one of the joint controllers is established.1. 在跨境登记处和数据库的情况下，特定登记处或数据库的健康数据持有者所注册的健康数据访问机构有权根据数据许可，就提供电子健康数据访问的健康数据访问申请作出决定。若此类登记处或数据库设有联合控制者，则负责就用于提供电子健康数据访问的健康数据访问申请作出决定的健康数据访问机构，应为其中一名联合控制者所在成员国的健康数据访问机构。

2. Where registries or databases from a number of Member States organise themselves into a single network of registries or databases at Union level, the associated registries or databases may designate a coordinator to ensure the provision of data from the registries' or databases' network for secondary use. The health data access body of the Member State in which the coordinator of the network is established shall be competent to decide on the health data access applications to be used to provide access to electronic health data for the network of registries or databases.2. 当多个成员国的登记处或数据库联合组成欧盟层面的单一登记处或数据库网络时，相关登记处或数据库可指定一名协调员，以确保从该登记处或数据库网络中提供用于二次使用的数据。网络协调员所在成员国的健康数据访问机构有权就健康数据访问申请作出决定，这些申请将用于为登记处或数据库网络提供电子健康数据的访问权限。

SECTION 5 第 5 节

Health data quality and utility for secondary use 用于二次使用的健康数据质量和效用

Article 77 第 77 条

Dataset description and dataset catalogue 数据集说明和数据集目录

1. Health data access bodies shall, through a publicly available and standardised machine-readable dataset catalogue, provide a description in the form of metadata of the available datasets and their characteristics. The description of each dataset shall include information concerning the source, scope, main characteristics, and nature of the electronic health data in the dataset and the conditions for making those data available.1. 健康数据访问机构应通过公开可用且标准化的机器可读数据集目录，以元数据的形式提供可用数据集及其特征的描述。每个数据集的描述应包括有关该数据集中电子健康数据的来源、范围、主要特征、性质以及提供这些数据的条件的信息。

2. The dataset descriptions in the national dataset catalogue shall be available in at least one official language of the Union. The dataset catalogue for Union institutions, bodies, offices and agencies provided by the Union health data access service shall be available in all official languages of the Union.2. 国家数据集目录中的数据集说明应至少以欧盟的一种官方语言提供。由欧盟健康数据访问服务提供的欧盟机构、团体、办事处和机构的数据集目录应以欧盟的所有官方语言提供。

3. The dataset catalogue shall be made available to single information points established or designated under Article 8 of Regulation (EU) 2022/868.3. 数据集目录应提供给根据《欧盟条例（EU）2022/868》第 8 条设立或指定的单一信息点。

4. By 26 March 2027, the Commission shall, by means of implementing acts, set out the minimum elements health data holders are to provide for datasets and the characteristics of those elements. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).4. 到 2027 年 3 月 26 日，委员会应通过实施法案，规定健康数据持有者应为数据集提供的最低要素以及这些要素的特征。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

Article 78 第 78 条

Data quality and utility label 数据质量和实用性标签

1. Datasets made available through health data access bodies may have a Union data quality and utility label applied by the health data holders.1. 通过健康数据访问机构提供的数据集，可能会带有健康数据持有者标注的欧盟数据质量和实用性标签。

2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label covering the elements set out in paragraph 3.2. 在欧盟或国家公共资金支持下收集和处理的包含电子健康数据的数据集，应带有涵盖第 3 款所列要素的数据质量和效用标签。

3. The data quality and utility label shall cover the following elements, where applicable:3. 数据质量和实用性标签应涵盖以下适用要素：

(a) （a）for data documentation: metadata, support documentation, the data dictionary, the format and standards used, the source of the data and, where applicable, the data model;用于数据文档：元数据、支持性文档、数据字典、所使用的格式和标准、数据来源，以及适用情况下的数据模型；

(b) （乙）for assessment of technical quality: the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;用于评估技术质量：数据的完整性、独特性、准确性、有效性、及时性和一致性；

(c) 电子健康记录之外的其他for data quality management processes: the level of maturity of 电子健康数据，包括来自移the data quality management processes, including review and 动健康应用程序、可穿戴设audit processes, and bias examination;用于数据质量管理流程：数备和远程患者监测设备的数据质量管理流程的成熟度水平，包括审查和审计流程以及偏差据； 检查；

(d) （d）for assessment of coverage: the period, population coverage and, where applicable, representativity of the population sampled, and the average timeframe in which a natural person appears in a dataset;用于覆盖范围评估：期限、人口覆盖范围，以及适用时所抽样人口的代表性，还有自然人出现在数据集中的平均时间范围；

(e)for information on access and provision: the time between the collection of the electronic health data and their addition to the dataset and the time needed to provide electronic health data following the issuing of a data permit or a health data request approval;关于获取和提供的信息：电子健康数据收集与添加到数据集之间的时间，以及在数据许可或健康数据请求获批后提供电子健康数据所需的时间；

(f) （f）for information on data modifications: merging and adding data to an existing dataset, including links with other datasets.有关数据修改的信息：合并数据并将数据添加到现有数据集中，包括与其他数据集的链接。

4. Where a health data access body has reason to believe that a data quality and utility label might be inaccurate, it shall assess whether the dataset covered by the label meets the quality requirements forming part of the elements of the data quality and utility label as referred to in paragraph 3 and, in the event the dataset does not meet the quality requirements, shall revoke the label.4. 当健康数据访问机构有理由相信数据质量和实用性标签可能不准确时，应当评估该标签所涵盖的数据集是否符合第 3 款所述构成数据质量和实用性标签要素一部分的质量要求；如果数据集不符合这些质量要求，则应当撤销该标签。

5. The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend this Regulation by modifying, adding or removing elements to be covered by the data quality and utility label provided for in paragraph 3 of this Article.5. 根据第 97 条，委员会有权通过授权法案修订本条例，对本条第 3 款规定的数据质量和效用标签所涵盖的要素进行修改、增加或删除。

6. By 26 March 2027, the Commission shall, by means of implementing acts, set out the visual characteristics and technical specifications of the data quality and utility

label, based on the elements referred to in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2) of this Regulation. Those implementing acts shall take into account the requirements in Article 10 of Regulation (EU) 2024/1689 and any adopted common specifications or harmonised standards supporting those requirements, where applicable.6. 到 2027 年 3 月 26 日，委员会应通过实施法案，根据本条第 3 款所述要素，规定数据质量和效用标签的视觉特征及技术规范。这些实施法案应依照本条例第 98 条第 2 款所述的审查程序通过。在适用情况下，这些实施法案应考虑到（欧盟）2024/1689 号条例第 10 条中的要求，以及支持这些要求的任何已通过的通用规范或协调标准。

Article 79 第 79 条

EU dataset catalogue 欧盟数据集目录

1. The Commission shall establish an EU dataset catalogue connecting the national dataset catalogues established by the health data access bodies in each Member State as well as the dataset catalogues of authorised participants in HealthData@EU.1. 委员会应建立一个欧盟数据集目录，连接每个成员国健康数据访问机构建立的国家数据集目录以及 HealthData@EU 中授权参与者的数据集目录。

2. The EU dataset catalogue, the national dataset catalogues and the dataset catalogues of authorised participants in HealthData@EU shall be made publicly available.2. 欧盟数据集目录、国家数据集目录以及 HealthData@EU 授权参与者的数据集目录应公开可用。

Article 80 第 80 条

Minimum specifications for datasets of high impact 高影响力数据集的最低规格

The Commission may, by means of implementing acts, determine the minimum specifications for datasets of high impact for secondary use, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).委员会可通过实施法案，在考虑到现有的欧盟基础设施、标准、指南和建议的情况下，确定具有高影响的二次使用数据集的最低规格。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

SECTION 6 第 6 节

Complaints 投诉

Article 81 第 81 条

Right to lodge a complaint with a health data access body 向健康数据访问机构投诉的权利

1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint in relation to the provisions laid down in this Chapter, individually or, where relevant, collectively, with a health data access body, provided that their rights or interests are negatively affected.1. 在不损害任何其他行政或司法救济的情况下，自然人及法人有权就本章规定的条款向健康数据访问机构提出申诉，前提是其权利或利益受到了不利影响，申诉可单独提出，也可在相关情况下集体提出。

2. The health data access body with which the complaint has been lodged shall inform the complainant of the progress made in dealing with the complaint and of the decision taken on the complaint.2. 收到投诉的健康数据访问机构应将处理投诉的进展情况以及就该投诉作出的决定告知投诉人。

3. Health data access bodies shall provide easily accessible tools for the submission of complaints.3. 健康数据访问机构应提供易于使用的投诉提交工具。

4. Where the complaint concerns the rights of natural persons pursuant to Article 71 of this Regulation, the complaint shall be transmitted to the competent supervisory authority under Regulation (EU) 2016/679. The relevant health data access body shall provide the necessary information at its disposal to that supervisory authority under Regulation (EU) 2016/679 in order to facilitate the assessment and investigation of the complaint.4. 当投诉涉及根据本条例第 71 条规定的自然人权利时，该投诉应转交至《欧盟条例（EU）2016/679》规定的主管监管机构。相关健康数据访问机构应向《欧盟条例（EU）2016/679》规定的该监管机构提供其掌握的必要信息，以促进对投诉的评估和调查。

CHAPTER V 第五章
ADDITIONAL ACTIONS 补充行动

Article 82 第 82 条
Capacity building 能力建设

The Commission shall support the sharing of best practices and expertise to build capacity within Member States to strengthen digital health systems for primary use and secondary use taking into account the specific circumstances of the different categories of stakeholders involved. To support that capacity building, the Commission shall in close cooperation and consultation with Member States establish indicators for self-assessment for primary use and secondary use.委员会应支持分享最佳实践和专业知识，以建设成员国的能力，加强用于主要用途和次要用途的数字健康系统，同时考虑到所涉及的不同类别利益相关者的具体情况。为支持这种能力建设，委员会应与成员国密切合作并协商，制定主要用途和次要用途的自我评估指标。

Article 83 第 83 条

Training programmes and information for health professionals 面向卫生专业人员的培训计划和信息

1. Member States shall develop and implement or provide access to training programmes and provide access to information for health professionals in order for them to understand and effectively carry out their role in the primary use of and in the accessing of electronic health data, including in relation to Articles 11, 13 and 16. The Commission shall support Member States in that regard.1. 成员国应制定和实施或提供获取培训计划的途径，并向卫生专业人员提供信息，以便他们理解并有效履行在电子健康数据的主要使用和获取方面的职责，包括与第 11 条、第 13 条和第 16 条相关的职责。欧盟委员会应在这方面为成员国提供支持。

2. The training programmes and information shall be accessible to and affordable for all health professionals, without prejudice to the organisation of healthcare systems at national level.2. 所有卫生专业人员都应能获得这些培训项目和信息，并且负担得起，同时不影响国家层面医疗体系的组织。

Article 84 第 84 条

Digital health literacy and digital health access 数字健康素养与数字健康获取途径

1. Member States shall promote and support digital health literacy and the development of relevant competences and skills for patients. The Commission shall support Member States in this regard. Awareness-raising campaigns or programmes shall aim, in particular, to inform patients and the public at large about primary use and secondary use in the framework of the EHDS, including the rights arising from it, as well as the advantages, risks and potential gains for science and society of primary use and secondary use.1. 成员国应促进和支持患者的数字健康素养以及相关能力和技能的发展。欧盟委员会应在这方面为成员国提供支持。提高认识的活动或计划应特别旨在向患者和广大公众宣传电子健康数据空间（EHDS）框架下的初级使用和次级使用，包括由此产生的权利，以及初级使用和次级使用对科学和社会的优势、风险和潜在收益。

2. The awareness-raising campaigns and programmes referred to in paragraph 1 shall be tailored to the needs of specific groups and shall be developed, reviewed and, where necessary, updated.2. 第 1 款所述的提高认识活动和计划应根据特定群体的需求量身定制，并应进行制定、审查，必要时还应更新。

3. Member States shall promote access to the infrastructure necessary for the effective management of natural persons' electronic health data, both for primary use and secondary use.3. 成员国应促进获取有效管理自然人电子健康数据所需的基础设施，无论是用于主要用途还是次要用途。

Article 85 第 85 条

Additional requirements for public procurement and Union funding 公共采购和欧盟资金的附加要求

1. Contracting authorities, including digital health authorities and health data access bodies and Union institutions, bodies, offices or agencies, shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 15, 23, 36, 73, 75 and 78 for public procurement procedures and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.1. 包括数字卫生主管部门、健康数据访问机构以及欧盟各机构、团体、办事处或 agencies 在内的签约机构，在进行公共采购程序、制定招标文件或征集建议书时，以及在确定本条例相关的欧盟资金条件（包括结构基金和凝聚基金的启用条件）时，均应参考第 15 条、第 23 条、第 36 条、第 73 条、第 75 条和第 78 条所述的适用技术规范、标准和概况。

2. The criteria for obtaining funding from the Union shall take into account the requirements developed in the framework of Chapters II, III and IV.2. 从欧盟获得资金的标准应考虑到在第二章、第三章和第四章框架内制定的要求。

Article 86 第 86 条

Storage of personal electronic health data for primary use 个人电子健康数据的主要用途存储

In accordance with the general principles of Union law, which include the fundamental rights enshrined in Articles 7 and 8 of the Charter of Fundamental Rights of the European Union, Member States shall ensure that a particularly high level of protection and security is in place when processing personal electronic health data for primary use, by means of appropriate technical and organisational measures. In this respect, this Regulation shall not preclude a requirement under national law, taking into account the national context, that, in cases where personal electronic health data are processed by healthcare providers for the provision of healthcare or by the national contact points for digital health connected to MyHealth@EU, the storage of personal electronic health data referred to in Article 14 of this Regulation for the purpose of primary use be located within the Union, in compliance with Union law and international commitments.根据欧盟法律的一般原则（其中包括《欧洲联盟基本权利宪章》第 7 条和第 8 条所载明的基本权利），成员国应通过适当的技术和组织措施，确保在为主要用途处理个人电子健康数据时，具备特别高的保护和安全水平。在这方面，本条例不排除国内法规定的要求，即考虑到本国国情，当医疗服务提供者为提供医疗服务而处理个人电子健康数据，或与 MyHealth@EU 相连的国家数字健康联络点处理个人电子健康数据时，为本条例第 14 条所述主要用途而存储的个人电子健康数据应位于欧盟境内，并遵守欧盟法律和国际承诺。

Article 87 第 87 条

Storage of personal electronic health data by health data access bodies and secure processing environments 健康数据访问机构对个人电子健康数据的存储以及安全处理环境

1. Health data access bodies, trusted health data holders and the Union health data access service shall store and process personal electronic health data in the Union when performing pseudonymisation, anonymisation and any other personal data processing operations referred to in Articles 67 to 72, through secure processing environments within the meaning of Article 73 and Article 75(9) or through HealthData@EU. That requirement shall apply to any entity performing those tasks on behalf of such bodies, holders or service.1. 健康数据访问机构、受信任的健康数据持有者以及欧盟健康数据访问服务在执行假名化、匿名化以及第 67 至 72 条所述的任何其他个人数据处理操作时，应通过第 73 条和第 75 条第 9 款所指的安全处理环境或通过 HealthData@EU 在欧盟境内存储和处理个人电子健康数据。这一要求适用于代表此类机构、持有者或服务执行这些任务的任何实体。

2. By way of exception from paragraph 1 of this Article, the data referred to in that paragraph may be stored and processed in a third country, or a territory or one or more specified sectors within that third country, where such country, territory or sector is covered by an adequacy decision adopted pursuant to Article 45 of Regulation (EU) 2016/679.2. 作为本条第 1 款的例外情况，该款所述数据可在第三国、第三国的某一地区或该第三国境内一个或多个特定部门进行存储和处理，前提是该国家、地区或部门被依据《欧盟条例（2016/679）》第 45 条通过的充分性决定所涵盖。

Article 88 第 88 条

Third-country transfer of non-personal electronic data 非个人电子数据的第三国转移

1. Non-personal electronic health data made available by health data access bodies to a health data user in a third country under a data permit issued pursuant to Article 68 of this Regulation or a health data request approved pursuant to Article 69 of this Regulation, to authorised participants in a third country or to an international organisation, and based on a natural person's electronic health data falling within one of the categories referred to in Article 51 of this Regulation, shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation (EU) 2022/868 where the transfer of such non-personal electronic data to third countries presents a risk of re-identification through means going beyond those reasonably likely to be used, in particular in view of the limited number of natural persons to whom those data relate, the fact that they are geographically scattered or the technological developments expected in the near future.1. 根据本条例第 68 条发放的数据许可或第 69 条批准的健康数据请求，由健康数据访问机构向第三国的健康数据用户、第三国的授权参与者或国际组织提供的非个人电子健康数据，若其基于属于本条例第 51 条所述类别之一的自然人电子健康数据，且向第三国传输此类非个人电子数据存在通过超出合理可能使用的手段进行重新识别的风险（特别是考虑到这些数据所涉及的自然人数量有限、这些人在地理上分散的事实或近期预期的技术发展），则应被视为符合《欧盟条例（EU）2022/868》第 5 条第（13）款含义的高度敏感数据。

2. The protective measures for the categories of data mentioned in paragraph 1 of this Article shall be detailed in a delegated act referred to in Article 5(13) of

Regulation (EU) 2022/868.2. 本条第 1 款所述各类数据的保护措施，应在《欧盟条例（EU）2022/868》第 5 条第 13 款提及的授权法案中作出详细规定。

Article 89 第 89 条

International governmental access to non-personal electronic health data 国际政府对非个人电子健康数据的访问

1. Digital health authorities, health data access bodies, authorised participants in the cross-border infrastructures provided for in Articles 23 and 75 and health data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent the transfer of non-personal electronic health data held in the Union to a third country or an international organisation, including for governmental access in a third country, where such transfer would create a conflict with Union law or the national law of the relevant Member State.1. 数字健康主管机构、健康数据访问机构、第 23 条和第 75 条规定的跨境基础设施中的授权参与者以及健康数据用户，应采取一切合理的技术、法律和组织措施，包括合同安排，以防止将欧盟境内持有的非个人电子健康数据转移到第三国或国际组织，包括为第三国政府获取数据而进行的转移，前提是此类转移会与欧盟法律或相关成员国的国内法产生冲突。

2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, health data access body or health data users to transfer or give access to non-personal electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union, or any such agreement between the requesting third country and a Member State.2. 第三国法院或法庭的任何判决，以及第三国行政机关要求数字健康主管部门、健康数据访问机构或健康数据使用者传输或允许访问在欧盟境内持有的本条例范围内的非个人电子健康数据的任何决定，只有在基于请求国与欧盟之间生效的国际协定（如司法协助条约），或请求国与某一成员国之间的此类协定时，方可以任何方式得到承认或执行。

3. In the absence of an international agreement as referred to in paragraph 2, where a digital health authority, a health data access body or a health data user is the addressee of a decision or judgment of a third-country court or tribunal or of a decision of a third-country administrative authority requiring them to transfer or to give access to non-personal data within the scope of this Regulation held in the Union, and compliance with such a decision or judgment would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, the transfer to, or accessing of such data by, that third-country court, tribunal or administrative authority shall only take place or be provided where:3. 在不存在第 2 款所指的国际协定的情况下，如果数字健康机构、健康数据访问机构或健康数据使用者收到第三国法院或法庭的裁决或判决，或第三国行政机关的决定，要求其转移或提供对在联盟境内持有的本条例范围内非个人数据的访问权限，且遵守该裁决、判决或决定可能导致收件人违反联盟法律或相关成员国国内法，那么仅在

以下情况下，方可向该第三国法院、法庭或行政机关转移此类数据或提供对其的访问权限：

(a) （a）the third-country legal system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected persons or infringements;第三国法律体系要求此类决定或判决需阐明理由并符合比例原则，且要求此类决定或判决具有特定性，例如通过与某些嫌疑人或侵权行为建立充分关联。

(b) （乙）the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and 收件人的合理异议须由有管辖权的第三国法院或法庭进行审查；并且

(c) 电子健康记录之外的其他电子健康数据，包括来自移动健康应用程序、可穿戴设备和远程患者监测设备的数据；the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered by the national law of the third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State.作出决定或判决、或对行政机关的决定进行审查的合格第三国法院或法庭，根据该第三国的国内法有权适当考虑依据欧盟法律或相关成员国国内法受到保护的数据提供者的相关合法权益。

4. If the conditions laid down in paragraph 2 or 3 are met, a digital health authority, a health data access body or a data altruism organisation shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.4. 若符合第 2 款或第 3 款规定的条件，数字健康机构、健康数据访问机构或数据利他主义组织应根据对请求的合理解读，提供满足请求所需的最低限度数据。

5. The digital health authorities, health data access bodies and health data users shall inform the health data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as compliance is necessary to preserve the effectiveness of the law enforcement activity.5. 数字卫生主管部门、健康数据访问机构和健康数据使用者在遵守第三国行政机关的数据访问请求之前，应将该请求的存在告知健康数据持有者，但该请求用于执法目的且为维护执法活动的有效性而必须遵守的情况除外。

Article 90 第 90 条

Additional conditions for transfer of personal electronic health data to a third country or an international organisation 向第三国或国际组织传输个人电子健康数据的附加条件

Transfer of personal electronic health data to a third country or an international organisation shall be granted in accordance with Chapter V of Regulation (EU) 2016/679. Member States may maintain or introduce further conditions on

international access to, and transfer of, personal electronic health data, including limitations, in accordance with Article 9(4) of Regulation (EU) 2016/679, in addition to the requirements laid down in Article 24(3) and Article 75(5) of this Regulation and in Chapter V of Regulation (EU) 2016/679.向第三国或国际组织传输个人电子健康数据，应依照《欧盟条例（EU）2016/679》第五章的规定进行。除本条例第 24 条第 3 款、第 75 条第 5 款以及《欧盟条例（EU）2016/679》第五章规定的要求外，成员国可根据《欧盟条例（EU）2016/679》第 9 条第 4 款，对个人电子健康数据的国际获取和传输设定额外条件，包括限制措施。

Article 91 第 91 条

Health data access applications and health data requests from third countries 来自第三国的健康数据访问申请和健康数据请求

1. Without prejudice to Articles 67, 68 and 69, health data access applications and health data requests submitted by a health data applicant established in a third country shall be considered eligible by health data access bodies and the Union health data access service if the third country concerned:1. 在不影响第 67 条、第 68 条和第 69 条规定的前提下，若相关第三国满足以下条件，由设立在该第三国的健康数据申请者提交的健康数据访问申请和健康数据请求，应被健康数据访问机构及欧盟健康数据访问服务视为符合资格：

(a) （a）is an authorised participant on the basis of having a national contact point for secondary use covered by an implementing act referred to in Article 75(5); or 是基于拥有第 75 条第 5 款所指实施法案涵盖的二次使用国家联络点而成为的授权参与者；或

(b) （乙）allows Union health data applicants access to electronic health data in that third country under conditions that are not more restrictive than those provided for in this Regulation, and therefore such access is covered by an implementing act referred to in paragraph 2 of this Article.允许欧盟健康数据申请者在不超过本条例规定条件的前提下，访问该第三国的电子健康数据，因此此类访问受本条第 2 款提及的实施法案的约束。

2. By means of implementing acts, the Commission may determine that a third country meets the requirement set out in paragraph 1, point (b), of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.2. 委员会可通过实施法案，认定某第三国符合本条第 1 款(b)项规定的要求。此类实施法案应依照第 98 条第(2)款所述的审查程序通过。委员会应将根据本款通过的实施法案清单公之于众。

3. The Commission shall monitor developments in third countries and international organisations that could affect the application of the implementing acts adopted pursuant to paragraph 2, and shall provide for a periodic review of the application of this Article.3. 委员会应监测第三国和国际组织中可能影响根据第 2 款通过的实施法案适用的动态，并应规定对本条适用情况的定期审查。

Where the Commission considers that a third country no longer meets the requirement laid down in paragraph 1, point (b), of this Article, it shall adopt an implementing act repealing the implementing act referred to in paragraph 2 of this Article relating to that third country that benefits from access. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).如果委员会认为某第三国不再符合本条第 1 款(b)项规定的要求，则应通过一项实施法案，废止与该受益于准入的第三国相关的本条第 2 款所指的实施法案。该实施法案应依照第 98 条第(2)款提及的审查程序通过。

CHAPTER VI 第六章

EUROPEAN GOVERNANCE AND COORDINATION 欧洲治理与协调

Article 92 第 92 条

European Health Data Space Board 欧洲健康数据空间委员会

1. A European Health Data Space Board (the 'EHDS Board') is hereby established to facilitate cooperation and the exchange of information among Member States and the Commission. The EHDS Board shall be composed of two representatives per Member State, namely one representative for primary use purposes and one for secondary use purposes, nominated by each Member State. Each Member State shall have one vote. Members of the EHDS Board shall undertake to act in the public interest and in an independent manner.1. 特此设立欧洲健康数据空间委员会（以下简称"EHDS 委员会"），以促进成员国与欧盟委员会之间的合作及信息交流。EHDS 委员会由每个成员国提名的两名代表组成，即一名负责主要使用目的的代表和一名负责次要使用目的的代表。每个成员国拥有一票表决权。EHDS 委员会成员承诺以公共利益为出发点，独立履行职责。

2. A representative of the Commission and one of the representatives of the Member States referred to in paragraph 1 shall co-chair the meetings of the EHDS Board.2. 委员会的一名代表和第 1 款所述的成员国代表之一应共同主持 EHDS 委员会的会议。

3. Market surveillance authorities referred to in Article 43, the EDPB and the European Data Protection Supervisor, the European Medicines Agency, the European Centre for Disease Prevention and Control and the European Union Agency for Cybersecurity (ENISA) shall be invited to attend the meetings, where relevant according to the EHDS Board.3. 根据电子健康数据空间委员会的相关规定，第 43 条所指的市场监督机构、欧洲数据保护委员会、欧洲数据保护监督员、欧洲药品管理局、欧洲疾病预防控制中心以及欧洲网络安全局（ENISA）应受邀参加会议。

4. The EHDS Board may invite national authorities, experts and observers as well as Union institutions, bodies, offices and agencies, in addition to those referred to in paragraph 3, and research infrastructures and other similar infrastructures to attend its meetings.4. 除第 3 款提及的机构外，电子健康数据空间委员会（EHDS Board）

还可邀请国家主管部门、专家、观察员，以及欧盟的机构、团体、办事处和代理机构，还有研究基础设施及其他类似基础设施的代表出席其会议。

5. The EHDS Board may cooperate with external experts where appropriate.5. 电子健康数据空间委员会可在适当情况下与外部专家合作。

6. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups for certain topics, in which digital health authorities or health data access bodies shall be represented. Those subgroups shall support the EHDS Board with specific expertise and may have joint meetings, as required.6. 根据与电子健康数据使用相关的职能，电子健康数据空间委员会（EHDS Board）可就特定议题设立分组开展工作，数字健康主管部门或健康数据访问机构应在这些分组中派代表参与。这些分组应凭借特定专业知识为电子健康数据空间委员会提供支持，并可根据需要召开联合会议。

7. The EHDS Board shall adopt its rules of procedure and a code of conduct, following a proposal from the Commission. Those rules of procedure shall provide for the composition, organisation, functioning and cooperation of the subgroups referred to in paragraph 6 of this Article and the cooperation of the EHDS Board with the stakeholder forum referred to in Article 93.7. 欧洲健康数据空间委员会应根据委员会的提案，通过其议事规则和行为准则。该议事规则应规定本条第 6 款所述 subgroups 的组成、组织、运作与合作，以及欧洲健康数据空间委员会与第 93 条所述利益相关者论坛的合作。

The EHDS Board shall adopt decisions by consensus as far as possible. If a consensus cannot be reached, the EHDS Board shall adopt decisions by a majority of two-thirds of the Member States.EHDS 委员会应尽可能以协商一致的方式通过决定。如果无法达成协商一致，EHDS 委员会应以三分之二成员国的多数票通过决定。

8. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board established by Article 29 of Regulation (EU) 2022/868, competent authorities designated in accordance with Article 37 of Regulation (EU) 2023/2854, supervisory bodies designated in accordance with Article 46b of Regulation (EU) No 910/2014, the EDPB established by Article 68 of Regulation (EU) 2016/679, cybersecurity bodies, including ENISA, and the European Open Science Cloud, with a view to reaching advanced solutions towards findable, accessible, interoperable and reusable (FAIR) data usage in research and innovation.8. 电子健康数据空间委员会应与其他相关机构、实体和专家开展合作，例如根据《欧盟条例（EU）2022/868》第 29 条设立的欧洲数据创新委员会、根据《欧盟条例（EU）2023/2854》第 37 条指定的主管当局、根据《欧盟条例（EU）第 910/2014 号》第 46b 条指定的监管机构、根据《欧盟条例（EU）2016/679》第 68 条设立的欧洲数据保护委员会、包括欧洲网络与信息安全局在内的网络安全机构以及欧洲开放科学云，以期在研究和创新领域实现可查找、可访问、互操作和可重用（FAIR）的数据使用方面达成先进解决方案。

9. The EHDS Board shall be assisted by a secretariat provided by the Commission.9. 电子健康数据空间委员会应得到欧盟委员会提供的秘书处的协助。

10. The EHDS Board shall publish its meeting dates and the minutes of its deliberations, and publish an activity report every two years.10. 电子健康数据空间委员会应公布其会议日期和审议纪要，并每两年发布一份活动报告。

11. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment and operation of the EHDS Board. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).11. 委员会应通过实施法案，为电子健康数据空间委员会的设立和运作采取必要措施。这些实施法案应根据第 98 条第（2）款所述的审查程序通过。

Article 93 第 93 条

Stakeholder forum 利益相关者论坛

1. A stakeholder forum is hereby established for the purpose of facilitating the exchange of information and promoting cooperation among stakeholders in relation to the implementation of this Regulation.1. 特此设立利益相关者论坛，旨在促进利益相关者之间就本条例的实施交流信息并加强合作。

2. The stakeholder forum shall have a balanced composition and be composed of relevant stakeholders, including representatives of patient organisations, health professionals, industry, consumer organisations, scientific researchers and academia, and shall represent their views. Where commercial interests are represented in the stakeholder forum, the representation of such interests shall be based on a balanced combination of large companies, small and medium-sized enterprises and start-ups. The tasks of the stakeholder forum shall encompass equally primary use and secondary use.2. 利益相关者论坛应具有均衡的组成，由相关利益相关者组成，包括患者组织、卫生专业人员、行业、消费者组织、科研人员和学术界的代表，并应代表他们的观点。如果利益相关者论坛中有商业利益的代表，此类利益的代表应基于大公司、中小企业和初创企业的均衡组合。利益相关者论坛的任务应同等涵盖初级使用和次级使用。

3. Members of the stakeholder forum shall be appointed by the Commission following a public call for interest and a transparent selection procedure. Members of the stakeholder forum shall make an annual declaration of interests which shall be made publicly available and updated, when relevant.3. 利益相关者论坛的成员应由委员会通过公开征集意向和透明的选拔程序任命。利益相关者论坛的成员应每年进行利益申报，申报内容应公开可查，并在相关情况下进行更新。

4. The stakeholder forum may establish standing or temporary subgroups, as appropriate, for the purpose of examining specific questions related to the objectives of this Regulation. The stakeholder forum shall adopt its rules of procedure.4. 利益相关者论坛可酌情设立常设或临时分组，以审查与本条例目标相关的具体问题。利益相关者论坛应通过其议事规则。

5. The stakeholder forum shall hold regular meetings, which shall be chaired by a Commission representative.5. 利益相关者论坛应定期举行会议，会议由委员会代表主持。

6. The stakeholder forum shall prepare an annual report of its activities. That report shall be made publicly available.6. 利益相关者论坛应编制其活动年度报告。该报告应公开可得。

Article 94 第 94 条

Tasks of the EHDS Board EHDS 委员会的任务

1. The EHDS Board shall have the following tasks relating to primary use in accordance with Chapters II and III:1. 根据第二章和第三章的规定，EHDS 委员会应承担与主要用途相关的以下任务：

(a) （a）assisting Member States in coordinating practices of digital health authorities;协助成员国协调数字卫生主管部门的做法；

(b) （乙）issuing written contributions and exchanging best practices on matters related to the coordination of the implementation at Member State level, taking into account the regional and local level, of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:就本条例及依据本条例通过的授权法案和实施法案在成员国层面的实施协调事宜（同时考虑区域和地方层面）发表书面意见并交流最佳实践，特别是在以下方面：

(i) （一）the provisions set out in Chapters II and III;第二章和第三章规定的条款；

(ii) （二）the development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons;开发便于安全访问的在线服务，包括为卫生专业人员和自然人提供安全的电子身份认证以访问电子健康数据；

(iii) （三） other aspects relating to primary use;与主要用途相关的其他方面；

(c) 电子健康记录之外的facilitating cooperation between digital health authorities through 其他电子健康数据，包括capacity building, establishing the framework for activity-reporting 来自移动健康应用程序、referred to in Article 20 and the exchange of information;通过能力建可穿戴设备和远程患者监设促进数字卫生主管部门之间的合作，建立第 20 条所述的活动报测设备的数据； 告框架和信息交流机制；

(d) （d）sharing among its members information concerning risks posed by EHR systems and serious incidents as well as the handling of such risks and incidents;在其成员之间共享有关电子健康记录系统带来的风险、严重事件以及此类风险和事件的处理的信息；

(e)facilitating the exchange of views on primary use with the stakeholder forum referred to in Article 93, as well as with regulators and policy-makers in the health sector.促进与第 93 条所述的利益相关者论坛以及卫生部门的监管机构和政策制定者就主要用途交换意见。

2. The EHDS Board shall have the following tasks related to secondary use in accordance with Chapter IV:2. 电子健康数据空间委员会应承担第四章规定的与二次使用相关的以下任务：

(a) （a）assisting Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapter IV, to ensure a consistent application of this Regulation;协助成员国协调健康数据访问机构在实施第四章规定时的做法，以确保本条例的统一适用；

(b) （乙）issuing written contributions and exchanging best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards: 就与成员国层面协调实施本条例以及依据本条例通过的授权法案和实施法案相关的事宜，发表书面意见并交流最佳实践，特别是在以下方面：

(i) （一）implementation of rules for access to electronic health data;电子健康数据访问规则的实施；

(ii) （二）technical specifications or existing standards regarding the requirements set out in Chapter IV;关于第四章规定的要求的技术规范或现有标准；

(iii) （三）incentives for promoting data quality and interoperability improvement;促进数据质量和互操作性提升的激励措施；

(iv) （四）policies concerning fees to be charged by the health data access bodies and health data holders;关于健康数据访问机构和健康数据持有者收取费用的政策；

(v) （五）measures to protect the personal data of health professionals involved in the treatment of natural persons;保护参与自然人治疗的卫生专业人员个人数据的措施；

(vi) (六) other aspects of secondary use; 二次使用的其他方面；

(c) 电子健康记录之外creating, in consultation and cooperation with relevant stakeholders, 的其他电子健康数据，including representatives of patients, health professionals and 包括来自移动健康应researchers, guidelines in order to help health data users to fulfil their 用程序、可穿戴设备和duties under Article 61(5), and in particular to determine whether their 远程患者监测设备的findings are clinically significant;与包括患者代表、卫生专业人员和研究数据； 人员在内的相关利益攸关方协商合作，制定指南，以帮助健康数据使用者履行其在第 61 条第 5 款下的义务，特别是确定其研究结果是否具有临床意义；

(d)facilitating cooperation between health data access bodies through capacity building, establishing the framework for activity-reporting referred to in Article 59(1), and the exchange of information;通过能力建设促进健康数据访问机构之间的合作，建立第 59 条第 1 款所述的活动报告框架，以及开展信息交流；

(e)sharing information concerning risks and incidents related to secondary use, as well as the handling of such risks and incidents;分享与二次使用相关的风险和事件的信息，以及对此类风险和事件的处理；

(f) （f）facilitating the exchange of views on secondary use with the stakeholder forum referred to in Article 93, as well as with health data holders, health data users, regulators and policy-makers in the health sector.促进与第 93 条所述的利益相关者论坛，以及卫生部门的健康数据持有者、健康数据使用者、监管机构和政策制定者就二次使用交换意见。

Article 95 第 95 条

Steering groups for MyHealth@EU and HealthData@EUMyHealth@EU 和 HealthData@EU 的指导小组

1. The MyHealth@EU steering group and the HealthData@EU steering group (the 'steering groups') are hereby established for the cross-border infrastructures provided for in Articles 23 and 75. Each steering group shall be composed of one representative per Member State appointed from the relevant national contact points.1. 特此为第 23 条和第 75 条规定的跨境基础设施设立"我的健康@欧盟"指导小组和"健康数据@欧盟"指导小组（以下简称"指导小组"）。每个指导小组应由每个成员国从相关国家联络点任命的一名代表组成。

2. The steering groups shall take operational decisions concerning the development and operation of MyHealth@EU and HealthData@EU.2. 指导小组应就 MyHealth@EU 和 HealthData@EU 的开发与运营做出运营决策。

3. The steering groups shall take decisions by consensus. Where a consensus cannot be reached, a decision shall be adopted by two-thirds of the members. For the adoption of the decisions, each Member State shall have one vote.3. 指导小组应通过共识作出决定。若无法达成共识，则应由三分之二的成员通过决定。在通过决定时，每个成员国拥有一票表决权。

4. The steering groups shall adopt rules of procedure, setting out their composition, organisation, functioning and cooperation.4. 指导小组应通过议事规则，明确其组成、组织、运作和合作事宜。

5. Other authorised participants may be invited to exchange information and views on relevant matters related to MyHealth@EU and HealthData@EU. Where those authorised participants are invited, they shall have an observer role.5. 可邀请其他授权参与者就与 MyHealth@EU 和 HealthData@EU 相关的事宜交流信息和观点。当这些授权参与者受到邀请时，他们应承担观察员角色。

6. Stakeholders and relevant third parties, including representatives of patients, health professionals, consumers and industry, may be invited to attend the meetings of the steering groups as observers.6. 利益相关者及相关第三方，包括患者、卫生专业人员、消费者和行业的代表，可受邀作为观察员参加指导小组的会议。

7. The steering groups shall elect chairs for their meetings.7. 指导小组应选举其会议的主席。

8. The steering groups shall be assisted by a secretariat provided by the Commission.8. 指导小组将由委员会提供的秘书处提供协助。

Article 96 第96 条

Roles and responsibilities of the Commission regarding the functioning of the EHDS 委员会在电子健康数据空间（EHDS）运行方面的角色和职责

1. In addition to its role in making available electronic health data held by Union institutions, bodies, offices or agencies, in accordance with Article 55, Article 56 and Article 75(2), and its tasks under Chapter III, in particular Article 40, the Commission shall develop, maintain, host and operate the infrastructures and central services required to support the functioning of the EHDS, for all relevant connected entities, by means of:1. 除了根据第 55 条、第 56 条和第 75 条第 2 款的规定提供欧盟机构、团体、办事处或代理机构持有的电子健康数据，以及履行第三章（特别是第 40 条）规定的任务外，委员会还应通过以下方式为所有相关关联实体开发、维护、托管和运营支持电子健康数据系统（EHDS）运行所需的基础设施和中央服务：

(a) （a）an interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Article 16(3) and (4);根据第 16 条第 3 款和第 4 款，为自然人及卫生专业人员建立的一种可互操作的跨境身份识别和认证机制；

(b)the central services and infrastructures for digital health of MyHealth@EU, in accordance with Article 23(1);根据第 23 条第 1 款，MyHealth@EU 数字健康的核心服务和基础设施；

(c) （c）compliance checks for connecting authorised participants to MyHealth@EU, in accordance with Article 23(9);根据第 23 条第 9 款，对授权参与者接入 MyHealth@EU 进行合规性检查；

(d)the supplementary cross-border digital health services and infrastructures referred to in Article 24(1);第 24 条第 1 款所指的补充性跨境数字健康服务及基础设施；

(e)as part of HealthData@EU, a service to submit health data access applications seeking access to electronic health data held by health data holders in more than one Member State or by other authorised participants in HealthData@EU and to automatically forward the health data access applications to the relevant contact points, in accordance with Article 67(3); 作为 HealthData@EU 的一部分，这是一项用于提交健康数据访问申请的服务，旨在根据第 67 条第 3 款，获取由一个以上成员国的健康数据持有者或 HealthData@EU 的其他授权参与者持有的电子健康数据，并自动将健康数据访问申请转发给相关联络点。

(f) （f）the central services and infrastructures of HealthData@EU, in accordance with Article 75(7) and (8);根据第 75 条第(7)和(8)款，HealthData@EU 的核心服务和基础设施；

(g) （g）a secure processing environment, in accordance with Article 75(9), in which health data access bodies can decide to make data available, in accordance with Article 68(8);一个符合第 75 条第 9 款规定的安全处理环境，健康数据访问机构可在该环境中依照第 68 条第 8 款的规定决定提供数据；

(h) (h) 在欧盟和国家层面开展合作，并就电子健康数compliance checks for connecting据的二次使用和管理技术及最佳实践向委员会提供authorised participants to建议； 通过第 75 条所述的 HealthData@EU，为跨境HealthData@EU, in accordance with

访问其他成员国托管的用于二次使用的电子健康数Article 75(5);根据第 75 条第 5 款，对授据提供便利，并彼此之间以及与委员会密切合作； 权参与者接入 HealthData@EU 进行合规性检查；

(i) （一）a federated EU dataset catalogue connecting the national dataset catalogues, in accordance with Article 79;一个根据第 79 条连接各国数据集目录的欧盟联合数据集目录；

(j) (j) 通过电子方式公开： 一份国家数据集目录，其中应根据a secretariat for the EHDS 第 77 条、第 78 条和第 80 条的规定，包含电子健康数据的来Board, in accordance with 源、性质详情以及提供电子健康数据的条件； 所有健康数据Article 92(9);根据第 92 条第 9 访问申请和健康数据请求，在初步接收后应立即公开，不得有款设立的欧洲健康数据空间不当延迟； 所有已签发的数据许可、已批准的健康数据请求委员会秘书处；
以及拒绝决定（包括其理由），应在签发、批准或拒绝后的
30 个工作日内公开；

(k)a secretariat for the steering groups, in accordance with Article 95(8).根据第 95 条第 8 款的规定，为各指导小组设立一个秘书处。

2. The services referred to in paragraph 1 of this Article shall meet sufficient quality standards in terms of availability, security, capacity, interoperability, maintenance, monitoring and development to ensure the EHDS functions effectively. The Commission shall provide those services in accordance with the operational decisions of the relevant steering groups established in Article 95.2. 本条第 1 款所述服务应在可用性、安全性、容量、互操作性、维护、监控和开发方面达到足够的质量标准，以确保电子健康数据空间（EHDS）有效运行。欧盟委员会应根据第 95 条设立的相关指导小组的运营决定提供这些服务。

3. The Commission shall prepare a report on the infrastructures and services supporting the EHDS that it provides in accordance with paragraph 1 every two years and make it publicly available.3. 委员会应每两年根据第 1 款的规定，就其提供的支持电子健康数据空间（EHDS）的基础设施和服务编写一份报告，并予以公开。

CHAPTER VII 第七章

DELEGATION OF POWERS AND COMMITTEE PROCEDURE 权力下放与委员会程序

Article 97 第 97 条

Exercise of the delegation 权力的行使

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.1. 根据本条规定的条件，授权委员会采取授权行为的权力。

2. The power to adopt delegated acts referred to in Article 14(2), Article 49(4) and Article 78(5) shall be conferred on the Commission for an indeterminate period of

time from 25 March 2025.2. 第 14 条第 2 款、第 49 条第 4 款和第 78 条第 5 款所述的通过授权法案的权力，应自 2025 年 3 月 25 日起无限期授予委员会。

3. The power to adopt delegated acts referred to in Article 14(2), Article 49(4) and Article 78(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.3. 欧洲议会或理事会可随时撤销第 14 条第（2）款、第 49 条第（4）款和第 78 条第（5）款所述的通过授权法案的权力。撤销决定应终止该决定所指明的权力委托。该决定应自其在《欧盟官方公报》上公布之日的次日起生效，或在决定中规定的更晚日期生效。该决定不影响任何已生效的授权法案的效力。

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.4. 在通过授权法案之前，委员会应咨询各成员国根据 2016 年 4 月 13 日《关于更好制定法律的机构间协议》规定的原则所指定的专家。

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.5. 委员会一旦通过一项授权法案，应立即将其同时通知欧洲议会和理事会。

6. A delegated act adopted pursuant to Article 14(2), Article 49(4) or Article 78(5) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.6. 根据第 14 条第 2 款、第 49 条第 4 款或第 78 条第 5 款通过的授权法案，只有在该法案通知欧洲议会和理事会后的三个月内，欧洲议会或理事会均未表示反对，或者在该期限届满前，欧洲议会和理事会均已通知委员会它们不会反对的情况下，方可生效。经欧洲议会或理事会提议，该期限可延长三个月。

Article 98 第 98 条

Committee procedure 委员会程序

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.1. 委员会将由一个委员会提供协助。该委员会应是《欧盟条例》（第 182/2011 号）所指的委员会。

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.2. 凡提及本款时，应适用《欧盟条例》第 182/2011 号第 5 条。

CHAPTER VIII 第八章
MISCELLANEOUS 杂项

Article 99 第九十九条
Penalties 处罚

Member States shall lay down the rules on penalties applicable to infringements of this Regulation, in particular for infringements which are not subject to administrative fines pursuant to Articles 63 and 64, and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by 26 March 2027, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.成员国应制定适用于违反本条例的处罚规则，特别是针对根据第 63 条和第 64 条不受行政罚款约束的违法行为，并应采取一切必要措施确保这些规则得到执行。所规定的处罚应有效、适当且具有威慑力。成员国应在 2027 年 3 月 26 日前将这些规则和措施通知委员会，并应毫不拖延地将影响这些规则和措施的任何后续修订通知委员会。

Member States shall take into account the following non-exhaustive and indicative criteria for the imposition of penalties for infringements of this Regulation, where appropriate:成员国在适当情况下，对违反本条例的行为处以处罚时，应考虑以下非详尽且具有指示性的标准：

(a) （a）the nature, gravity, scale and duration of the infringement;侵权行为的性质、严重性、规模和持续时间；

(b)any action taken by the infringer to mitigate or remedy the damage caused by the infringement;侵权人为减轻或补救侵权所造成损害而采取的任何行动；

(c) （c） any previous infringements by the infringer;侵权者以往的任何侵权行为；

(d)the financial benefits gained or losses avoided by the infringer due to the infringement, insofar as such benefits or losses can be reliably established;侵权人因侵权所获得的经济利益或避免的损失，只要这些利益或损失能够被可靠地确定；

(e)any other aggravating or mitigating factors applicable to the circumstances of the case;适用于案件具体情况的任何其他加重或减轻处罚的因素；

(f) （f）the infringer’s annual turnover in the Union in the preceding financial year.侵权者在上一财政年度在欧盟的年营业额。

Article 100 第 100 条
Right to receive compensation 获得赔偿权

Any natural or legal person that has suffered material or non-material damage as a result of an infringement of this Regulation shall have the right to receive compensation in accordance with Union and national law.任何因违反本条例而遭受物质或非物质损害的自然人或法人，均有权根据欧盟法律和国内法获得赔偿。

Article 101 第101 条

Representation of a natural person 自然人的代表权

Where a natural person considers that his or her rights under this Regulation have been infringed, he or she shall have the right to mandate a not-for-profit body, organisation or association, constituted in accordance with national law, having statutory public interest objectives and active in the field of the protection of personal data, to lodge a complaint on his or her behalf or to exercise the rights referred to in Articles 21 and 81.当自然人认为其根据本条例享有的权利受到侵犯时，有权委托依据国家法律成立、具有法定公共利益目标且在个人数据保护领域积极活动的非营利性机构、组织或协会，代表其提出申诉或行使第 21 条和第 81 条所指的权利。

Article 102 第102 条

Evaluation, review and progress report 评估、审查和进展报告

1. By 26 March 2033, the Commission shall carry out a targeted evaluation of this Regulation, and submit a report on its main findings to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. That evaluation shall cover the following:1. 到 2033 年 3 月 26 日，委员会应对本条例进行有针对性的评估，并向欧洲议会、理事会、欧洲经济和社会委员会以及地区委员会提交一份关于其主要调查结果的报告，必要时附上修订提案。该评估应涵盖以下内容：

(a) （a）the possibilities of further extending interoperability between EHR systems and electronic health data access services other than those established by the Member States;进一步扩大电子健康记录系统与成员国已建立的电子健康数据访问服务之外的其他电子健康数据访问服务之间互操作性的可能性；

(b)the need to update the data categories referred to in Article 51 and the purposes listed in Article 53(1);更新第 51 条所指的数据类别以及第 53 条第（1）款所列目的的必要性；

(c) （c）the implementation and use by natural persons of the mechanisms to opt out from secondary use referred to in Article 71, in particular on the impact of those mechanisms on public health, scientific research and fundamental rights;自然人对第 71 条所述的退出二次使用机制的实施和使用，特别是这些机制对公共卫生、科学研究和基本权利的影响；

(d)the use and implementation of any stricter measures introduced pursuant to Article 51(4);根据第 51 条第 4 款采取的任何更严格措施的使用和实施；

(e)the exercise and implementation of the right referred to in Article 8;第 8 条所指权利的行使与实施；

(f) （f）an assessment of the certification framework for EHR systems established in Chapter III and the need to introduce further tools regarding conformity assessment;对第三章确立的电子健康记录系统认证框架的评估，以及引入更多合格评定相关工具的必要性；

(g) （g）an assessment of the functioning of the internal market for EHR systems;对电子健康记

录系统内部市场运行情况的评估；

(h) (h) 在欧盟和国家层面开展合作，并就电子健康数an assessment of the costs and benefits 据的二次使用和管理技术及最佳实践向委员会提供of the implementation of the provisions 建议； 通过第 75 条所述的 HealthData@EU，为跨境for secondary use laid down in 访问其他成员国托管的用于二次使用的电子健康数Chapter IV;对第四章规定的二次使用条 据提供便利，并彼此之间以及与委员会密切合作； 款实施的成本和收益的评估；

(i) （一） the application of fees as referred to in Article 62.第 62 条所述费用的适用。

2. By 26 March 2035, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment or other appropriate measures. That evaluation shall include an assessment of the efficiency and functioning of the systems providing for access to electronic health data for further processing, carried out on the basis of Union or national law referred to in Article 1(7), with regard to their impact on the implementation of this Regulation.2. 到 2035 年 3 月 26 日，委员会应对本条例进行全面评估，并向欧洲议会、理事会、欧洲经济和社会委员会以及地区委员会提交一份关于其主要调查结果的报告，必要时附上修订提案或其他适当措施。该评估应包括对根据第 1 条第 7 款提及的欧盟或国家法律建立的、为进一步处理提供电子健康数据访问途径的系统的效率和运行情况的评估，同时考虑这些系统对本条例实施产生的影响。

3. Member States shall provide the Commission with the information necessary for the preparation of the reports referred to in paragraphs 1 and 2 and the Commission shall take that information duly into account in those reports.3. 成员国应向委员会提供编写第 1 款和第 2 款所述报告所需的信息，委员会在编写这些报告时应适当考虑该信息。

4. Every year following 25 March 2025 until the end of the year in which all provisions of this Regulation apply as provided for in Article 105, the Commission shall submit a progress report to the Council on the preparations for the full implementation of this Regulation. That progress report shall contain information about the degree of progress and the readiness of the Member States in relation to the implementation of this Regulation, including an assessment of the feasibility of reaching the timeframes laid down in Article 105, and may also contain recommendations for Member States to improve preparedness for the application of this Regulation.4. 自 2025 年 3 月 25 日之后的每年，直至第 105 条规定的本条例所有条款适用的年度结束为止，委员会应向理事会提交一份关于本条例全面实施准备工作的进展报告。该进展报告应包含与本条例实施相关的进展程度和成员国准备情况的信息，包括对实现第 105 条规定的时间框架的可行性评估，还可包含关于成员国如何改进本条例适用准备工作的建议。

Article 103 第 103 条

Amendment to Directive 2011/24/EU 对第 2011/24/EU 号指令的修订

Article 14 of Directive 2011/24/EU is deleted with effect from 26 March 2031.《2011/24/EU 号指令》第 14 条自 2031 年 3 月 26 日起废止。

Article 104 第 104 条

Amendment to Regulation (EU) 2024/2847 对《(欧盟)2024/2847 号条例》的修订

Regulation (EU) 2024/2847 is amended as follows:对《(欧盟)第 2024/2847 号条例》的修订如下：

(1)in Article 13, paragraph 4 is replaced by the following:第 13 条第 4 款替换为以下内容：

'4. When placing a product with digital elements on the market, the manufacturer shall include the cybersecurity risk assessment referred to in paragraph 3 of this Article in the technical documentation required pursuant to Article 31 and Annex VII. For products with digital elements as referred to in Article 12 and Article 32(5a), which are also subject to other Union legal acts, the cybersecurity risk assessment may be part of the risk assessment required by those Union legal acts. Where certain essential cybersecurity requirements are not applicable to the product with digital elements, the manufacturer shall include a clear justification to that effect in that technical documentation.'"4. 制造商在将带有数字元素的产品投放市场时，应将本条第 3 款所述的网络安全风险评估纳入根据第 31 条和附件七要求编制的技术文件中。对于第 12 条和第 32 条第（5a）款所述的带有数字元素的产品，若其同时受其他欧盟法律行为约束，则网络安全风险评估可作为这些欧盟法律行为所要求的风险评估的一部分。如果某些基本网络安全要求不适用于该带有数字元素的产品，制造商应在技术文件中对此提供明确的理由说明。"

;

(2)in Article 31, paragraph 3 is replaced by the following:第 31 条第 3 款替换为以下内容：

'3. For products with digital elements as referred to in Article 12 and Article 32(5a), which are also subject to other Union legal acts which provide for technical documentation, a single set of technical documentation shall be drawn up containing the information referred to in Annex VII and the information required by those Union legal acts.'"3. 对于第 12 条和第 32 条第(5a)款所述的包含数字元素的产品，若其同时受其他规定了技术文件要求的欧盟法律行为约束，则应编制一套单一的技术文件，其中包含附件七所述的信息以及这些欧盟法律行为所要求的信息。"

;

(3)in Article 32, the following paragraph is inserted:在第 32 条中，插入以下段落：

'5a. Manufacturers of products with digital elements that are classified as EHR systems under Regulation (EU) 2025/327 of the European Parliament and of the Council (*1) shall demonstrate conformity with the essential requirements set out in Annex I to this Regulation using the relevant conformity assessment procedure provided for in Chapter III of Regulation (EU) 2025/327."5a. 根据欧洲议会和理事会第(EU)2025/327 号条例(*1)被归类为电子健康记录系统且包含数字元素的产品制造商，应使用第(EU)2025/327 号条例第三章规定的相关合格评定程序，证明其符合本条例附件一规定的基本要求。

(*1) Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (OJ L, 2025/327, 5.3.2025,

ELI: http://data.europa.eu/eli/reg/2025/327/oj)."（*1）欧洲议会和理事会 2025 年 2 月 11 日关于欧洲健康数据空间并修订第 2011/24/EU 号指令及第 2024/2847 号条例（EU）的第 2025/327 号条例（EU）（《欧盟官方公报》，2025/327，2025 年 3 月 5 日，欧洲法律标识：http://data.europa.eu/eli/reg/2025/327/oj）。'。

CHAPTER IX 第九章

DEFERRED APPLICATION, TRANSITIONAL AND FINAL PROVISIONS 延迟适用、过渡性及最终条款

Article 105 第 105 条

Entry into force and application 生效与适用

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.本条例应在《欧盟官方公报》上公布后的第二十天生效。

This Regulation shall apply from 26 March 2027.本条例自 2027 年 3 月 26 日起适用。

However, Articles 3 to 15, Article 23(2) to (6), Articles 25, 26, 27, 47, 48 and 49 shall apply as follows:然而，第 3 条至第 15 条、第 23 条第（2）款至第（6）款、第 25 条、第 26 条、第 27 条、第 47 条、第 48 条和第 49 条应按如下规定适用：

(a) （a）from 26 March 2029 to priority categories of personal electronic health data referred to in Article 14(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data;自 2029 年 3 月 26 日起，适用于第 14 条第（1）款（a）、（b）和（c）项所指的个人电子健康数据优先类别，以及制造商意图用于处理此类数据类别的电子健康记录系统；

(b)from 26 March 2031 to priority categories of personal electronic health data referred to in Article 14(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;自 2031 年 3 月 26 日起，适用于第 14 条第（1）款（d）、（e）和（f）项所指的个人电子健康数据的优先类别，以及制造商意图用于处理此类数据类别的电子健康记录系统；

(c) （c）from one year from the date established in a delegated act to be adopted pursuant to Article 14(2) for each amendment of the main characteristics of personal electronic health data set out in Annex I, provided that that date is subsequent to the date of application referred to in points (a) and (b) of this subparagraph for the categories of personal electronic health data concerned.自根据第 14 条第 2 款通过的授权法案中确定的日期起一年后，该授权法案针对附件 I 所列个人电子健康数据主要特征的每一项修订，前提是该日期晚于本项（a）目和（b）目所述相关类别的个人电子健康数据的适用日期。

Chapter III shall apply to EHR systems put into service in the Union referred to in Article 26(2) from 26 March 2031.第三章应适用于根据第 26 条第 2 款提及的、自 2031 年 3 月 26 日起在欧盟投入使用的电子健康记录系统。

Chapter IV shall apply from 26 March 2029. However, Article 55(6), Article 70, Article 73(5), Article 75(1) and (12), Article 77(4) and Article 78(6) shall apply from

26 March 2027; Article 51(1), points (b), (f), (g), (m) and (p), shall apply from 26 March 2031; and Article 75(5) shall apply from 26 March 2035.第四章自 2029 年 3 月 26 日起适用。但第五十五条第六款、第七十条、第七十三条第五款、第七十五条第一款及第十二款、第七十七条第四款和第七十八条第六款自 2027 年 3 月 26 日起适用；第五十一条第一款第（b）、（f）、（g）、（m）和（p）项自 2031 年 3 月 26 日起适用；第七十五条第五款自 2035 年 3 月 26 日起适用。

The implementing acts referred to in Article 13(4), Article 15(1), Article 23(4) and Article 36(1) shall apply from the dates referred to in the third paragraph of this Article depending on the categories of personal electronic health data referred to in Article 14(1), points (a), (b) and (c), or Article 14(1), points (d), (e) and (f), respectively.第 13 条第 4 款、第 15 条第 1 款、第 23 条第 4 款和第 36 条第 1 款所指的实施法案，应分别根据第 14 条第 1 款（a）、（b）、（c）项或第 14 条第 1 款（d）、（e）、（f）项所指的个人电子健康数据类别，自本条第三款所指的日期起适用。

The implementing acts referred to in Article 70, Article 73(5), Article 75(12), Article 77(4) and Article 78(6) shall apply from 26 March 2029.第 70 条、第 73 条第 5 款、第 75 条第 12 款、第 77 条第 4 款和第 78 条第 6 款所指的实施法案应自 2029 年 3 月 26 日起适用。

This Regulation shall be binding in its entirety and directly applicable in all Member States.本条例全文具有约束力，并直接适用于所有成员国。

Done at Strasbourg, 11 February 2025.2025 年 2 月 11 日于斯特拉斯堡完成。

For the European Parliament 为欧洲议会

The President 总统

R. METSOLA R.

梅索拉

For the Council 致理事会

The President 总统

A. SZŁAPKA A.

停止

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(1) OJ C 486, 21.12.2022, p. 123.(1) 《欧盟公报》（C 系列）第 486 期，2022 年 12 月 21 日，第 123 页。

(2) OJ C 157, 3.5.2023, p. 64.(2) 《欧盟官方公报》C 系列 157 期，2023 年 5 月 3 日，第 64 页。

([3]) Position of the European Parliament of 24 April 2024 (not yet published in the Official Journal) and decision of the Council of 21 January 2025.（3） 欧洲议会 2024 年 4 月 24 日的立场（尚未在《官方公报》上公布）和理事会 2025 年 1 月 21 日的决定。

([4]) Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).（4） 欧盟委员会 2019 年 7 月 26 日第 2019/1269 号实施决定，修订了规定欧洲参考网络及其成员的建立和评估标准以及为建立和评估此类网络而促进信息和专业知识交流的第 2014/287/EU 号实施决定（《欧盟官方公报》L 200，2019 年 7 月 29 日，第 35 页）。

([5]) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).（5） 欧洲议会和理事会 2016 年 4 月 27 日关于个人数据处理和此类数据自由流动中对自然人保护的第（EU）2016/679 号条例，该条例废止了第 95/46/EC 号指令（《通用数据保护条例》）（《欧盟公报》L 119，2016 年 5 月 4 日，第 1 页）。

([6]) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).（6） 欧洲议会和理事会 2018 年 10 月 23 日关于欧盟机构、团体、办事处和机构处理个人数据时保护自然人以及此类数据自由流动，并废止（EC）第 45/2001 号条例和第 1247/2002/EC 号决定的（EU）2018/1725 号条例（《官方公报》L 295，2018 年 11 月 21 日，第 39 页）。

([7]) Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).（7）欧洲议会和理事会 2014 年 7 月 23 日关于内部市场电子交易中的电子身份识别和信任服务并废止第 1999/93/EC 号指令的（欧盟）第 910/2014 号条例（《官方公报》L 257 号，2014 年 8 月 28 日，第 73 页）。

([8]) Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022 establishing the Digital Decade Policy Programme 2030 (OJ L 323, 19.12.2022, p. 4).（8） 欧洲议会和理事会 2022 年 12 月 14 日关于设立 2030 年数字十年政策计划的（欧盟）2022/2481 号决定（《欧盟公报》L 323，2022 年 12 月 19 日，第 4 页）。

([9]) Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (OJ L 39, 11.2.2019, p. 18).（9）欧盟委员会 2019 年 2 月 6 日关于欧洲电子健康记录交换格式的建议（EU）2019/243（《官方公报》L 39，2019 年 2 月 11 日，第 18 页）。

([10]) Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).（10） 欧洲议会和理事会 2024 年 6 月 13 日关于人工智能统一规则并修订第（EC）300/2008 号、第（EU）167/2013 号、第（EU）168/2013 号、第（EU）2018/858 号、第（EU）2018/1139 号、第（EU）2019/2144 号条例以及第 2014/90/EU 号、第（EU）2016/797 号、第（EU）2020/1828 号指令的第（EU）2024/1689 号条例（《人工智能法案》）（《欧盟官方公报》，2024/1689，2024 年 7 月 12 日，ELI：http://data.europa.eu/eli/reg/2024/1689/oj）。

([11]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).（11） 欧洲议会和理事会 2017 年 4 月 5 日关于医疗器械的（欧盟）2017/745 号条例，该条例修订了 2001/83/EC 号指令、（欧共体）第 178/2002 号条例和（欧共体）第 1223/2009 号条例，并废止了理事会 90/385/EEC 号和 93/42/EEC 号指令（《欧盟公报》L 117，2017 年 5 月 5 日，第 1 页）。

([12]) Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (OJ L 152, 3.6.2022, p. 1).（12） 欧洲议会和理事会 2022 年 5 月 30 日关于欧洲数据治理并修订（欧盟）2018/1724 号条例的（欧盟）2022/868 号条例（《数据治理法案》）（《官方公报》L 152，2022 年 6 月 3 日，第 1 页）。

([13]) Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act) (OJ L, 2023/2854, 22.12.2023, ELI: http://data.europa.eu/eli/reg/2023/2854/oj).（13） 欧洲议会和理事会 2023 年 12 月 13 日关于数据公平获取和使用的统一规则并修订（欧盟）2017/2394 号条例和（欧盟）2020/1828 号指令的（欧盟）2023/2854 号条例(《数据法》)(《欧盟官方公报》,2023/2854 号,2023 年 12 月 22 日,欧洲法律信息:http://data.europa.eu/eli/reg/2023/2854/oj)。

([14]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).（14） 欧洲议会和理事会 2011 年 3 月 9 日关于在跨境医疗中适用患者权利的第 2011/24/EU 号指令（《官方公报》L 88 号，2011 年 4 月 4 日，第 45 页）。

([15]) Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).（15）欧洲议会和理事会 2024 年 10 月 23 日关于带数字元素产品的横向网络安全要求并修订（欧盟）第 168/2013 号条例、（欧盟）2019/1020 号条例及（欧盟）2020/1828 号指令的（欧盟）2024/2847 号条例（《网络韧性法案》）（《欧盟公报》，2024/2847 号，2024 年 11 月 20 日，欧洲法律信息：http://data.europa.eu/eli/reg/2024/2847/oj）。

([16]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).（16） 欧洲议会和理事会 2017 年 4 月 5 日关于体外诊断医疗器械并废止第 98/79/EC 号指令和委员会第 2010/227/EU 号决定的（EU）2017/746 号法规（《欧盟官方公报》L 117，2017 年 5 月 5 日，第 176 页）。

([17]) Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).（17） 欧洲议会和理事会 2019 年 6 月 20 日关于产品市场监督与合规并修订第 2004/42/EC 号指令及第 765/2008 号（EC）和第 305/2011 号（EU）条例的第 2019/1020 号（EU）条例（《官方公报》L 169，2019 年 6 月 25 日，第 1 页）。

([18]) Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).（18）</b0 欧盟委员会 2003 年 5 月 6 日关于微型、小型和中型企业定义的第 2003/361/EC 号建议（《欧盟官方公报》L124 号，2003 年 5 月 20 日，第 36 页）。

([19]) Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 8.8.2009, p. 1).（19） 2009 年 6 月 25 日关于欧洲研究基础设施联盟（ERIC）共同体法律框架的理事会条例（EC）第 723/2009 号（《欧盟公报》L 206，2009 年 8 月 8 日，第 1 页）。

([20]) Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).（20） 欧洲议会和理事会 2018 年 10 月 2 日《建立单一数字门户以提供信息、程序及协助与问题解决服务并修订第 1024/2012 号（欧盟）条例的第 18/1724 号（欧盟）条例》（《欧盟官方公报》L 295，2018 年 11 月 21 日，第 1 页）。

([21]) Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).（21） 欧洲议会和理事会 2019 年 4 月 17 日关于欧洲网络安全局（ENISA）以及信息和通信技术网络安全认证的第（EU）2019/881 号条例，并废止第（EU）526/2013 号条例（《网络安全法》）（《欧盟官方公报》L 151，2019 年 6 月 7 日，第 15 页）。

(22) OJ L 123, 12.5.2016, p. 1.(22) 《欧盟官方公报》L 123 号，2016 年 5 月 12 日，第 1 页。

(23) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).（23） 欧洲议会和理事会 2011 年 2 月 16 日第 182/2011 号条例（EU），该条例规定了成员国对委员会行使执行权进行控制的机制的规则和一般原则（《欧盟公报》L 55 号，2011 年 2 月 28 日，第 13 页）。

(24) Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).（24） 欧洲议会和理事会 2009 年 3 月 11 日关于欧洲统计的第 223/2009 号条例（EC），该条例废止了欧洲议会和理事会关于向欧洲共同体统计局传输受统计保密约束的数据的第 1101/2008 号条例（EC、Euratom）、关于共同体统计的理事会第 322/97 号条例（EC）以及设立欧洲共同体统计方案委员会的理事会第 89/382/EEC 号决定（Euratom）（《官方公报》L 87，2009 年 3 月 31 日，第 164 页）。

(25) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).（25） 欧洲议会和理事会 2014 年 4 月 16 日关于人用药品临床试验并废止第 2001/20/EC 号指令的（EU）第 536/2014 号条例（《官方公报》L 158 号，2014 年 5 月 27 日，第 1 页）。

(26) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).（26）欧洲议会和理事会 2002 年 7 月 12 日关于电子通信领域个人数据处理和隐私保护的第 2002/58/EC 号指令（隐私和电子通信指令）（《欧盟官方公报》L 201 号，2002 年 7 月 31 日，第 37 页）。

(27) Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).（27） 欧洲议会和理事会 2016 年 6 月 8 日关于保护未披露的专有技术和商业信息（商业秘密）免受非法获取、使用和披露的第（EU）2016/943 号指令（《欧盟官方公报》L 157 号，2016 年 6 月 15 日，第 1 页）。

(28) Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).（28） 欧洲议会和理事会 2014 年 2 月 26 日关于公共采购的第 2014/24/EU 号指令，该指令废止了第 2004/18/EC 号指令（《官方公报》L 94，2014 年 3 月 28 日，第 65 页）。

(29) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work (OJ L 354, 31.12.2008, p. 70).（29）欧洲议会和理事会 2008 年 12 月 16 日关于共同体公共卫生及工作健康与安全统计的（EC）第 1338/2008 号条例（《官方公报》L 354，2008 年 12 月 31 日，第 70 页）。

(30) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).（30） 欧洲议会和理事会 2008 年 7 月 9 日第 765/2008 号条例（EC）规定了认证要求，并废止第 339/93 号条例（EEC）（OJ L 218，2008 年 8 月 13 日，第 30 页）。

(31) Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70).（31）欧洲议会和理事会 2019 年 4 月 17 日关于产品和服务无障碍要求的第（EU）2019/882 号指令（《欧盟官方公报》L 151，2019 年 6 月 7 日，第 70 页）。

(32) Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive) (OJ L 333, 27.12.2022, p. 80).（32） 欧洲议会和理事会 2022 年 12 月

14 日关于在欧盟范围内实现高水平共同网络安全的措施的第（EU）2022/2555 号指令，该指令修订了第（EU）910/2014 号条例和第（EU）2018/1972 号指令，并废止了第（EU）2016/1148 号指令（《网络与信息系统安全 2 号指令》）（《欧盟官方公报》L 333 号，2022 年 12 月 27 日，第 80 页）。

(33) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).（33） 欧洲议会和理事会 2015 年 9 月 9 日关于制定技术法规领域及信息社会服务规则信息提供程序的第（EU）2015/1535 号指令（《官方公报》L 241 号，2015 年 9 月 17 日，第 1 页）。

(34) Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union (OJ L 303, 28.11.2018, p. 59).（34） 欧洲议会和理事会 2018 年 11 月 14 日关于欧盟非个人数据自由流动框架的（欧盟）2018/1807 号条例（《欧盟官方公报》L 303，2018 年 11 月 28 日，第 59 页）。

(35) Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).（35） 欧洲议会和理事会 2024 年 6 月 13 日关于用于人体的人体来源物质质量和安全标准并废除第 2002/98/EC 号和第 2004/23/EC 号指令的（欧盟）2024/1938 号法规（《欧盟官方公报》，2024/1938，2024 年 7 月 17 日，ELI：http://data.europa.eu/eli/reg/2024/1938/oj）。

(36) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).（36） 欧洲议会和理事会 2001 年 11 月 6 日关于人用药品共同体法规的第 2001/83/EC 号指令（《官方公报》L 311，2001 年 11 月 28 日，第 67 页）。

(37) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).（37）欧洲议会和理事会 2004 年 3 月 31 日关于制定欧盟人用药品授权和监督程序并设立欧洲药品管理局的第 726/2004 号条例（EC）（《欧盟官方公报》L 136 号，2004 年 4 月 30 日，第 1 页）。

ANNEX I 附录一

Main characteristics of priority categories of personal electronic health data for primary use 主要用途的个人电子健康数据优先类别的主要特征

Electronic health data category 电子健康数据类别	Main characteristics of electronic health data included under the category 归入此类别的电子健康数据的主要特征
1. Patient summaries 患者摘要	Electronic health data that include significant clinical facts related to an identified natural person and that are essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary:包含与已识别自然人相关的重要临床事实，且对向该人提供安全高效的医疗服务至关重要的电子健康数据。以下信息属于患者摘要的一部分： 1. Personal details. 个人详细信息。 2. Contact information. 联系信息。 3. Information on insurance. 保险相关信息。

	4. Allergies. 过敏症。 5. Medical alerts. 医疗警报。 6.Vaccination/prophylaxis information, possibly in the form of a vaccination card.疫苗接种/预防信息，可能以疫苗接种卡的形式呈现。 7.Current, resolved, closed or inactive problems, including in an international classification coding.当前、已解决、已结束或未活跃的问题，包括国际分类编码中的问题。 8.Textual information related to medical history.与病史相关的文本信息。 9. Medical devices and implants. 医疗器械和植入物。 10. Medical or care procedures. 医疗或护理程序。 11. Functional status. 功能状态。 12.Current and relevant past medicines.当前及相关的既往药物。 13.Social history observations related to health.与健康相关的社会史观察结果。 14. Pregnancy history. 妊娠史。 15. Patient-provided data. 患者提供的数据。 16.Observation results pertaining to the health condition.与健康状况相关的观察结果。 17. Plan of care. 护理计划。 18.Information on a rare disease, such as details about the impact or characteristics of the disease.罕见疾病的相关信息，例如关于该疾病的影响或特征的详细说明。
2.Electronic prescriptions 电子处方	Electronic health data constituting a prescription for a medicinal product as defined in Article 3, point (k), of Directive 2011/24/EU.构成《2011/24/EU 号指令》第 3 条（k）点所定义的药品处方的电子健康数据。
3.Electronic dispensations 电子配药	Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.关于药店根据电子处方向自然人提供药品的信息。
4.Medical imaging studies and related imaging reports 医学影像研究及相关影像报告	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor or treat medical conditions.与用于观察人体以预防、诊断、监测或治疗疾病的技术的使用相关或由这些技术产生的电子健康数据。
5.Medical test results, including	Electronic health data representing results of studies performed in

laboratory and other diagnostic results and related reports 医疗检测结果，包括实验室检测及其他诊断结果和相关报告	particular through *in vitro* diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology and others, and including, where relevant, reports supporting the interpretation of the results.电子健康数据代表特定研究的结果，这些研究尤其通过体外诊断开展，例如临床生物化学、血液学、输血医学、微生物学、免疫学等领域的诊断，且在相关情况下，还包括支持结果解读的报告。
6. Discharge reports 出院报告	Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.与医疗就诊或护理过程相关的电子健康数据，包括自然人的入院、治疗和出院的基本信息。

ANNEX II 附录二

Essential requirements for the harmonised software components of EHR systems and for products for which interoperability with EHR systems has been claimed 电子健康记录系统统一软件组件的基本要求，以及声称可与电子健康记录系统实现互操作性的产品的基本要求

The essential requirements laid down in this Annex shall apply *mutatis mutandis* to medical devices, *in vitro* diagnostic medical devices, AI systems and wellness applications claiming interoperability with EHR systems.本附件规定的基本要求经必要修改后，适用于声称可与电子健康记录系统互操作的医疗器械、体外诊断医疗器械、人工智能系统和健康应用程序。

1. General requirements 1. 一般要求

1.1. The harmonised software components of an EHR system shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose and their use does not put at risk patient safety.电子健康记录系统的协调软件组件应达到其制造商预期的性能，并且其设计和制造方式应确保在正常使用条件下，这些组件适用于其预期用途，且使用过程不会危及患者安全。

1.2. The harmonised software components of the EHR system shall be designed and developed in such a way that the EHR system can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use.电子健康记录系统的协调软件组件的设计和开发应确保该系统能够按照制造商提供的说明和信息进行供应和安装，且在其预期使用过程中不会对其特性和性能产生不利影响。

1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II.电子健康记录系统的设计和开发应确保其互操作性、安全性和保障功能符

合第二章规定的该系统预期用途，并维护自然人的权利。

1.4. The harmonised software components of an EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system in relation to those harmonised software components of an EHR system.电子健康记录系统中旨在与包括医疗设备在内的其他产品一同运行的协调软件组件，其设计和制造方式应确保互操作性和兼容性可靠且安全，并且个人电子健康数据能够在设备与电子健康记录系统之间就这些协调软件组件进行共享。

2. Requirements for interoperability2. 互操作性要求

2.1. Where an EHR system is designed to store or intermediate personal electronic health data, it shall provide an interface enabling access to the personal electronic health data processed by it in the European electronic health record exchange format, by means of the European interoperability software component for EHR systems.如果电子健康记录系统旨在存储或中转个人电子健康数据，则该系统应提供一个接口，通过用于电子健康记录系统的欧洲互操作性软件组件，以欧洲电子健康记录交换格式访问其处理的个人电子健康数据。

2.2. Where an EHR system is designed to store or intermediate personal electronic health data, it shall be able to receive personal electronic health data in the European electronic health record exchange format, by means of the European interoperability software component for EHR systems.如果电子健康记录系统旨在存储或中转个人电子健康数据，那么它应当能够借助适用于电子健康记录系统的欧洲互操作性软件组件，接收欧洲电子健康记录交换格式的个人电子健康数据。

2.3. Where an EHR system is designed to provide access to personal electronic health data, it shall be able to receive personal electronic health data in the European electronic health record exchange format, by means of the European interoperability software component for EHR systems.如果电子健康记录系统旨在提供对个人电子健康数据的访问，那么它应当能够借助用于电子健康记录系统的欧洲互操作性软件组件，接收欧洲电子健康记录交换格式的个人电子健康数据。

2.4. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data with sufficient granularity to enable the provision of the entered personal electronic health data in the European electronic health record exchange format.包含结构化个人电子健康数据录入功能的电子健康记录（EHR）系统，应能以足够精细的粒度录入数据，以便能够以欧洲电子健康记录交换格式提供所录入的个人电子健康数据。

2.5. The harmonised software components of an EHR system shall not include features that prohibit, restrict or place an undue burden on authorised access, personal electronic health data sharing or use of personal electronic health data for permitted purposes.电子健康记录系统的统一软件组件不得包含禁止、限制授权访问、个人电子健康数据共享,或对出于允许目的使用个人电子健康数据施加不当负担的功能。

2.6. The harmonised software components of an EHR system shall not include features that prohibit, restrict or place an undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by

another product.电子健康记录系统的统一软件组件不应包含因用其他产品替换该电子健康记录系统而禁止、限制或过度阻碍授权导出个人电子健康数据的功能。

3. Requirements for security and logging.3. 安全和日志记录要求。

3.1. An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals.供医疗专业人员使用的电子健康记录系统应提供可靠的机制，用于医疗专业人员的身份识别和认证。

3.2. The European logging software component of an EHR system designed to enable access by healthcare providers or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record at least the following information on every access event or group of events:电子健康记录（EHR）系统的欧洲日志软件组件旨在使医疗服务提供者或其他个人能够访问个人电子健康数据，该组件应提供充足的日志机制，以记录每次访问事件或事件组的至少以下信息：

(a) （a）identification of the healthcare provider or other individuals having accessed the personal electronic health data;对访问过个人电子健康数据的医疗服务提供者或其他个人的识别；

(b)identification of the specific natural person or persons having accessed the personal electronic health data;已访问个人电子健康数据的特定自然人的识别

(c) （c） the categories of data accessed; 所访问数据的类别；

(d) the time and date of access; 访问的时间和日期；

(e) the origin or origins of data. 数据的来源。

3.3. The harmonised software components of an EHR system shall include tools or mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes.电子健康记录系统的统一软件组件应包含用于审查和分析日志数据的工具或机制，或者应支持为相同目的连接和使用外部软件。

3.4. The harmonised software components of an EHR system that store personal electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.电子健康记录系统中存储个人电子健康数据的统一软件组件应支持不同的保留期和访问权限，这些保留期和访问权限需考虑电子健康数据的来源和类别。

ANNEX III 附录三

Technical documentation 技术文档

The technical documentation referred to in Article 37 shall contain at least the following information, as applicable to the harmonised software components of an EHR system in the relevant EHR system:第 37 条所指的技术文档应至少包含以下信息，这些信息适用于相关电子健康记录系统中经过协调的软件组件：

1.A detailed description of the EHR system including:电子健康记录系统的详细说明，包括：

(a) （a）its intended purpose, and the date and version of the EHR system;其预期用途，以及电子健康记录系统的日期和版本；

(b)the categories of personal electronic health data that the EHR system has been designed to process;电子健康记录系统设计用于处理的个人电子健康数据类别；

(c) （c）how the EHR system interacts or can be used to interact with hardware or software that is not part of the EHR system itself;电子健康记录系统如何与不属于其自身的硬件或软件进行交互，或者如何被用于与这些硬件或软件进行交互；

(d)the versions of relevant software or firmware and any requirement related to version update;相关软件或固件的版本以及与版本更新相关的任何要求；

(e)the description of all forms in which the EHR system is placed on the market or put into service;电子健康记录系统投放市场或投入使用的所有形式的描述；

(f) （f）the description of hardware on which the EHR system is intended to run;电子健康记录系统预定运行的硬件描述；

(g)a description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing, including, where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts or software components and including sufficient explanation to understand the drawings and diagrams;对系统架构的描述，解释软件组件如何相互构建或相互提供信息，并整合到整体处理中，适当时应包括带标签的图示（如图表和绘图），清晰标明关键部分或软件组件，并包含足够的说明以理解这些绘图和图表。

(h)the technical specifications, such as features, dimensions and performance attributes, of the EHR system and any variants or configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the data structures, storage and input/output of data;电子健康记录（EHR）系统及其任何变体、配置和配件的技术规格，如功能、尺寸和性能属性，这些通常会出现在向用户提供的产品规格中，例如在宣传册、目录和类似出版物中，包括对数据结构、数据存储以及数据输入/输出的详细描述；

(i) （一）a description of any change made to the system throughout its lifecycle;对系统在其整个生命周期中所做任何变更的描述；

(j)the instructions for use for the user and, where applicable, installation instructions.用户使用说明，以及适用情况下的安装说明。

2.A detailed description of the system in place to evaluate the EHR system performance, where applicable.对已实施的用于评估电子健康记录系统性能的系统的详细描述（如适用）。

3.The references to any common specification used in accordance with Article 36 and in relation to which conformity is declared.根据第 36 条提及的任何通用规范，以及与之相关的符合性声明。

4.The results and critical analyses of all verifications and validation tests undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III, in

particular the applicable essential requirements.为证明电子健康记录系统符合第三章规定的要求（特别是适用的基本要求）而进行的所有验证和确认测试的结果及关键分析。

5.A copy of the information sheet referred to in Article 38.第 38 条所提及的信息表副本。

6. A copy of the EU declaration of conformity.欧盟符合性声明副本。

ANNEX IV 附件四

EU declaration of conformity 欧盟符合性声明

The EU declaration of conformity for the harmonised software components of an EHR system shall contain all of the following information:电子健康记录系统统一软件组件的欧盟符合性声明应包含以下所有信息：

1.The name of the EHR system, version and any additional unambiguous reference allowing identification of the EHR system.电子健康记录系统的名称、版本以及任何其他可明确识别该电子健康记录系统的参考信息。

2.Name and address of the manufacturer or, where applicable, its authorised representative.制造商的名称和地址，或适用时其授权代表的名称和地址。

3.A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer.一份声明，表明欧盟合格声明是在制造商的唯一责任下发布的。

4.A statement that the EHR system in question is in conformity with the provisions laid down in Chapter III and, if applicable, with any other relevant Union law that provides for the issuing of an EU declaration of conformity, complemented by the result from the testing environment mentioned in Article 40.一份声明，表明所涉电子健康记录系统符合第三章规定，并且如适用，还符合任何其他规定需出具欧盟合规声明的相关欧盟法律，并附上第 40 条所述测试环境的结果。

5.References to any relevant harmonised standards used and in relation to which conformity is declared.提及所使用的任何相关协调标准，以及声明符合这些标准的情况。

6.References to any common specifications used and in relation to which conformity is declared.对所使用且声明符合的任何通用规范的引用。

7.Place and date of issue of the declaration, signature plus name and function of the person who signed and, if applicable, an indication of the person on whose behalf it was signed.声明的出具地点和日期、签名以及签名人的姓名和职务，如适用，还需注明代签人的信息。

8. Where applicable, additional information.如适用，附加信息。

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