



**2022/0140(COD)**

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# **DRAFT COMPROMISE AMENDMENTS**

**Rapporteurs: Tomislav Sokol, Annalisa Tardino**

European Health Data Space

Proposal for a regulation  
(COM(2022)0197 – C9-11202 – 2022/0140(COD))

(Joint committee procedure – Rule 58 of the Rules of Procedure)

2022/0140 (COD)

Proposal for a

## **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

### **on the European Health Data Space**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  
Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Having regard to the opinion of the Committee of the Regions<sup>2</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

#### **COMPROMISE AMENDMENT 75: Recitals**

Replacing the following amendments: 170 S&D, 171 S&D, 172 EPP, 173 S&D, 174 EPP, 175 NA, 176 S&D, 177 S&D, 178 ID, 179 S&D, 180 S&D, 181 RE, 182 NA,(1 Rapporteurs, 183 ID, 184S&D, 185 S&D, 186 Greens/EFA, 187 Greens/EFA, 188 S&D, 189 EPP, 190 RE, 445 EPP LIBE, 446 Greens, 191 ID, 192 S&D, 193 EPP, 194 S&D, 195 ECR, 196 S&D, 2 Rapporteurs, 197 Greens, 198 NA, 199 NA, 200 S&D, 201 RE, 202 ECR, 203 EPP, 204 S&D, 205 Greens/EFA, 206 ID, 207 ECR, 208 The Left, 209 S&D, 210 Greens/EFA, 211 S&D, 212 ECR, 213 EPP, 4 Rapporteurs, 214 S&D, 215 EPP, 5 Rapporteurs, 216 Greens/EFA, 217 EPP, 218 NI/ID, 219 EPP, 220 RE, 221 S&D, 222 S&D, 223 ID, 224 Greens/EFA, 225 S&D, 226 EPP, 227 NA, 228 Greens, 229 ID, 230 ID, 231 EPP, 232 RE, 233 S&D, 234 ECR, 235 S&D, 236 Greens/EFA, 6 Rapporteurs, 237 S&D, 238 S&D, 239 EPP, 240 Greens/EFA, 241 ECR, 242 S&D, 245 S&D, 246 Renew, 247 S&D, 243 Greens partially, 244 ID partially, .248 ID, 249 EPP, 250 Greens/EFA, 251 EPP, 252 NA, 253 S&D, 254 ECR, 256 RE, 257 S&D, 258 Greens/EFA, 259 S&D, 7 Rapporteurs, 259 S&D, 260 Greens/EFA, 261 S&D, 262 EPP, 263 ECR, 264 EPP, 265 S&D, 266

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<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C , , p. .

Greens/EFA, 267 The Left, 268 The Left, 269 ID, 270 RE, 271 S&D, 272 ECR, 273 RE, 274 The Left, 8 Rapporteurs, 275 NI, 276 ID, 277 S&D, 278 S&D, 279 ID, 280 EPP, 281 ECR, 282 Greens/EFA, 283 NA, 284 ID, 285 S&D, 286 ECR, 287 ID, 288 NA/ID, 289 The Left, 290 S&D, 291 S&D, 292 S&D, 293 ID, 294 The Left, 295 RE, 296 Greens/EFA, 297 EPP, 298 The Left, 299 S&D, 300 RE, 301 EPP, 302 S&D, 303 S&D, 304 S&D, 305 ID, 306 S&D, 307 the Left, 308 greens/EFA, 309 ECR, 310 EPP, 311 S&D, 312 ECR, 313 The Left, 314 Greens/EFA, 315 ECR, 10 rapporteurs, 316 Renew, 317 EPP, 11 Rapporteurs, 318 Greens/EFA, 319 EPP, 320 ID/NA, 321 EPP, 322 NA, 323 ID, 324 S&D, 325 The Left, 326 EPP, 327 ID, 328 Greens/EFA, 329 S&D, 330 S&D, 331 ID, 332 NA, 333 EPP, 334 EPP, 335 ECR, 336 ID, 337 The Left, 338 ECR, 339 S&D, 340 S&D, 341 Greens/EFA, 344 NA, 345 S&D, 346 EPP, 347 Greens, 348 S&D, 349 RE, 350 EPP, 351 ID, 352 Greens/EFA, 353 RE, 14 Rapporteurs, 354 Greens/EFA, 355 EPP, 356 S&D, 357 The Left, 358 ID, 359 S&D, 360 The Left, 361 NA, (362 S&D, 363 EPP, 364 EPP, 365 S&D, 366 S&D, 367 RE, 368 Greens, 369 EPP, 370 S&D, 371 S&D, 372 RE, 373 Greens/EFA, 374 EPP, 375 RE, 376 S&D, 377 EPP, 378 Greens/EFA, 379 The Left, 380 S&D, 15 Rapporteurs, 381 EPP, 382 EPP, 383 ID, 384 Greens/EFA, 385 NA, 386 Greens/EFA, 387 S&D, 388 EPP, 16 Rapporteurs, 389 S&D, 390 Greens/EFA, 391 EPP, 392 EPP, 393 S&D, 394 The Left, 395 ECR, 396 EPP, 397 S&D, 398 EPP, 399 EPP, 400 RE, 401 RE, 402 Greens/EFA, 403 EPP, 408 ID, 409 S&D, 410 Greens/EFA, 411 S&D, 17 Rapporteurs, 412 ID, 413 ECR, 414 S&D, 415 The Left, 416 Renew, 417 Greens, 418 S&D, 419 EPP, 19 Rapporteurs, 425 EPP, 426 RE, 427 Greens/EFA, 428 EPP, 429 EPP, 430 EPP, 20 Rapporteurs, 431 S&D, 432 EPP, 433 EPP, 21 Rapporteurs, 436 EPP, 435 EPP, 434 S&D, 436 EPP, 437 EPP, 438 Greens/EFA, 439 EPP LIBE, 440 EPP, 441 S&D, 22 Rapporteurs, 442 EPP LIBE, 23 Rapporteurs, 443 EPP, 444 ID, 445 EPP, 446 Greens/EFA, 447 EPP, 448 The Left, 449 RE, 450 S&D, 451 The Left, 24 Rapporteurs, , 552 The Left, 26 Rapporteurs, 453 The Left, 454 EPP, 455 RE, 456 S&D, 457 S&D, 458 Greens/EFA, 459 S&D, 28 Rapporteurs, 460 The Left, 449 Renew, 450 S&D, 461 Greens/EFA, 462 S&D, 462 RE, 464 S&D, 465 The Left, IMCO 1 to 17, ITRE 1 to 15.

- (1) The aim of this Regulation is to establish the European Health Data Space ('EHDS') in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for ***better achieving*** other purposes ***in the health sector (174 EPP)*** that would benefit society such as research such as innovation, policy-making, ***health threats preparedness and response***, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data). In addition, the 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. ***(171 S&D)***
- (1a) ***The EHDS is intended to constitute a key component in the creation of a strong and resilient European Health Union to better protect the health of Union citizens, prevent and address future pandemics and improve resilience of Union healthcare systems. (176 S&D)***

- (1b) ***This Regulation should complement with Union programmes such as the EU4Health Programme, Digital Europe Programme, Connecting Europe Facility and Horizon Europe. The Commission should ensure that Union programmes complement and facilitate the implementation of the European Health Data Space. (177 S&D)***
- (2) The COVID-19 pandemic has 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 ***through the*** secondary use of health data. Such timely access ***can potentially contribute***, through efficient public health surveillance and monitoring, to a more effective management of the pandemic, ***to a reduction of costs and to improve response to health threats*** and ultimately ***can help*** to save ***more lives in the future***. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by Commission Implementing Decision (EU) 2019/1269<sup>3</sup>, to allow Member States to share electronic health data of COVID-19 patients moving between healthcare providers and Member States during the peak of the pandemic, but this was only an emergency solution, showing the need for a structural ***and consistent*** approach at Member States and Union level ***on access to electronic health data to steer effective policy responses and contribute to high standards of human health. (1 Rapporteurs, 179 S&D, 184 S&D, 181 Renew)***
- (3) The COVID-19 crisis strongly anchored the work of the eHealth Network, a voluntary network of digital health authorities, as the main pillar for the development of mobile contact tracing and warning applications 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 (‘FAIR principles’), and ensuring that ***the necessary*** electronic health data ***are available*** ~~are as open as possible and as closed as necessary~~ ***while respecting the principle of data minimisation***. Synergies between the EHDS, the European Open Science Cloud<sup>4</sup> and the European Research Infrastructures should be ensured, as well as lessons learned from data sharing solutions developed under the European COVID-19 Data Platform.
- (3a) ***Given the sensitivity of personal 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 the health data of natural persons for primary and secondary uses. To achieve these objectives, pursuant to Article 9(4) of Regulation (EU) 2016/679, Member States can impose further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. (186 Greens/EFA (partially))***
- (4) The processing of personal electronic health data is subject to the provisions of Regulations (EU) 2016/679 of the European Parliament and of the Council<sup>5</sup>, Regulation

<sup>3</sup> 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).

<sup>4</sup> [EO SC Portal \(eosc-portal.eu\)](https://eosc-portal.eu).

<sup>5</sup> 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).

(EU) 2018/1725 of the European Parliament and of the Council<sup>6</sup>, as regards Union institutions, bodies, offices and agencies, **and Regulation (EU) 2022/868** of the European Parliament and of the Council. **(187 Greens/EFA)** 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. ***In relation to mixed datasets, where personal and non-personal data are inextricably linked, and where it is difficult to distinguish between those categories which results in the possibility to infer personal data from non-personal data, the provisions of Regulation (EU) 2016/679 and of this Regulation concerning personal electronic health data should apply.***(445 EPP LIBE, 446 Greens)

- (4a) *The implementation of the EHDS should take into consideration the European ethical principles for digital health adopted by the eHealth network<sup>7</sup> on 26 January 2022. Monitoring the application of those ethical principles should be one of the tasks of the EHDS Board. (Renew, AM 190)***
- (5)** More and more Europeans cross national borders to work, study, visit relatives or to travel. To facilitate the exchange of health data, and in line with the need for empowering 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 the provision of health care services, which reveal information about their 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, physical influences, medical care, social or educational factors. Electronic health data also includes data that has been initially collected for research, statistics, ***health threat assessment, (196 S&D)*** policy making or regulatory purposes and may be made available according to the rules in Chapter IV. The electronic health data concern all categories of those data, irrespective to the fact that such data is provided by the data subject or other natural or legal persons, such as health professionals, or is 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 automatic means.
- (5a) *The scope of this Regulation should not cover natural persons who are not Union citizens or third-country nationals not legally residing on the territory of the Member States. Therefore, where Member States require electronic registration of health data or where health data holders register health data regarding those natural persons, processors can only process the electronic health data of such persons, in accordance with Articles 6(1) and 9(2) of Regulation (EU) 2016/679 including for any secondary use.***

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<sup>6</sup> 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).

<sup>7</sup> Established following Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

- (6) Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. EHDS builds upon these rights and further develops some of them. The EHDS should support the coherent implementation of those rights as applied to electronic health data, regardless of the Member State in which the personal electronic health data are processed, type of healthcare provider, sources of 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 Chapter II and III of this Regulation concern all categories of those data, irrespective of how they have been collected or who has provided them, of the legal ground for the processing under Regulation (EU) 2016/679 or the status of the controller as a public or private organisation of the legal ground for their processing.
- (7) In health systems, personal electronic health data is usually gathered in electronic health records, which typically contain a natural person's medical history, diagnoses and treatment, medications, allergies, immunisations, as well as radiology images and laboratory results, **and other complementary exams of diagnosis and therapeutics (200 S&D)**, spread between different entities from the health system (general practitioners, hospitals, pharmacies, care services). In order to enable that electronic health data to be accessed, shared and changed by the 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. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported or provided health data access services for patients and health professionals (for instance through patients or health professional portals). They have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented manner. In order to facilitate the free movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved access to their own personal electronic health data and are empowered to share it. **To that end, Member States should ensure a common standard is in place for the exchange of electronic health data to ensure and facilitate its transfer and translation to the Union official languages. (200 S&D) In this respect, appropriate funding and support at Union and national level should be fairly distributed and considered as a means to reduce fragmentation, heterogeneity, and division and to achieve a system that is user-friendly and intuitive in all Member States. (3 Rapporteurs, 200 S&D)**
- (8) The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679, should be further developed in the health sector. Under Regulation (EU) 2016/679, controllers do not have to provide access immediately. While patient portals, mobile applications and other personal health data access services exist in many places, including national solutions in some Member States, 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. This may severely impair timely access to health data by natural persons, and may have a

negative impact on natural persons who need such access immediately due to urgent circumstances pertaining to their health condition.

- (9) At the same time, it should be considered that immediate access *of natural persons* to certain types of *their* personal electronic health data may be harmful for the safety of natural persons, unethical or inappropriate. For example, it could be unethical to inform a patient through an electronic channel about a diagnosis with an incurable disease that is likely to lead to their swift passing instead of providing this information in a consultation with the patient first. Therefore, a possibility for limited exceptions in the implementation of this right should be ensured. Such an exception may be imposed by the Member States where this exception constitutes a necessary and proportionate measure in a democratic society, in line with the requirements of Article 23 of Regulation (EU) 2016/679. Such restrictions should be implemented by delaying the display of the concerned personal electronic health data to the natural person for a limited period, *for instance until the moment where the patient and the health professional get in contact*. ~~data is only available on paper, if the effort to make data available electronically is disproportionate, there should be no obligation that such~~ *Member States should be encouraged to require that health data available prior to the implementation of this Regulation be converted into an<sup>into</sup> electronic format through a process facilitated by Member States. (214 S&D)* Any digital transformation in the healthcare sector should aim to be inclusive and benefit also natural persons with limited ability to access and use digital services. Natural persons should be able to provide an authorisation to the natural persons of their choice, such as to their relatives or other close natural persons, enabling them to access or control access to their personal electronic health data or to use digital health services on their behalf. Such authorisations may also be useful for convenience reasons in other situations. Proxy services should be established by Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals on patient-facing mobile applications. The proxy services should also enable guardians to act on behalf of their dependent children; in such situations, authorisations could be automatic. In order to take into account cases in which the display of some personal electronic health data of minors to their guardians could be contrary to the interests or will of the minor, Member States should be able to provide for such limitations and safeguards in national law, as well as the necessary technical implementation. Personal health data access services, such as patient portals or mobile applications, should make use of such authorisations and thus enable authorised natural persons to access personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect.
- (10) Some Member States allow natural persons to add electronic health data to their EHRs or to store additional information in their separate personal health record that can be accessed by health professionals. However, this is not a common practice in all Member States and therefore should be established by the EHDS across the EU. Information inserted by natural persons may 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 a health professional (221 S&D)*, therefore it should be clearly marked to indicate the source of such additional data *and should be validated only by a health professional*. More *specifically, relevant fields in the EHR should be clearly marked.*, (5 Rapporteurs, 217 EPP, 218 NI/ID) Enabling natural persons to more easily and quickly access their electronic health data also further enables them to notice

possible errors such as incorrect information or incorrectly attributed patient records and have them rectified using their rights under Regulation (EU) 2016/679. In such cases, natural person should be enabled to request rectification of the incorrect electronic health data online, immediately and free of charge, for example through the personal health data access service. Data rectification requests should be assessed and, where relevant, implemented by the data controllers on case by case basis, ~~if necessary~~ **(221 S&D)** involving health professionals, **with relevant specialisation, responsible for the natural person's treatment. (216 Greens (partially))**.

- (11) Natural persons should be further empowered to exchange and to provide access to personal electronic health data to the health professionals of their choice, going beyond the right to data portability as established in Article 20 of Regulation (EU) 2016/679 **and to download their health data**. This is necessary to tackle objective difficulties and obstacles in the current state of play. Under Regulation (EU) 2016/679, portability is limited only to data processed based on consent or contract, which excludes data processed under other legal bases, such as when the processing is based on law, for example when their processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. It only concerns data provided by the data subject to a controller, excluding many inferred or indirect data, such as diagnoses, or tests. Finally, under Regulation (EU) 2016/679, the natural person has the right to have the personal data transmitted directly from one controller to another only where technically feasible. That Regulation, however, does not impose an obligation to make this direct transmission technically feasible. All these elements limit the data portability and may limit its benefits for provision of high-quality, safe and efficient healthcare services to the natural person.
- (12) Natural persons should be able to exercise control over the transmission of personal electronic health data to other healthcare providers. Healthcare providers and other organisations providing EHRs should facilitate the exercise of this right. Stakeholders such as healthcare providers, digital health service providers, manufacturers of EHR systems or medical devices should not limit or block the exercise of the right of portability because of the use of proprietary standards or other measures taken to limit the portability. **In accordance with Regulation (EU) 2016/679, healthcare providers should follow the data minimisation principle when accessing personal health data, limiting the data accessed to strictly necessary and justified data for a given service (225 S&D)**. For these reasons, the framework laid down by this Regulation builds on the right to data portability established in Regulation (EU) 2016/679 by ensuring that natural persons as data subjects can transmit their electronic health data, including inferred data, irrespective of the legal basis for processing the electronic health data. This right should apply to electronic health data processed by public or private controllers, irrespective of the legal basis for processing the data under in accordance with the Regulation (EU) 2016/679. This right should apply to all electronic health data.
- (13) Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, **natural persons should be informed of the patient safety risks associated with limiting access to health data (224 Greens)**. However, such restrictions may have life threatening consequences and, therefore, access to personal electronic health data should be possible to protect vital interests as an emergency override. According to Regulation (EU) 2016/679, vital interests refer to situations in which it is necessary to protect an interest which is



essential for the life of the data subject or that of another natural person. Processing of personal electronic health data based on the vital interest of another natural person should in principle take place only where the processing cannot be manifestly based on another legal basis. More specific legal provisions on the mechanisms of restrictions placed by the natural person on parts of their personal electronic health data should be provided by Member States in national law, *in particular as regards medical liability in the event that restrictions have been placed by the natural person*. Because the unavailability of the restricted personal electronic health data may impact the provision or quality of health services provided to the natural person, he/she should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services.

- (14) In the context of the EHDS, natural persons should be able to exercise their rights *under this Regulation without prejudice to* Regulation (EU) 2016/679. The supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679 should remain competent, in particular to monitor the processing of personal electronic health data and to address any complaints lodged by the natural persons. In order to carry out their tasks in the health sector and uphold the natural persons' rights, digital health authorities should cooperate with the supervisory authorities under Regulation (EU) 2016/679.
- (15) Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of sensitive **(237 S&D)** data is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health care or treatment or the management of health care systems and services on the basis of Union or Member State law. This Regulation should provide conditions and safeguards for the processing of electronic health data by healthcare providers and health professionals in line with Article 9(2), point (h), of Regulation (EU) 2016/679 with the purpose of accessing personal electronic health data provided by the natural person or transmitted from other healthcare providers. However, this Regulation should be without prejudice to the national laws concerning the processing of health *data outside the scope of this Regulation, including for other secondary use purposes established by this Regulation*, including the legislation establishing categories of health professionals that can process different categories of electronic health data.
- (16) Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care, ~~and~~ avoiding duplications and errors *and reducing costs (238 S&D)*. 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 for both health systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, 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 *appropriate electronic and digital devices and (238 S&D)* health professional portals, to use personal electronic health data for the exercise of their duties *on a need-to-know basis*. Moreover, the access to personal health records should be transparent to the natural persons and natural persons should be able to exercise full control over such access, including by limiting

access to all or part of the personal electronic health data in their records. Health professionals should refrain from hindering the implementation of the rights of natural persons, such as refusing to take into account electronic health data originating from another Member State and provided in the interoperable and reliable European electronic health record exchange format. ***This Regulation should not be construed as should be interpreted as limiting the obligation of health professionals to 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. (238 S&D, 239 EPP, 241 ECR). For that purpose, providers of electronic health records should keep a record of who has accessed data in the previous 36 months and which data they accessed.***

- (16a) ***Health professionals are faced with a profound change in the context of digitalisation and implementation of the EHDS. Health professionals need to develop their digital health literacy and digital skills.[ Therefore, health professionals who qualify as micro enterprises, as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC, should be temporarily exempted from the obligations laid down in this Regulation in order to avoid a disproportionate administrative burden for micro enterprises. During the period of exemption, Member States should enable health professionals working as micro enterprises to take digital literacy courses to be able to prepare to work in EHR systems.(6 Rapporteurs)***
- (17) The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity in 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 categories of electronic health data is needed. Categories of electronic health data such as patient summary, electronic prescription and dispensation, laboratory results and reports, hospital discharge reports, medical images and 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. When further needs for the exchange of more categories of electronic health data are identified for healthcare purposes, the list of priority categories should be expanded, ~~The Commission should be empowered to extend the list of priority categories,~~ after analysing relevant aspects related to the necessity and possibility for the exchange of new datasets, such as their support by systems established nationally or regionally by the Member States. Particular attention should be given to the 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. ***(246 Renew, 243 Greens partially, 244 ID partially)***
- (18) Access and sharing of electronic health data should be enabled for all the data that exist in the EHR of a natural person, when technically feasible. However, some electronic health data may not be structured or coded, and the transmission between healthcare providers may be limited or only possible in formats that do not allow for translation (when data is shared cross-borders). In order to provide enough time to prepare for implementation, dates of deferred application should be determined to allow for achieving legal, organisational, semantic and technical readiness for the transmission of different categories of electronic health data. When need for the exchange of new

categories of electronic health data is identified, related dates of application should be determined in order to allow for the implementation of this exchange.

- (19) 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 *as well as for them to have better control over accessing and sharing 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 the Policy Programme “Path to the Digital Decade”. 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 images and image reports, laboratory results and discharge reports, subject to transition periods. Where personal electronic health data is made available to a healthcare provider or a pharmacy by a natural person, or is transmitted by another data controller in the European electronic health record exchange format, the electronic health data should be read and accepted for the provision of healthcare or for dispensation of a medicinal product, thus supporting the provision of the health care services or the dispensation of the electronic prescription. Commission Recommendation (EU) 2019/243<sup>8</sup> provides the foundations for such a common European electronic health record exchange format. ***The interoperability of the EHDS should contribute to a high quality of European health data sets. (255 S&D)*** The use of European electronic health record exchange format should become more generalised at EU and national level. While the eHealth Network under Article 14 of Directive 2011/24/EU of the European Parliament and of the Council<sup>9</sup> recommended Member States to use the European electronic health record exchange format in procurements, in order to improve interoperability, uptake was limited in practice, resulting in fragmented landscape and uneven access to and portability of electronic health data.
- (20) While EHR systems are widely spread, 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 implementation 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 according to 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. The Commission should be empowered to adopt ~~implementing~~ ***delegated (258 Greens/EFA)*** acts for determining ~~additional aspects related to the registration of electronic health data, such as categories of healthcare providers that are to register health data electronically, categories of data to be registered electronically, or~~ ***(256 RE)*** data quality requirements.
- (20a) In order to support the successful implementation of the EHDS and the creation of effective conditions for European health data cooperation, the Commission and***

<sup>8</sup> 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).

<sup>9</sup> 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).

*Member States should agree on time-based targets to implement conditions for improved health data interoperability across the Union with a range of targets and milestones, including in respect of disease-specific registry interoperability, to be reviewed and assessed in an annual report. (7 Rapporteurs, 259 S&D)*

- (21) 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 decisions on the services (~~including telemedicine~~) that they provide and reimburse. Different reimbursement policies should, however, not constitute barriers to the free movement of digital health services such as telemedicine, including online pharmacy services. When digital services accompany the physical provision of a healthcare service, the digital service should be included in the overall care provision. *Telemedicine is becoming an increasingly important tool that can provide patients with access to care and tackle inequities and 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. However, telemedicine should not be viewed as a replacement for in-person medicine, as there are certain conditions and procedures that require in-person physical examination and intervention. (265 S&D)*
- (22) Regulation (EU) No 910/2014 of the European Parliament and of the Council<sup>10</sup> 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 a secure access to electronic health data, including in cross-border scenarios where the health professional and the natural person are from different Member States, to avoid cases of unauthorised access. At the same time, the existence of different means of electronic identification should not be a barrier for exercising the rights of natural persons and health professionals. *Therefore, natural persons and health professionals should have the right to electronic identification using any recognised electronic identification, including eID schemes where such are offered.* The rollout of interoperable, cross-border identification and authentication mechanisms for natural persons and health professionals across the EHDS requires strengthening cooperation at Union level in the European Health Data Space Board ('EHDS Board'). As the rights of the natural persons in relation to the access and transmission of personal electronic health data should be implemented uniformly across the Union, a strong governance and coordination is necessary at both Union and Member State level.
- (22a) Member States should establish relevant digital health authorities for the planning and implementation of standards for electronic health data access, transmission and enforcement of rights of natural persons and health professionals. In addition, governance elements are needed in Member States to facilitate the participation of national actors in the cooperation at Union level, channelling expertise and advising the design of solutions necessary to achieve the goals of the EHDS. Digital health authorities exist in most of the Member States and they deal with EHRs, interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of the currently existing authorities.

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<sup>10</sup> 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).

- (23) Digital health authorities should have sufficient technical skills, possibly 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 necessary measures to ensuring rights of natural persons by setting up national, regional, and local technical solutions such as national EHR, patient portals, data intermediation systems. When doing so, they should apply common standards and specifications in such solutions, promote the application of the standards and specifications in procurements 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 undertaken. In particular, health professionals should be informed and trained with respect to their rights and obligations under this Regulation. (271 S&D)*** To carry out their tasks, the digital health authorities should cooperate at national and Union level with other entities, including with insurance bodies, healthcare providers, ***health professionals, (271 S&D)*** manufacturers of EHR systems and wellness applications, as well as ***other (271 S&D)*** stakeholders from 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.
- (24) Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may 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, crossing the border frequently to get health care. In many border regions, some specialised health care services may be available closer across the border rather than in the same Member State. An 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. A voluntary infrastructure for that purpose, MyHealth@EU, has been established as part of the actions provided for in Article 14 of Directive 2011/24/EU. Through MyHealth@EU, Member States started to provide natural persons with the possibility to share their personal electronic health data with healthcare providers when travelling abroad. To further support such possibilities, the participation of Member States in the digital infrastructure MyHealth@EU should become mandatory. All Member States should join the infrastructure and connect healthcare providers and pharmacies to it, as this is necessary for the implementation of the rights of natural persons to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually expanded to support further categories of electronic health data, ***and funding as well as other means of support at Union level should be considered (8 Rapporteurs, 277 S&D)***.
- (25) In the context of MyHealth@EU, a central platform should provide a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way. In order to guarantee compliance with data protection rules and to provide a risk management framework for the transmission of personal electronic health data, the Commission should, by means of implementing acts, allocate specific responsibilities ***with time-based targets (9 Rapporteurs, 285 S&D)*** among the Member States, as joint controllers, and prescribe its own obligations, as processor.

- (26) 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 may 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. This would be also important for introducing additional functionality for handling public health crises, such as support for contact tracing for the purposes of containing infectious diseases. ~~Connection of national contact points for digital health of third countries or interoperability with digital systems established at international level should be subject to a check ensuring the compliance of the national contact point with the technical specifications, data protection rules and other requirements of MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU.~~
- (27) In order to ensure respect for the rights of natural persons and health professionals, EHR systems marketed in the internal market of the Union should be able to store and transmit, in a secure way, high quality electronic health data. This is a key principle of the EHDS to ensure the secure and free movement of electronic health data across the Union. To that end, a mandatory self-certification 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 this self-certification, EHR systems should prove compliance with essential requirements on interoperability and security, set at Union level. In relation to security, essential requirements should cover elements specific to EHR systems, as more general security properties should be supported by other mechanisms such as cybersecurity schemes under Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>11</sup>.
- (28) 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 as EHR systems, even when used in a healthcare setting, and should therefore not be required to comply with the provisions of Chapter III.
- (29) Software or module(s) of software which falls within the definition of a medical device or high-risk artificial intelligence (AI) system should be certified in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>12</sup> and Regulation [...] of the European Parliament and of the Council [AI Act COM/2021/206 final], as applicable. The essential requirements on interoperability of this Regulation should only apply to the extent that the manufacturer of a medical device or 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

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<sup>11</sup> 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).

<sup>12</sup> 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).

common specifications for EHR systems should be applicable to those medical devices and high-risk AI systems.

- (30) To further support interoperability and security, Member States may maintain or define specific rules for the procurement, reimbursement, financing or use 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 procurements organised by healthcare providers, national or regional authorities. Mandatory certification of EHR systems at Union level should establish a baseline that can be used in procurements at national level.
- (31) In order to guarantee effective exercise by patients of their rights under this Regulation, where healthcare providers develop and use an EHR system ‘in house’ to carry out internal activities without placing it on the market in return of payment or remuneration, they should also comply with this Regulation. In that context, such healthcare providers should comply with all requirements applicable to the manufacturers.
- (32) It is necessary to provide for a clear and proportionate division of obligations corresponding to the role of each 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.
- (33) 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, including standards, specifications and profiles for data exchange, as well as requirements and principles related to security, confidentiality, integrity, patient safety and protection of personal data as well as 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.
- (34) In order to ensure an appropriate and effective enforcement of the requirements and obligations laid down in Chapter III of this Regulation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 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 or a separate market surveillance authority responsible for EHR systems. While designating digital health authorities as market surveillance authorities could have important practical advantages for the implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.
- (34a) EHR systems may qualify as medical device under Regulation (EU) 2017/745 or in-vitro diagnostic devices under Regulation (EU) 2017/746. While those EHR systems need to fulfil the requirements under each applicable regulation, Member States should take appropriate measures to ensure that the respective conformity assessment is carried out as a joint or coordinated procedure, as appropriate, *inter alia* by encouraging the

same notified bodies to become responsible for the conformity assessment under each applicable regulation.

- (35) Users of wellness applications, such as mobile applications, 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 is 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 be informed about the compliance of such 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 ~~voluntary~~ **mandatory** labelling scheme **for wellness applications claiming interoperability with EHR systems** should therefore be established as an appropriate mechanism for enabling the transparency for the users of wellness applications regarding compliance with the requirements, thereby supporting users in their choice of appropriate wellness applications with high standards of interoperability and security. The Commission ~~may~~ **should (311 S&D partially)** set out in implementing acts the details regarding the format and content of such label.
- (36) 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 are not falling within the scope of Regulations (EU) 2017/745 and [...] [AI act COM/2021/206 final] 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 of interoperable 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 [...] [AI act COM/2021/206 final], but the compliance with interoperability requirements should be indicated when claimed by manufacturers, to provide information to procurers.
- (36a) ***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. (316 Renew)***
- (37) For the secondary use of ~~the clinical~~ **personal electronic health (11 Rapporteurs, 323 ID)** data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by Regulation (EU) 2016/679 for a Union law should be used as a basis ~~and~~ **for** rules and mechanisms ~~and~~ providing suitable and specific measures to safeguard the rights and freedoms of the natural persons. ***For processing of electronic health data for secondary use, one of the legal bases set out in Article 6(1), points (a), (c), (e) or (f), of Regulation (EU) 2016/679 combined with Article 9(2) of that Regulation (EU) 2016/679 should be required. The most relevant processing condition listed in Article 9(2) of Regulation (EU) 2016/679 in this context are those of substantial public interest , the provision***



*of health or social care , public interest in the area of public health and research. (11 Rapporteurs, 318 Greens/EFA (partially)) Hence, this Regulation provides the legal basis in accordance with Article 6 and Articles 9(2) (g), (h), (i) and (j) of Regulation (EU) 2016/679 for the secondary use of health data, establishing the safeguards for processing, in terms of lawful purposes, trusted governance for providing access to health data (through health data access bodies) and processing in a secure environment, as well as modalities for data processing, set out in the data permit. ~~At the same time, the data applicant should demonstrate a legal basis pursuant to Article 6 of Regulation (EU) 2016/679, based on which they could request access to data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV. (11 Rapporteurs)~~ More specifically, for processing of electronic health data held by the **health** data holder pursuant to this Regulation, this Regulation creates the legal obligation in the sense of Article 6(1), point (c), of Regulation (EU) 2016/679 for disclosing the data by the **health** data holder to health data access bodies, while the legal basis for the purpose of the initial processing (e.g. delivery of care) is unaffected. This Regulation ~~also meets the conditions for such processing pursuant to Articles 9(2) (h),(i),(j) of the Regulation (EU) 2016/679.~~ This Regulation assigns tasks in the public interest to the health data access bodies (running the secure processing environment, processing data before they are used, etc.) in the sense 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)(h),(i) and(j), of the Regulation (EU) 2016/679. ~~Therefore, in this case, At the same time, the health data access body should verify the compliance with Article 6 of Regulation (EU) 2016/679, combined with Article 9(2) thereof, based on which they 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 provides the legal basis under Article 6 and meets the requirements of Article 9 of that Regulation on the conditions under which electronic health data can be processed set out in Chapter IV of this Regulation. (11 Rapporteurs)~~*

- (37a) In the case where the **health data** user has access to electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the **health** data user should demonstrate ~~its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 and explain (11 Rapporteurs)~~ the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation: on the basis of the applicable legislation, where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on Article 6(1), point (f), thereof. If the **health data** user relies upon a legal basis offered by Article 6(1), point (e), it should make reference to another Union or national law, different from this Regulation, mandating the user to process personal health data for the compliance of its tasks. If the lawful ground for processing by the **health data** user is Article 6(1), point (f), of Regulation (EU) 2016/679, **appropriate and necessary safeguards should be determined in accordance with** ~~in this case it is this Regulation that provides the safeguards (324 S&D).~~ In this context, the data permits issued by the health data access bodies are an administrative decision defining the conditions for the access to the data.
- (38) In the context of the EHDS, the electronic health data already exists and is being collected by healthcare providers, professional associations, public institutions, regulators, researchers, insurers etc. in the course of their activities. Some categories of data are collected primarily for the provisions of healthcare (e.g. electronic health records, genetic data, claims data, etc.), others are collected also for other purposes such

as research, statistics, patient safety, regulatory activities or policy making (e.g. disease registries, policy making registries, registries concerning the side effects of medicinal products or medical devices, etc.). For instance, European databases that facilitate data (re)use are available in some areas, such as cancer (European Cancer Information System) or rare diseases (European Platform on Rare Disease Registration, ERN registries, etc.). These data should also be made available for secondary use. However, much of the existing health-related data is not made available for purposes other than that for which they were collected. This limits the ability of researchers, innovators, policy-makers, regulators and doctors to use those data for different purposes, including research, innovation, policy-making, regulatory purposes, patient safety or personalised medicine. In order to fully unleash the benefits of the secondary use of electronic health data, 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, such as aggregation and randomisation, and with due respect to professional duties, including but not limited to, confidentiality duties (329 S&D, 331 ID).***

- (39) 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. It can also include relevant data from the health system (electronic health records, claims data, disease registries, genomic data etc.), as well as data with an impact on health (for example consumption of different substances, ~~homelessness, health insurance, minimum income, professional status~~ **socio-economic status**, behaviour, including environmental factors (for example, pollution, radiation, use of certain chemical substances). They can also include ***automatically generated data from medical devices and*** person-generated data, such as wellness applications ~~or other wearables and digital health applications~~. The **health** data user who benefits from access to datasets provided under this Regulation could enrich the data with various corrections, annotations and other improvements, for instance by supplementing missing or incomplete data, thus improving the accuracy, completeness or quality of data in the dataset. ***Health data users should be encouraged to report critical errors in datasets to health data access bodies. (12 Rapporteurs)*** To support the improvement of the original database and further use of the enriched dataset, the dataset with such improvements and a description of the changes should be made available free of charge to the original data holder. The data holder should make available the new dataset, unless it provides a justified notification against it to the health data access body, for instance in cases of low quality of the enrichment. Secondary use of non-personal electronic data should also be ensured. In particular, pathogen genomic data hold significant value for human health, as proven during the COVID-19 pandemic. Timely access to and sharing of such data has proven to be essential for the rapid development of detection tools, medical countermeasures and responses to public health threats. The greatest benefit from pathogen genomics effort will be achieved when public health and research processes share datasets and work mutually to inform and improve each other.
- (39a) ***In order to guarantee trust in the patient-physician relationship, the principle of professional secrecy and patient's right to confidentiality should be safeguarded when digitalising healthcare services. A relationship of trust between patients and health professionals and healthcare providers and other holders of personal health data is a paramount element of the provision of health or social care or treatment. It is within***

*that context that the patient or the legal representative of the patient should have a say in the processing of their health data for secondary use in the form of a right to opt-out of the processing of all or parts of their health data for secondary use for some or all purposes. An easily understandable and accessible opt-out mechanism in a user-friendly format should be provided for in this regard. (362 S&D). However, due to the sensitive nature of human genetic, genomic and proteomic data, data from biobanks and to the nature of the use of data from wellness applications , it is appropriate to provide that the secondary use of such data can only be occur following the consent of the natural person concerned in accordance with Article 4(11) of the Regulation (EU) 2016/679. An opt-in mechanism whereby data subjects explicitly consent or give their permission to the processing of part or all of such data for some or all secondary use purposes should be envisaged. Where data subjects explicitly consent to the use of parts or all of this data for some or all secondary use purposes, they should be made aware of the sensitive nature of the data they are sharing. Moreover, it is imperative to provide natural persons with sufficient information regarding their right to opt-out, including on the possibility to reconsider and agree to some or all of their health data being processed for secondary use at a later point. (13 Rapporteurs, 342 EPP LIBE, 343 EPP)*

- (40) The *health* data holders *in the context of secondary use of electronic health data (349 Renew)* can be public, non for profit or private health or care providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the health sector that process the categories of health and health related data mentioned above *To the extent that they process personal electronic health data, they are controllers within the meaning of Regulation (EU) 2016/679 in the health or care sector.* In order to avoid a disproportionate burden on small entities, micro-enterprises are excluded from the obligation to make their data available for secondary use in the framework of EHDS. *Health data access bodies should provide specific support to small enterprises, in particular medical practioners and pharmacies, in complying with their obligation to make data available for secondary use.* The public or private entities often receive public funding, from national or Union funds to collect and process electronic health data for research, statistics (official or not) or other similar purposes, including in area where the collection of such data is fragmented or difficult, such as rare diseases, cancer etc. Such data, collected and processed by *health* data holders with the support of Union or national public funding, should be made available by *health* data holders to health data access bodies, in order to maximise the impact of the public investment and support research, innovation, patient safety or policy making benefitting the 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. At the same time, data benefiting from specific legal protection such as intellectual property from medical device companies or pharmaceutical companies often enjoy copyright protection or similar types of protection *and should be made available while taking all necessary measures to protect such rights. (349 Renew, 350 EPP).* However, public authorities and regulators should have access to such data, for instance in the event of pandemics, to verify defective devices and protect human health. In times of severe public health concerns (for example, PIP breast implants fraud) it appeared very difficult for public authorities to get access to such data to understand the causes and knowledge of manufacturer concerning the defects of some devices. The COVID-19 pandemic also revealed the

difficulty for policy makers to have access to health data and other data related to health. Such data should be made available for public and regulatory activities, supporting public bodies to carry out their legal mandate, while complying with, where relevant and possible, the protection enjoyed by commercial data. Specific rules in relation to the secondary use of health data should be provided. Data altruism activities may be carried out by different entities, in the context of Regulation [...] [Data Governance Act COM/2020/767 final] and taking into account the specificities of the health sector.

- (40a) *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. In addition to the right for natural persons to authorise another natural person of their choice to access or control their electronic health data on their behalf, 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. (366 S&D). 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 (228 Greens).*
- (40b) *Clinical trials and studies are of utmost importance in fostering innovation within the Union for the benefit of Union patients. In order to incentivise continuous Union leadership in this domain, the sharing of the clinical trials data through the EHDS for secondary use should be consistent with the relevant transparency provisions laid down in Union law including [...] [proposal for a Regulation on Blood, tissue, cells and organs (SoHO) COM(2022)338 final, Regulations (EC) No 726/2004 and (EU) No 2019/6 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council regarding veterinary and human medicines and establishing the EMA, Regulation (EC) No 141/2000 of the European Parliament and of the Council related to medicinal products for rare diseases ('orphan medicines'), Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for children, Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products, Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials, Regulation (EU) No 2017/745 of the European Parliament and of the Council on medical devices and Regulation (EU) No 2017/746 of the European Parliament and of the Council on in vitro diagnostic devices.(353 Renew)*
- (41) The secondary use of health data under EHDS should enable the public, private, not for profit entities, as well as individual researchers, **with a demonstrated link to the field of public health**, to have access to health data for research, innovation, policy making, educational activities, patient safety, regulatory activities or personalised medicine, in line with the purposes set out in this Regulation. Access to data for secondary use should contribute to the general interest of the society. **In particular, the secondary use of health data for research and development purposes should contribute to a benefit to society in the form of new medicines, medical devices, health care products and services at affordable and fair prices for Union citizens, as well as enhancing access to and the availability of such products and services in all Member States. (356 S&D)** Activities for which access in the context of this Regulation is lawful may include using the electronic health data for tasks carried out by public bodies, such as exercise of

public duty, including public health surveillance, planning and reporting duties, health policy making, ensuring patient safety, quality of care, and the sustainability of health care systems. Public bodies and Union institutions, bodies, offices and agencies may require to have regular access to electronic health data for an extended period of time, including in order to fulfil their mandate, which is provided by this Regulation. Public sector bodies may carry out such research activities by using third parties, including sub-contractors, as long as the public sector body remain at all time the supervisor of these activities. The provision of the data should also support activities related to scientific research (including private research, **development and innovation, producing goods and services for the health or care sectors, such as innovation activities or training of artificial intelligence algorithms that could protect the health or care of natural persons**). In some cases, the information of some natural persons (such as genomic information of natural persons with a certain disease) could support the diagnosis or treatment of other natural persons. There is a need for public bodies to go beyond the emergency scope of Chapter V of Regulation [...] [Data Act COM/2022/68 final]. However, the public sector bodies may request the support of health data access bodies for processing or linking data. This Regulation provides a channel for public sector bodies to obtain access to information that they require for fulfilling their tasks assigned to them by law, but does not extend the mandate of such public sector bodies. Any attempt to use the data for any measures detrimental to the natural person, to increase insurance premiums, to advertise products or treatments, **to automate individual decision-making (354 Greens (partially), to re-identify natural persons**, or develop harmful products should be prohibited.

- (42) The establishment of one or more health data access bodies, supporting access to electronic health data in Member States, is an essential component for promoting the secondary use of health-related data. Member States should therefore establish one or more health data access body, for instance to reflect their constitutional, organisational and administrative structure. However, one of these health data access bodies should be designated as a coordinator in case there are more than one data access body. Where a Member State establishes several bodies, it should lay down rules at national level to ensure the coordinated participation of those bodies in 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 may vary in terms of organisation and size (spanning from a dedicated full-fledged organization to a unit or department in an existing organization) but should have the same functions, responsibilities and capabilities. Health data access bodies should not be influenced in their decisions on access to electronic data for secondary use, **Members of the governance and decision-making bodies and staff of each health data access body should therefore refrain from any action that is incompatible with their duties and should not engage in any incompatible occupation**. However, their independence should not mean that the health data access body cannot be subject to control or monitoring mechanisms regarding its financial expenditure or to judicial review. Each health data access body should be provided with the financial, **technical (367 Renew)** and human resources, **ethics bodies**, 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 **and have**

*separate structures for application processing on the one hand, anonymisation, pseudonymisation and reidentification on the other hand.* Each health data access body should have a separate, public annual budget, which may be part of the overall state or national budget. In order to enable better access to health data and complementing Article 7(3) of Regulation [...] of the European Parliament and of the Council [Data Governance Act COM/2020/767 final], 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 [...] [Data Governance Act COM/2020/767 final] or in designating existing or new sectoral bodies responsible for such tasks in relation to access to health data. ***Given the central role of the health data access bodies in the context of secondary use of electronic health data, and especially the decision-making on granting or refusing a health data permit and preparing the data to make it available to health data users, their members and staff should have the necessary qualifications, experience and skills, including legal and technical expertise as regards the protection of personal data and specifically data concerning health and expertise in the areas of ethics, healthcare, scientific research, cybersecurity, protection of intellectual property and trade secrets, , artificial intelligence and other relevant areas. In addition, the decision-making process regarding the granting or refusal of the health data permit should involve ethical considerations (367 Renew). The staff of health access bodies should not have any conflict of interest that is prejudicial to their independence and impartial conduct. (368 Greens)***

- (43) The 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, the health data access bodies should cooperate with each other and with the Commission, without the need for any agreement between Member States on the provision of mutual assistance or on such cooperation. The health data access bodies should also cooperate with stakeholders, including patient organisations. ***The selection procedure for health stakeholders should be transparent, public and free of any conflict of interest (Greens 373).*** Since the secondary use of health data involves the processing of personal data concerning health, the relevant provisions of Regulation (EU) 2016/679 apply and the supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 should ***remain the only authorities competent for enforcing these rules. (371 S&D).*** Moreover, given that health data are sensitive data and in a duty of loyal cooperation, the health data access bodies should inform the data protection authorities of any issues related to the data processing for secondary use, including ***administrative fines and enforcement measures.*** 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, ~~support the development of AI in health~~ and promote the development of common standards. They should apply tested ***state-of-the-art (372 Renew)*** techniques that ensure electronic health data is 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. ***In that regard, health data access bodies should cooperate across borders and agree on common definitions and techniques. (372 Renew)*** Health data access bodies can prepare datasets to the data user requirement linked to the issued data permit. This includes rules for ***anonymisation*** of microdata sets.

- (44) ~~Considering the administrative burden for~~ **Health data access bodies *should comply with the obligations laid down in Article 14 of Regulation (EU) 2016/679 and (375 Renew)*** ~~to~~ inform the natural persons whose data are used in data projects within a secure processing environment. ~~The exceptions provided for in Article 14(5) of Regulation (EU) 2016/679 should~~ ***can*** apply. ~~Therefore~~ ***Where such exceptions are applied (375 Renew)***, health data access bodies should provide general information concerning the conditions for the secondary use of their health data containing the information items listed in Article 14(1) and, where necessary to ensure fair and transparent processing, Article 14(2) of Regulation (EU) 2016/679, e.g. information on the purpose and the data categories processed, ***allowing natural persons to understand whether their data are being made available for secondary use pursuant to data permits (375 Renew)***. Exceptions from this rule should be made when the results of the research could assist in the treatment of the natural person concerned. In this case, the ***health*** data user should inform the health data access body, which should inform the ~~data subject or his~~ health professional ***treating the natural person concerned (375 Renew) or, in the event that the treating health professional is not traceable, the natural person, with due regard for their stated wish not to be informed while fully respecting the principles of medical confidentiality and professional secrecy (378 Greens) (376 S&D, 379 The Left)***. Natural persons should be able to access the results of different research projects on the website of the health data access body, ideally in an easily searchable manner. The list of the data permits should also be made public. In order to promote transparency in their operation, each health data access body should publish an annual activity report providing an overview of its activities.
- (45) Regulation [...] [Data Governance Act COM/2020/767 final] sets out the general rules for the management of data altruism. At the same time, given that the health sector manages sensitive data, additional criteria should be established through the rulebook foreseen in Regulation [...] [Data Governance Act COM/2020/767 final]. Where such a rulebook foresees the use of a secure processing environment for this sector, this should comply with the criteria established in this Regulation. The health data access bodies should cooperate with the bodies designated under Regulation [...] [Data Governance Act COM/2020/767 final] to supervise the activity of data altruism organisations in the health or care sector.
- (46) In order to support the secondary use of electronic health data, the data holders should refrain from withholding the data, requesting unjustified fees that are not transparent nor proportionate with the costs for making data available (and, where relevant, with marginal costs for data collection), requesting the data users to co-publish the research or other practices that could dissuade the data users from requesting the data. Where ethical approval is necessary for providing a data permit, its evaluation should be based on its own merits. On the other hand, ***public sector bodies and*** Union institutions, bodies, offices and agencies ***with a legal mandate in the field of public health, including EMA, ECDC and the Commission,*** have very important and insightful data. Access to data of such institutions, bodies, offices and agencies should be granted through the health data access body where the controller is located.
- (47) Health data access bodies ~~and single data holders~~ ***(15 Rapporteurs, 384 Greens (partially), 383 ID)*** should be allowed to charge fees based on the provisions of ***applicable legislation in this*** Regulation [...] ***and the provisions of the*** [Data Governance Act COM/2020/767 final] ***and the [Data Act COM/2022/68 final]*** in relation to their tasks. Such fees may take into account the situation and interest of

SMEs, individual researchers or public bodies. **Health data** holders should be allowed to also charge fees for making data available. Such fees should reflect the costs for providing such services. Private **health** data holders may also charge fees for the collection of data. In order to ensure a harmonised approach concerning fee policies and structure, the Commission ~~may~~ **should** adopt implementing acts. Provisions in Article 10 of the Regulation [Data Act COM/2022/68 final] should apply for fees charged under this Regulation. **Public sector bodies and Union institutions, bodies, offices and agencies with a legal mandate in the field of public health should not be charged.**

- (48) In order to strengthen the enforcement of the rules on the secondary use of electronic health data, appropriate measures **should be envisaged** that can lead to **administrative fines or enforcement measures by health data access bodies (387 S&D)** or temporary or definitive exclusions from the EHDS framework of the **health** data users or **health** data holders that do not comply with their obligations. The health data access body should be empowered to verify compliance and give **health** data users and holders the opportunity to reply to any findings and to remedy any infringement. **When deciding on the amount** ~~The imposition of penalties should be subject to appropriate procedural safeguards in accordance with the general principles of law of the~~ **administrative fine or enforcement measure for each individual case, relevant Member State health data access bodies should take into account the margins and criteria set out in this Regulation.** ~~, including effective judicial protection and due process. (386 Greens)~~
- (49) Given the sensitivity of electronic health data, it is necessary to reduce risks on the privacy of natural persons by applying the data minimisation principle as set out in Article 5 (1), point (c) of Regulation (EU) 2016/679. Therefore, **common standards for data anonymisation should be further developed and (389 S&D, 391 EPP)** the use of anonymised electronic health data which is devoid of any personal data should be made available when possible ~~and if the data user asks it.~~ If the data user needs to use personal electronic health data, it should clearly indicate in its request the justification for the use of this type of data for the planned data processing activity **and the health data access body should determine the validity of this justification.** The personal electronic health data should only be made available in pseudonymised format and the encryption key can only be held by the health data access body. **When providing access to a anonymised or pseudonymised dataset, a health data access body should follow state-of-the-art anonymisation or pseudonymisation technology ensuring to the maximum extent possible that natural persons cannot be re-identified (49 Rapporteurs, 389 S&D, 391 EPP, 392 EPP).** **Health** data users should not attempt to re-identify natural persons from the dataset provided under this Regulation, subject to administrative **fines and enforcement measures laid down in this Regulation** or possible criminal penalties, where the national laws foresee this. However, this should not prevent, in cases where the results of a project carried out based on a data permit has a **significant** health benefit or impact to a concerned natural person (for instance, discovering treatments or risk factors to develop a certain disease), the **health** data users **to** inform the health data access body, which in turn would inform the **treating health professional of the concerned natural person or, in the event that the treating health professional is not traceable, the natural person, with due regard for their stated wish not to be informed(389 S&D, 394 The Left).** **To that end, the health data user should be guided by ethical principles, and guidelines of EMA and ECDC as regards what constitutes a significant finding.** Moreover, ~~the~~ **a health data** applicant can request the health data



access bodies to provide the answer to a *health* data request, including in *an anonymised or aggregated statistical format*. In this case, the *health* data user would not process health data and the health data access body would remain sole controller for the data necessary to provide the answer to the *health* data request.

- (50) In order to ensure that all health data access bodies issue 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 information elements that would help the body evaluate the *application* and decide if the applicant may receive a data permit for secondary use of data, also ensuring coherence between different health data access bodies. Such information includes: the legal basis under Regulation (EU) 2016/679 to request access to data (exercise of a task in the public interest assigned by law or legitimate interest), purposes for which the data would be used, *the identity of the health data applicant as well as the concrete persons who are authorised to have access to the electronic health data in the secure processing environment and how they are qualified vis-à-vis the intended secondary use (401 Renew, 402 Greens)*, description of the needed data and possible data sources, a description of the tools needed to process the data, as well as characteristics of the secure environment that are needed, *a description of the safeguards planned to prevent any other use, misuse or possible re-identification, and an explanation of the expected benefits of the secondary use*. Where data is requested in pseudonymised format, the *health* data applicant should explain why this is necessary and why anonymous data would not suffice. An ethical assessment may be requested based on national law. *A thorough assessment of the health data access applications and documents submitted by the health data applicant should be required and the health data access body should only issue a data permit if all the conditions set out in this Regulation are met*. The health data access bodyies 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* applicant needs *data in an anonymised and aggregated statistical format*, it should submit a data request application, requiring the health data access body to provide directly the result. *A refusal of a data permit by the health data body should not preclude the health data applicant to submit a new data access application*. In order to ensure a harmonised approach between health data access bodies *and to limit unnecessary administrative burden for the health data applicants to the greatest extent possible*, the Commission should support the harmonisation of *health data access applications*, as well as *health data requests, including by establishing, by means of implementing acts, templates for health data access applications and requests (EPP 1782)*

- (50a) *A standard ethics assessment should be carried out by ethics bodies within health data access bodies', which should be an important part of the process. However, where the health data applicant had previously obtained the approval of the competent ethics committee in accordance with national law for research purposes for which they are requesting data through the EHDS, the health data applicant should make that information available to the health data access body as part of the data access application.*

- (51) As the resources of health data access bodies are limited, they can apply prioritisation rules, for instance prioritising public institutions before private entities, but they should not make any discrimination between the national or from organisations from other

Member States within the same category of priorities. The *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 publication or to enable additional analysis of the dataset based on the initial findings. This would require an amendment of the *health* data permit and may be subject to an *additional* fee. However, in all the cases, the data permit should reflect these additional uses of the dataset. Preferably, the *health* data user should mention them in their initial request for the issuance of the data permit. In order to ensure a harmonised approach between health data access bodies, the Commission should support the harmonisation of data permit.

- (52) 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 is *(411 S&D)* may be the case not only *for* in specific circumstances *stipulated by Union or national law (410, Greens)* in times of crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data may be required in specific Member States or throughout the whole territory of the Union.
- ~~(53) For requests to access electronic health data from a single data holder in a single Member State and in order to alleviate the administrative burden for health data access bodies of managing such request, the data user should be able to request this data directly from the data holder and the data holder should be able to issue a data permit while complying with all the requirements and safeguards linked to such request and permit. Multi-country requests and requests requiring combination of datasets from several data holders should always be channelled through health data access bodies. The data holder should report to the health data access bodies about any data permits or data requests they provide. (17 Rapporteurs, 412 ID, 413 ECR, 414 S&D, 415 The Left, 416 Renew, 417 Greens, 418 S&D)~~
- (54) Given the sensitivity of electronic health data, data users should not have an unrestricted access to such data, *in accordance with the data minimisation principle (18 Rapporteurs, 423 The Left)*. All secondary use access to the requested electronic health data should be done through a secure processing environment. In order to ensure strong technical and security safeguards for the electronic health data, the health data access body ~~or, where relevant, single data holder~~ *(18, Rapporteurs, 424 Renew, 423 The Left)* 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. Some Member States took measures to locate such secure environments in Europe. The processing of personal data in such a secure environment should comply with Regulation (EU) 2016/679, including, where the secure environment is managed by a third party, the requirements of Article 28 and, where applicable, Chapter V. *Nevertheless, in order to ensure the proper supervision and security of personal data, such environments need to be located in the Union if they are used to access personal health data.* 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 data users. The health data access body or the data holder providing this service should remain at all time in control of the access to the electronic health data with access granted to the data users determined by the conditions of the issued data permit. Only non-personal electronic health data which do not contain any electronic health data should be extracted by the data users from such secure processing environment. Thus, it 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 State in developing common security standards in order to promote the security and interoperability of the various secure environments.

- (55) For the processing of electronic health data in the scope of a granted permit, *the health data holders, the health data access bodies and the health data users should each, in turn, be deemed a controller for a specific part of the process and according to their respective roles in it. The health data holder should be deemed controller for the disclosure of the requested personal electronic health data to the health data access body, while the health data access body should in turn be deemed controller for the processing of the personal electronic health data when preparing the data and making them available to the health data user. The health data user should be deemed controller for the processing of personal electronic health data in pseudonymised form in the secure processing environment pursuant to its data permit. The health data access body should be deemed as a processor for the health data user's processing pursuant to a data permit in the secure processing environment.* (426 Renew) ~~the health data access bodies and the data users should be joint controllers in the sense of Article 26 of Regulation (EU) 2016/679, meaning that the obligations of joint controllers under that Regulation will apply. To support health data access bodies and data users, the Commission should, by means of an implementing act, provide a template for the joint controller arrangements health data access bodies and data users will have to enter into. In order to achieve an inclusive and sustainable framework for multi-country secondary use of electronic health data, a cross-border infrastructure should be established. HealthData@EU should accelerate the secondary use of electronic health data 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”, “*privacy by default*”, (19 Rapporteurs) and “bring questions to data instead of moving data” should be respected whenever possible. Authorised participants in HealthData@EU could be health data access bodies, research infrastructures established as an European Research Infrastructure Consortium (‘ERIC’) under Council Regulation (EC) No 723/2009<sup>13</sup> or similar structures established under another Union legislation, as well as other types of entities, including infrastructures under the European Strategy Forum on Research Infrastructures (ESFRI), infrastructures federated under the European Open Science Cloud (EOSC). Other authorised participants should obtain the approval of the joint controllership group for joining HealthData@EU. On the other hand, HealthData@EU should 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 environment, agriculture, social etc. 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 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 may also set up a secure environment, allowing data from different national infrastructures to be transmitted and analysed, at the request of the controllers. The Commission digital strategy promote the linking of the various common European data~~

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<sup>13</sup> 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).

spaces. For the health sector, interoperability with the sectors such as the environmental, social, agricultural sectors may be relevant for additional insights on health determinants. For the sake of IT efficiency, rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, like those being built for the exchange of evidences under the once only technical system of Regulation (EU) 2018/1724 of the European Parliament and of the Council<sup>14</sup>.

- (56) In 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 where the coordinator of the registry is located should be responsible for providing access to data.
- (57) The authorisation process to gain access to personal health data in different Member States can be repetitive and cumbersome for data users. Whenever possible, synergies should be established to reduce the burden and barriers for data users. One way to achieve this aim is to adhere to the “single application” principle whereby, with one application, the data user obtains (*431 S&D*) authorisation from multiple health data access bodies in different Member States.
- (58) The health data access bodies should provide information about the available datasets and their characteristics so that data users can be informed of elementary facts about the dataset and assess their possible relevance to them. For this reason, each dataset should include, at least, information concerning the source, nature of data and conditions for making data available. Therefore, an EU datasets catalogue should be established to facilitate the discoverability of datasets available in the EHDS; to help data holders to publish their datasets; to provide all stakeholders, including the general public, also taking into account people with disabilities, with information about datasets placed on the EHDS (such as quality and utility labels, dataset information sheets); to provide the data users with up-to-date data quality and utility information about datasets.
- (59) 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, recommendations for data collection and data exchange (i.e. FAIR principles: Findable, Accessible, Interoperable and Reusable), benefits also data holders, health professionals, natural persons and the Union economy overall. A data quality and utility label for datasets would inform 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 data holders and 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 in frameworks described in Article 10 of Regulation [...] [AI Act COM/2021/206 final] and its relevant documentation specified in Annex IV should be taken into account when developing the data quality and utility framework. *The labels should be subject to the evaluation by*

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<sup>14</sup> 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).

*the health data access bodies.* Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support these activities.

- (60) The EU datasets catalogue should minimise the administrative burden for the data holders and other database users; be user-friendly, accessible and cost-effective, connect national data catalogues and avoid redundant registration of datasets. The EU datasets catalogue could be aligned with the data.europa.eu initiative and without prejudice to the requirements set out in the Regulation [...] [Data Governance Act COM/2020/767 final]. Member states should ensure that national data catalogues are interoperable with existing dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.
- (61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is more advanced in areas such as cancer, rare diseases, *cardiovascular and metabolic diseases, risk factors assessment*, and statistics and shall be taken into account when defining new standards *and disease-specific harmonised templates for structured data elements.* (434 S&D) 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 provision, coding and registration of electronic health data. Member States should work towards delivering sustainable economic and social benefits of European electronic health systems and services and interoperable applications, 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 put in place by institutions and stakeholders can contribute to defining and implementing data standards, to ensuring interoperability and should be leveraged to allow for continuity and build on existing expertise.* (436 EPP, 434 S&D)
- (62) The Commission should support Member States in building capacity and effectiveness in the area of digital health systems for primary and secondary use of electronic health data. 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 this respect.
- (62a) *Improving digital health literacy for both natural persons and their health professionals is key in order to achieve trust, safety and appropriate use of health data and hence achieving a successful implementation of this Regulation. Improving digital health literacy is fundamental in order to empower natural persons to have true control over their health data and actively manage their health and care, and understand the implications of the management of such data for both primary and secondary use. 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. (267 The Left, 268 The Left, 266 Greens) Particular attention should be given to persons with disabilities and vulnerable groups including migrants and the elderly. Health professionals and IT operators should have sufficient training in working with new digital infrastructures to ensure cybersecurity and ethical management of health data. (197 Greens)*

- (63) 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, as well as 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. ***To procure or fund services provided by controllers and processors established in the Union that process personal electronic health data, they should be required to demonstrate that they will store the data in the Union and that they are not subject to third country law that conflicts with Union data protection rules. (438 Greens) Union funds should be distributed transparently and sufficiently among the Member States, ensuring its well-endowment and taking into account different levels of health system digitalisation and the costs involved in making national data infrastructures interoperable and compatible with the requirements of the EHDS.(439 EPP LIBE, 440 EPP). Making data available for secondary use requires additional resources for healthcare systems, notably public systems. This additional burden for public entities should be addressed and minimised to the greatest possible extent during the implementation phase of the EHDS (347 Greens/EFA).***
- (63a) ***The economic costs of implementing this Regulation will be borne at both Member State and Union level, while a fair burden sharing between national and Union funds should be found. The initial Union funding to achieve a timely application of the EHDS is limited to what can be mobilised under the 2021-2027 Multiannual Financial Framework (MFF) where 220 million EUR can be made available under the EU4Health and Digital Europe programmes. The successful and coherent application of the EHDS across all Member States will however require higher funding. The implementation of the EHDS requires appropriate investments in capacity building and training and a well-funded commitment to public consultation and engagement. The Commission should therefore mobilise further resources for the EHDS as part of the review of the 2021-2027 MFF and for the forthcoming MFF under the principle that new initiatives should be matched with new funding. (22 Rapporteurs, 442 EPP LIBE).***
- (64) Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically foreseen in the Data Governance Act. Even in situations of the use of state of the art anonymization techniques, 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 (a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Union), where the limited numbers of cases reduce the possibility to fully aggregate 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. It can affect different types of health data depending on the level of granularity and description of the characteristics of data subjects, the number of people affected or and for instance in cases of data included in electronic health records, disease registries, biobanks, person generated data etc. where the identification characteristics are broader and where, in combination with other information (e.g. in very small geographical areas) or through

the technological evolution of methods which had not been available at the moment of anonymisation, can lead to the re-identification of the data subjects using means that are beyond those reasonably likely to be used. The realisation of such risk of re-identification of natural persons would present a major concern and is likely to put the acceptance of the policy and 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 in the reporting on clinical trials, and enforcement of breaches of trade secrets outside the Union is more difficult in the absence of a sufficient international protection standard. Therefore, for these types of health data, there remains a risk for re-identification after the anonymisation or aggregation, which could not be reasonably mitigated initially. This falls within the criteria indicated in Article 5(13) of Regulation [...] [Data Governance Act COM/2020/767 final]. These types of health data would thus fall within the empowerment set out in Article 5(13) of Regulation [...] [Data Governance Act COM/2020/767 final] for transfer to third countries. The protective measures, proportional to the risk of re-identification, would need to take into account the specificities of different data categories or of different anonymization or aggregation techniques and will be detailed in the context of the Delegated Act under the empowerment set out in Article 5(13) of Regulation [...] [Data Governance Act COM/2020/767 final].

- (64a) *The functioning of the EHDS involves processing of a large quantity of personal and non-personal health data of a highly sensitive nature. Article 8(3) of the Charter of Fundamental Rights of the European Union (the ‘Charter’) requires control over the processing of such health data by an independent authority. The control of the compliance with the requirements of protection and security by an independent supervisory authority, carried out on the basis of Union law, is an essential component of the protection of individuals with regard to the processing of personal data and cannot be fully ensured in the absence of a requirement to retain the electronic health data in question within the Union. Therefore, taking into account the need to mitigate the risks of unlawful access and ineffective supervision, in compliance with the principle of proportionality, this Regulation should require Member States to store electronic health data within the Union. Such storage requirements should ensure a uniform high level of protection for data subjects across the Union, preserve the proper functioning of the internal market, in line with Article 114 TFEU on which this Regulation is based and serve to enhance citizens’ trust in the EHDS. (23 Rapporteurs, 448 The Left)***
- (64b) *The obligation to store electronic health data in the Union does not preclude transfers of those data to third countries or international organisations by means of granting access to electronic health data. Access of data through the secure processing environment can entail the transfer of personal data, as defined in Chapter V of Regulation (EU) 2016/679. It is possible to reconcile a general requirement to store personal data in the Union with specific transfers being allowed in compliance with Union law on personal data protection, for instance in the context of scientific research, disbursement of care or international cooperation. In particular, when personal data are transferred from the Union to controllers, processors or other recipients in third countries or to international organisations, the level of protection of natural persons ensured in the Union by Regulation (EU) 2016/679 should not be undermined, including in cases of onward transfers of personal data from the third***

*country or international organisation to controllers, processors in the same or another third country or international organisation. Transfers of personal health data to third countries and international organisations can only be carried out in full compliance with Chapter V of Regulation (EU) 2016/679. For instance, controllers and processors processing personal electronic health data remain subject to Article 48 of that Regulation on transfers or disclosures not authorised by Union law and should comply with this provision in case of an access request stemming from a third country. In accordance with and under the conditions of Article 9(4) of Regulation (EU) 2016/679, Member States can maintain or introduce further conditions, including limitations, to transfers of personal health data to third countries or international organisations. (24 Rapporteurs, 451 The Left).*

- (64c) *Access to electronic health data for entities from third countries should take place only on the basis of the reciprocity principle. Making available of health data to a third country can take place only where the Commission has established by means of a delegated act that the third country concerned allows for the use of health data by Union entities under the same conditions and with the same safeguards as within the Union. The Commission should monitor that list and provide for a periodic review thereof. Where the Commission finds that a third country no longer ensures access on the same terms, that third country should be removed from that list. (26 Rapporteurs, 453 The Left).*
- (65) In order to promote the consistent application of this Regulation, *including cross-border interoperability of health data, and potential mechanisms of funding support to ensure equal development of data systems across the Union in respect to the primary and secondary use of electronic health data*, a European Health Data Space Board (EHDS Board) should be set up. The Commission should participate in its activities and chair it. ‡ *The EHDS Board (455 Renew)* should contribute to the consistent application of this Regulation throughout the Union, including by helping Member State to coordinate the use of electronic health data for healthcare, certification, but also concerning the secondary use of electronic health data. Given that, at national level, digital health authorities dealing with the primary use of electronic health data may be different to the health data access bodies dealing with the secondary use of electronic health data, the functions are different and there is a need for distinct cooperation in each of these areas, the EHDS Board should be able to set up subgroups dealing with these two functions, as well as other subgroups, as needed. For an efficient working method, the digital health authorities and health data access bodies should create networks and links at national level with different 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 [...], [...], [...] and [...] [Data Governance Act, Data Act, AI Act and Cybersecurity Act]. *The EHDS Board should operate in line with its Code of Conduct, impartially, independently, in the public interest and transparently with open publication of meeting dates and minutes of the discussion as well as an annual report . It is furthermore appropriate to lay down sufficient guarantees that Members of the EHDS Board refrain from any conflicts of interest. (459 S&D)*
- (65a) *An advisory forum should be set up to advise the EHDS Board in the fulfilment of its tasks by providing stakeholder input in matters pertaining to this Regulation. The advisory forum should be composed of representatives of patients, consumers, 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. (455 Renew, 456 S&D)*

- (66) In order to manage the cross-border infrastructures for primary and secondary use of electronic health data, it is necessary to create the Joint controllership group for authorised participants (e.g. to ensure the compliance with data protection rules and this Regulation for the processing operations performed in such infrastructures).
- (66a) *Any natural person should have the right to lodge a complaint with a digital health authority or with a health data access body, in particular in the Member State of his or her habitual residence, and the right to an effective judicial remedy in accordance with Article 47 of the Charter if the natural person considers that his or her rights under this Regulation are infringed or where the digital health authority or health data access body does not act on a complaint, partially or wholly rejects or dismisses a complaint or does not act where such action is necessary to protect the rights of the natural person. The investigation following a complaint should be carried out, subject to judicial review, to the extent that is appropriate in the specific case. The digital health authority or health data access body should inform the natural 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, intermediate information should be given to the natural 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 other means of communication. Where the complaint concerns the rights of natural persons, the health data access body should inform and send a copy of the complaint to the supervisory authorities under Regulation (EU) 2016/679.*
- (66b) *Where a natural person considers that his or her rights under this Regulation are infringed, he or she should have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal data, to lodge a complaint on his or her behalf.*
- (66c) *Any natural or legal person has the right to bring an action for annulment of decisions of the EHDS Board before the Court of Justice under the conditions provided for in Article 263 TFEU. As addressees of such decisions, the digital health authorities or health data access bodies concerned which wish to challenge them have to bring action within two months of being notified of them, in accordance with Article 263 TFEU. Where decisions of the EHDS Board are of direct and individual concern to a health data holder, health data applicant, health data user or complainant, the latter can bring an action for annulment against those decisions within two months of their publication on the website of the EHDS Board, in accordance with Article 263 TFEU. Without prejudice to this right under Article 263 TFEU, each natural or legal person should have an effective judicial remedy before the competent national court against a decision of a digital health authority or health data access body which produces legal effects concerning that person. Such a decision concerns in particular the exercise of investigative, corrective and authorisation powers by the health data access body or the dismissal or rejection of complaints. However, the right to an*

*effective judicial remedy does not encompass measures taken by digital health authorities and health data access bodies which are not legally binding, such as opinions issued or advice provided. Proceedings against a digital health authority or health data access body should be brought before the courts of the Member State where the digital health authority or health data access body is established and should be conducted in accordance with that Member State's procedural law. Those courts should exercise full jurisdiction, which should include jurisdiction to examine all questions of fact and law relevant to the dispute before them. Where a complaint has been rejected or dismissed by a digital health authority or health data access body, the complainant can bring proceedings before the courts in the same Member State.*

- (66d) Where a court seized of proceedings against a decision by a digital health authority or health data access body has reason to believe that proceedings concerning the same access to electronic health data by the same health data user, such as for the same purpose for processing for secondary use, are brought before a competent court in another Member State, it should contact that court in order to confirm the existence of such related proceedings. If related proceedings are pending before a court in another Member State, any court other than the court first seized can stay its proceedings or can, on request of one of the parties, decline jurisdiction in favour of the court first seized if that court has jurisdiction over the proceedings in question and its law permits the consolidation of such related proceedings. Proceedings are deemed to be related where they are so closely connected that it is expedient to hear and determine them together in order to avoid the risk of irreconcilable judgments resulting from separate proceedings.*
- (66e) For proceedings against a health data holder or health data user, the plaintiff should have the choice to bring the action before the courts of the Member States where the health data holder or health data user has an establishment or where the natural person resides, unless the health data holder is a public authority of a Member State acting in the exercise of its public powers.*
- (66f) The digital health authority, health data access body, health data holder or health data user should compensate any damage which a person could suffer as a result of processing that infringes this Regulation. The digital health authority, health data access body, health data holder or health data user should be exempt from liability if it proves that it is not in any way responsible for the damage. The concept of damage should be broadly interpreted in the light of the case-law of the Court of Justice 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 rules in Union or national law. Processing that infringes this Regulation also includes processing that infringes delegated and implementing acts adopted in accordance with this Regulation and national law specifying rules of this Regulation. Natural persons should receive full and effective compensation for the damage they have suffered. Where digital health authorities, health data access bodies, health data holders or health data users are involved in the same processing, each actor should be held liable for the entire damage. However, where they are joined to the same judicial proceedings, in accordance with Member State law, compensation may be apportioned according to the responsibility of each digital health authority, health data access body, health data holder or health data user for the damage caused by the processing, provided that full and effective compensation of the natural person who suffered the damage is ensured. Any digital health authority, health data access body,*

*health data holder or health data user which has paid full compensation may subsequently institute recourse proceedings against other digital health authorities, health data access bodies, health data holders or health data users involved in the same processing.*

- (66g)** *Where specific rules on jurisdiction are contained in this Regulation, in particular as regards proceedings seeking a judicial remedy including compensation, against a digital health authority, health data access body, health data holder or health data user, general jurisdiction rules such as those of Regulation (EU) No 1215/2012 of the European Parliament and of the Council should not prejudice the application of such specific rules.*
- (66h)** *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 the digital health authority or health data access body pursuant to this Regulation. In a case of a minor infringement or if the fine likely to be imposed would constitute a disproportionate burden to a natural person, a reprimand may be issued instead of a fine. Due regard should however be given to the nature, gravity and duration of the infringement, the intentional character of the infringement, actions taken to mitigate the damage suffered, degree of responsibility or any relevant previous infringements, the manner in which the infringement became known to the digital health authority or health data access body, compliance with measures ordered against the health data holder or health data user, adherence to a code of conduct and any other aggravating or mitigating factor. 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, including effective judicial protection and due process.*
- (66i)** *Member States should be able to lay down the rules on criminal penalties for infringements of this Regulation, including for infringements of national rules adopted pursuant to and within the limits of this Regulation. Those criminal penalties can also allow for the deprivation of the profits obtained through infringements of this Regulation. However, the imposition of criminal penalties for infringements of such national rules and of administrative penalties should not lead to a breach of the principle of ne bis in idem, as interpreted by the Court of Justice.*
- (66j)** *It is appropriate to lay down provisions enabling health data access bodies to apply administrative fines for certain infringements to this Regulation whereby certain infringements are to be regarded as serious infringements, such as re-identification of natural persons, downloading personal health data outside of the secure processing environment and processing of data for prohibited uses or outside a data permit. This Regulation should indicate 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 relevant circumstances of the specific situation, with due regard in particular to the nature, gravity and duration of the infringement and of 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. Where administrative fines are imposed on an undertaking, an undertaking should be understood to be an undertaking in accordance with Articles 101 and 102 TFEU for those purposes.*

*Where administrative fines are imposed on persons that are not an undertaking, the health data access body should take account of the general level of income in the Member State as well as the economic situation of the person in considering the appropriate amount of the fine. The consistency mechanism may also be used to promote a consistent application of administrative fines. It should be for the Member States to determine whether and to which extent public authorities should be subject to administrative fines. Imposing an administrative fine or giving a warning does not affect the application of other powers of the health data access bodies or of other penalties under this Regulation.*

- (66k) *The legal systems of Denmark and Estonia do not allow for administrative fines as set out in this Regulation. The rules on administrative fines can be applied in such a manner that in Denmark the fine is imposed by competent national courts as a criminal penalty and in Estonia the fine is imposed by the supervisory authority in the framework of a misdemeanour procedure, provided that such an application of the rules in those Member States has an equivalent effect to administrative fines imposed by supervisory authorities. Therefore the competent national courts should take into account the recommendation by the health data access body initiating the fine. In any event, the fines imposed should be effective, proportionate and dissuasive.*
- (66l) *Where this Regulation does not harmonise administrative penalties or where necessary in other cases, for example in cases of serious infringements of this Regulation, Member States should implement a system which provides for effective, proportionate and dissuasive penalties. The nature of such penalties, criminal or administrative, should be determined by national law.*
- (67) Since the objectives of this Regulation: to empower natural persons through increased control of their personal health data and support their free movement by ensuring that health data follows them; to foster a genuine single market for digital health services and products; to ensure a consistent and efficient framework for the reuse of natural persons' health data for research, innovation, policy-making 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 the 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 and secondary use of electronic health data, 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.
- (68) In order to ensure that EHDS fulfils its objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of different provisions of primary and secondary use of electronic health data. 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<sup>15</sup>. In particular, to ensure equal participation in the

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<sup>15</sup> OJ L 123, 12.5.2016, p. 1.

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.

- (69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>16</sup>.
- (69a) *In accordance with Article 42 of Regulation (EU) 2018/1725, the Commission should, when preparing delegated acts or implementing acts, consult the European Data Protection Supervisor where there is an impact on the protection of individuals' rights and freedoms with regard to the processing of personal data, and where such an act is of particular importance for the protection of individuals' rights and freedoms with regard to the processing of personal data, the Commission can also consult the European Data Protection Board. The Commission should moreover consult the European Data Protection Board in the cases specified in Regulation (EU) 2016/679 and when relevant in the context of this Regulation. (28 Rapporteurs, 460 The Left)***
- (70) Member States should take all necessary measures 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*** ~~For certain specific infringements,~~ Member States should take into account the margins and criteria set out in this Regulation. ***Re-identification of natural persons should be considered a particularly serious breach of this Regulation. Member States can consider criminalising re-identification by health data users to serve as a deterrent measure. (449 Renew, 450 S&D).***
- (71) 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 partial evaluation of this Regulation 5 years after its entry into force, ~~on the self-certification of EHR systems~~ ***(464 S&D, 463 Renew)***, and an overall evaluation 7 years after the entry into force of this Regulation. 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.
- (72) For a successful cross-border implementation of EHDS, the European Interoperability Framework<sup>17</sup> to ensure legal, organisational, semantic and technical interoperability should be considered as common reference.
- (73) The evaluation of the digital aspects of Directive 2011/24/EU shows limited effectiveness of eHealth Network, but also strong potential for EU work in this area, as shown by the work during pandemic. Therefore, the article 14 of the Directive will be repealed and replaced by the current Regulation and the Directive will be amended accordingly.

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<sup>16</sup> 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).

<sup>17</sup> European Commission, [European Interoperability Framework](#).

- (74) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered **Joint an opinion n. 03/2022 on 12 July 2022 on [...]. (29 Rapporteurs)**
- (75) This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 of the Treaty. The measures provided for in this Regulation should not be used to restrict competition in a manner contrary to the Treaty.
- (76) Given the need for technical preparation, this Regulation should apply from [12–24 months after entry into force],

HAVE ADOPTED THIS REGULATION:

HAVE ADOPTED THIS REGULATION:

### COMPROMISE AMENDMENT 1: Article 1 + recitals 1-4

Replacing the following amendments: **30-31 Rapporteurs, 466 RE, 467 RE, 468 S&D, 469 ID, 470 ECR, 471 S&D, 472 RE, 473 Greens/EFA, 474 S&D ENVI, 475 EPP, 476 S&D, 477 S&D, 478 S&D, 479 S&D, 480 EPP, 481 RE, 482 Greens/EFA, 483 The Left LIBE, 484 S&D LIBE, 485 ECR, 486 The Left LIBE, 487 EPP LIBE, 488 ECR, 489 EPP LIBE, 30 Rapporteurs, 490 S&D LIBE, 491 S&D LIBE, 31 Rapporteurs, 492 S&D LIBE, 493 Greens/EFA, 494 The Left LIBE, 495 Greens/EFA, 496 EPP LIBE, 497 S&D, 498 EPP LIBE, 499 EPP LIBE, ITRE 16, ITRE 17, ITRE 18, ITRE 19, IMCO 18**

## Chapter I

### General provisions

#### *Article 1*

#### *Subject matter and scope*

1. This Regulation establishes the European Health Data Space ('EHDS') by providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data.
2. This Regulation:
  - (a) ~~strengthens~~ **specifies (473 Greens; 474 S&D (similar))** the rights of natural persons in relation to the availability, **sharing (472 RE, 469 ID (partially))** and control of their electronic health data;
  - (b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems ('EHR systems') in the Union;

- (c) lays down rules and mechanisms supporting the secondary use of electronic health data;
  - (d) establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the Union;
  - (e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data.
3. This Regulation applies to:
- (a) manufacturers and suppliers of EHR systems and wellness applications, **and of products claiming interoperability with EHR systems, (480 EPP LIBE, 481 RE, 482 Greens)** placed on the market and put into service in the Union and the users of such products;
  - (b) controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States.
  - (c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);
  - (d) data users to whom electronic health data are made available by data holders in the Union.
4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, **(EU) 2022/868 [...]** ~~[Data Governance Act COM/2020/767 final]~~ **(31 Rapporteurs, 493 Greens, 494 The Left LIBE, 497 S&D)** and [...] [Data Act COM/2022/68 final] **and Directive 2002/58/EC (490, 492 S&D LIBE).**
- 4a. References to the provisions of Regulation (EU) 2016/679 shall be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant. (30 Rapporteurs, 491 S&D LIBE, 494 The Left LIBE)**
5. This Regulation shall be without prejudice to Regulations (EU) 2017/745 and [...] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.
- 5a. This Regulation shall be without prejudice to Regulation (EU) No 536/2014 (499 EPP LIBE, 490 S&D LIBE) and Directive (EU) 2016/943. (496 EPP LIBE)**
6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.

## COMPROMISE AMENDMENT 2: Article 2

Replacing the following amendments: **500 The Left LIBE, 32 Rapporteurs, 501 RE, 502 S&D LIBE, 33 Rapporteurs, 34 Rapporteurs, 503 NI, 504 The Left LIBE, 505 RE, 506**

S&D LIBE, 507 EPP, 508 EPP LIBE, 509 RE, 510 ID, 511 Greens/EFA, 512 The Left LIBE, 35 Rapporteurs, 513 RE, 514 Greens/EFA, 515 S&D ENVI, 516 S&D ENVI, 517 ID, 518 S&D LIBE, 519 EPP ENVI Rapporteur, 520 EPP, 521 EPP, 522 EPP, 523 ECR, 524 RE, 525 The Left ENVI, 36 Rapporteurs, 526 RE, 527 EPP, 528 ID/NA ENVI, 529 S&D LIBE, 530 ECR LIBE, 531 The Left LIBE, 532 Greens/EFA, 533 EPP, 534 S&D ENVI, 535 Greens/EFA, 536 RE, 537 EPP, 538 S&D ENVI, 539 ECR, 540 The Left LIBE, 541 S&D ENVI, 542 Greens/EFA, 543 The Left LIBE, 544 RE, 545 Greens/EFA, 546 EPP, 547 ECR, 548 S&D ENVI, 37 Rapporteurs, 549 S&D ENVI, 550 RE, 551 The Left LIBE, 552 S&D LIBE, 553 EPP LIBE, 38 Rapporteurs, 554 ID, 555 S&D ENVI, 556 RE, 557 The Left LIBE, 558 S&D, 559 EPP, 560 ECR LIBE, 561 The Left LIBE, 562 ECR, 563 S&D LIBE, 564 S&D ENVI, 39 Rapporteurs, 565 The Left LIBE, 566 Greens/EFA, 567 NI, 568 NI, 569 NI, 570 NI, 571 NA/ID ENVI, 572 S&D ENVI, 573 EPP, 574 The Left LIBE, 575 Greens/EFA, 576 EPP, 577 EPP, 578 RE, 579 The Left LIBE, 580 NI, 581 The Left LIBE, 582 The Left LIBE, 40 Rapporteurs, 583 RE, 584 Greens/EFA, 585 The Left LIBE, 586 EPP, 41 Rapporteurs, 587 The Left LIBE, 588 ECR LIBE, 589 The Left LIBE, 590 RE, 591 EPP, 592 Greens/EFA, 593 The Left LIBE, 594 S&D ENVI, 595 The Left LIBE, 42 Rapporteurs, 596 NI, 597 EPP, 600 Greens/EFA, 605 EPP, 607 S&D ENVI, 609 EPP ENVI Rapporteur, 610 NI, 611 EPP, 612 S&D ENVI, 614 EPP, 615 S&D ENVI, 616 EPP, 618 RE, ITRE 21, ITRE 22, ITRE 23, IMCO 19, IMCO 20, IMCO 21, IMCO 22, IMCO 23, IMCO 24, IMCO 25, IMCO 26.

## *Article 2*

### *Definitions*

1. For the purposes of this Regulation, *the (500 The Left)* following definitions shall apply:
  - (a) the definitions in Regulation (EU) 2016/679;
  - (b) the definitions of ‘healthcare’, ‘Member State of affiliation’, ‘Member State of treatment’, ‘health professional’, ‘healthcare provider’, ‘medicinal product’ and ‘prescription’, pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU;
  - (c) the definitions of ‘data’, ‘access’, ‘data altruism’, ‘public sector body’ and ‘secure processing environment’, pursuant to Article 2 (1), (8), (10), (11) and (14) of *Regulation (EU) 2022/868 (33 Rapporteurs)* [~~Data Governance Act COM/2020/767 final~~];
  - (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’, ‘risk’, ‘recall’ and ‘withdrawal’, pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020;
  - (e) the definitions of ‘medical device’, ‘intended purpose’, ‘instructions for use’, ‘performance’, ‘health institution’ and ‘common specifications’, pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;



- (f) the definitions of ‘electronic identification’, ‘electronic identification means’ and ‘person identification data’ pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.

2. In addition, for the purposes of this Regulation the following definitions shall apply:

- (a) ‘personal electronic health data’ means data concerning health and genetic data as defined in Regulation (EU) 2016/679, [~~as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, ]~~ **(508 EPP LIBE, 507 EPP, 506 S&D LIBE, 509 RE, 505 RE, 511 Greens, 504 The Left LIBE) that are processed in an electronic form;**
- (b) ‘non-personal electronic health data’ means data concerning health and **aggregated** genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679; **where personal and non-personal data in a data set are inextricably linked, the entire dataset shall be processed as personal electronic health data; (514 Greens/EFA, 512 The Left LIBE)**
- (c) ‘electronic health data’ means personal or non-personal electronic health data;
- (d) ‘primary use of electronic health data’ means the processing of ~~personal~~ electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;
- (e) ‘secondary use of electronic health data’ means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of **Chapter IV of this Regulation** ~~the secondary use;~~ **(36 Rapporteurs, 526 RE (partially), 532 Greens/EFA, 528 ID (partially))**
- (f) ‘interoperability’ means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;
- (g) ‘European electronic health record exchange format’ means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;
- (h) ‘registration of electronic health data’ means the recording of health data in an electronic format, through manual entry of data, through the collection of 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];
- (i) ‘electronic health data access service’ means an online service, such as a portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health

data of those natural persons whose electronic health data they are legally authorised to access;

- (j) ‘health professional access service’ means a service, supported by an EHR system, that enables health professionals to access data of natural persons under their *care (541 S&D ENVI (partially) treatment*;
- (k) ‘*health (544 RE, 543 The Left LIBE) data recipient*’ means *recipient as defined in Article 4(9) of Regulation (EU) 2016/679*, ~~a natural or legal person that receives data from another controller~~ in the context of the primary use of electronic health data;
- (l) [‘telemedicine’ means the provision of healthcare services, [including remote care ~~and online pharmacies,~~] through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location; (546 EPP, 547 ECR)]\*
- (m) ‘EHR’ (electronic health record) means a collection of electronic health data *(553 EPP LIBE)* related to a natural person and collected in the health system, processed for *the purpose of the provision of healthcare services (37 Rapporteurs, 549 S&D ENVI (partially), 552 S&D LIBE, 550 RE, 551 The Left LIBE)* purposes;
- (n) ‘EHR system’ (electronic health record system) means any ~~appliance~~ *product (hardware or software) primarily (38 Rapporteurs, 555 S&D ENVI, 556 RE, 557 The Left LIBE, 559 EPP)* intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records *between health professionals (556 RE) [or that can be reasonably expected by the manufacturer to be used for these purposes (555 S&D ENVI)]*;
- (o) ~~‘wellness application’ means any appliance or software intended by the manufacturer to be used by a natural person for processing *personal* electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life styles; notably for informing on, managing, maintaining, and improving health of a natural person;~~
- (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 legislation providing for its affixing;
- (q) ‘serious incident’ means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, ~~might have~~ *has* led or ~~might~~ *is likely to (39 Rapporteurs, 565 The Left LIBE (partially))* lead to any of the following:
  - (i) the death of a natural person or serious damage to a natural person’s health *or rights*;
  - (ii) a serious disruption of the management and operation of critical infrastructure in the health sector;
- (r) ‘national contact point for digital health’ means an organisational and technical gateway for the provision of cross-border digital health information services for

primary use of electronic health data, under the responsibility of the Member States;

- (s) ‘central platform for digital health’ means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health;
- (t) ‘MyHealth@EU’ means the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the central platform for digital health;
- (u) ‘national contact point for secondary use of electronic health data’ means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;
- (v) ‘central platform for secondary use of electronic health data’ means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;
- (x) ‘HealthData@EU’ means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;
- (y) ‘**health** data holder’ means any natural or legal person, which is an entity or a body in the health , **social security**, care sector **or reimbursement services**, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies, **and which**, in accordance with this Regulation, applicable Union law or national legislation implementing Union law,
  - (i) **is a controller as set out in Regulation (EU) 2016/679 and has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, to process personal electronic health data; or**
  - (ii) **has the ability to make available, including to register, provide, restrict access or exchange** ~~in the case of non-personal electronic health data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;~~
- (za) ~~‘health data applicant’ means a natural or legal person who has submitted a data access application for access to electronic health data for secondary use in accordance with this Regulation; (41 Rapporteurs, 587 The Left LIBE)~~ **means any natural or legal person with a demonstrable professional link to the areas of health care, public health or medical research, who submitted the application; (RE 1724 and Greens 1725 adapted)**
- (z) ‘**health** data user’ means a natural or legal person **as well as Union institutions, bodies, offices and agencies**, who has **been granted** lawful access, **in accordance with this Regulation, (583 RE)** ~~to personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit [or a health data request]; (40 Rapporteurs, 584 Greens, 585 The Left LIBE, 586 EPP)**
- (aa) ‘**health** data permit’ means an administrative decision issued to a data user by a health data access body [or data holder] to process the electronic health data

specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in this Regulation; (*590 RE, 589 The Left LIBE*)

- (ab) ‘dataset’ means a structured collection of electronic health data;
- (ac) ‘dataset catalogue’ means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;
- (ad) ‘data quality’ means the degree to which characteristics of electronic health data are suitable for secondary use;
- (ae) ‘data quality and utility label’ means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset;
- (af) ‘wellness application’ means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data specifically for *informing on*, managing, maintaining or improving health of individual persons, or the delivery of care.

## Chapter II

### Primary use of electronic health data

#### SECTION 1

Access to and transmission of personal electronic health data for primary use

#### COMPROMISE AMENDMENT 3: Article 3 + recitals 8 to 15

Replacing the following amendments: 44 to 49, 619 to 709

*44 Rapporteurs, 45 Rapporteurs, 46 Rapporteurs, 47 Rapporteurs, 48 Rapporteurs, 49 Rapporteurs, 619 Greens/EFA, 620 EPP LIBE, 621 S&D, 622 EPP, 623 EPP, 624 Greens/EFA, 625 EPP, 626 Greens/EFA, 627 ID, 628 ECR, 629 RE, 630 Greens/EFA, 631 The Left LIBE, 632 EPP, 633 S&D ENVI, 634 S&D, 635 S&D, 636 RE, 637 Greens/EFA, 638 S&D ENVI, 639 ECR, 640 The Left ENVI, 641 The Left LIBE, 642 RE, 643 RE, 644 S&D ENVI, 645 The Left LIBE, 646 ECR, 647 EPP LIBE, 648 Greens/EFA, 649 The Left ENVI, 650 RE, 651 The Left ENVI, 652 RE, 653 Greens/EFA, 654 S&D ENVI, 655 S&D, 656 RE, 657 EPP LIBE, 658 The Left LIBE, 659 EPP, 660 Greens/EFA, 661 ECR, 662 S&D ENVI, 663 RE, 664 The Left LIBE, 665 Greens/EFA, 666 EPP LIBE, 667 RE, 668 S&D ENVI, 669 ID, 670 S&D, 671 RE, 672 Greens/EFA, 673 S&D ENVI, 674 S&D ENVI, 675 The Left LIBE, 676 The Left LIBE, 677 The Left ENVI, 678 Greens/EFA, 679 RE, 680 S&D ENVI, 681 Greens/EFA, 682 S&D LIBE, 683 S&D, 684 EPP, 685 The Left LIBE, 686 ECR,*

687 *The left ENVI*, 688 *Greens/EFA*, 689 *Greens/EFA*, 690 *The Left LIBE*, 691 *S&D ENVI*, 692 *ECR*, 693 *S&D*, 694 *RE*, 695 *S&D LIBE*, 696 *EPP*, 697 *EPP*, 698 *EPP*, 699 *RE*, 700 *RE*, 701 *RE*, 702 *Greens/EFA*, 703 *S&D LIBE*, 704 *EPP*, 705 *The Left LIBE*, 706 *The Left LIBE*, 707 *S&D LIBE*, 708 *RE*, 709 *Greens/EFA*, *IMCO 27*

### Article 3

#### *Rights of natural persons in relation to the primary use of their personal electronic health data*

1. Natural persons shall have the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form.
2. Natural persons shall have the right to receive an electronic copy, in the European electronic health record exchange format referred to in Article 6, of ~~at least~~ their electronic health data, ***or upon request of the natural person, a printed copy thereof, in accordance with Article 15(3) of Regulation (EU) 2016/679. (624 Greens/EFA, 622 EPP, 625 EPP)*** ~~in the priority categories referred to in Article 5.~~
- 2a. ***The rights referred to in paragraphs 1 and 2 shall be deemed complementary to and be without prejudice to the rights and obligations established by Article 15 of Regulation (EU) 2016/679. (626 Greens/EFA)***
3. In accordance with ***paragraph 1, point (i) of Article 23 of Regulation (EU) 2016/679***, Member States may restrict the scope of ~~this right~~ ***rights referred to in this Article*** whenever necessary for the protection of the natural person based on patient safety and ethics by delaying their access to their personal electronic health data for a limited period of time until a health professional can properly communicate and explain to the natural person information that can have a significant impact on ***this person*** ~~his or her~~ health. ***(633 S&D ENVI, 629 RE, 630 Greens/EFA, 631 The Left LIBE, 632 EPP (partially))***
4. ~~Where the personal health data have not been registered electronically prior to the application of this Regulation, Member States may require that such data is made available in electronic format pursuant to this Article. This shall not affect the obligation to make personal electronic health data registered after the application of this Regulation available in electronic format pursuant to this Article. (636 RE, 635 S&D)~~
5. Member States shall:
  - (a) establish one or more electronic health data access services at national, regional or local level enabling the exercise of rights referred to in ***this Article*** paragraphs 1 and 2;
  - (b) establish one or more proxy services enabling a natural person to ***legally*** authorise other natural persons of their choice to access their electronic health data on their behalf ***for a specified or indeterminate period of time and if needed, for a specific purpose only, or enabling legal representatives of patients to access electronic health data of the natural persons whose affairs***

*they administer, in accordance with national law. (44 Rapporteurs, 647 EPP, 643 RE, 644 S&D ENVI, 645 the Left LIBE)*

The proxy services shall provide authorisations *in a transparent and easily understandable way*, free of charge, electronically or on paper. *Natural persons and those acting on their behalf shall be informed about what authorisation rights they have, how to exercise them, and what they can expect from the authorisation process. (650 RE)*

*The electronic health data access services as well as the proxy services shall be easily accessible for persons with disabilities, vulnerable groups or persons with low digital literacy. (650 RE)*

*The proxy services* They shall enable ~~guardians or other~~ *legal* representatives of *patients* to be authorised, either automatically or upon request, to access electronic health data of the natural persons whose affairs they administer *either for a specific purpose and time period or without limitation to administer their affairs*. Member States may provide that authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States. *(650 RE)*

*The proxy services shall provide an easy complaint mechanism with a contact point designated to inform individuals of a way to seek redress or remedy if they believe that their authorisation rights have been violated. (650 RE)*

5a. *In addition to the electronic services referred to in this Article, Member States shall also establish easily accessible support services for natural persons with adequately trained staff dedicated to assist them with exercising their rights referred to in this Article.*

6. Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services ~~or~~ *and* applications linked to these services. That information shall be marked as inserted by the natural person or by ~~their legal~~ representative *and as non-validated. That information shall only be considered as a clinical fact if validated by a health professional. (657 EPP LIBE (partially), 654 S&D ENVI (partially), 656 RE, 653 Greens/EFA (partially)) Without prejudice to the right to insert data, health professionals shall not be obliged to validate any inserted data in the EHR.*

6a. *Natural persons shall have the right to download their electronic health data from their own EHR or of natural persons whose health information they can access through electronic health data access services and applications linked to these services. (657 EPP LIBE, 654 S&D ENVI, 658 The Left LIBE (partially), 659 EPP)*

7. ~~Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679, natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article~~

*Member States shall ensure that electronic health data services referred to in paragraph 5, point (a), of this Article allow for the possibility for natural person to easily request rectification of their personal data online as a way to exercise their right to rectification under Article 16 of Regulation (EU) 2016/679. ~~natural persons~~*

~~can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article. In accordance with Article 16 of Regulation (EU) 2016/679, Natural persons shall not have the possibility to directly change data inserted by health professionals. (657 EPP LIBE (partially), 654 S&D ENVI, 656 RE, 653 Greens, 658 The Left LIBE (partially), 659 EPP). Such rectifications of clinical facts shall be validated, without undue delay, by a registered healthcare professional of relevant specialisation responsible for the natural person's treatment. The original data holder shall be responsible for the rectification. (662 S&D ENVI, 663 RE, 660 Greens)~~

8. Natural persons shall have the right to ~~give access to or~~ request a **health** data holder from the health or social security sector **or reimbursement services**, to transmit **all or part of** their electronic health data to a **health** data recipient of their choice from the health or social security sector **or reimbursement services**, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder. **The health data recipient shall be clearly identified by the natural persons to the health data holder and their affiliation to the health or social security sector shall be demonstrated. Health data holders and their processors shall comply with the request and shall transmit the data in the format provided for in Article 5. (46 Rapporteurs, 666 EPP LIBE, 668 S&D ENVI, 667 RE (partially), 671 RE, 726 RE, 665 Greens, 664 The Left LIBE, 669 ID)**

Natural persons shall have the right that, where the **health** data holder and the **health** data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the **health** data holder shall transmit the data in the European electronic health record exchange format referred to in Article 6 and the **health** data recipient shall read and accept it.

By way of derogation from Article 9 of Regulation [...] [Data Act COM/2022/68 final], the **health** data recipient shall not be required to compensate the **health** data holder for making electronic health data available. **A health data holder, a health data recipient or a third party shall not directly or indirectly charge data subjects a fee, compensation or costs for sharing data or accessing it. (672 Greens/EFA).**

Natural persons shall have the right that, where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers. **(674 S&D ENVI)**

9. ~~Without prejudice to~~ ~~Notwithstanding~~ Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of **specific (679 RE)** health professionals **or categories of health professionals** to all or part of their electronic health data. **When restricting the information, natural persons shall be made aware that restricting access may impact the provision of healthcare provided to them. These restrictions shall apply also for cross-border transfers of electronic health data. The fact that a restriction has been made by the natural person shall not be visible to healthcare providers. (47 Rapporteurs, 682 S&D LIBE (partially), 679 RE, 681 Greens/EFA, 685 The Left LIBE (partially))**

Member States shall establish the rules and specific safeguards regarding such restriction mechanisms. *Those rules shall include the possibility to modify restrictions and to restrict access to anyone except the health professional who inserted the electronic health data. Those rules shall also establish the conditions of medical liability as a consequence of applying restrictions to electronic health data. The Commission shall establish guidelines regarding the implementation of this paragraph (680 S&D ENVI (partially), 679 RE, 687 The Left ENVI (partially), 684 EPP, 683 S&D (partially))*

10. Natural persons shall have the right to *obtain information, including through automatic notifications*, on the healthcare providers and health professionals that have accessed their electronic health data ~~in the context of healthcare~~ , *including access provided in accordance with Article 4(4) and on the substance of the accessed data. Natural persons shall have the possibility to disable those notifications. In order to demonstrate compliance with this right, all relevant entities shall maintain a system of automated recording for at least three years showing who and when has accessed electronic health data.* The information shall be provided immediately and free of charge through electronic health data access services. *Member States may provide for restrictions to this right 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. (48 Rapporteurs, 695 S&D LIBE (partially), 691 S&D ENVI, 694 RE (partially), 689 Greens, 690 The Left LIBE (partially), 696 EPP, 697 EPP, 693 S&D, 699 RE, 692 ECR).*
11. The supervisory authority or authorities responsible for monitoring the application of Regulation (EU) 2016/679 shall also be responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. ~~They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation may, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.~~
12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this Article, *including technical and organisational measures to ensure the process of authentication of the authorised person referred to in point (b) of paragraph 5.* Those implementing acts shall be adopted in accordance with the *examination* procedure referred to in Article 68(2a). *(49 Rapporteurs, 707 S&D LIBE (partially), 708 RE, 706 The Left LIBE)*
- 12 a. *Member States, including regional and local authorities, shall provide easily understandable information to natural persons in relation to the use of the electronic health records and primary use of their personal electronic health data laid down in this Article. Such guidance shall take into account different user groups, including persons with disabilities and vulnerable groups, without compromising the quality and the scope of the information. (709 Greens)*

<b>COMPROMISE AMENDMENT 4: Article 4 + recital 16</b>
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Replacing the following amendments: 50-51, 710 to 749

**50 Rapporteur, 51 Rapporteurs, 710 The Left LIBE, 711 RE, 712 Greens/EFA, 713 RE, 714 S&D ENVI, 715 EPP LIBE, 716 S&D LIBE, 717 The Left LIBE, 718 S&D ENVI, 719 ECR, 720 EPP LIBE, 721 RE, 722 The Left LIBE, 723 Greens/EFA, 724 ECR, 725 S&D LIBE, 726 RE, 727 EPP, 728 RE, 729 Greens/EFA, 730 RE, 731 S&D ENVI, 732 EPP, 733 ECR, 734 S&D LIBE, 735 EPP ENVI Rap, 736 ECR, 737 The Left LIBE, 738 EPP, 739 EPP ENVI Rap, 740 ECR, 741 S&D, 742 RE, 743 RE, 744 Greens/EFA LIBE, 745 EPP, 746 EPP LIBE, 747 Greens/EFA, 748 The Left LIBE, 749 S&D, 750**

#### Article 4

##### *Access by health professionals to personal electronic health data*

1. ***Access to EHR for primary use shall be strictly limited to healthcare providers.***
  - 1a. Where they process data in an electronic format, health professionals shall:
    - (a) have access, ***based on the data minimisation and purpose limitation principles***, to the electronic health data of natural persons under their treatment ***and exclusively for that purpose, including relevant administration***, irrespective of the Member State of affiliation and the Member State of treatment, ***in accordance with Article 9(2)(h) of Regulation 2016/679 ( 715 EPP LIBE, 716 S&D LIBE, 714 S&D ENVI, 713 RE, 712 Greens/EFA (partially), 717 The Left LIBE)***;
    - (b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.
  2. In line with the data minimisation ***and purpose limitation*** principles provided for in Regulation (EU) 2016/679, Member States ***shall*** establish rules providing for the categories of personal electronic health data required by different ***categories of*** health professions ***or different healthcare tasks***. Such rules shall not be based on the source of electronic health data. ***(50 Rapporteurs, 720 EPP LIBE, 725 S&D LIBE, 721 RE (partially), 723 Greens/EFA, 722 The Left LIBE, 724 ECR)***
  - 2a. ***In the case of treatment in a Member State other than the Member State of affiliation, the rules referred to in paragraph 1a and 2 of the Member States of treatment apply. (728 RE)***
  - 2b. ***The Commission shall issue guidelines for the implementation of paragraphs 1, 2 and 2a, including time limitations for the access of electronic health data of natural persons by health professionals.***
3. Member States ***and, where appropriate, local or regional authorities*** shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals, ***including for cross-border care***, through health professional access services, ***where the processing of health data is necessary and for the purposes of Article 9(2)(h) of Regulation 2016/679***. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge ***(51 Rapporteurs, 735 ENVI Rapporteur, 731 S&D ENVI, 734 S&D LIBE, 729 Greens, 737 The Left LIBE, 733 EPP, 736 ECR)***

***The electronic health data in the electronic health records shall be structured in a user-friendly manner to allow for an easy use by health professionals. (730 RE)***

- 3a. *Member States shall establish policies aimed at providing health professionals with the digital skills, competences, infrastructures and tools required to fulfill the obligations set out in paragraph 1 of this Article. (739 ENVI Rapporteur, 727 EPP, 732 EPP, 738 EPP)*
4. Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the *restricted* content of the electronic health data without prior *explicit consent pursuant to Article 9(2)(a) of Regulation (EU) 2016/679* by the natural person. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person or, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards. *(746 EPP LIBE, 743 RE, 744 Greens LIBE, 747 Greens, 748 The Left LIBE, 745 EPP, 741 S&D (partially), 749 S&D, 742 RE)*

#### COMPROMISE AMENDMENT 5: Article 5 + recital 17

Replacing the following amendments: 52-54 Rapporteurs, 751 S&D, 752 ECR, 753 ECR, 754 ECR, 755 RE, 756 EPP, 757 RE, 759 EPP, 760 EPP, 761 RE, 762 EPP, 763 S&D, 764 LEFT, 765 S&D, 766 LEFT, 767 S&D, 768 Greens/EFA, 769 ECR, 770 LEFT, 771 Greens/EFA, 772 S&D, 773 LEFT, 774 RE, 775 ECR, 776 RE, 777 RE, 778 RE, 779 EPP, 780 LEFT

#### *Article 5*

##### *Priority categories of personal electronic health data for primary use*

1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories *making use of the International Classification of Diseases (ICD) codes, where applicable:*
  - (a) patient summaries
  - (b) electronic prescriptions ;
  - (c) electronic dispensations;
  - (d) medical images and image reports;
  - (e) laboratory results , *medical test results and other complementary and diagnostic (RE 758);*
  - (f) *patient* discharge reports; *(Rapporteurs 52, RE 761)*
  - (fa) medical directives of the natural persons and information about consent for substances of human origin and organ donations. (RE 755)*

The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I **and limited to those categories**.

**Member States may by law enable (Greens 768, ECR 769) access to and exchange of electronic health data for primary use ~~may be enabled~~ for other categories of personal electronic health data available in the EHR of natural persons.**

2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to ~~amend the list of priority categories of electronic health data in paragraph 1. Such delegated acts may also amend Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data, as laid down in paragraph 1. and indicating, where relevant, deferred application date.~~ The categories of electronic health data added through such delegated acts shall satisfy the following criteria:
- (a) ~~the category is relevant for health services provided to natural persons;~~
  - (b) ~~according to the most recent information, the category is used in a significant number of EHR systems used in Member States;~~
  - (c) ~~international standards exist for the category that have been examined for the possibility of their application in the Union. (RE 774) (partially Greens 771, S&D 772 LIBE, The Left ENVI 773)~~

## COMPROMISE AMENDMENT 6: Article 6 + recital 18-19

Replacing the following amendments:

**55 Rapporteurs, 781 The Left LIBE, 782 EPP, 783 Greens/EFA, 784 EPP, 785 S&D ENVI, 786 The Left ENVI, 787 RE, 788 RE, 789 RE, 790 S&D ENVI, 791 ECR, 792 S&D, 793 RE, 794 The Left LIBE, IMCO 29**

### Article 6

#### *European electronic health record exchange format*

1. 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 5, setting out the European electronic health record exchange format, **taking into account its Recommendation EU 2019/243 on a European Health Record Format**. The format shall include the following elements:
- (a) **harmonised** datasets containing electronic health data and defining structures, such as **minimum** data fields and data groups for the content representation of clinical content and other parts of the electronic health data, **which can be enlarged to include disease-specific data; (55 Rapporteurs, 785 S&D ENVI, 787 RE, 786 the Left ENVI)**
  - (b) coding systems and values to be used in datasets containing electronic health data;
  - (c) technical **interoperability** specifications for the exchange of electronic health data, including its content representation, standards and profiles, **and for the**

*translation of electronic health data (54 Rapporteurs, 780 The Left covered; partially: 790 S&D ENVI, 793 RE, 791 ECR).*

*The Commission shall ensure that those implementing acts contain the latest versions of healthcare coding systems and nomenclatures and that they are updated regularly in order to keep up with the revisions of the healthcare coding systems and nomenclatures. (AM 788)*

2. Those implementing acts shall be adopted in accordance with the *examination* advisory procedure referred to in Article 68(2a). ~~Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.~~
3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1 *across the continuum of care* and such data shall be read and accepted by the data recipient. (792 S&D)

#### **COMPROMISE AMENDMENT 7: Article 7 + recital 20**

Replacing the following amendments: 56 Rapporteurs, , 795 S&D, 796 S&D, 797 S&D, 798 Greens/EFA, 799 RE, 800 Greens/EFA, 801 S&D, 802 RE, 803 RE, 804 Greens/EFA, 805 The Left, 806 S&D, 807 The Left, 808 RE, 809 Greens/EFA, 810 The Left, 811 RE, 812 Greens/EFA, 813 The Left, 814 The Left, 815 Greens/EFA, 816 S&D, 817 S&D

#### *Article 7*

##### *Registration of personal electronic health data*

1. Member States shall ensure that, where *health* data is processed ~~in electronic format~~, health professionals ~~systematically~~ register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in the electronic format in an EHR system. **(797 S&D LIBE, 798 Greens/EFA). Member States shall provide support to healthcare providers in fulfilling these tasks.**
2. Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.
3. The Commission ~~shall, by means of implementing~~ *adopt delegated* acts; *in accordance with Article 67* to determine the *data quality* requirements for the *electronic* registration of ~~electronic~~ health data by healthcare providers and natural persons, as relevant. ~~Those implementing acts shall establish the following:~~ **(806 S&D ENVI, 803 RE (partially), 804 Greens/EFA, 805 The Left LIBE (partially))**
  - ~~(a) categories of healthcare providers that are to register health data electronically;~~
  - ~~(b) categories of health data that are to be registered systematically in electronic format by healthcare providers referred to in point (a);~~

(e) — data quality requirements pertaining to the electronic registration of health data. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

*When health data is registered or updated, electronic health records must identify the health professional, time and health care provider of the registration (AM 817, S&D ENVI). Member States may by law enable other aspects of data registration to be recorded.*

- 3a. *Where the personal health data have not been registered electronically prior to the application of this Regulation, Member States may require that such data is made available in electronic format pursuant to this Article. This shall not affect the obligation to make personal electronic health data, registered after the application of this Regulation, available in electronic format, pursuant to this Article. (AM 799, Renew)*

### **COMPROMISE AMENDMENT 8: Article 8 + recital 21**

Replacing the following amendments: 57 Rapporteurs, 818 ECR, 819 ECR, 820 The Left, 821 EPP, 822 ECR, 823 Greens/EFA, 824 The Left, 825 S&D, 826 S&D, 827 RE

#### *Article 8*

##### *Telemedicine in the context of cross-border healthcare*

Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions **and in a non-discriminatory manner**, accept the provision of the services of the same type by healthcare providers located in other Member States, **without prejudice of the same rights and obligations to access and register electronic health data.** (Rapporteurs AM 57, AM 826 S&D ENVI (partially), 827 RE)

### **COMPROMISE AMENDMENT 9: Article 9 + recital 22**

Replacing the following amendments: 828 RE, 829 Greens/EFA, 830 RE, 831 RE, 832 RE, 833 Greens/EFA, 834 the Left, 835 S&D, 836 S&D, 837 Greens/EFA, 838 Greens/EFA, ITRE 24, ITRE 25, ITRE 26

#### *Article 9*

##### *Identification management*

1. Where a natural person **or a health professional** uses [telemedicine services or] personal health data access services referred to in Article 3(5), point (a), **Article 4(3) and where applicable, Article 8** that natural person **or health professional** shall have the right to identify electronically using any electronic identification means which is recognised pursuant to Article 6 of Regulation (EU) No 910/2014, **including eID schemes where such systems are offered.**

2. The Commission shall, ~~by means of implementing~~ **adopt delegated** acts, **in accordance with Article 67** to 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 ~~as amended by [COM(2021)281 final]~~. The mechanism shall facilitate the transferability of electronic health data in a cross-border context.
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 digital health infrastructure referred to in Article 12(3).
4. **Member States' competent** ~~digital health~~ authorities and the Commission shall implement the cross-border identification and authentication mechanism at Union and Member States' level, respectively, **in accordance with Regulation (EU) No 910/2014 as amended by [COM(2021) 281 final]. (838 Greens)**

<p><b>COMPROMISE AMENDMENT 10: Article 10 + recital 23</b></p>
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Replacing the following amendments: 58-61 Rapporteurs, 839 S&D, 840 Greens/EFA, 841 ID, 842 RE, 843 S&D, 844 NA, 845 Greens/EFA, 846 EPP, 847 EPP, 848 S&D, 849 Greens/EFA, 850 ECR, 851 Greens/EFA, 852 Greens/EFA, 853 S&D, 854 RE, 855 S&D, 856 S&D, 857 EPP, 858 Greens/EFA, 859 The Left, 860 RE, 861 EPP, 862 Greens/EFA, 863 The Left, 864 Greens/EFA, 865 Greens/EFA, 866 ECR, 867 Greens /EFA, 868 RE, 869 S&D, 870 the Left, 871 Greens/EFA, 872 RE, 873 the Left, 874 S&D, 875 Greens/EFA, 876 S&D, 877 the Left, 878 The Left, 879 RE, 880 Greens/EFA, 881 the Left, 882 S&D, 883 Greens/EFA, 884 EPP, 885 EPP, 886 RE, 887 EPP, 888 RE, 889 ECR, 890 ID, 891 The Left, 892 the Left, 893 RE, 894 EPP, IMCO 30, ITRE 27

*Article 10*

*Digital health authority*

1. Each Member State shall designate a digital health authority responsible for the implementation and enforcement of this Chapter at national level. The Member State shall communicate the identity of the digital health authority to the Commission by the date of application of this Regulation. Where a designated digital health authority is an entity consisting of multiple organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.
2. Each digital health authority shall be entrusted with the following tasks **and powers (840 Greens)**:
  - (a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;
  - (b) ensure that complete and up to date information about the implementation of rights and obligations provided for in in Chapters II and III is made readily available to natural persons, health professionals and healthcare providers **and**

*that appropriate training initiatives are undertaken at the local, regional and national level (843 S&D);*

- (c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;
- (d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise their rights and obligations set out in this Chapter;
- (e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council<sup>18</sup>.
- (f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;
- (g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;
- (h) contribute, at Union level, **and, where relevant, in cooperation with the local and regional level within the Member States (847 EPP)**, to the development of the European electronic health record exchange format and to the elaboration of common specifications addressing **quality**, interoperability, security, safety, **ease of use, accessibility, non-discrimination (849 Greens)** or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;
- (i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;
- (j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity building activities at Union level;
- (k) offer, in compliance with national legislation, telemedicine services and ensure that such services are easy to use, accessible **and equitable (853 S&D)** to different groups of natural persons and health professionals, including natural persons with disabilities, **under the same non-discriminatory conditions (854 Renew) do not discriminate** and offer the possibility of choosing between in person and digital services;
- (l) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;
- (m) cooperate with other relevant entities and bodies at **local, regional**, national or Union level, to ensure interoperability, data portability and security of electronic health data, ~~as well as with stakeholders representatives, including patients<sup>2</sup>~~

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<sup>18</sup> Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)

~~representatives, healthcare providers, health professionals, and industry associations; (858 Greens partially, Rapporteurs, 857 EPP, 859 The Left, EPP 861)~~

- (n) cooperate with supervisory authorities in accordance with Regulation (EU) 910/2014, Regulation (EU) 2016/679 and Directive (EU) 2016/1148 of the European Parliament and of the Council<sup>19</sup> with other relevant authorities, including those competent for cybersecurity, electronic identification, the European Artificial Intelligence Board, the Medical Device Coordination Group, the European Data Innovation Board and the competent authorities under Regulation [...] [Data Act COM/2022/68 final];
- (o) draw up, in collaboration where relevant with market surveillance authorities, an annual activity report, which shall contain a comprehensive overview of its activities. The report shall be transmitted to the Commission. The annual activity report shall follow a structure that is agreed at Union level within EHDS Board, to support benchmarking pursuant to Article 59. The report shall contain at least information concerning:
  - (i) measures taken to implement this Regulation;
  - (ii) percentage of natural persons having access to different data categories of their electronic health records;
  - (iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;
  - (iv) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;
  - (v) volumes of electronic health data of different categories shared across borders through MyHealth@EU;
  - (vi) level of natural person satisfaction with MyHealth@EU services;
  - (vii) number of certified EHR systems and labelled wellness applications enrolled in the EU database;
  - (viii) number of non-compliance cases with the mandatory requirements;
  - (ix) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;

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<sup>19</sup> **DIRECTIVE (EU) 2016/1148 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 JULY 2016 CONCERNING MEASURES FOR A HIGH COMMON LEVEL OF SECURITY OF NETWORK AND INFORMATION SYSTEMS ACROSS THE UNION (OJ L 194, 19.7.2016, P. 1).**



- (x) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.
- ~~3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by entrusting the digital health authorities with additional tasks necessary to carry out the missions conferred on them by this Regulation and to modify the content of the annual report.~~
- 3a. The digital health authorities and the data protection authorities shall consult each other and cooperate in the enforcement of this Regulation, within the remit of their respective competences. (874 S&D LIBE, 872 RE, 59 Rapporteurs, 873 The Left)**
4. 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.
5. Members of the digital health authority shall avoid any conflicts of interest. **Members shall not have financial or other interests in industries or economic activities which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to such industries or economic activities shall be entered in a register available to the public, upon request. The Commission may adopt guidance on what is likely to constitute a conflict of interests together with the procedure to be followed in such cases. (60 Rapporteurs)**
- 5a. In the performance of its tasks, the digital health authorities shall actively cooperate and consult with relevant stakeholders' representatives, including patients' representatives, health care providers and health professionals' representatives, including health professional associations, consumer organisations and industry associations (882 S&D ENVI, 888 RE (partially), 886 RE (partially), 889 ECR, 858 Greens partially, Rapporteurs, 857 EEP, 859 The Left, EPP 861). Stakeholders shall declare any conflict of interests. (61 Rapporteurs, 894 EPP, 893 RE)**

## COMPROMISE AMENDMENT 11: Article 11

Replacing the following amendments: 62-63 Rapporteurs, 895 RE, 896 S&D, 897 Greens/EFA, 898 RE, 899 The Left, 900 RE, 901 RE, 902 ECR, 903 S&D, 904 RE, 905 S&D, 906 The Left

### Article 11

#### *Right to lodge a complaint with a digital health authority*

1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority, **where their rights laid down in this Regulation are affected**. Where the complaint concerns the rights of natural persons pursuant to Article 3 of this Regulation **or Regulation (EU) 2016/679**, the digital health authority shall ~~inform~~ **send a copy of the complaint to and consult with the competent supervisory authority under Regulation (EU) 2016/679 in order to facilitate its assessment and investigation. The decision of the digital health**

*authority shall not prejudice any measures taken by the data protection authorities, which shall be competent to treat the complaint in a separate proceeding, pursuant to their tasks and powers under Regulation (EU) 2016/679. (62 Rapporteurs, 896 S&D LIBE, 895 RE (partially), 897 Greens/EFA, 899 The Left LIBE, 898 RE, 902 ECR)*

2. The digital health authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken, *including where applicable that the complaint was referred to the relevant supervisory authority under Regulation (EU) 2016/679, and that the supervisory authority will, from that time on, be the sole point of contact for the complainant in that matter. (900 RE)*
3. Digital health authorities shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.
- 3a. *Each digital health authority shall facilitate submitting complaints, in particular by providing a complaint submission form which can also be completed electronically, without excluding other means of communication.*

#### *Article 11a*

##### *Right to an effective judicial remedy against a digital health authority*

1. *Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a digital health authority concerning them.*
2. *Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy where the digital health authority which is competent pursuant to Article 10 does not handle a complaint or does not inform the natural or legal person within three months on the progress or outcome of the complaint lodged pursuant to Article 11.*
3. *Proceedings against a digital health authority shall be brought before the courts of the Member States where the digital health authority is established. (63 Rapporteurs, 905 S&D LIBE, 906 The Left LIBE)*

#### **COMPROMISE AMENDMENT 12: Article 12**

Replacing the following amendments: 64-65, 907 ID, 908 Greens/EFA, 909 The Left, 910 NA, 911 NA, 912 the Left, 913 NA, 914 The Left, 915 The Left, 916 Greens/EFA, 917 S&D, 918 S&D, 919 RE, 920 EPP, 921 S&D, 922 S&D, 923 EPP, 924 RE, 925 ECR, 926 EPP, 927 ECR, 928 NA, 929 NA, 930 The Left, 931 ECR, 932 ECR, 933 ECR, IMCO 31

## SECTION 2

### CROSS-BORDER INFRASTRUCTURE FOR PRIMARY USE OF ELECTRONIC HEALTH DATA

#### *Article 12*

#### *MyHealth@EU*

1. The Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States.
2. Each Member State shall designate one national contact point for digital health to ensure the connection to all other national contact points for digital health and to the central platform for digital health. Where a designated national contact point is an entity consisting of multiple organisations responsible for implementing different services, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The national contact point for digital health shall be considered an authorised participant in the infrastructure. Each Member State shall communicate the identity of its national contact point to the Commission by [*the date of application of this Regulation*]. Such contact point may be established within the digital health authority established by Article 10 of this Regulation. Member States shall communicate to the Commission any subsequent modification of the identity of those contact points. The Commission and the Member States shall make this information publicly available.
3. Each national contact point for digital health shall enable the exchange of the personal electronic health data referred to in Article 5 with all other national contact points. The exchange shall be based on the European electronic health record exchange format.
4. 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 electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the *examination* ~~advisory~~ procedure referred to in Article 68(2a). ***The implementing act shall include the target implementation dates, including for cross border health data interoperability, in consultation with the EHDS board. (Rapporteurs AM 64, S&D AM 918) The European Union Agency for Cyber Security shall be consulted and closely involved in all steps of the examination procedure. Any measures adopted shall meet the highest technical standards in terms of security, confidentiality and protection of electronic health data. (The Left AM 915, Greens AM 916, S&D 917, Renew AM 919, EPP LIBE AM 920)***
5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.

6. Member States shall ensure that pharmacies operating on their territories, including online pharmacies, are enabled to dispense electronic prescriptions issued by other Member States, under the conditions laid down in Article 11 of Directive 2011/24/EU. The pharmacies shall access and accept electronic prescriptions transmitted to them from other Member States through MyHealth@EU, ***granted that the requirements in Article 11 of Directive 2011/24/EU are fulfilled (EPP LIBE AM 923, Renew AM 924)***. Following dispensation of medicinal products based on an electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.
7. The national contact points for digital health shall act as joint controllers of the electronic health data communicated through ‘MyHealth@EU’ for the processing operations in which they are involved. The Commission shall act as processor.
8. The Commission shall, by means of implementing acts, allocate responsibilities among controllers and as regards the processor referred to in paragraph 7 of this Article, in accordance with Chapter IV of Regulation (EU) 2016/679 ***and of Regulation (EU) 2018/1725 (Rapporteurs AM 65)***. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).
9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be issued by the Joint Controllershship group, based on the results of the compliance checks.

## **COMPROMISE AMENDMENT 13 - ART 13**

Replacing the following amendments: 66, 934 ECR, 935 NA, 936 S&D, 937 RE, 938 ECR, 939 S&D, 940 S&D, 941 Greens/EFA, 942 NA, 943 RE, 944 ECR

### *Article 13*

#### *Supplementary cross-border digital health services and infrastructures*

1. Member States may provide through MyHealth@EU supplementary services that facilitate telemedicine, mobile health, access by natural persons to their translated 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 provision. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).
2. The Commission and Member States may facilitate the exchange of 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 to 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 advisory procedure referred

to in Article 68(2). The connection of another infrastructure to the central platform for digital health shall be subject to a decision of the joint controllership group for MyHealth@EU referred to in Article 66.

3. ~~Member States and the Commission shall seek to ensure interoperability of MyHealth@EU with technological systems established at international level for the exchange of electronic health data. The Commission may adopt *a delegated* act establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of MyHealth@EU for the purposes of the electronic health data exchange. Before adopting such *a delegated* act, a compliance check of the national contact point of the third country or of the system established at an international level shall be performed under the control of the Commission,~~

~~The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the procedure referred to in Article 68. The connection of the national contact point of the third country or of the system established at an international level to the central platform for digital health, as well as the decision to be disconnected shall be subject to a decision of the joint controllership group for MyHealth@EU referred to in Article 66.~~

~~The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.~~

## **COMPROMISE AMENDMENT 14: TITLE OF CHAPTER + ARTICLE 14**

Compromise amendment replacing Amendment(s): 945 (ECR), 946 (The LEFT), 947 (Greens/EFA), 948 (EPP), 949-950 (Greens/EFA), IMCO 33, IMCO 34

### **Chapter III**

## **EHR systems and wellness applications**

### **SECTION 1**

#### **GENERAL PROVISIONS FOR EHR SYSTEMS**

##### *Article 14*

*Interplay with legislation governing medical devices and AI systems*

1. EHR systems intended by their manufacturer for primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter.
2. This Chapter shall not apply to general software used in a healthcare environment ***that do not claim interoperability with EHR systems. (948)***
3. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.
4. ***Notwithstanding the obligations laid down in Regulation [AI act COM/2021/206 final]***, providers of high-risk AI systems as defined in Article 6 of Regulation [...] [AI act COM/2021/206 final], which ***does do*** not fall within the scope of Regulation (EU) 2017/745, that claim interoperability of those AI systems with EHR systems will need to prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk AI systems.
5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.

## COMPROMISE AMENDMENT 15: ARTICLE 15

Compromise amendment replacing Amendment(s): 951 (Renew), 952 (ECR), 953 (S&D), 954 (The LEFT), 955 (S&D), 956 (Greens/EFA), IMCO 35

### *Article 15*

#### *Placing on the market and putting into service*

1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in section 3 of this Chapter ***and in Annex II (956)***.
2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the meaning of Article 1(1), point (b), of

Directive (EU) 2015/1535 of the European Parliament and of the Council<sup>20</sup> to a natural or legal person established in the Union shall be considered as having been put into service.

## COMPROMISE AMENDMENT 16: ARTICLE 16

Compromise amendment replacing Amendment(s): 67-69 (Rapporteurs), 957 (The LEFT), IMCO 36, IMCO 37

### *Article 16*

#### *Claims*

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 under Regulation (EU) 2018/1807 (67)** with regard to its intended purpose, interoperability and security by:

- (a) ascribing functions and properties to the EHR system which it does not have;
- (b) failing to inform the **professional (68)** user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose;
- (c) suggesting uses for the EHR system other than those stated in the technical documentation to form part of the intended purpose.

## COMPROMISE AMENDMENT 17: ARTICLE 17

Compromise amendment replacing Amendment(s): 958 (ID), 959-960 (Renew), 961 (EPP), 962 (S&D), 963-964 (Greens/EFA), 965-966 (S&D), 968 (Greens/EFA), 969 (S&D), 970 (Greens/EFA), 971 (S&D), 972-974 (Greens/EFA), 975-976 (S&D), 977 (Renew), 978 (Greens/EFA), 979-980 (S&D), 981 (Greens/EFA), 982 (S&D), 983 (Greens/EFA), 984

(S&D), 985-988 (Greens/EFA), IMCO 39, IMCO 40, IMCO 41, IMCO 42, IMCO 43, IMCO 44, IMCO 45, IMCO 46 TO IMCO 50

## SECTION 2

### OBLIGATIONS OF ECONOMIC OPERATORS WITH REGARD TO EHR SYSTEMS

#### Article 17

##### *Obligations of manufacturers of EHR systems*

#### 1. Manufacturers of EHR systems shall

(a) ~~ensure that~~ **obtain for** their EHR systems ~~are in~~ **a certificate of compliance from an independent third-party body to attest their (960)** conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 23 ~~ensure that their EHR systems are in conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 23;~~

(b) draw up ~~and keep up to date (963)~~ the technical documentation of their EHR systems in accordance with Article 24 **before placing their system on the market and subsequently keep it up to date (962);**

(c) ensure that their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use **including in accessible formats for vulnerable groups and persons with disabilities (964);**

(d) **carry out the relevant conformity assessment procedures (965)** as referred to in Article 27a and annex IVa ~~draw up an EU declaration of carry out the relevant conformity assessment procedures (965)~~ as referred to in Article 26;

**((da) draw up the EU declaration of conformity in accordance with Article 26)**

(e) affix the CE marking in accordance with Article 27 **after the conformity assessment procedure has been completed ;**

**(ea) indicate the name, registered trade name or registered trade mark, and the postal address and website, e-mail address or other digital contact at which they can be contacted, on the front office of the EHR system. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and market surveillance authorities;**

(f) comply with the registration obligations in Article 32;

(g) take ~~without undue delay~~ **immediately** any necessary corrective action in respect of their EHR systems ~~which~~ **when manufacturers consider or have reasons to believe that such systems (968) are not or no longer (969)** in conformity with the essential re-



requirements laid down in Annex II, or recall or withdraw such systems. ***The manufacturers shall then inform the national authorities of the Member States in which they made their EHR systems available or put them into service of the non-conformity and of any corrective action taken;***

(h) ***immediately (970)*** inform the distributors of their EHR systems and, where applicable, the authorised representative and importers ***of the non-conformity and of any corrective action, recall or withdrawal of that system;***

~~(i) ***immediately (972)*** inform the market surveillance authorities ***and notified bodies (971)*** of the Member States in which they made their EHR systems available or put them into service of the non-conformity and of any corrective action taken;~~

~~(ia) ***immediately inform the market surveillance authorities of the Member States in which they made their EHR systems available, where manufacturers consider or have reasons to believe that such systems prevent a risk to the health or safety of natural persons or to other aspects of public interest protection; (973)***~~

(j) upon request of authority, provide it market surveillance ***authorities in the Member States (974, 975)*** with all the information and documentation ***in paper or digital format***, necessary to demonstrate the conformity of ~~their~~ ***the*** EHR system ***which they have placed on the market or put into service*** with the essential requirements laid down in Annex II ***and Article 27a in the official language of the Member State.***

(k) cooperate with market surveillance authorities, at their request, on any action taken to bring their EHR systems ***which they have placed on the market or put into service*** in conformity with the essential requirements laid down in Annex II ***and Article 27a in the official language of the Member State.***

***(ka) establish channels of complaint and keep a register of complaints, of non-conforming EHR systems, and keep distributors informed of any such monitoring***

2. Manufacturers of EHR systems shall ensure that procedures are in place to ensure that the design, development and deployment of an EHR system continues to comply with the essential requirements laid down in Annex II and the common specifications referred to in Article 23 ***for EHR systems to remain in conformity with this Regulation. Changes in EHR system design or characteristics and changes in the technical standards and the technical specifications referred to in Annex II and III by reference to which the conformity of the EHR system is declared shall be adequately taken into account and reflected in the technical documentation.***

***Manufacturers shall establish reporting channels and ensure their accessibility to allow for users to submit complains, keep a register of complaints, of non-conforming EHR systems and EHR systems recalls.***

3. Manufacturers of EHR systems shall keep the technical documentation and the EU declaration of conformity ***at the disposal of the market surveillance authorities for at least (981)*** 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market. ***The source code or the programming logic included in the technical documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them to be able to check compliance with the essential requirements set out in Annex II. The personnel of competent national authorities***

*shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment activities in accordance with Annexes IVa, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected. Manufacturers shall establish reporting channels and ensure their accessibility to allow for users to submit complains, keep a register of complaints, of non-conforming EHR systems and EHR systems recalls.*

- 3a. *A manufacturer of EHR systems established outside of the Union shall ensure that its authorised representative has the necessary documentation readily available in order to fulfil the tasks referred to in Article 18(2). (983)*
- 3b. *Manufacturers shall, further to 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 set out in Annex II and the common specifications referred to in Article 23, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks posed by the EHR system, which they have placed on the market or put into service. (984)*
- 3c. *Liability rules under [Directive 85/374/EEC], shall apply to manufacturers of EHR systems without prejudice to more protective measures under national law. (985)*

## COMPROMISE AMENDMENT 18: ARTICLE 18

Compromise amendment replacing Amendment(s): 989 (Greens/EFA), 990 (S&D), 991-993 (Greens/EFA), 994 (S&D), 995-997 (Greens/EFA), IMCO 51 TO IMCO 56

### *Article 18*

#### *Authorised representatives*

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.
2. An authorised representative shall perform the tasks specified in the mandate ~~received from~~ **agreed with (989)** the manufacturer. The mandate shall allow the authorised representative to do at least the following:
  - (a) keep the EU declaration of conformity and the technical documentation at the disposal of **the Member State (990)** market surveillance authorities for the period referred to in Article 17(3);
  - (b) further to a reasoned request from a market surveillance ~~authority~~, ~~provide that~~ **authorities of the Member States concerned a copy of the mandate** with all

the information and documentation necessary to demonstrate the conformity of an EHR system with the essential requirements laid down in Annex II (991);

*(ba) immediately inform the manufacturer if the authorised representative has a reason to believe that an EHR system is no longer in conformity with the essential requirements laid down in Annex II; (992)*

*(bb) immediately inform the manufacturer about complaints received by consumers and professional users; (993)*

(c) cooperate with the market surveillance authorities *in the Member State*, at their request, on any corrective action taken in relation to the EHR systems covered by their mandate.

**2a.** *In case of change of the authorised representative, the detailed arrangements for the change shall address at least the following aspects:*

*(a) the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;*

*(b) the transfer of documents, including confidentiality aspects and property rights; (IMCO 56)*

## **COMPROMISE AMENDMENT 19: ARTICLE 19**

Compromise amendment replacing Amendment(s): 998 (Greens/EFA), 999 (S&D), 1000 (S&D), 1001 (Greens/EFA), 1002 (S&D), 1003-1004 (Greens/EFA), 1005 (S&D), 1006 (Greens/EFA), 1007 (S&D), 1008 (Greens/EFA), 1009 (NI), 1010 (S&D), 1011-1014 (Greens/EFA), IMCO 57 to IMCO 64

### *Article 19*

#### *Obligations of importers*

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

2. Before making an EHR system available on the market, importers shall ensure that:

*(a) the manufacturer has obtained a certificate of compliance from an independent third body to attest to the relevant conformity assessment procedure referred to in Article 27a and drawn up the EU declaration of conformity in accordance with Article 26a;(1016 S&D ENVI) and drawn up the technical documentation, in accordance with Article 24 before placing their system on the market (962);*

*(ab) the manufacturer is identified and an authorised representative in accordance with Article 18 has been appointed; (1001)*

(b) the EHR system bears the CE marking of conformity *referred to in article 27 (1002) after the conformity assessment procedure has been completed;*

(c) *the EHR system is accompanied by the information sheet referred to in Article 25 with clear and complete instructions for use including in accessible formats (964) (1003).;*

3. Importers shall indicate their name, registered trade name or registered trade mark and the *postal address and website, e-mail address or other digital contact* at which they can be contacted in a document accompanying the EHR system. *The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and the market surveillance authorities. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer. (1004)*

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 Article 27a* is jeopardised.

5. Where an importer considers or has reason to believe that an EHR system *is not or no longer (969)* in conformity with the essential requirements in Annex II *and Article 27a*, it shall not make that system available on the market, *or should recall it or withdraw it if was already available on the market*, until that system has been brought into conformity. The importer shall inform ~~without undue delay~~ *immediately* the manufacturer of such EHR system and the market surveillance authorities of the Member State in which it made the EHR system available, to that effect, *giving details, in particular, of the non-conformity and of any corrective measures, recall or withdrawal of that system taken. 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 immediately inform the market surveillance authority of the Member State in which the importer is established, as well as the manufacturer and where applicable, the authorised representative.*

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 17(3) and ensure that the technical documentation can be made available to those authorities, upon request.

7. Importers shall, further to a reasoned request from a market surveillance ~~authority~~ *authorities of Member States concerned*, provide it with all the information and documentation *in paper or digital format* necessary to demonstrate the conformity of an EHR system. ~~in the official languages (1009)~~ *language of the Member State where the market surveillance authority is located.* They shall cooperate with that authority, at its request, *and with the manufacturer and, where applicable, with the manufacturer's authorised representative* on any action taken to bring their EHR systems in conformity with the essential requirements laid down in Annex II, *and article 27a, or to ensure that their EHR systems are withdrawn or recalled (1008).*

*7a. Manufacturers shall establish reporting channels and ensure their accessibility to allow for users to submit complains, keep a register of complaints, of non-conforming EHR systems and EHR systems recalls. Importers shall verify whether the established channels of complaint referred to in Article 17(2) are publicly available allowing them to submit complaints and communicate any risk related to their health and safety or to other aspects of public interest protection and of any serious incident involving an EHR system. If such channels are not available, the importer shall provide for them, taking into account accessibility needs of vulnerable groups and persons with disabilities. (1011)*

*7c. Importers shall investigate complaints and information on incidents involving an EHR system they made available on the market and file those complaints, as well as of systems recalls and any corrective measures taken to bring the EHR system into conformity, in the register referred to in Article 17(3d) 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 performed and of the results of the investigation. (1013)*

Compromise amendment 20: Article 20

Compromise amendment replacing Amendment(s): 1016 (S&D), 1017 (Greens/EFA), 1018 (S&D), 1019-1020 (Greens/EFA), 1021 (S&D), IMCO 65, IMCO 66, IMCO 67

## *Article 20*

### *Obligations of distributors*

1. Before making an EHR system available on the market, distributors shall verify that:
  - (a) the manufacturer has ***obtained a certificate of compliance from an independent third body to attest to the relevant conformity assessment procedure referred to in Article 27a and drawn up the EU declaration of conformity, in accordance with Article 26a; (1016 S&D ENVI) and drawn up the technical documentation, in accordance with Article 24 before placing their system on the market (962);***
  - (b) the EHR system bears the CE marking of conformity *referred to in article 27 (1002) after the conformity assessment procedure has been completed;*
  - (c) the EHR system is accompanied by the information sheet referred to in Article 25 ***with clear and complete*** instructions for use ***in accessible formats (1017);***
  - (d) where applicable, the importer has complied with the requirements set out in Article 19(3).
  
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 article 27a*** is jeopardised.
  
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 article 27a***, it shall not make the EHR system available on the market, ***or should recall it or withdraw it if was already available on the market***, until it has been brought into conformity. Furthermore, the distributor shall inform ~~without undue delay~~ ***immediately*** the manufacturer or the importer, as well as the market surveillance authorities of the Member states where the EHR system has been 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 immediately inform the market surveillance authority of the Member State in which the distributor is established, as well as the manufacturer, the importer and where applicable, the authorised representative. (1019 Greens/EFA)***

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 their EHR systems in conformity with the essential requirements laid down in Annex II ***or to withdraw or recall it (1020 Greens/EFA)***.

<b>Compromise amendment 21: Article 21</b>
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Compromise amendment replacing Amendment(s): 1025-1026 (Greens/EFA), IMCO 68 - 71

*Article 21*

Cases in which obligations of manufacturers of an EHR system apply to ***economic operators (1025 Greens/EFA)***

***If any economic operator other than the manufacturer (1026 Greens/EFA) makes modifications to the EHR system whilst deploying or using it, which lead to changes in the intended purpose and deployment recommendations for the EHR system as declared by the manufacturer, in any case of any malfunctioning or deterioration in performance quality due to the changes made by the economic operator during deployment or use of the EHR system contrary to the manufacturer's recommendations for technical deployment of the system or purpose of its use, the economic operator shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations laid down in Article 17.)***

*Article 22*

*Identification of economic operators*

Economic operators shall, on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:

- (a) any economic operator who has supplied them with an EHR system;
- (b) any economic operator to whom they have supplied an EHR system.

<b>Compromise amendment 22: Article 23</b>
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Compromise amendment replacing Amendment(s): 70, 71, 1028, 1030 The Left, 1031, 1032 The Left, 1033 Renew, 1034 Greens/EFA, IMCO 72, ITRE 28, IMCO 73, ITRE 29 and IMCO74

*Article 23*

**SECTION III**

**~~CONFORMITY OF THE EHR SYSTEM ASSESSMENT~~**

*Article 23*

*Common specifications*

1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including **a common template document and (70, 1028, 1030)** a time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities **and verify compatibility with sectorial legislation and harmonized standards** of medical devices and high risk AI systems referred to in paragraphs 3 and 4 of Article 14, **including the state-of-the art standards for health informatics and the European electronic health record exchange format (1028)**.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2) **after consultation with the EHDS board and the Advisory Forum (71, 1031, 1032)**.

2. The common specifications referred to in paragraph 1 shall include the following elements:

- (a) scope;
- (b) applicability to different categories of EHR systems or functions included in them;
- (c) version;
- (d) validity period;
- (e) normative part;
- (f) explanatory part, including any relevant implementation guidelines.

3. The common specifications may include elements related to the following:

- (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;
- (b) coding systems and values to be used in datasets containing electronic health data;
- (c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;
- (d) technical specifications, standards and profiles for the exchange of electronic health data;
- (e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;
- (f) specifications and requirements related to identification management and the use of electronic identification.

4. EHR systems, medical devices and high risk AI systems referred to in Article 14 that are in conformity with the common specifications referred to in paragraph 1 shall be considered to be in

conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.

**4a. Where common specifications have an impact on data protection requirements of EHR systems, they shall be subject to consultation with EDPB and EDPS before their adoption, pursuant to Article 42(2) of Regulation (EU) 2018/1725. (1033)**

5. Where common specifications covering interoperability and security requirements of EHR systems affect medical devices or high-risk AI systems falling under other acts, such as Regulations (EU) 2017/745 or [...] [AI Act COM/2021/206 final], the adoption of those common specifications ~~may~~ **shall** be preceded by a consultation with the Medical Devices Coordination Group (MDCG) referred to in Article 103 of Regulation (EU) 2017/745 or the European Artificial Intelligence Board referred to in Article 56 of Regulation [...] [AI Act COM/2021/206 final], as applicable, **as well as the European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 (1034).**

6. Where common specifications covering interoperability and security requirements of medical devices or high-risk AI systems falling under other acts such as Regulation (EU) 2017/745 or Regulation [...] [AI Act COM/2021/206 final], impact EHR systems, the adoption of those common specifications shall be preceded by a consultation with the EHDS Board, especially its subgroup for Chapters II and III of this Regulation, **and, where applicable, the European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 (1035).**

## **COMPROMISE AMENDMENT 23: Article 24**

Replacing the following amendments: 1036 Greens/EFA, 1037 Greens/EFA, 1038 EPP, 1039 NA, IMCO 75, IMCO 76

### *Article 24*

#### *Technical documentation*

1. **Manufacturers shall draw up** ~~The technical documentation shall be drawn up~~ before the EHR system is placed on the market or put into service and shall be kept up-to-date.

2. The technical documentation shall be drawn up in such a way as to 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. It shall contain, at a minimum, the elements set out in Annex III. **In case the system or any part of it complies with European standards or common specifications, the list of the relevant European standards and common specifications shall also be indicated. (1037)**

**2a. To ensure conformity, a single unified template for technical documentation shall be provided by the Commission. (1038)**

3. The technical documentation shall be drawn up in ~~one of~~ the official languages of ~~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 the official language of that Member State.

4. When a market surveillance authority requests the technical documentation or a translation



of parts thereof from a manufacturer, it shall set a deadline of 30 days for receipt of such documentation or translation, 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, 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 23.

## **COMPROMISE AMENDMENT 24: Article 25**

Replacing the following amendments: 1040 Greens/EFA, 1041 Greens/EFA, 1042 The Left, 1043 ECR, 1044 S&D, IMCO 77

### *Article 25*

#### *Information sheet accompanying the EHR system*

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.
2. The information sheet referred to in paragraph 1 shall specify:
  - (a) the identity, registered trade name or registered trademark, and the contact details of the manufacturer **including the postal and electronic address and the telephone number (1040)** and, where applicable, of its authorised representative;
  - (b) the name and version of the EHR system and date of its release;
  - (c) its intended purpose;
  - (d) the categories of electronic health data that the EHR system has been designed to process;
  - (e) the standards, formats and specifications and versions thereof supported by the EHR system.

***If the EHR system is not accompanied by the information sheet provided in this Article, and by clear and complete instructions for use in accessible formats for persons with disabilities (1093), it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators that the sheet is added.***

3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by allowing manufacturers to enter the information referred to in paragraph 2 into the EU database of EHR systems and wellness applications referred to in Article 32 (**1041, 1042, 1043**), as an alternative to supplying the information sheet referred to in paragraph 1 with the EHR system.

## **COMPROMISE AMENDMENT 25: Article 26**

Replacing the following amendments: 1045 Greens, 1046 S&D, 1047 NA, 1048 Greens/EFA, 1049 S&D, 1050 Greens/EFA, 1051 The Left, 1052 EPP, 1053 S&D, IMCO 78, IMCO 79

## Article 26

### *EU declaration of conformity*

1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.

2. Where EHR systems are subject to other Union legislation in respect of aspects not covered by this Regulation, which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the EHR system. The declaration shall contain all the information required for the identification of the Union legislation to which the declaration relates.

3. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available. ***Manufacturers shall provide a translation of the relevant parts of the technical documentation into the official language of the Member States where they have placed products on the market. (1047)***

***3a. Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the EHR system and in any event for at least 10 years after the placing on the market or the putting into service of the EHR system.***

4. By drawing up the EU declaration of conformity the manufacturer) shall assume responsibility for the ***compliance*** of the EHR system ***with the requirements laid down in this Regulation. (1048)***

***4a. The Commission is empowered to adopt delegated acts in accordance with Article 67 amending the minimum content of the EU declaration of conformity set out in Annex IV. (1050)***

***4aa. The Commission shall publish a standard uniformed template for EU declaration of conformity and make it available in digital format in all the official Union languages. (1051, 1052)***

## **COMPROMISE AMENDMENT 26: Article 27**

Replacing the following amendments: 1054 Greens/EFA, 1055 Greens/EFA, 1056 The Left, 1057 S&D, 1058 S&D, 1059 S&D, 1060 S&D, 1061 S&D, 1062 S&D, 1063 S&D, 1064 S&D, 1065 S&D, 1066 S&D, 1067 S&D, 1068 S&D, 1069 S&D, 1070 S&D, 1071 S&D, 1072 S&D, 1073 S&D, 1074 S&D, IMCO 80

## Article -27

### ***General principles of the CE marking***

***The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.***

## Article 27

### *CE marking*

1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the packaging.

***1a. The CE marking shall be affixed before making the EHR system available on the market. (1054)***

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) 765/2008 of the European Parliament and of the Council<sup>21</sup>.

***2a. Where EHR systems are subject to other Union legislation in respect of aspects not covered by this Regulation, which also requires the affixing of the CE marking, the CE marking shall indicate that the systems also fulfil the requirements of that other legislation. (1055)***

***2b. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.***

### *Article 27a*

#### *Conformity assessment for EHR systems*

***1. In order to certify the conformity of an EHR system with this Regulation, prior to placing an EHR system on the market, the manufacturer, its authorised representative, or any economic operator referred to in Article 21 shall apply for a conformity assessment procedure.***

***2. The conformity assessment procedure requires the notified body to assess:***

***(1) if the EHR system is in conformity with the requirements laid down in Annex II;***

***(2) if the EHR system is in conformity with the requirements laid down in Regulation [.. (Cyber Resilience Act COM/2022/457)];***

***(3) if the technical documentation is available and complete;***

***(4) if the technical design of an EHR system meets the applicable requirements of this Regulation as provided in an EU type examination procedure laid down in Annex IVa;***

***The EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an EHR system and verifies and attests that the technical design of the EHR system meets the applicable requirements of this Regulation.***

***Only after an EU wide approval has been issued, the CE marking can be affixed, together with an identification number.***

***3. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment and reduce those fees proportionately to their specific interests and needs. (1056, 1057)***

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<sup>21</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

## *Article 27b*

### *Notification*

*Member States shall notify the Commission and the other Member States of conformity assessment bodies authorised to carry out conformity assessments in accordance with this Regulation. (1058)*

## *Article 27c*

### *Notifying authorities*

- 1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 27h.*
- 2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.*
- 3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 27d. In addition, that body shall have arrangements to cover liabilities arising out of its activities.*
- 4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3. (1059)*

## *Article 27d*

### *Requirements relating to notifying authorities*

- 1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.*
- 2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.*
- 3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment of the EHR system.*
- 4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.*
- 5. A notifying authority shall safeguard the confidentiality of the information it obtains.*
- 6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks. (1060)*

## *Article 27e*

### *Information obligation on notifying authorities*

*Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto. The Commission shall make that information publicly available. (1061)*

#### *Article 27f*

##### *Requirements relating to notified bodies*

- 1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.*
- 2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.*
- 3. A conformity assessment body shall be a third-party body independent of the organisation or the EHR system it assesses.*
- 4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of an EHR system, that they assess, nor the representative of any of those parties. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, installation, use or maintenance of EHR systems, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services. A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.*
- 5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.*
- 6. A conformity assessment body shall be capable of carrying out all the conformity assessment activities mentioned in Annexes IVa in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. At all times, and for each conformity assessment procedure and each kind of a EHR system for which it has been notified, a conformity assessment body shall have at its disposal the necessary:
  - (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;*
  - (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;*
  - (c) appropriate policies and procedures to distinguish between activities that it carries out as a notified body and other activities;*
  - (d) procedures for the performance of conformity assessment activities which take**

*due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the technology in question.*

*A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.*

*7. The personnel responsible for carrying out conformity assessment tasks shall have the following:*

*(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;*

*(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;*

*(ba) appropriate knowledge and understanding of the applicable harmonised standards and common specifications referred to in this Regulation, and of the relevant provisions of Union harmonisation legislation and of national legislation;*

*(c) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.*

*8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment activities shall be guaranteed.*

*The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment activities shall not depend on the number of conformity assessments carried out or on the results of those assessments.*

*9. A conformity assessment body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.*

*10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment activities in accordance with Annexes IVa, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.*

*11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 27q and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group. (1062)*

#### *Article 27 g*

##### *Presumption of conformity of notified bodies*

*Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 27f in so far as the applicable harmonised standards cover those requirements. (1063)*

#### *Article 27 h*

##### *Use of subcontractors and subsidiaries by notified bodies*

- 1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 27f and shall inform the notifying authority accordingly.*
- 2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established.*
- 3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.*
- 4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex IVa.*

#### *Article 27 i*

##### *Application for notification*

- 1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.*
- 2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annex IVa as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 27f.*
- 3. Where the conformity assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 27f. (1066)*

#### *Article 27 j*

##### *Notification procedure*

- 1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 27f.*
- 2. The notifying authority shall send a notification to the Commission and the other Member States of each conformity assessment body referred to in paragraph 1, using the electronic notification tool developed and managed by the Commission.*
- 3. The notification referred to in paragraph 2 shall include the following:*
  - (a) full details of the conformity assessment activities to be performed;*
  - (b) the relevant attestation of competence.*
- 4. Where a notification is not based on an accreditation certificate referred to in Article 27i(2), the notifying authority shall provide the Commission and the other Member States*

*with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 27f.*

*5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 27i(2), or within two months of the notification where it includes documentary evidence referred to in paragraph 4 of this Article 27..*

*Only such a body shall be considered a notified body for the purposes of this Regulation.*

*6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2. (1065)*

#### *Article 27 k*

##### *Identification numbers and lists of notified bodies*

*1. The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Union acts.*

*2. The Commission shall make publicly available the list of notified bodies including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified. The Commission shall ensure that the list is kept up to date. (1067)*

#### *Article 27 l*

##### *Changes to notification*

*1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 27f, or that it is failing to fulfil its obligations as set out in Article 27n the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.*

*2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request. (1068)*

#### *Article 27 m*

##### *Challenge of the competence of notified bodies*

*1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.*

*2. The notifying authority shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified*



*body concerned.*

*3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.*

*4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying authority to take the necessary corrective measures, including the withdrawal of the notification if necessary.*

*That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 68(2). (1069)*

#### *Article 27 n*

##### *Operational obligations of notified bodies*

*1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Article 27a.*

*2. A notified body shall perform its activities in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the structure of the undertaking, the degree of complexity of the EHR system in question.*

*In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the EHR system with the requirements of this Regulation.*

*2a. Where a notified body finds that the harmonised standards or common specifications referred in this Regulation have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective actions and shall not issue an EU-type examination certificate.*

*3. Where, in the course of the monitoring of conformity following the issuance of a certificate of conformity or the adoption of an approval decision, a notified body finds that a EHR system no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate of conformity or the approval decision, if necessary.*

*Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates of conformity or approval decisions, as appropriate. (1070)*

#### *Article 27 o*

##### *Appeals against decisions of notified bodies*

*A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available. (1071)*

#### *Article 27 p*

##### *Information obligation on notified bodies*

*1. A notified body shall inform the notifying authority of the following:*

*(a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval decision;*

*(b) any circumstances affecting the scope of, or the conditions for, its notification;*

*(c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;*

*(d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.*

#### *Article 27 q*

##### *Coordination of notified bodies*

*The Commission shall ensure that appropriate coordination and cooperation between notified bodies are put in place and properly operated in the form of a sectoral group of notified bodies.*

*Notified bodies shall participate in the work of that group, directly or by means of designated representatives. (1073)*

#### *Article 27 r*

##### *Exchange of experience*

*The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy. (1074)*

### **COMPROMISE AMENDMENT 27: Article 28 + section 4**

Replacing the following amendments: 1075 S&D, 1076 Greens/EFA, 1077 Greens/EFA, 1078 Greens/EFA, 1079 S&D, 1080 S&D, IMCO 81

#### **SECTION 4**

### **MARKET SURVEILLANCE OF EHR SYSTEMS**

#### *Article 28*

##### *Market surveillance authorities*

1. Regulation (EU) 2019/1020 shall apply to EHR systems covered by Chapter III of this Regulation.
2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the *necessary* powers, *financial* resources, equipment, *technical expertise, adequate staffing, (1076)* and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. Member States shall communicate the identity of the market surveillance authorities to the Commission which shall publish a list of those authorities.

**2a. Staff of market surveillance authorities shall have no direct or indirect economic, financial or personal conflicts of interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct. (1077)**

**2b. Pursuant to paragraph 2 of this article, Member States shall determine and publish the selection procedure for market surveillance authorities. They shall ensure that the procedure is transparent and does not allow for conflicts of interest. (1078)**

3. Market surveillance authorities designated pursuant to this Article may be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, any conflict of interest shall be avoided.

4. Market surveillance authorities shall report to the Commission on a regular basis the outcomes of relevant market surveillance activities.

**4a. Market surveillance authorities shall immediately inform notified bodies about manufacturers of EHR systems that no longer comply with the requirements on the declaration of conformity. (1079)**

**4b. When a manufacturer or, pursuant to Article 21, other economic operator fails to cooperate with market surveillance authorities or if the information and documentation provided is incomplete or incorrect, market surveillance authorities shall take all appropriate measures to prohibit or restrict the relevant EHR system from being available on the market until the manufacturer cooperates or provides complete and correct information (978) or to withdraw it from the market or to recall.**

5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.

6. For medical devices or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745 or Article 59 of Regulation [...] [AI act COM/2021/206 final], as applicable.

## **COMPROMISE AMENDMENT 28: Article 29**

Replacing the following amendments: 72 Rapporteurs, 1081 S&D, 1082 Greens/EFA, 1083 S&D, 1084 Greens/EFA, 1085 S&D, 1086 RE, 1087 S&D, 1088 EPP, 1089 S&D, IMCO 82

### *Article 29*

#### *Handling of risks posed by EHR systems and of serious incidents*

1. Where a market surveillance authority ~~finds~~ **of one Member State have a reason to believe** that an EHR system presents a risk to the ~~health or, safety or rights~~ **health or, safety or rights** of natural persons, ~~to the protection of personal data (72, 1081) or to other aspects of public interest protection, it~~ **to the protection of personal data (72, 1081)** ~~or to other aspects of public interest protection, it~~ **they** shall ~~require~~ **carry out an evaluation in relation to** the EHR system concerned ~~covering all relevant requirements laid down in this regulation.~~ **covering all relevant requirements laid down in this regulation.** Its authorised ~~representative~~ **representatives** and all other relevant economic operators ~~to~~ **shall cooperate as necessary with the market surveillance authorities for that purpose and** take all appropriate measures to ensure that the

EHR system concerned no longer presents that risk when placed on the market to withdraw the EHR system from the market or to recall it within a reasonable period.

***The market surveillance authorities shall inform the relevant notified body accordingly. (1080)***

***1b. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take. (1083)***

***1c. Where a market surveillance authority considers or has reason to believe that an EHR system has caused damage to the health or safety of natural persons or to other aspects of public interest protection, it shall immediately provide information and documentation, as applicable, to the affected person or user and, as appropriate, other third parties affected by the damage caused to the person or user, without prejudice to data protection rules. (1084)***

2. The economic operator 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 market throughout the Union.

3. The market surveillance authority, ***or, where applicable, the supervisory authority under Regulation (EU) 2016/679***, shall immediately inform the Commission and the market surveillance authorities, ***or, if applicable, the supervisory authorities under Regulation (EU) 2016/679, (1085)*** of other Member States of the measures ordered pursuant to paragraph 1. 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.

***3a. Where a finding of a market surveillance authority, or a serious incident it is informed of, concerns personal data protection, the market surveillance authority shall immediately inform and cooperate with the relevant supervisory authorities under Regulation (EU) 2016/679.***

4. Manufacturers of EHR systems placed on the market shall report any serious incident involving an EHR system to the market surveillance authorities, ***or, in cases involving personal data, the supervisory authorities under Regulation (EU) 2016/679 (1087)*** of the Member States where such serious incident occurred and the corrective actions taken or envisaged by the manufacturer.

Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, 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 ~~15~~ ***7 (1088)*** days after the manufacturer becomes aware of the serious incident involving the EHR system.

5. The ~~market surveillance~~ authorities referred to in paragraph 4 shall inform the other ~~market surveillance~~ ***authorities (1089)***, 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.

6. Where the tasks of the market surveillance authority are not performed by the digital health authority, it shall cooperate with the digital health authority. It shall inform the digital health authority of any serious incidents and of EHR systems presenting a risk, including risks related to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.

## COMPROMISE AMENDMENT 29: Article 30

Replacing the following amendments: 1090 Greens/EFA, 1091 Greens/EFA, 1092 Greens/EFA, 1093 Greens/EFA, 1094 Greens/EFA, 1095 Greens/EFA, 1096 S&D, 1097 S&D, 1098 S&D, 1099 S&D, 1100 S&D, IMCO 83, IMCO 84, IMCO 85, IMCO 86, IMCO 87, IMCO 88

### *Article 30*

#### *Handling of non-compliance*

1. Where a market surveillance authority makes one, *inter alia*, of the following findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to ~~put an end to the non-compliance concerned~~ **bring the EHR system into conformity; (1090)**

(a) the EHR system is not in conformity with essential requirements laid down in Annex II **and with the common specifications in accordance with Article 23; (1091)**

(b) the technical documentation is either not available or not complete **or not in accordance with Article 24; (1092)**

**(ba)**

(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly **as referred to in Article 26; (1094)**

(d) the CE marking has been affixed in violation of Article 27 or has not been affixed.

**(da) the registration obligations of Article 32 has not been fulfilled. (1095)**

**1a. Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the EHR system does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the EHR system into compliance with those requirements, to withdraw the EHR system from the market, or to recall it within a reasonable period.**

**1b. Where the relevant economic operator does not take adequate corrective action within the period referred to in Article 29, paragraph 1, second subparagraph, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the EHR system being made available on their national market, to withdraw the EHR systems from that market or to recall it.**

**The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures. (1096)**

**1c. The information referred to in paragraph 1.a, second subparagraph, shall include all available details, in particular the data necessary for the identification of the noncompliant 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 national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the noncompliance is due to any of the following:**

**(a) failure of the EHR system to meet the requirements relating to the essential requirements set out in Annex II;**

*(b) shortcomings in the harmonised standards referred to in Article 25a(1);*

*(c) shortcomings in the technical specifications referred to in Article 25a(4). (1097)*

*1d. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and 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. (1098)*

*1e. Where, within three months of receipt of the information referred to in paragraph 1a, second subparagraph, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. (1099)*

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.

### *Article 30 a*

#### *Union safeguard procedure*

*1. Where, on completion of the procedure set out in Article 29(2) and Article 30(1a), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 68(2a).*

*2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant EHR system is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure. Where the national measure is considered justified and the non-compliance of the EHR system is attributed to shortcomings in the harmonised standards or technical specifications referred to in Article 30(1b), points (b) and (c), of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012. (1100)*

## SECTION 5

### OTHER PROVISIONS ON INTEROPERABILITY

**COMPROMISE AMENDMENT 30: Article 31**

Replacing the following amendments: 73-74 Rapporteurs, 1101 RE, 1102 S&D, 1103 Greens/EFA, 1104 ECR, 1105 The left, 1106 S&D, 1107 S&D, 1108 S&D, 1109 NA, 1110 RE, IMCO 89, and IMCO 90

### *Article 31*

#### *Labelling of wellness applications*

1. Where a manufacturer of a wellness application claims interoperability with an EHR system and therefore compliance with the essential requirements laid down in Annex II and common specifications in Article 23, such wellness application **shall** be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application **and the competent market surveillance authority shall be informed (1106 S&D)**.
2. The label shall indicate the following information:
  - (a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;
  - (b) reference to common specifications to demonstrate compliance;
  - (c) validity period of the label
3. The Commission ~~may~~ **shall (1107)**, by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).
4. The label shall be drawn-up in one or more official languages of the Union, **obligatorily in the language of (1108)** ~~or languages determined by the Member State(s) in which the~~ in which the wellness application is placed on the market.
5. The validity of the label shall not exceed 5 years.
6. If the wellness application is **an integral part of a device or** embedded in a device **after its putting into service**, the accompanying label shall be **shown in the application itself or (73)** placed on the device **and in the case of software a digital label (1110)**. 2D barcodes may also be used to display the label.
7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II. 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 with the label for each individual unit, free of charge.
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 ~~or, upon request, in physical form (74)~~.
10. ~~The requirements of this Article shall not apply to wellness applications which are high-risk AI systems as defined under Regulation [...] [AI Act COM/2021/206 final].~~

### *Article 31a*

#### *Interoperability of wellness applications with EHR systems*

1. **Manufacturers of wellness applications may claim interoperability with an EHR system,**

*after relevant conditions are met. When this is the case, the users of such wellness applications shall be duly informed about such interoperability and its effects.*

*2. The interoperability of wellness applications with EHR systems shall not mean automatic sharing or transmission of all or part of the health data from the wellness application with the EHR system. The sharing or transmission of such data shall only be possible following the consent of the natural person and pursuant to and in line with Article 3(6) of this Regulation and interoperability shall be limited exclusively to this end. The manufacturers of wellness applications claiming interoperability with an EHR system shall ensure that the user is able to choose which categories of health data from the wellness application they want to insert in the EHR system and on the occasions of that sharing or transmission.*

*3. Wellness applications shall not be able to access the information in EHRs nor extract or process information from it. (1101)*

### **COMPROMISE AMENDMENT 31: Article 32**

Replacing the following amendments: 1111 ECR, 1112 Greens/EFA, 1113 Greens/EFA, 1114 The Left, 1115 ECR, 1116 Greens/EFA, 1117 S&D, 1118 The Left, 1119 ECR, 1120 Greens/EFA, 1121 The Left, 1122 ECR, 1123 Greens/EFA, 1124 The Left

#### *Article 32*

#### Registration of EHR systems and wellness applications

1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to ~~Article~~ **Articles 26 and 26a** wellness applications for which a label has been issued pursuant to Article **34 (1114, 1115, 1116, 1117)**.

2. Before placing on the market or putting into service an EHR system referred to in Article 14 or a wellness application referred to in Article 31, the manufacturer of such EHR system or wellness application **(1118, 1119, 1120)** or, where applicable, its authorised representative shall register the required data into the EU database referred to in paragraph 1.

3. Medical devices or high-risk AI systems referred to in paragraphs 3 and 4 of Article 14 of this Regulation shall **also (1121)** be registered in the database established pursuant to Regulations (EU) 2017/745 or [...] [AI Act COM/2021/206 final], as applicable.

4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and



wellness applications (*1122, 1123, 1124*) pursuant to paragraph 2.

## CHAPTER IV

### Secondary use of electronic health data

#### SECTION 1

#### GENERAL CONDITIONS WITH REGARD TO THE SECONDARY USE OF ELECTRONIC HEALTH DATA

#### COMPROMISE AMENDMENT 32: Article 33

Replacing the following amendments: 75-84 Rapporteurs, 1125 RE, 1126 RE, 1127 RE, 1128 S&D, 1129 Greens/EFA, 1130 EPP, 1131 ECR, 1132 S&D, 1133 The Left, 1134 ID, 1135 RE, 1136 EPP, 1137 ECR, 1138 EPP, 1139 S&D, 1140 EPP, 1141 ECR, 1142 S&D, 1143 RE, 1144 ECR, 1145 S&D, 1146 ECR, 1147 EPP, 1148 EPP, 1149 Greens/EFA, 1150 RE, 1151 S&D, 1152 S&D, 1153 ECR, 1154 ECR, 1155 EPP, 1156 S&D, 1157 S&D, 1158 ECR, 1159 ECR, 1160 EPP, 1161 ECR, 1162 The Left, 1163 ECR, 1164 ECR, 1165 Greens/EF, 1166 S&D, 1167 Greens/EFA, 1168 S&D, 1169 The Left, 1170 RE, 1171 ECR, 1172 RE, 1173 The Left, 1174 RE, 1175 ECR, 1176 RE, 1177 Greens/EFA, 1178 S&D, 1179 NA/ID, 1180 EPP, 1181 RE, 1182 EPP, 1183 RE, 1184 EPP, 1185 NA/ID, 1186 EPP, 1187 EPP, 1188 RE, 1189 EPP, 1190 NA/ID, 1191 NA/ID, 1192 RE, 1193 EPP, 1194 RE, 1195 EPP, 1196 Greens/EFA, 1197 S&D, 1198 EPP, 1199 ECR, 1200 The Left, 1201 ECR, 1202 RE, 1203 ECR, 1204 ECR, 1205 RE, 1206 Greens/EFA, 1207 S&D, 1208 RE, 1209 The Left, 1210 EPP, 1211 EPP, 1212 EPP, 1213 EPP, 1214 The Left, 1215 ECR, 1216 RE, 1217 EPP, 1218 ECR, 1219 Greens/EFA, 1220 S&D, 1221 EPP, 1222 S&D, 1223 S&D, 1124 RE, 1125 S&D, 1126 NA, 1227 The Left, 1228 Greens/EFA, 1229 S&D, 1230 RE, 1231 EPP, 1232 RE, 1233 EPP, 1234 S&D, 1235 RE, 1236 EPP, 1237 EPP, 1238 ECR, 1239 EPP, 1240 EPP, 1241 RE, 1242 EPP, 1243 EPP, 1244 RE, 1245 EPP, 1246 RE, 1247 RE, 1248 EPP, 1249 The Left, 1250 RE, 1251 S&D, 1252 EPP, 1253 EPP, 1254 Greens/EFA, 1255 EPP, 1256 The Left, 1257 S&D, 1258 EPP, 1259 EPP, 11260 ID, 1261 EPP, 1262 NA, 1263 S&D, 1264 RE, 1265 S&D, 1266 The Left, 1267 RE, 1268 S&D, 1269 EPP, 1270 Greens/EFA, 1271 S&D, 1272 The Left, 1273 RE, 1274 S&D, 1275 Greens/EFA, 1276 The Left, 1277 EPP, 1278 EPP, 1279 RE, 1280 S&D, 1281 NA, 1282

*Article 33*

~~Minimum categories~~ **Categories of electronic health data for secondary use**

1. ~~Data holders~~ **This chapter shall make apply to** the following categories of electronic **health** data available for secondary use ~~in accordance with the provisions of this Chapter: (1135 Renew)~~
  - (a) **electronic health data from EHRs; (75 Rapporteurs, 1138 EPP LIBE, 1142 S&D ENVI, 1139 S&D LIBE, 1143 RE, 1140 EPP, 1141 ECR)**
  - (b) data **on factors** impacting on health, including ~~social~~ **socio-economic**, environmental **and** behavioural determinants of health **(76 Rapporteurs, 1147 EPP LIBE (partially), 1151 S&D ENVI, 1150 Renew ENVI)**
  - (c) relevant pathogen ~~genomic~~ data, impacting on human health **(1153 ECR)**;
  - (d) **healthcare-related** administrative data, including claims and reimbursement data; **(77 Rapporteurs, 1156 S&D ENVI, 1157 S&D LIBE)**
  - (e) **extracts from** human genetic, genomic and proteomic data, **such as genetic markers; (1166 S&D ENVI)**
  - (f) **automatically (Rapporteurs 78)** ~~person-generated~~ electronic health data, ~~including via~~ medical devices, ~~wellness applications or other digital health applications;~~ **(1172 and 1174 Renew, 1171 ECR, 1175 ECR, 1173 The Left ENVI)**
  - (fa) **data from wellness applications after receiving the consent of the natural person;**
  - (g) identification data related **to healthcare providers and categories of health professionals** involved in the treatment of a natural person **or in research (79 Rapporteurs)**;
  - (h) population wide health data registries (public health registries);
  - (i) electronic health data from medical registries for specific diseases;
  - (j) electronic health data from clinical trials **subject to transparency provisions under Union law; (80 Rapporteurs, 1186 EPP ENVI, 1188 Renew, 1187 and 1189 EPP, 1185 ID)**
  - (k) electronic health data from medical devices and from registries for medicinal products and medical devices;
  - (l) **data from (81 Rapporteurs, 1197 S&D LIBE, 1196 Greens)** research cohorts, questionnaires and surveys related to health;
  - (m) electronic health data from biobanks and dedicated databases;
  - (n) ~~electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health;~~

- (o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data permit.
- ~~2. The requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC<sup>22</sup>.~~
2. ***The Commission, after consulting the EDPB and EDPS and the Member States, shall adopt guidelines on measures to protect the personal data of health professionals involved in the treatment of natural persons. (S&D ENVI 1222, adapted).***
3. The electronic health data referred to in paragraph 1 shall cover data processed for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, collected by entities and bodies in the health or care sectors, including public and private providers of health or care, entities or bodies performing research in relation to these sectors, and Union institutions, bodies, offices and agencies.
- ~~4. Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken.~~
5. ~~Where the consent of the *n*Natural persons shall have the right to opt-out of the processing of their electronic health data for secondary use is required by national law, health data access bodies Member States shall rely on the obligations laid down in this Chapter to provide for an accessible and easily understandable opt-out mechanism, whereby natural persons *must* shall be offered the possibility to explicitly express their wish not to have all or part of their personal access to electronic health data processed for some or all secondary use purposes. The exercise of this right to opt-out shall not affect the lawfulness of the processing that took place under Chapter IV before the individual opted-out. (84 Rapporteurs, 1252 EPP LIBE, 1256 The Left, 1265 S&D, 1266 The Left, 1267 Renew) (1126 Renew).~~
- 5a. ***Without prejudice to paragraph 5, electronic health data referred to under point 1(e) (fa) & (m) shall only be made available for secondary use after obtaining the consent of the natural person. Such an opt-in mechanism shall be easily understandable and accessible and provided for in a user-friendly format whereby data subjects are made aware of the sensitive nature of the data***
6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation [...] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combining it with other data for joint analysis.
- ~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list in paragraph 1 to adapt it to the evolution of available electronic~~

<sup>22</sup> Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

health data. (1274 S&D ENVI, 1271 S&D LIBE, 1273 RE, 1275 Greens, 1276 The Left ENVI, 1272 The Left LIBE,

~~Health data access bodies may provide access to additional categories of electronic health data that they have been entrusted with pursuant to national law or based on voluntary cooperation with the relevant data holders at national level, in particular to electronic health data held by private entities in the health sector.~~

**COMPROMISE AMENDMENT 33: Article 33a (1861, 1860, 1230, 1231, 1232, 1233, 1234, 1235, 1236, 1237, 1238, 1239, 1240, IMCO 92, ITRE 36)**

### *Article 33a*

#### *IP rights and trade secrets in secondary use*

*Electronic health data entailing content protected by intellectual property rights, trade secrets or data covered by regulatory data protection shall be made available for secondary use. In these cases, the following procedure shall apply:*

- a) Health data access bodies shall take measures necessary to preserve the confidentiality of such data and to ensure such rights are not infringed;*
- b) The Commission shall, after consultation with the EHDS Board, ~~adopt a guidance~~ ~~and~~ ~~issue~~ ~~guidelines~~ on the identification of commercially confidential information. ~~The guidelines~~ ~~The guidance~~ shall outline procedural steps and measure the health data access bodies ~~shall~~ ~~may~~ undertake to identify and preserve the confidentiality of such information before providing data access to the health data users. The guidance shall be made publicly available;*
- c) Health data holders may, when requested to make available to health data access bodies relevant electronic health data pursuant to Article 41(1) which it considers to contain content protected by intellectual property rights ~~intellectual property~~, trade secrets or data covered by regulatory data protection, inform the data access body that this is the case and indicate which parts of the datasets are concerned. The determination of which data contains intellectual property, trade secrets or data covered by regulatory data protection shall nevertheless rest with the health data access body;*
- d) Health data holders and the health data users may conclude data sharing agreements, in order to share additional data containing protected content protected by intellectual property rights ~~intellectual property~~, trade secrets or data covered by regulatory data protection, that would otherwise be made available under point a). Such agreements shall set out the relevant conditions for the use of such data. The health data holder or the health data user shall inform the health data access body of the conclusion of such an agreement. The Commission shall, by implementing acts draw up templates with standard clauses for such agreements. The implementing acts shall be adopted following the advisory procedure;*
- e) Should the health data access body deem any measures under point (a) to be insufficient to ensure the protection of IP rights, the confidentiality of trade*

*secrets or the data covered by regulatory data protection for regulatory approval, it shall refuse the granting of the relevant health data access permit to the health data user;*

- f) The decision of health data access bodies on the measures in point a) or the refusal of the data in point e) shall be binding. Health data holders and health data users shall have the right to lodge a complaint according to Article 38a and to a judicial remedy according to Article 38b regarding such decisions.*

COMPROMISE AMENDMENT 34: Article 34

Replacing the following amendments: 85-94 Rapporteurs, 1286 GREENS/EFA, 1287 THE LEFT, 1288 S&D, 1289 THE LEFT, 1290 RE, 1291 RE, 1292 EPP, 1293 RE, 1294 S&D, 1295 S&D, 1296 EPP, 1297 RE, 1298 ECR, 1299 S&D, 1300 S&D, 1301 GREENS/EFA, 1302 RE, 1303 ECR, 1304 The Left, 1305 The Left, 1306 EPP, 1307 NA, 1308 Greens/EFA, 1309 S&D, 1310 RE, 1311 S&D, 1312 Greens/EFA, 1313 RE, 1314 S&D, 1315 S&D, 1316 ECR, 1317 NA, 1318 Greens/EFA, 1319 S&D, 1320 ECR, 1321 The Left, 1322 The Left, 1323 RE, 1324 RE, 1325 S&D, 1326 EPP, 1327 RE, 1328 ECR, 1329 EPP, 1330 ECR, 1331 Greens/EFA, 1332 S&D, 1333 The Left, 1334 ECR, 1335 The Left, 1336 RE, 1337 EPP, 1338 RE, 1339 S&D, 1340 RE, 1341 ECR, 1342 EPP, 1343 ECR, 1344 THE LEFT, 1345 GREENS/EFA, 1346 RE, 1347 RE, 1348 S&D, 1349 EPP, 1350 RE, 1351 EPP, 1352 RE, 1353 RE, 1354 S&D, 1355 S&D, 1356 S&D, 1357 EPP, 1358 RE, 1359 EPP, 1360 EPP, 1361 GREENS/EFA, 1362 EPP, 1363 THE LEFT, ITRE 40, IMCO 93, IMCO 94, IMCO 95, ITRE 41

*Article 34*

*Purposes for which electronic health data can be processed for secondary use*

1. Health data access bodies shall only provide access to electronic health data referred to in Article 33 *to a health data user* where the processing *of the data* by ~~the applicant~~ *the data user is necessary for one of the following purposes, and in accordance with Article 6(1)(c) and Article 9(2)(g), (h), (i) and (j) of Regulation (EU) 2016/679; (85 Rapporteurs, 1288 S&D LIBE, 1290 RE, 1287 The Left)*

- (a) activities for reasons of public interest in the area of public ~~and occupational~~ health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices; *(86 Rapporteurs)*
- (b) to support public sector bodies ~~and Union public sector~~ ~~+~~ Union institutions, agencies and bodies ~~including regulatory authorities~~, in the health or care sector to carry out their tasks defined in their mandates *where processing is necessary for reasons of substantial public interest in the area of public health; (1299 S&D LIBE, 1301 Greens)*
- (c) to produce national, multi-national and Union level official statistics *defined in Regulation (EU) 223/2009* related to health or care sectors; *(87 Rapporteurs, 1304 and 1305 The Left)*
- ~~(d) teaching activities in health or care sectors;~~

- (e) scientific research related to health or care sectors, *contributing to public health or health technology assessment, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices, with the aim to benefit the end-users, such as patients, health professionals and health administrators, of the activity*, including: (89 Rapporteurs, 1315 S&D LIBE, 1339 S&D ENVI, 1322/1335 The Left ENVI, 1323/1336 RE MEPs)
- i) *development and innovation activities for products or services; (90 Rapporteurs)*
- ii) *training, testing and evaluating of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications; (91 Rapporteurs, 1337 EPP)*
- iii) *university and post-university teaching activities related to scientific research (88 Rapporteurs, 1311 S&D ENVI)*
- ~~(f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;~~
- ~~(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;~~
- (h) *improving delivery of care, treatment optimisation and providing personalised healthcare.* (RE 1350 and EPP MEP 1349, S&D LIBE 1348 )
2. ~~Access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant fulfils one of the purposes referred to in points (a) to (c) of paragraph 1 shall only be granted to~~ *be reserved for* public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies. (RE1353)
3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in accordance with Article 15 of the Regulation [...] [Data Act COM/2022/68 final].
- ~~4. Public sector bodies or Union institutions, agencies and bodies that obtain access to electronic health data entailing IP rights and trade secrets in the exercise of the tasks conferred to them by Union law or national law, shall take all specific measures necessary to preserve the confidentiality of such data.~~ (RE 1358)

### COMPROMISE AMENDMENT 35: Article 35

Replacing the following amendments: 95-96 Rapporteurs, 1364 RE, 1365 Greens/EFA, 1366 ID, 1367 RE, 1368 NA, 1369 RE, 1370 The Left, 1371 RE, 1372 S&D, 1373 S&D, 1374 EPP, 1375 EPP, 1376 EPP, 1377 S&D, 1378 ID, 1379 S&D, 1380 S&D, 1381 EPP, 1382 EPP, 1383 NA, 1384 Greens/EFA, 1385 S&D, 1386 The Left, 1387 The Left, 1388 S&D, 1389 S&D, 1390 RE, 1391 Greens/EFA, 1392 Greens/EFA, 1393 S&D, 1394 EPP, 1395

ECR, 1396 RE, 1397 S&D, 1398 EPP, 1399 S&D, 1400 EPP, 1401 EPP, 1402 RE, 1403 The Left, 1404 S&D, 1405 EPP, 1406 NA/ID, 1407 EPP, 1409 EPP, 1409 NA/ID, 1410 EPP, 1411 EPP, 1412 S&D, 1413 S&D, 1414 EPP, 1415 S&D, 1416 EPP, 1417 S&D, 1418 RE, 1419 NA, 1420 ECR, 1421 ECR, ITRE 42, ITRE 43

### Article 35

#### *Prohibited secondary use of electronic health data*

~~Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 or a data request granted pursuant to Article 47 for the following purposes shall be prohibited:~~

1. *Secondary use of electronic health data outside the data permit pursuant to Article 46 or data request pursuant to Article 47 shall be prohibited. (1418 RE)*
2. *Any secondary use of electronic health data for purposes other than those referred to in Article 34 shall be prohibited.; (AM 1365 Greens)*
3. Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 or a data request granted pursuant to Article 47 for the following purposes shall be prohibited:
  - (a) taking decisions detrimental to a natural person *or group of natural persons (1372 LIBE ENVI, 1371 RE)* based on their electronic health data; in order to qualify as “decisions”, they must produce legal, *economic or social* effects or similarly significantly affect those natural persons;
  - (b) taking decisions in relation to a natural person or groups of natural persons *in relation to job offers or offering less favourable terms in the provision of goods or services, including (95 Rapporteurs, 1379 S&D LIBE, 1369 RE, 1368 NI)* to exclude them from the benefit of an insurance *or credit* contract or to modify their contributions and insurance premiums *or conditions of loans (96 Rapporteurs, 1377 S&D ENVI (partially), 1380 Left LIBE, 1378 ID)*, *or taking any other decisions in relation to a natural person or groups of natural persons having the effect to discriminate on the basis of the health data obtained (AM 1376, EPP)*;
  - (c) advertising or marketing activities ~~towards health professionals, organisations in health or natural persons~~ *(1388 S&D ENVI, 1385 S&D LIBE, 1389 RE, 1384 Greens, 1386/1387 The Left, 1390 RE)*
  - (d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit;
  - (e) developing products or services that may harm individuals, *public health* ~~and~~ societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco *and nicotine* products, *weaponries* or *products* goods or services which are designed or modified in such a way that they *incite addiction or that they* contravene public order or morality *(1393 S&D ENVI, 1396 RE, 1392 Greens (partially), 1397 The Left LIBE, 1395 ID)*;

- (ea) *automated individual decision-making, including profiling, in accordance with Article 22 of the Regulation (EU) 2016/679, whether solely on the basis of the datasets shared under this Regulation or in combination with other data; (1404 S&D ENVI, 1413 S&D LIBE, 1391 Greens (partially), 1403 The Left ENVI, 1411 EPP, 1402 RE)*

## SECTION 2

### GOVERNANCE AND MECHANISMS FOR THE SECONDARY USE OF ELECTRONIC HEALTH DATA

#### COMPROMISE AMENDMENT 36: Article 36

Replacing the following amendments: 97-99 Rapporteurs, 1422 EPP, 1423 EPP, 1424 NA, 1425 RE, 1426 Greens/EFA, 1427 RE, 1428 EPP, 1429 EPP, 1429 EPP, 1430 EPP, 1431 EPP, 1432 EPP, 1433 Greens/EFA, 1434 RE, 1435 S&D, 1436 S&D, 1437 RE, 1438 S&D, 1439 RE, 1440 RE, 1441 RE, 1442 Greens/EFA, 1443 The Left, 1444 EPP, 1445 RE, 1446 EPP, 1447 RE, 1448 RE, 1449 The Left, 1450 S&D, 1451 EPP, 1451 Greens/EFA, 1453 EPP, 1454 RE, ITRE 44,

#### *Article 36*

##### *Health data access bodies*

1. Member States shall designate one or more health data access bodies responsible for ~~granting access to electronic health data for secondary use~~ ***the tasks and obligations referred to in Articles 37, 38 and 39 of this Regulation (1425 Renew)***. 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.

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 ***data access applications and (1425 Renew)*** requests with the other health data access bodies.

***Each health data access body shall contribute to the consistent application of this Regulation throughout the Union. For that purpose, the health data access bodies shall cooperate with each other and with the Commission, and, for concerns regarding data protection, with the supervisory authorities under Regulation (EU) 2016/679 as well as with the EDPB and the EDPS. (1427 Renew)***

2. Member States shall ensure that each health data access body is provided with the human ***and financial resources, including necessary expertise, and ethics bodies, to support their tasks as provided for in Article 37(1)(a) and (aa) (1433 Greens/EFA), and shall guarantee that all rights of natural persons under this Chapter are respected.***

***Member States shall also ensure*** technical resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers, ***in a timely manner (1436 S&D ENVI).***



- 2a. ~~Where a~~ Member States ***shall ensure that designated separate structures are set up within health data access bodies for the authorization of the data permit, on the one hand, and for the reception and preparation of the data set, including anonymisation, pseudonymization of the electronic health data and possible re-identification of natural persons (97 Rapporteurs, 1435 S&D LIBE, 1426 Greens/EFA) for the purposes of Article 33 (5) and 38 (3), on the other hand.***
3. In the performance of their tasks, health data access bodies shall actively cooperate with ***relevant*** stakeholders' representatives, especially with representatives of patients, ***consumers***, data holders and data users (1450 S&D LIBE, 1442 Greens, 1443 The Left ENVI, 1449 The Left LIBE). ~~Staff of health data access bodies shall avoid any conflicts of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.~~
- 3a. ***Each health data access body shall act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation. The members of the governance and decision-making bodies and staff of each health data access body shall, in the performance of their tasks and exercise of their powers in accordance with this Regulation, remain free from external influence, whether direct or indirect and shall neither seek nor take instructions from anybody. Members of the governance and decision-making bodies and staff of each health data access body shall refrain from any action incompatible with their duties and shall not, during their term of office, engage in any incompatible occupation, whether gainful or not.***
4. Member States shall communicate to the Commission the identity of the health data access bodies designated pursuant to paragraph 1 by the date of application of this Regulation. They shall also communicate to the Commission any subsequent modification of the identity of those bodies. The Commission and the Member States shall make this information publicly available.

### **COMPROMISE AMENDMENT 37: Article 37**

Replacing the following amendments: 100-102 Rapporteurs, 1455 EPP, 1456 Greens/EFA, 1457 EPP, 1458 Greens/EFA, 1459 EPP, 1460 RE, 1461 RE, 1462 RE, 1463 EPP, 1464 Greens/EFA, 1465 EPP, 1466 Greens/EFA, 1467 EPP, 1468 S&D, 1469 EPP, 1470 RE, 1471 Greens, 1472 EPP, 1473 Greens/EFA, 1474 EPP, 1475 EPP, 1476 EPP, 1477 RE, 1478 Greens/EFA, 1479 EPP, 1480 RE, 1481 EPP, 1482 Greens/EFA, 1483 ECR, 1484 S&D, 1485 The Left, 1486 Greens/EFA, 1487 EPP, 1488 EPP, 1489 Greens/EFA, 1490 S&D, 1491 S&D, 1492 NA, 1493 EPP, 1494 RE, 1495 EPP, 1496 EPP, 1497 RE, 1498 NA, 1499 EPP, 1500 EPP, 1501 NA, 1502 RE, 1503 EPP, 1504 Greens//EFA, 1505 EPP, 1506 EPP, 1507 EPP, 1508 RE, 1509 NA, 1510 RE, 1511 RE, 1512 Greens/EFA, 1513 Greens/EFA, 1514 NA, 1515 EPP, 1516 EPP, 1517 RE, 1518 EPP, 1519 EPP, 1520 NA, 1521 Greens/EFA, 1522 EPP, 1523 Greens/EFA, 1524 RE, 1525 EPP, 1526 Greens/EFA, 1527 EPP, 1528 EPP, 1529 Greens/EFA, 1530 EPP, 1531 NA, 1532 S&D, 1533 NA, 1534 Greens/EFA, 1535 EPP, 1536 The Left, 1537 RE, 1538 NA/ID, IMCO 96, ITRE 45 - ITRE 48

## Article 37

### Tasks of health data access bodies

1. Health data access bodies shall carry out the following tasks:
  - (a) ~~decide on data access applications pursuant to Article 45, authorise and issue data permits pursuant to Article 46 to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II of Regulation [...] [Data Governance Act COM/2020/767 final] and this Chapter; ***This includes deciding on whether the data shall be made accessible in anonymised or pseudonymised form, based on its own thorough assessment of any reasons provided by the health data applicant pursuant to point (d) of paragraph 2 of Article 45; (1458 Greens)***~~
  - (aa) ***assess and issue data permits pursuant to Article 46 and assess data request pursuant to Article 47 to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II of Regulation [...] [Data Governance Act COM/2020/767 final] and this Chapter; (1461 Renew)***
  - (ab) ***request electronic health data referred to in Article 33 from relevant health data holders pursuant to a data permit or a data request granted; (1462 Renew)***
  - (b) support public sector bodies in carrying out the tasks enshrined in their mandate, based on national or Union law;
  - (c) support Union institutions, bodies, offices and agencies in carrying out tasks enshrined in the mandate of Union institutions, bodies, offices and agencies, based on national or Union law;
  - (d) process electronic health data for the purposes set out in Article 34, including the combination, preparation, ***anonymisation and pseudonymisation*** and disclosure of those data for secondary use on the basis of a data permit, ***while also ensuring proper security of that data; (1467 Renew partially, 1468 S&D)***
  - ~~(e) process electronic health data from other relevant data holders based on a data permit or a data request for a purposes laid down in Article 34;~~
  - (f) take all measures necessary to preserve the confidentiality of IP rights and ***regulatory data protection, and the confidentiality*** of trade secrets ***as provided for in Article 33a; (partially: 1474 EPP LIBE, 1476 EPP)***
  - (g) ~~gather and compile or provide access to the necessary electronic health data from the various data holders whose electronic health data fall within the scope of this Regulation and~~ ***based on a data permit, put those the relevant electronic health data at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50 and store the data for the period of the duration of the data permit; (1480 Renew partially)***
  - (h) contribute to data altruism activities in accordance with Article 40;
  - ~~(i) support the development of AI systems, the training, testing and validating of AI systems and the development of harmonised standards and guidelines under Regulation [...] [AI Act COM/2021/206 final] for the training, testing and validation of AI systems in health;~~

- (j) cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;
- (ja) support data holders that are small enterprises in accordance with Commission Recommendation 2003/361/EC notably medical practitioners and pharmacies to comply with their obligations under Article 41**
- (k) maintain a management system to record and process data access applications, data requests, **the decisions on those applications** and the data permits issued and data requests answered, providing at least information on the name of the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request; **(1494 Renew)**
- (l) maintain a public information system to comply with the obligations laid down in Article 38;
- (m) cooperate at Union and national level to lay down **a common standards, technical requirements and** appropriate measures ~~and requirements~~ for accessing electronic health data in a secure processing environment; **(1497 Renew)**
- (n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for **the secondary use and management of** electronic health data ~~use and management~~; (1500 EPP LIBE, 1502 Renew)
- (o) facilitate cross-border access to electronic health data for secondary use hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.
- (p) send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset; (1506 EPP)
- (q) make public, through electronic means:
  - (i) a national dataset catalogue that shall include details about the source and nature of electronic health data, in accordance with Articles 55, 56 and 58, and the conditions for making electronic health data available. The national dataset catalogue shall also be made available to single information points under Article 8 of Regulation [...] [Data Governance Act COM/2020/767 final]; **(1508 Renew)**
  - (ii) all **health** data ~~permits, requests and applications and on their websites within 30 working days requests without undue delay~~ after issuance of the data permit or reply to a data request **their reception**; **(1510 Renew)**
  - (ii a) **all health data permits or requests granted as well as denied, together with justification, within 30 working days after their issuance**; **(1511 Renew)**
  - (iii) ~~penalties~~ **enforcement measures applied pursuant to Article 43 and administrative fines** applied pursuant to Article 43a;
  - (iv) results communicated by data users pursuant to Article 46(11);
- (r) fulfil obligations towards natural persons pursuant to Article 38;

- (ra) *monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter; ~~where personal data are concerned, the monitoring and compliance shall be carried out in close cooperation with relevant supervisory authorities under Regulation (EU) 2016/679; monitoring and supervision shall include regular audits on health data users regarding their processing of electronic health data in the secure processing environment; (1517 Renew)~~*
- (s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;
- (t) fulfil any other tasks related to making available the secondary use of electronic health data in the context of this Regulation.
2. In the exercise of their tasks, health data access bodies shall:
- (a) cooperate with supervisory authorities under Regulation (EU) 2016/679 ~~and Regulation (EU) 2018/1725~~ in relation to personal electronic health data and the EHDS Board;
- (aa) *immediately notify the relevant supervisory authorities under Regulation (EU) 2016/679 of any potential issue related to the processing of personal electronic health data for secondary use and exchange any relevant information at their disposal to ensure application and enforcement of this Regulation and relevant provisions of the aforementioned Regulations, including penalties; (1524 Renew)*
- (b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 ~~and Regulation (EU) 2018/1725~~ where a health data access body has imposed ~~penalties or other~~ **enforcement** measures pursuant to Article 43 ~~or administrative fines pursuant to article 43a~~ in relation to processing personal electronic health data and where such processing refers to an attempt to re-identify an individual or unlawful processing of personal electronic health data;
- (c) cooperate with **all relevant** stakeholders, including patient organisations, representatives from natural persons, health professionals, ~~health industry,~~ researchers, and ~~ethical~~ **ethics** committees, where applicable in accordance with Union and national law; (1528 EPP)
- (d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation [...] [Data Governance Act COM/2020/767 final], the competent authorities under Regulation [...] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745 and Regulation [...] [AI Act COM/2021/206 final]
3. The health data access bodies may provide assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation [...] [Data Act COM/2022/68 final].
4. ~~The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of tasks in paragraph 1 of this Article, to reflect the evolution of activities performed by health data access bodies.~~

<b>COMPROMISE AMENDMENT 38: Article 38</b>
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Replacing the following amendments: 103-110 Rapporteurs, 1539 EPP, 1540 RE, 1541 EPP, 1542 NA, 1543 S&D, 1544 RE, 1545 S&D, 1546 Greens/EFA, 1547 RE, 1548 The Left, 1549 S&D, 1550 S&D, 1551 S&D, 1552 The Left, 1553 The Left, 1554 RE, 1555 S&D, 1556 RE, 1557 ECR, 1558 S&D, 1559 The Left, 1560 The Left, 1561 EPP, 1562 ECR, 1563 Greens/EFA, 1564 RE, 1565 Greens/EFA, 1566 S&D, 1567 EPP, 1568 NA, 1569 The Left, 1570 EPP, 1571 S&D, 1572 RE, 1573 The Left, 1574 S&D, 1575 Greens/EFA, 1576 The Left, 1577 NA, 1578 EPP, 1579 NA, 1580 NA, 1581 S&D, 1582 The Left, 1583 Greens/EFA, 1584 Greens/EFA, 1585 S&D, 1586 The Left, 1587 Greens/EFA, ITRE 49,

### Article 38

#### *Obligations of health data access bodies towards natural persons*

1. Health data access bodies shall make publicly available and easily searchable **and accessible for natural persons** the conditions under which electronic health data is made available for secondary use, with information concerning: (1540 Renew)
  - (a) the legal basis under which access is granted **to the health data user**;
  - (b) the technical and organisational measures taken to protect the rights of natural persons;
  - (c) the applicable rights of natural persons in relation to secondary use of electronic health data, **including the right to opt-out pursuant to Article 33(5) and the right to opt-in pursuant to Article 33(5a), and detailed information on how to exercise them**; (103 Rapporteurs, 1543 S&D ENVI (partially), 1544 Renew, 1542 NI)
  - (d) the ~~arrangements~~ **modalities** for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679; (1547 Renew)
  - (da) the identity and the contact details of the health data access body** (104 Rapporteurs, 1549 S&D LIBE, 1548 The Left LIBE)
  - (db) the record on who has been granted access to which sets of electronic health data and a justification regarding the purposes for processing them as referred to in Article 34(1)**; (105 Rapporteurs, 1550 S&D ENVI, 1551 S&D LIBE, 1552 The Left LIBE, 1553 The Left ENVI, 1554 Renew)
  - (e) the results or outcomes of the projects for which the electronic health data were used.
2. ~~Health data access bodies shall not be obliged to provide the specific information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.~~
3. Where a health data access body is informed by a **health** data user of a **significant** finding **related to that may impact on** the health of a natural person, **as referred to in Article 41a(5) of this Regulation**, the health data access body ~~may~~ **shall** inform the **treating health professional with the relevant competence of the** natural person and **if that health professional cannot be found, and shall inform the natural person** ~~his~~ or her ~~treating health professional~~ about that finding. **Natural persons shall have the right to request not to be informed of such findings. In accordance with Article 23(1), point (i), of Regulation (EU) 2016/679, Member States may by law restrict the**

*scope of the obligation to inform the natural person whenever necessary for the protection of the natural person based on patient safety and ethics by delaying their information until a health professional can communicate and explain to the natural person information that potentially can have an impact. (1565 Greens)*

#### **Article 38a**

##### **Right to lodge a complaint with a health data access body**

- 1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the health data access body, where their rights laid down in this Chapter are affected. Where the complaint concerns the rights of natural persons pursuant to Article 38(1)(d) of this Regulation, the health data access body shall inform and send a copy of the complaint to the competent supervisory authorities under Regulation (EU) 2016/679.**
- 2. The health data access body with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken.**
- 3. Health data access bodies shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.**
- 4. Each health data access body shall facilitate submitting complaints, in particular by providing a complaint submission form which can also be completed electronically, without excluding other means of communication.**

(109 Rapporteurs, 1581 S&D LIBE, 1582 The Left, 1583 Greens, 1579 NI)

#### **Article 38b**

##### **Right to an effective judicial remedy against a health data access body**

- 1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a health data access body concerning them.**
- 2. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy where the health data access body which is competent pursuant to Article 37 does not handle a complaint or does not inform the natural or legal person within three months on the progress or outcome of the complaint lodged pursuant to Article 38a.**
- 3. Proceedings against a health data access body shall be brought before the courts of the Member States where the health data access body is established.**

(110 Rapporteurs, 1584 Greens, 1585 S&D LIBE, 1586 The Left, 1580 NI)

<b>COMPROMISE AMENDMENT 39: Article 39</b>
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Replacing the following amendments: 111 Rapporteurs, 1588 EPP, 1589 EPP, 1590 EPP, 1591 RE, 1592 EPP, 1593 RE, 1594 RE, 1595 RE, 1596 RE, 1597 RE, 1598 EPP, 1599 RE, 1600 Greens/EFA, 1601 EPP, 1602 S&D, 1603 the Left, 1604 The Left, 1605 EPP, ITRE 50, ITRE 52

### Article 39

#### *Reporting by health data access bodies*

1. Each health data access body shall publish an annual activity report **and make it publicly available on its website**, which shall contain at least the following **categories of information**:
  - (a) information relating to the data access applications **and data requests** for electronic health data access submitted, such as the types of applicants, number of data permits granted or refused, purposes of access and categories of electronic health data accessed, and a summary of the results of the electronic health data uses, where applicable; (1591 Renew)
  - (b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;
  - (c) information on the fulfilment of regulatory and contractual commitments by data users and data holders, as well as **the number and amount of penalties administrative fines** imposed **by health data access bodies**; (1593 Renew)
  - (d) information on audits carried out on data users to ensure compliance of the processing **within the secure processing environment as referred to in Article 50 of** this Regulation;
  - (e) 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 50(3) of this Regulation; (Renew 1595)**
  - (f) information on the handling of requests from natural persons on the exercise of their data protection rights;
  - (g) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;
  - (h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence;
  - (i) revenues from data permits and data requests;
  - ~~(j) satisfaction from applicants requesting access to data;~~
  - ~~(k)~~(j) average number of days between application and access to data;
  - ~~(l)~~(k) number of data quality labels issued **by data holders**, disaggregated per quality category;

- ~~(m)~~(l) number of peer-reviewed research publications, policy documents, regulatory procedures using data accessed via the EHDS;
  - ~~(n)~~(m) number of digital health products and services, including AI applications, developed using data accessed via EHDS.
2. The report shall be transmitted to the Commission, **which shall make it publicly available on its website.** (1600 Greens)
  3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to ~~modify~~ **amend paragraph 1 by adding the categories to the ones listed therein** content of the annual activity report.

## COMPROMISE AMENDMENT 40: Article 40

Replacing the following amendments: 1606 EPP, 1607 RE, 1608 The Left, 1609 RE, IMCO 97

### *Article 40*

#### *Data altruism in health*

1. ~~When processing personal electronic health data,~~ **In addition to rules regarding data altruism established by Regulation (EU) 2022/868, where** data altruism organisations shall comply with the rules set out in ~~recognised under~~ Chapter IV of ~~that~~ Regulation [...]~~[Data Governance Act COM/2020/767 final]~~. Where data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation. (1607 Renew)
2. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of Regulation [...]~~[Data Governance Act COM/2020/767 final]~~ **(EU) 2022/868** in the monitoring of entities carrying out data altruism activities, **where electronic health data are concerned.** (1609 Renew)

## COMPROMISE AMENDMENT 41: Article 41

Replacing the following amendments: 1610 RE, 1611 EPP, 1612 ECR, 1613 EPP, 1614 EPP, 1615 Greens/EFA, 1616 RE, 1617 RE, 1618 EPP, 1619 Greens/EFA, 1620 The Left, 1621 EPP, 1622 Greens/EFA, 1623 Greens/EFA, 1624 RE, 1625 EPP, 1626 EPP, 1627 S&D, 1628 EPP, 1629 RE,

### *Article 41*

#### *Duties of health data holders*

1. ~~Where a data holder is obliged to make~~ **Health data holders shall make relevant** electronic health data available under Article 33 ~~or under other Union law or national legislation implementing Union law,~~ **it available upon request to the health data access body pursuant to a data permit issued or data request granted by such a body.**



*Health data holders* shall cooperate in good faith with the health data access bodies, where relevant. (*Renew 1610, 1615 Greens, EPP 1611, ECR 1612*)

- 1a. *The requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises (1220 S&D ENVI, Greens 1219, 1218 ECR) as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC<sup>23</sup>.*
- 1b. *The health data holder shall put the electronic health data at the disposal of the health data access body within 3 months from receiving the request from the health data access body. In justified cases, after consultation with the health data holder concerned, that period may be extended by the health data access body for a maximum of 2 months. The health data access body may decide that the extension be shorter than 2 months. (RE 1616, S&D 1627, EPP 1626 partial)*
- 1c. *Paragraphs 1 and 1a constitute a legal obligation pursuant to Article 6(1)(c) in combination with Article 9(2), points (g) (h), (i) and (j), of Regulation 2016/679 for the health data holder to disclose personal electronic health data to the health data access body. (RE 1617, Greens/EFA 1619, Left LIBE 1620)*
2. The *health* data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55.
3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the *health* data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.
- ~~4. The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months. (1624 Renew)~~
45. Where a *health* data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.
56. ~~*Health data*~~ holders of non-personal electronic health data shall ensure 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 a robust, transparent and sustainable governance and a transparent model of user access.
- ~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the duties of the data holders in this Article, to reflect the evolution of activities performed by data holders. (1628 EPP)~~

#### *Article 41 a*

#### *Duties of health data users*

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<sup>23</sup> Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

1. *Health data users may access and process the electronic health data for secondary use referred to in Article 33 only in accordance with the data permit issued by the health data access body in line with Article 46 of this Regulation.*
3. *Health data users shall not re-identify or seek to re-identify the natural persons to which the electronic health data belong which they obtained based on the data permit or data request. Such conduct shall be considered a serious breach of this Regulation.*
4. *Health data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those results or output shall not contain personal data. In justified cases, especially cases referred to in Article 34(1), point (e), this period may be extended by the relevant health data access body, after consultation with the health data user. The health data users shall inform the health data access bodies from which a data permit was obtained about the results or output and provide them with necessary support in order to make them public also on health data access bodies' websites. The result shall also be made publicly available in lay summaries (AM 1851 S&D). Whenever the health data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS.*
5. *Without prejudice to paragraph 2, health data users shall inform the health data access body of any significant findings related to the health of the natural person whose data are included in the dataset.*
6. *The ECDC and the EMA shall, in consultation and cooperation with relevant stakeholders, including representatives of patients, health professionals and researchers, create guidelines in order to help health data users to fulfil their obligation under paragraph 5, especially to determine whether their findings are clinically significant.*
7. *Health data users shall cooperate in good faith with the health data access bodies, where relevant.*

(1630 Renew)

<b>COMPROMISE AMENDMENT 42: Article 42</b>
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Replacing the following amendments: 112-113 Rapporteurs, 1631 NA, 1632 S&D, 1633 RE, 1634 Greens/EFA, 1635 EPP, 1636 The Left, 1637 ECR, 1638 RE, 1639 ECR, 1640 ECR, 1641 NA, 1642 NA, 1643 Greens/EFA, 1644 EPP, 1645 NA, 1646 S&D, 1647 EPP, 1648 EPP, 1649 RE, 1650 Greens/EFA, 1651 NA, 1652 EPP, 1653 EPP, 1654 S&D, 1655 NA, 1656 Greens/EFA, 1657 S&D, IMCO 98

*Article 42*

*Fees*

1. Health data access bodies ~~and single data holders~~ (112 Rapporteurs partial, 1632 S&D, 1634 Greens partial, 1637 The Left LIBE partial) may charge fees to health data users for making electronic health data available for secondary use. Any fees

shall include and be derived from the costs related to the *set up, combination, preparation, anonymisation, pseudonymisation, maintenance, tasks according to Article 33a, making available or updating of the dataset and* conducting the procedure for requests, including for assessing a data application or a data request, granting, refusing or amending a data permit pursuant to Articles 45 and 46 or providing an answer to a data request pursuant to Article 47, in accordance with Article 6 of Regulation [...] [Data Governance Act COM/2020/767 final]. ***No fees shall be charged to public sector bodies and Union institutions, offices, agencies and bodies when making data available for the purposes referred to in points (a) to (c) of Article 34(1). (S&D 1632 adapted, 1633 RE (partially), 1634 Greens). No fees shall be charged to public sector bodies and Union institutions, offices, agencies and bodies with a legal mandate in the field of public health.***

2. ***In case of health data holders***, where the data in question are not held by the *health data access body or a public sector body or a Union institution, office, agency and body*, the fees may ***be derived from*** the costs for ~~collecting~~ *gathering, enriching, and preparing* the electronic health data specifically under this Regulation in addition to the fees that may be charged pursuant to paragraph 1. The part of the fees linked to the *health data holder's* costs shall be paid to the *health data holder*. ***(Renew 1638)***
3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the electronic health data. That fee shall be paid to the entity that enriched the electronic health data.
4. Any fees charged to *health data users* pursuant to this Article by the health data access bodies or *health data holders* shall be transparent, ***non-discriminatory, (1649 Renew partial)*** and proportionate to the cost of making electronic health data available for secondary use, objectively justified and shall not restrict competition. The support received by the *health data holder* from donations, public national or Union funds, to set up, develop or update ~~that~~ ***that*** dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, ***academic and*** educational institutions, ***non-commercial entities*** (1648 EPP) and healthcare providers shall be taken into account when setting the fees, by reducing those fees proportionately to their size or budget (113 Rapporteurs, 1647 (partially))
5. Where *health data holders* and *health data users* do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the *health data holder* or the *health data user* disagree with the fee set out by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation [...] [Data Act COM/2022/68 final]. (1652 EPP)
6. The Commission ~~may~~ ***shall***, by means of implementing acts, lay down principles and rules for the fee policies and fee structures, ***including deductions for the entities listed in paragraph 4, second sub-paragraph***. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). (1657 S&D, 1656 Greens partial).

<b>COMPROMISE AMENDMENT 43: Article 43</b>
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Replacing the following amendments: 114-115 Rapporteurs, 1658 Greens/EFA, 1659 RE, 1660 RE, 1661 EPP, 1662 RE, 1663 Greens/EFA, 1664 The Left, 1665 S&D, 1666 The Left, 1667 RE, 1668 EPP, 1669 NA, 1670 The Left, 1671 S&D, 1672 RE, 1673 The Left, 1674 EPP, 1675 Greens/EFA, 1676 EPP, 1677 S&D, 1678 RE, 1679 Greens/EFA, 1680 RE, 1681 ECR, 1682 Greens/EFA, 1683 Greens/EFA, 1684 ECR, 1685 S&D, 1686 RE, 1687 EPP, 1688 NA/ID, 1689 NA/ID

### Article 43

#### **Enforcement by health data access bodies (1658 Greens)**

1. ~~Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter. (1659 Renew)~~
2. ~~When requesting from data users and data holders the information that is necessary carrying out its monitoring and supervisory tasks to verify compliance with this Chapter, as referred to in Article 37(1), point (ra), the health data access bodies shall be proportionate to request information from health data holders and users that is proportionate for the performance of the compliance verification task. (1660 Renew)~~
3. 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 shall give it the opportunity to state its views within ~~4 weeks~~2 months.

***Where the finding of non-compliance concerns a possible breach of Regulation (EU) 2016/679, the health data access body shall immediately inform the supervisory authorities under Regulation (EU) 2016/679 and provide them with all relevant information at their disposal of this finding to ensure application and enforcement of the relevant provisions of the aforementioned Regulation, including penalties. (1662 Renew)***

4. Health data access bodies shall have the power to revoke the data permit issued pursuant to Article 46 and stop the affected electronic health data processing operation carried out by the **health** data user in order to ensure the cessation of the non-compliance referred to in paragraph 3, immediately or **without undue delay** ~~within a reasonable time limit~~, and shall take appropriate and proportionate measures aimed at ensuring compliant processing by the **health** data users. In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the **health** data user from any access to electronic health data for a period of up to 5 years.
5. Where **health** data holders withhold the electronic health data from health data access bodies with the manifest intention of obstructing the use of electronic health data, or do not respect the deadlines set out in Article 41, the health data access body shall have the power to fine the **health** data holder with fines for each day of delay, which shall be transparent and proportionate. The amount of the fines shall be established by the health data access body. In case of repeated breaches by the **health** data holder of the obligation of loyal cooperation with the health data access body, that body can exclude the **health** data holder from ~~participation in the EHDS~~ **submitting data access applications pursuant to Chapter IV** for a period of up to 5 years, **while still being**

~~*obliged to make data accessible* Where a data holder has been excluded from the participation in the EHDS pursuant to this Article, following manifest intention of obstructing the secondary use of electronic health data, it shall not have the right to provide access to health data in accordance with Article 49 Chapter IV, where applicable. (Greens 1675)~~

6. The health data access body shall communicate the measures imposed pursuant to paragraphs 4 **and 5** and the reasons on which they are based to the **health** data user or holder concerned, without delay, and shall lay down a reasonable period for the **health** data user or holder to comply with those measures. **(1678 Renew)**
7. Any ~~penalties and~~ **enforcement** measures imposed pursuant to paragraph 4 shall be ~~made available~~ **notified** to other health data access bodies **and made publicly available on the website of the EHDS Board.** **(1679 Greens, 1680 Renew)**
- 7a. **The health data access body should ensure coherent enforcement based on the provisions of this Regulation and the Regulation (EU) 2016/679 by taking into account any decision or investigation ongoing in supervisory authorities.**
8. The Commission may, by means of implementing act, set out the architecture of an IT tool aimed to support and make transparent to other health data access bodies the activities referred to in this Article, especially penalties and exclusions. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).
- ~~9. Any natural or legal person affected by a decision of a health data access body shall have the right to an effective judicial remedy against such decision.~~
10. The Commission ~~may~~ **shall** issue guidelines on ~~penalties~~ **administrative fines enforcement measures** to be applied by the health data access bodies, **in line with the principles set out in Article 68a.** **(1681, 1683 Greens, 1684 ECR, 1685 S&D ENVI, 1686 Renew, 1687 EPP)**

### *Article 43a*

#### *General conditions for the imposition of administrative fines by health data access bodies*

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 shall in each individual case be effective, proportionate and dissuasive.**
2. **Administrative fines shall, depending on the circumstances of each individual case, be imposed in addition to, or instead of, measures referred to in Article 43(4) and (5). When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case due regard shall be given to the following:**
  - (a) **the nature, gravity and duration of the infringement;**

- (aa) *whether any penalties or administrative fines have already been applied by other competent authorities to the same infringing party for the same infringement;*
  - (b) *the intentional or negligent character of the infringement;*
  - (c) *any action taken by the health data holder or health data user to mitigate the damage suffered by natural persons;*
  - (d) *the degree of responsibility of the health data user taking into account technical and organisational measures implemented by them pursuant to points (e) and (f) of Article 45(2) and Article 45(4);*
  - (e) *any relevant previous infringements by the health data holder or health data user;*
  - (f) *the degree of cooperation with the health data access body, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;*
  - (g) *the manner in which the infringement became known to the health data access body, in particular whether, and if so to what extent, the health data user notified the infringement;*
  - (h) *where measures referred to in Article 43(4) and (5) have previously been ordered against the controller or processor concerned with regard to the same subject-matter, compliance with those measures;*
  - (i) *any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.*
3. *If a health data holder or health data user intentionally or negligently, for the same or linked health data permits or health data requests, infringes several provisions of this Regulation, the total amount of the administrative fine shall not exceed the amount specified for the gravest infringement.*
  4. *In accordance with paragraph 2, infringements of the obligations of the health data holder or health data user pursuant to Articles 41 and 41a(1), (4), (5) and (7) shall be subject to administrative fines up to 10 000 000 EUR, or in the case of an undertaking, up to 2 % of the total worldwide annual turnover of the preceding financial year, whichever is higher.*
  5. *Infringements of the following provisions shall, in accordance with paragraph 2, be subject to administrative fines up to 20 000 000 EUR, or in the case of an undertaking, up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher;*
    - (a) *health data users processing electronic health data obtained via a data permit issued in line with Article 46 for the purposes referred to in Article 35;*

- (b) *health data users extracting personal health data outside the secure processing environment provided by the health data access body pursuant to Article 50;*
- (c) *re-identifying or seeking to re-identify the natural persons to which the electronic health data belong which they obtained based on the data permit or data request pursuant to Article 41a(3);*
- (d) *non-compliance with enforcement measures by the health data access body pursuant to Article 43.*

- ~~(a) the basic principles for processing, including conditions for consent, pursuant to Articles 5, 6, 7 and 9;~~
- ~~(b) the data subjects' rights pursuant to Articles 12 to 22;~~
- ~~(c) the transfers of personal data to a recipient in a third country or an international organisation pursuant to Articles 44 to 49;~~
- ~~(d) any obligations pursuant to Member State law adopted under Chapter IX;~~
- ~~(e) non-compliance with an order or a temporary or definitive limitation on processing or the suspension of data flows by the supervisory authority pursuant to Article 58(2) or failure to provide access in violation of Article 58(1).~~

~~6. Non-compliance with an order by the supervisory authority as referred to in Article 58(2) shall, in accordance with paragraph 2 of this Article, be subject to administrative fines up to 20 000 000 EUR, or in the case of an undertaking, up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher.~~

7. Without prejudice to the corrective powers of *health data access bodies* supervisory authorities pursuant to Article 43 58(2), each Member State may lay down the rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.

8. The exercise by the *health data access body* of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedy and due process.

9. Where the legal system of the Member State does not provide for administrative fines, this Article may be applied in such a manner that the fine is initiated by the competent *health data access body* supervisory authority and imposed by competent national courts, while ensuring that those legal remedies are effective and have an equivalent effect to the administrative fines imposed by *health data access bodies* supervisory authorities. In any event, the fines imposed shall be effective, proportionate and dissuasive. Those Member States shall notify to the Commission the provisions of their laws which they adopt pursuant to this paragraph by xxxx *[date of application]* 25 May 2018 and, without delay, any subsequent amendment law or amendment affecting them.

## SECTION 3

### DATA PERMIT FOR THE SECONDARY USE OF ELECTRONIC HEALTH DATA

#### COMPROMISE AMENDMENT 44: Article 44

Replacing the following amendments: 116-118 Rapporteurs, 1690 RE, 1691 The Left, 1692 Greens/EFA, 1693 S&D, 1694 EPP, 1695 ECR, 1696 ECR, 1697 The Left, 1698 EPP, 1699 Greens, 1700 EPP, 1701 EPP, 1702 Greens/EFA, 1703 Greens/EFA, 1704 ECR, 1705 The Left, 1706 EPP, 1707 RE, 1708 EPP, 1709 ID, 1710 Greens/EFA, 1711 EPP, 1712 EPP, 1713 EPP, 1714 S&D, 1715 S&D, 1716 S&D, 1717 S&D, 1718 The Left, 1719 The Left, 1720 Greens/EFA, 1721 S&D, 1722 EPP, 1723 NA, IMCO 99

#### *Article 44*

##### *Data minimisation and purpose limitation*

1. The health data access body shall ensure that access is only provided to requested electronic health data **that are adequate**, relevant **and limited to what is necessary in relation to** the purpose of processing indicated in the data access application by the data user and in line with the data permit granted. **(116 Rapporteurs, 1692 Greens, 1693 S&D LIBE, 1691 The Left)**
2. The health data access bodies shall provide the electronic health data in an anonymised format, **in any event** 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.
3. **Where the health data user has sufficiently demonstrated that (1707 Renew)** the purpose of the data user's processing cannot be achieved with anonymised data in line with Article 46(1c), taking into account the information provided by the **health** data user the health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary **(117 Rapporteurs, 1711 EPP LIBE)** to reverse the pseudonymisation shall be available only to the health data access body. **Health** Data users shall not re-identify the electronic health data provided to them in **anonymised or** pseudonymised format. **(1710 Greens partially)**
- 3a. The **health** data user's failure to respect the health data access body's measures ensuring **anonymisation and (118 Rapporteurs, 1714 S&D, 1710 Greens partially)** pseudonymisation shall be **considered a particularly serious breach of this Regulation and shall be** subject to appropriate **effective, proportionate and dissuasive** penalties. **(1707 Renew)**
- 3b. **The Commission shall, by means of implementing acts, set out the procedures and requirements, and provide technical tools, for a unified procedure for anonymising and pseudonymising the electronic health data. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). (1720 Greens)**

#### COMPROMISE AMENDMENT 45: Article 45



Replacing the following amendments: 119-123 Rapporteurs, 1724 RE, 1725 Greens/EFA, 1726 NA, 1727 RE, 1728 S&D, 1729 S&D, 1730 S&D, 1731 Greens/EFA, 1732 RE, 1733 The Left, 1734 The Left, 1735 The Left, 1736 RE, 1737 Greens/EFA, 1738 The Left, 1739 The Left, 1740 RE, 1741 RE, 1742 The Left, 1743 S&D, 1744 RE, 1745 S&D, 1746 RE, 1747 S&D, 1748 The Left, 1749 EPP, 1750 The Left, 1751 The Left, 1752 S&D, 1753 Greens/EFA, 1754 RE, 1755 The Left, 1756 S&D, 1757 The Left, 1758 The Left, 1759 RE, 1760 S&D, 1761 S&D, 1762 The Left, 1763 NA, 1764 EPP, 1765 RE, 1766 EPP, 1767 S&D, 1768 The Left, 1769 S&D, 1770 RE, 1771 The Left, 1772 EPP, 1773 EPP, 1774 Greens/EFA, 1775 RE, 1776 RE, 1777 S&D, 1778 The Left, 1779 RE, 1780 The Left, 1781 EPP, 1782 EPP, 1783 EPP, 1784 NA, 1785 RE, 1786 RE, ITRE 55,

## *Article 45*

### *Data access applications*

1. ***Health data applicants*** ~~Any natural or legal person with a demonstrable professional link to the areas of health care, public health or medical research (RE 1724 and Greens 1725 adapted)~~ may submit a data access application for the purposes referred to in Article 34.
2. The data access application shall include:
  - (-a) ***the health data applicant's identity, description of professional functions and operations, including the identity of the natural persons who will have access to electronic health data, if a data permit is granted; the list of natural persons can be updated and in that case it shall be notified to the health data access body;***
  - (a) a detailed explanation of the intended use of the electronic health data including for which of the purposes referred to in Article 34(1) ***(19 rapp)***, access is ~~sought~~ ***necessary; (Greens 1731)***
  - (aa) ***a description of how the health data applicant is qualified vis-à-vis the intended purposes of data use, including professional qualifications to demonstrate appropriate expertise, consistent with ethical practice and applicable laws and regulations; (Rapp 121, S&D ENVI 1761, RE 1736 adapted, 1751 The Left LIBE)***
  - (ab) ***an explanation of the expected benefits and how these benefits contribute to the purposes referred to in Article 34 (1); (RE 1740) (The Left 1735)***
  - (b) a description of the requested electronic health data, their ***timeframe***, (RE 1741) format and data sources, where possible, including geographical coverage where data is requested from several Member States;
  - (c) an ***explanation*** ~~indication~~ whether electronic health data ~~should~~ ***needs to*** be made available in ***a pseudonymised format and why the envisaged purpose for processing cannot be pursued using anonymised format data (RE 1744);***
  - ~~(d) where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format; (S&D 1745)~~
  - (d) a description of the safeguards planned to prevent any other use ***or any misuse*** of the electronic health data; (S&D, AM 1747)

- (e) a description of the safeguards *proportionate to the risks*, planned to protect the rights and interests of the *health* data holder;
  - (f) *for personal electronic health data, a description of the necessary technical and organizational measures pursuant to Article 32 of Regulation (EU) 2016/679; (Left LIBE 1750, EPP 1749), to protect the rights and interests of the natural persons concerned, including to prevent any re-identification of natural persons in the dataset, (120 rapp, 1746 RE, 1747 S&D LIBE, 1748 The Left LIBE adapted);*
  - (g) ~~an~~ *a justified* (S&D 1752) estimation of the period during which the electronic health data is needed for processing;
  - (h) a description of the tools and computing resources needed for a secure environment.
  - (ha) *where applicable, information on the assessment of ethical aspects of the processing and details of any necessary ethics approval obtained by the competent ethics committee in line with national law, which may serve to replace their own ethics assessment; (RE 1754 adapted)*
  - (hb) *a plan defining audiences and tools to publicly inform on the results or outcomes of the access to the data in accordance with Article 46(11); (123 rapp, 1756 S&D ENVI, 1757 The Left ENVI)*
  - (hc) *a declaration that the intended uses of the data requested do not pose a risk of stigmatisation or dignitary harm to both individuals and the groups implicated in the dataset requested. (Renew, AM 1759)*
3. *Health data applicants* seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the *application with the* other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data access application. *In such a case*, the health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application. (RE 1765)
4. Where the *health data applicants* ~~applicant~~ intend to access the personal electronic health data in a pseudonymised format, the following additional information shall be provided together with the data access application:
- (a) a description of how the processing would comply with ~~Article 6(1) of~~ *applicable Union and national law on data protection and privacy, notably Regulation (EU) 2016/679;*
  - (b) ~~information on the assessment of ethical aspects of the processing, where applicable and in line with national law. (RE1777)~~
5. For the implementation of the tasks referred to in Article 37(1), points (b) and (c), the public sector bodies and the Union institutions, bodies, offices and agencies shall provide the same information as requested under Article 45(2), except for point (g), where they shall submit information concerning the period for which the data can be accessed, the frequency of that access or the frequency of the data updates.

6. The Commission *shall (RE 1786)*, by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 68(2).
7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of the list for processing a data access application at national or cross-border level.

## COMPROMISE AMENDMENT 46: Article 46

Replacing the following amendments: 124-127 Rapporteurs, 1787 S&D, 1788 EPP, 1789 EPP, 1790 S&D, 1791 Greens/EFA, 1792 The Left, 1793 ECR, 1794 RE, 1795 EPP, 1796 Greens/EFA, 1797 Greens/EFA, 1798 Greens/EFA, 1799 Greens/EFA, 1800 Greens/EFA, 1801 Greens/EFA, 1802 RE, 1803 The Left, 1804 NA, 1805 S&D, 1806 RE, 1807 Greens/EFA, 1808 NA, 1809 EPP, 1810 EPP, 1811 EPP, 1812 ID, 1813 S&D, 1814 RE, 1815 EPP, 1816 Greens/EFA, 1817 The Left, 1818 S&D, 1819 The Left, 1820 EPP, 1821 NA, 1822 S&D, 1823 EPP, 1824 Greens/EFA, 1825 The Left, 1826 ID, 1827 EPP, 1828 EPP, 1829 RE, 1830 RE, 1831 RE, 1832 RE, 1833 EPP, 1834 EPP, 1835 The Left, 1836 EPP, 1837 Greens/EFA, 1838 S&D, 1839 RE, 1840 RE, 1841 EPP, 1842 S&D, 1843 S&D, 1844 S&D, 1845 RE, 1846 EPP, 1847 EPP, 1848 NA, 1849 EPP, 1850 RE, 1851 S&D, 1852 The Left, 1853 EPP, 1854 RE, 1855 S&D, 1856 EPP, 1857 EPP, 1858 RE, 1859 Greens/EFA, 1860 EPP, 1861 EPP, IMCO 100, ITRE 57, ITRE 58

### *Article 46*

#### *Data permit*

1. Health data access bodies shall *issue a data permit only when, after an assessment of the data access*~~assess if the application, they find that it fulfils all of the following criteria: one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant.~~
  - (a) *the purpose described in the health data access application is one of the purposes listed in Article 34(1);*
  - (b) *the requested data is necessary, adequate and proportionate for the purpose or purposes listed in the health data access application;*
  - (c) *in the case of pseudonymised data, there is sufficient justification that the purpose cannot be achieved with anonymised data;*
  - (d) *the processing complies with Articles 6(1) and 9(2) of Regulation (EU) 2016/679 in case of access to pseudonymised electronic health data; ;*
  - (e) *the health data applicant demonstrates sufficient technical and organisational measures to prevent any other use or misuse of the electronic health data and*

*to protect the rights and interests of the data holder and of the natural persons concerned;*

- (f) the information on the assessment of ethical aspects of the processing, where applicable, is in line with national law;*
- (g) all other requirements in this Chapter are fulfilled by the health data applicant.*

If that is the case, the health data access body shall issue a data permit.

2. Health data access bodies shall refuse all applications ~~including one or more purposes listed in Article 35 or where requirements in this Chapter are not met.~~
3. *After the health data applicant has demonstrated the effective implementation of their security measures referred to in Article 45(2), points (e) and (f) (AM 1837 Greens, 1838 S&D), the* A health data access body shall issue or refuse a data permit within 2 months of receiving *a complete* data access application. *If the health data access body finds that the data access application is incomplete, it shall notify the health data applicant, who shall be given the possibility to complete their application .If the health data applicant does not fulfill this request within 4 weeks, a permit will not be granted.* (EPP 1811) By way of derogation from ~~that~~ Regulation (EU) 2022/868 the health data access body may extend the period for responding to a data access application by 2 additional months where necessary, taking into account the complexity of the request. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. ~~Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued.~~
4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the data holder *and inform them whether the data will be made accessible in anonymised or pseudonymised form (Greens 1824)*. The health data access body shall make available the electronic health data to the *health data user* within 2 months after receiving them from the data holders, ~~unless the health data access body specifies that it will provide the data within a longer specified timeframe.~~
5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the *health data applicant*.
6. The data permit shall set out the general conditions applicable to the *health data user*, in particular:
  - (a) *categories (RE1829)* and format of electronic health data accessed, covered by the data permit, including their sources;
  - (b) *a detailed description of the* purpose for which data are made available;
  - b a) the identity of the user as well as the concrete persons who are authorised to have access to the electronic health data in the secure processing environment;*
  - (c) duration of the data permit;
  - (d) information about the technical characteristics and tools available to the *health data user* within the secure processing environment;
  - (e) fees to be paid by the *health data user*;

- (f) any additional specific conditions in the data permit granted.
7. 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 delivered to them on the basis of this Regulation.
  8. The Commission is empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph ~~67~~ of this Article, in accordance with the procedure set out in Article 67.
  9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed 5 years. This duration may be extended once, at the request of the data user, based on arguments and documents to justify this extension provided, 1 month before the expiry of the data permit, for a period which cannot exceed 5 years. By way of derogation from Article 42, the health data access body may charge increasing fees to reflect the costs and risks of storing electronic health data for a longer period of time exceeding the initial 5 years. In order to reduce such costs and fees, the health data access body may also propose to the data user to store the dataset in storage system with reduced capabilities. The data within the secure processing environment shall be deleted *without undue delay* ~~within 6 months~~ following the expiry of the data permit. Upon request of the data user, the formula on the creation of the requested dataset shall be stored by the health data access body.
  10. If the data permit needs to be updated, the data user shall submit a request for an amendment of the data permit.
  - ~~11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS.~~
  - ~~12. Data users shall inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset.~~
  13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 68(2).
  14. The liability of health data access bodies as ~~joint~~ controller is limited to the scope of the issued data permit until the completion of the processing activity *and in accordance with Article 51 (AM 1858 RE)*.

#### **COMPROMISE AMENDMENT 47: Article 47**

Replacing the following amendments: 1862 NA, 1863 RE, 1864 Greens/EFA, 1865 EPP, 1866 NA, 1867 RE, 1868 NA, 1869 NA, 1870 NA, 1871 RE, 1872 EPP, 1873 ID

Article 47

**Health data request**

1. ~~The health data applicant~~~~Any natural or legal person~~ may submit a **health** data request for the purposes referred to in Article 34 **with the aim of obtaining an answer only in anonymised or aggregated statistical format**. A health data access body shall ~~only~~ **not** provide an answer to a **health** data request in ~~an anonymised statistical~~ **any other** format and the **health** data user shall have no access to the electronic health data used to provide this answer. **(1863 Renew)**
2. A **health** data request shall include the elements mentioned in paragraphs 2 (a) and (b) of Article 45 and if needed may also include:
  - (a) a description of the result expected from the health data access body;
  - (b) a description of the statistic's content.
3. ~~Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request,~~ The health data access body shall assess **the health data request (1871 Renew)**, within 2 months and, where possible, provide the result to the **health** data user within 2 months. **(1872 EPP)**

**COMPROMISE AMENDMENT 48: Article 48**

Replacing the following amendments: 1874 EPP, 1875 NA, 1876 S&D, 1877 S&D, 1878 S&D, 1879 Greens/EFA, 1880 EPP, 1881 RE, EPP, 1883 The Left, 1884 RE, 1885 S&D, ITRE 59

Article 48

*Making data available, without a data permit, for public sector bodies and Union institutions, bodies, offices and agencies with a legal mandate in the field of public health*

By derogation from Article 46 of this Regulation, a **health** data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform *public sector bodies* and ~~the Union institutions, offices, agencies,~~ **Union institutions, offices, agencies and bodies with a legal mandate in the field of public health**, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation [...] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation [...] [Data Governance Act COM/2020/767 final ], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make available the electronic health data to the **health** data user within 2 months after receiving them from the **health** data holders, unless it specifies that it will provide the data within a longer specified timeframe. **Articles 43 and 43a shall be applicable to situations covered under this Article.**

**COMPROMISE AMENDMENT 49: Article 49**

Replacing the following amendments: 128 rapporteurs, 1886 ID, 1887 EPP, 1888 NA, 1889 S&D, 1890 S&D, 1891 The Left, 1892 Greens/EFA, 1893 RE, 1894 NA, 1895 NA, 1896 NA, 1897 NA, 1898 EPP, IMCO 101

#### *Article 49*

##### *Access to electronic health data from a single data holder*

- ~~1. Where an applicant requests access to electronic health data only from a single data holder in a single Member State, by way of derogation from Article 45(1), that applicant may file a data access application or a data request directly to the data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several data holders shall be addressed to health data access bodies.~~
- ~~2. In such case, the data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. The data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.~~
- ~~3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controllers.~~
- ~~4. Within 3 months the data holder shall inform the relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.~~

*(128 Rapporteurs, 1889 S&D LIBE, 1890 S&D ENVI, 1891 The Left, 1892 Greens, 1893 Renew)*

#### **COMPROMISE AMENDMENT 50: Article 50**

Replacing the following amendments: 129-131 Rapporteurs, 1899 EPP, 1900 S&D, 1901 The Left, 1902 Greens/EFA, 1903 EPP, 1904 Greens/EFA, 1905 EPP, 1906 RE, 1907 EPP, 1908 S&D, 1909 Greens/EFA, 1910 S&D, 1911 RE, 1912 Greens/EFA, 1913 NA/ID, 1914 RE, 1915 Greens/EFA

#### *Article 50*

##### *Secure processing environment*

1. The health data access bodies shall provide access to electronic health data ***pursuant to a data permit (129 Rapporteurs)*** only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures:
  - (a) restrict access to the secure processing environment to authorised persons listed in the respective data permit;
  - (b) minimise 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*; (130 Rapporteurs, 1901 The Left, 1902 Green partially)

- (c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;
- (d) ensure 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;
- (e) keep identifiable logs of access to the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment *and not shorter than one year* (1904 Greens);
- (f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.

*(fa) ensure that the secure processing environment is located within the Union.*

- 2. The health data access bodies shall ensure that electronic health data *from health data holders in the format determined by the data permit* (131 Rapporteurs, 1908 S&D LIBE) can be uploaded by *health* data holders and can be accessed by the *health* data user in a secure processing environment. The *health* data users shall only be able to download *or copy* (1909 Greens) non-personal electronic health data from the secure processing environment, *in accordance with article 37*.
- 3. The health data access bodies shall ensure regular audits, *including by third parties* (1911 Renew), of the secure processing environments *and take immediate corrective action of any shortcomings, risks or vulnerabilities identified in the secure processing environments* (1910 S&D ENVI).
- 4. The Commission shall, by means of implementing acts, provide for the technical, *organisational*, (1915 Greens) information security, *confidentiality*, [data protection] and interoperability requirements for the secure processing environments, *after having consulted with ENISA* (1914 Renew). Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

## COMPROMISE AMENDMENT 51: Article 51

Replacing the following amendments: 132-134 Rap., 1916 RE, 1917 S&D, 1918 RE, 1919 S&D, 1920 EPP, 1921 S&D, 1922 Greens/EFA, 1923 RE, 1924 S&D, 1925 S&D

### Article 51

*Joint-controllers Controllership* (132 Rapporteurs, 1916 Renew, 1917 S&D ENVI)

- 1. ~~The health data access bodies and the data users, including Union institutions, bodies, offices and agencies, shall be deemed joint controllers of electronic health data processed in accordance with data permit.~~ *The health data holder shall be deemed controller for making data available the requested personal electronic health data to the health data access body pursuant to Article 41(1) and (1a) of this Regulation. The health data access body shall be deemed controller for the processing of the personal electronic health data when fulfilling its tasks pursuant to Article 37(1)(d) of this Regulation. The health data user shall be deemed controller for the*



*processing of personal electronic health data in pseudonymised form in the secure processing environment pursuant to its data permit. The health data access body shall act as a processor for the health data user's processing pursuant to a data permit in the secure processing environment. (133 Rapporteurs, 1919 S&D LIBE, 1921 S&D ENVI (partially), 1918 Renew)*

## SECTION 4

### CROSS-BORDER ACCESS TO ELECTRONIC HEALTH DATA FOR SECONDARY USE

#### COMPROMISE AMENDMENT 52: Article 52

Replacing the following amendments: 135-137 Rap., 1926 EPP, 1927 NA, 1928 EPP, 1929 S&D, 1930 EPP, 1931 ECR, 1932 RE, 1933 NA, 1934 S&D, 1935 Greens/EFA, 1936 S&D, 1937 EPP, 1938 S&D, 1939 NA, 1940 EPP, 1941 Greens/EFA, 1942 Greens/EFA, 1943 Greens/EFA, 1944 Greens/EFA, 1945 S&D, 1946 Greens/EFA, 1947 S&D, 1948 RE, 1949 The Left, 1950 Greens/EFA, 1951 Greens/EFA, 1952 S&D, 1953 The Left, 1954 Greens/EFA, 1955 The Left, 1956 Greens/EFA, 1957 The Left, 1958 Greens/EFA, 1959 The Left, 1960 RE, 1961 S&D, 1962 The Left, 1963 NA, 1964 Greens/EFA, 1965 ECR, 1966 ECR, ITRE 61

#### *Article 52*

*Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)*

1. Each Member State shall designate a national contact point for secondary use of electronic health data, responsible for making electronic health data available for secondary use in a cross-border context and shall communicate their names and contact details to the Commission. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.
2. The national contact points referred to in paragraph 1 shall be authorised participants in the cross-border infrastructure for secondary use of electronic health data (HealthData@EU). The national contact points shall facilitate the cross-border access to electronic health data for secondary use for different authorised participants in the infrastructure and shall cooperate closely with each other and with the Commission.
3. Union institutions, bodies, offices and agencies involved in **health** research, health policy or analysis, shall be authorised participants of HealthData@EU. **(1929 S&D)**
4. Health-related research infrastructures, or similar structures whose functioning is based on Union law, and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory purposes shall be authorised participants of HealthData@EU.
5. Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation, **where the transfer stemming from such connection complies with the rules in Chapter V of Regulation (EU) 2016/679 (136 Rapporteurs, 1934 S&D ENVI, 1936 S&D LIBE, 1932 Renew (partially)) and Article 63a** and **where** provide access to data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies. The Commission may adopt implementing acts

establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of HealthData@EU for the purposes of secondary use of health data, is compliant with the Chapter IV of this Regulation *and Chapter V of Regulation (EU) 2016/679 (136 Rapporteurs, 1934 S&D ENVI, 1936 S&D LIBE, 1932 Renew, Greens 1935 (similar))* and provides access to data users located in the Union to the electronic health data it has access to on equivalent terms and conditions. The compliance with these legal, organisational, technical and security requirements, including with the standards for secure processing environments pursuant to Article 50 shall be checked under the control of the Commission. These implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.

6. Each authorised participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross-border infrastructure and to allow the authorised participants to connect to each other within it.
7. The Commission is empowered to adopt delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.
8. 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 of electronic health data of all Member States and authorised participants in that infrastructure.
9. The Commission shall develop, deploy and operate a core platform for HealthData@EU by providing information technology services needed to facilitate the connection between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the ~~joint~~ controllers as a processor.
10. Where requested by two or more health data access bodies, the Commission may provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50. Where two or more health data access bodies put electronic health data in the secure processing environment managed by the Commission, they shall be joint controllers and the Commission shall be processor.
11. The authorised participants shall act as joint controllers of the processing operations in which they are involved carried out in HealthData@EU and the Commission shall act as a processor.
12. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations [...] [~~Data Governance Act COM/2020/767 final~~] (EU) 2022/868 and [...] [Data Act COM/2022/68 final].
13. The Commission ~~may~~ **shall**, by means of *delegated* acts, set out: *(1945 S&D ENVI)*
  - (a) requirements, technical specifications, the IT architecture of HealthData@EU, *which shall ensure state-of-the-art data security, confidentiality, and*

*protection of electronic health data in the cross border infrastructure, (1947 S&D ENVI, 1950 Greens (partially), 1949*

- (aa) *conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and conditions for temporary or definitive exclusion from HealthData@EU, including specific provisions for cases of serious misconduct or repeated violation; (1951 Greens, 1952 S&D ENVI, 1959 The Left LIBE)*
- (b) the minimum criteria that need to be met by the authorised participants in the infrastructure;
- (c) the responsibilities of the joint controllers and processor(s) participating in the cross-border infrastructures;
- (d) the responsibilities of the joint controllers and processor(s) for the secure environment managed by the Commission;
- (e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.

Those *delegated* acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). *The Commission shall consult with the European Union Agency for Cyber Security (ENISA) in the drawing up of the delegated act. (1961 S&D ENVI, 1962 The Left LIBE)*

14. The approval for individual authorised participants to join HealthData@EU or to disconnect a participant from the infrastructure shall be issued by the Joint Controllershship group, based on the results of the compliance checks.

### **COMPROMISE AMENDMENT 53: Article 53**

Replacing the following amendments 1967 RE, 1968 EPP, 1969 EPP, 1970 Greens/EFA

#### *Article 53*

*Access to cross-border ~~sources of electronic health data~~ registries and databases for secondary use (1967 Renew)*

1. In the case of cross-border registries and databases, the health data access body in which the data holder is registered shall be competent to decide on data access applications to provide access to electronic health data. Where the registry has joint controllers, the health data access body that shall provide access to electronic health data shall be the body in the Member State where one of the joint controllers is established.
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 may designate one of their members as a coordinator to ensure the provision of data from the registries' network for secondary use. The health data access body of the Member State in which the coordinator of the network is located shall be competent to decide on the data access applications to provide access to electronic health data for the network of registries or databases.

3. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common procedures for handling cross-border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

#### **COMPROMISE AMENDMENT 54: Article 54**

Replacing the following amendments: 1971 RE, 1972 RE, 1973 EPP, 1974 EPP, 1975 S&D, 1976 S&D

##### *Article 54*

##### ***Cross-border access and mutual recognition of data permits (1971 Renew)***

1. When handling an access application for cross-border access to electronic health data for secondary use, health data access bodies and relevant authorised participants shall remain responsible for taking decisions to grant or refuse access to electronic health data within their remit in accordance with the requirements for access laid down in this Chapter. ***After a decision is made regarding the granting or refusal of the health data permit, the health data access body shall inform the other health data bodies concerned by the same application about the decision. (1972 Renew)***
2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies.

#### **COMPROMISE AMENDMENT 55: Article 55**

Replacing the following amendments 1977 RE, 1978 EPP, 1979 Greens/EFA

##### *Article 55*

##### ***Dataset description and dataset catalogue (1977 Renew)***

1. The health data access bodies shall inform the data users about the available datasets and their characteristics through a metadata catalogue. Each dataset shall include information concerning the source, the scope, the main characteristics, nature of electronic health data and conditions for making electronic health data available.
2. The Commission shall, by means of implementing acts, set out the minimum information elements data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

#### **COMPROMISE AMENDMENT 56: Article 56**

Replacing the following amendments: 1980 RE

## Article 56

### *Data quality and utility label*

1. Datasets made available through health data access bodies may have a Union data quality and utility label provided by the data holders.
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, in accordance with the principles set out in paragraph 3.
  - 2a. ***The health data access body shall assess whether the data meets the requirements in paragraph 3 and shall revoke the label in case the data does not meet the required quality.***
3. The data quality and utility label shall ~~comply with~~ ***cover (137 Rapporteurs)*** the following elements:
  - (a) for data documentation: meta-data, support documentation, data model, data dictionary, standards used, provenance;
  - (b) technical quality, showing the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;
  - (c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;
  - (d) coverage: representation of multi-disciplinary electronic health data, representativity of population sampled, average timeframe in which a natural person appears in a dataset;
  - (e) information on access and provision: time between the collection of the electronic health data and their addition to the dataset, time to provide electronic health data following electronic health data access application approval;
  - (f) information on data enrichments: merging and adding data to an existing dataset, including links with other datasets;
4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of principles for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.
5. 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. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). Those implementing acts shall take into account the requirements in Article 10 of Regulation [...] [AI Act COM/2021/206 final] and any adopted common specifications or harmonised standards supporting those requirements.

### **COMPROMISE AMENDMENT 57: Article 57**

Replacing the following amendments: 1981 S&D

*Article 57*

*EU Datasets Catalogue*

1. The Commission shall establish an EU Datasets Catalogue connecting the national catalogues of datasets established by the health data access bodies and other authorised participants in HealthData@EU ***taking into consideration the health interoperability resources already developed across the Union (1981 S&D ENVI)***.
2. The EU Datasets Catalogue and the national datasets catalogues shall be made publicly available.

*Article 58*

*Minimum dataset specifications*

The Commission may, by means of implementing acts, determine the minimum specifications for cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

**Chapter V**

**Additional actions**

**COMPROMISE AMENDMENT 58: Article 59**

Replacing the following amendments: 1982 EPP, 1983 EPP, 1984 EPP, 1985 Greens/EFA, 1986 RE

*Article 59*

*Capacity building*

The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall draw up benchmarking guidelines for the primary and secondary use of electronic health data. ***The Commission shall issue guidance with regard to compliance of data holders with the provisions of Chapter IV, taking into account the specific conditions of data holders that are civil society, researchers, medical societies and SMEs.***

*Article 59 a*

*Digital health literacy and digital health access*

1. ***In order to ensure successful implementation of the EHDS, Member States shall support digital health literacy, promote public awareness, including through educational programmes to natural persons, health professionals and stakeholders, to inform of the rights and obligations in the EHDS and inform the natural person of the advantages, risks and potential gains to science and society of the primary and secondary use of electronic health data and offer free of charge accessible training to health professionals in this regard (S&D 855) Those programmes shall be tailored to***

*the needs of specific groups and shall be developed and reviewed, and where necessary updated, on a regular basis in consultation and cooperation with relevant experts and stakeholders.*

*The Commission shall support Member States in this regard.*

2. *Member States shall monitor and evaluate, on a regular basis, the digital health literacy of health professionals and natural persons, notably about the primary and secondary use of health data, functionalities and conditions as well as rights of natural persons within the EHDS.*
3. *Member States shall promote the access to the infrastructure necessary for the effective management of natural persons' electronic health data, both within primary and secondary use.*

*(1986 Renew)*

- 3a. *Member States shall regularly inform the public at large about the role and benefits of the secondary use of health data and the role of health data access bodies, as well as the risks and consequences linked with individual and collective digital health data rights arising from this Regulation. (108 Rapporteurs, 1571/1574 S&D ENVI, 1572 Renew, 1573 The Left, 1576 The Left)*

## **COMPROMISE AMENDMENT 59: Article 60**

Replacing the following amendments: 138-139 Rap., 1987 Greens/EFA, 1988 S&D, 1989 RE, 1990 S&D, 1991 Greens, 1992 RE

### *Article 60*

#### *Additional requirements for public procurement and Union funding*

1. Public procurers, national competent authorities, including digital health authorities and health data access bodies, and the Commission shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, 23, 50, 56, as relevant, as points of orientation for public procurements 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.
2. The ex-ante conditionality for Union funding shall take into account the requirements developed in the framework of Chapters II, III and IV.
- 2a. *Public procurers, national competent authorities, including digital health authorities and health data access bodies, and the Commission shall require, as a condition to procure or fund services provided by controllers and processors established in the Union processing personal electronic health data, that such controllers and processors*
  - (a) *will store this data in the Union, in accordance with Article 60a of this Chapter, and*

*(b) have duly demonstrated that they are not subject to third country legislation conflicting with Union data protection rules.*

*(138 Rapporteurs, 1987 Greens, 1988 S&D LIBE, 1989 Renew)*

#### *Article 60a*

##### *Storage of personal electronic health data*

*For the purposes of primary and secondary use of personal electronic health data, the storage of personal electronic health data shall exclusively take place within the territory of the Union, without prejudice to the provisions of Article 63.*

*(139 Rapporteurs, 1990 S&D LIBE, 1991 Greens, 1992 Renew))*

### **COMPROMISE AMENDMENT 60: Article 61**

Replacing the following amendments: 1993 EPP, 1994 S&D, 1995 The Left, 1996 Greens/EFA, 1997 The Left, 1998 EPP, 1999 EPP, 2000 NA/ID, 2001 EPP, 2002 The Left, 2003 The Left, 2004 S&D, 2005 Greens/EFA, 2006 S&D, 2007 The Left, 2008 The Left, ITRE 65

#### *Article 61*

##### *~~Third country transfer~~ Sensitive nature of non-personal electronic health data*

1. Non-personal electronic **health** data made available by health data access bodies, that are based on a natural person's electronic data falling within one of the categories of Article 33 [(a), (e), (f), (i), (j), (k), (m)] shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation [...] [Data Governance Act COM/2020/767 final], ~~provided that their transfer to third countries presents a risk of re-identification through means going beyond those likely reasonably to be used, in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.~~  
*(1994 S&D, 1995 The Left, 1996 Greens, 1997 The Left)*
2. The protective measures for the categories of data mentioned in paragraph 1 **shall depend on the nature of the data and anonymization techniques and** (AM 2002, AM 2003, AM 2004, AM 205) shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation (EU) 2022/868 of the European Parliament and of the Council.

### **COMPROMISE AMENDMENT 61: Article 62**

Replacing the following amendments: 2009 EPP, 2010 EPP, 2011 RE, 2012 EPP, 2013 EPP, 2014 EPP

#### *Article 62*

##### *International access and transfer of non-personal electronic health data*



1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent international transfer or governmental access to non-personal electronic health data held in the Union where such transfer or access would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.
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 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.
3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body or a data users is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer or give access to non-personal data within the scope of this Regulation held in the Union and compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only where:
  - (a) the third-country 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;
  - (b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and
  - (c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that 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
4. If the conditions laid down in paragraph 2 or 3 are met, digital health authority, a health data access body or a data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.
5. The digital health authorities, health data access bodies, data users shall inform the 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 this is necessary to preserve the effectiveness of the law enforcement activity.

#### **COMPROMISE AMENDMENT 62: Article 63**

Replacing the following amendments: 140-141 Rap., 2015 EPP, 2016 The Left, 2017 S&D, 2018 S&D, 2019 The Left, 2020 S&D

### Article 63

#### *International access and transfer of personal electronic health data*

~~In the context of~~ International access and transfer of personal electronic health data **shall be granted in accordance with Chapter V of Regulation (EU) 2016/679 (140 Rapporteurs, 2018 S&D LIBE)**. Member States may maintain or introduce further conditions **on international access to, and transfer of, personal electronic health data**, including limitations, in accordance with and under the conditions of article 9(4) of the Regulation (EU) 2016/679.

### COMPROMISE AMENDMENT 63: Article 63a

#### Article 63a

##### *Reciprocity of access to electronic health data for secondary use*

**1. Notwithstanding Articles 62 and 63, only entities and bodies that are established in third countries included in the list referred to in paragraph 2 shall be allowed access to electronic health data in the secure processing environment and have the possibility of downloading non personal electronic health data held in the Union for the purposes of secondary use.**

**2. The Commission is empowered to adopt delegated acts in accordance with Article 67 supplementing this Regulation by setting up a list of third countries which are considered to allow for equivalent access to, and transfer of, electronic health data of its data holders for the purposes of secondary use of electronic health data by entities and bodies within the Union.**

**3. The Commission shall monitor the list of third countries benefiting from such access, and shall provide for a periodic review of the functioning of this Article.**

**4. Where the Commission considers that a third country no longer meets the requirement to be included on the list referred to in paragraph 2, it shall adopt a delegated act to remove a third country that benefits from access.**

*(141 Rapporteurs, 2020 S&D LIBE)*

## Chapter VI

### European governance and coordination

### COMPROMISE AMENDMENT 64: Article 64

Replacing the following amendments: 142-144 Rap., 2021 EPP, 2022 RE, 2023 S&D, 2024 ID, 2025 RE, 2026 EPP, 2027 The Left, 2028 Greens/EFA, 2029 S&D, 2030 The Left, 2031 Greens/EFA, 2032 Greens/EFA, 2033 ID, 2034 RE, 2035 Greens/EFA, 2036 S&D, 2037 RE, 2038 The Left, 2039 S&D, 2040 S&D, 2041 The Left, 2042 RE, 2043 RE, 2044 RE, ITRE 66, IMCO 102, ITRE 67,

## Article 64

### European Health Data Space Board (EHDS Board)

1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of, ***one high level representative of digital health authorities and one high level representative of health data access bodies per Member State appointed by the Member State concerned. Where a Member State has designated several health data access bodies, the representative of the coordinating health data access body shall be a member of the EHDS Board (2022 Renew)***;

Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor ***and Union agencies within the field of public health and cybersecurity shall*** also be invited to the meetings, where the issues discussed are of relevance for them. The Board may invite ***stakeholders***, experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures ***may*** have an observer role. ***The EHDS Board shall invite a representative of the European Parliament to attend its meetings as an observer. (144 Rapporteurs)***.

2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups, where digital health authorities or health data access bodies for a certain area shall be represented. The subgroups may have joint meetings, as required.

***Members of the EHDS Board shall not have financial or other interests in industries or economic activities which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to such industries or economic activities shall be entered in a register held by the Commission which is accessible to the public, upon request, at the Commission's offices.***

***The EHDS Board's code of conduct shall make reference to the application of this Article, in particular in relation to the acceptance of gifts.***

3. ***The EHDS Board shall adopt rules of procedure and a code of conduct, following proposal of the Commission. The rules of procedure shall provide for the composition, organisation, functioning and cooperation of the Board and its cooperation with the Advisory Board, sub-groups shall be set out in the rules of procedure put forward by the Commission.***
- ~~4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~
5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article 26 of Regulation [...] [Data Governance Act COM/2020/767 final], competent bodies set up under Article 7 of Regulation [...] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation [...] [eID Regulation], European Data Protection Board

referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies, *in particular the European Agency for Cybersecurity (ENISA) 2039 S&D.*

6. The Commission shall chair the meetings of the EHDS Board.
7. The EHDS Board shall be assisted by a secretariat provided by the Commission.
- 7a. ***The EHDS Board shall publish meeting dates and minutes of the discussions and publish an annual report on its activities. (RE AM 2043)***
8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment ~~management and functioning~~ ***and operations*** of the EHDS Board. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

<b>COMPROMISE AMENDMENT 65: Article 64a</b>
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*Article 64a*

*Advisory forum*

1. ***A advisory forum to advise the EHDS Board in the fulfilment of its tasks by providing stakeholder input in matters covered by this Regulation is hereby established.***
2. ***The advisory forum shall be composed of relevant stakeholders, including representatives of patients' organizations, health professionals, industry, consumer organizations, scientific researchers and academia. The advisory forum shall have a balanced composition and represent the views of different relevant stakeholders. - Where commercial interests are represented in the advisory forum, they shall be balanced between large companies, SMEs and start-ups. Focus on primary and secondary use of electronic health data shall also be balanced.***
3. ***Members of the advisory forum shall be appointed by the Commission following a public call for interest and a transparent selection procedure, in consultation with the European Parliament.***  
***Members of the advisory forum shall make an annual declaration of their interests, to be updated whenever relevant, which shall be made publicly available. (AM 2031, Greens).***
4. ***The term of office of the members of the advisory forum shall be two years and it shall be renewable only once consecutively.***
5. ***The advisory forum may establish standing or temporary subgroups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation.***
6. ***The advisory forum shall draw up its rules of procedure and elect one co-chair from among its members whose term of office shall be two years, renewable once. A Commission representative shall be the other co-chair.***

7. *The advisory forum shall hold regular meetings. The advisory forum can invite relevant experts and other relevant stakeholders to its meetings. The Chair of the EHDS Board may attend, ex officio, the meetings of the advisory forum.*
8. *In fulfilling its tasks as set out in paragraph 1, the advisory forum shall prepare opinions, recommendations or written contributions.*
9. *The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available.*

*(2044 Renew)*

## **COMPROMISE AMENDMENT 66: Article 65**

Replacing the following amendments: 145-153 Rap., 2045 RE, 2046 NA, 2047 EPP, 2048 Greens/EFA, 2049 S&D, 2050 RE, 2051 RE, 2052 Greens/EFA, 2053 Greens/EFA, 2054 RE, 2055 NA, 2056 EPP, 2057 EPP, 2058 ID, 2059 Greens/EFA, 2060 S&D, 2061 RE, 2062 Greens/EFA, 2063 EPP, 2064 RE, 2065 EPP, 2066 S&D, 2067 EPP, 2068 NA, 2069 The Left, IMCO 103, IMCO 104

### *Article 65*

#### *Tasks of the EHDS Board*

- 1. ***The EHDS Board shall promote the consistent application of this Regulation. (2045 RE)***
  1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:
    - (a) to assist Member States in coordinating practices of digital health authorities;
    - (b) to issue written contributions and to exchange 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, ***taking into account the regional and local level, (2047 EPP ENVI)*** in particular as regards:
      - (i) the provisions set out in Chapters II and III;
      - (ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons;
      - (iii) other aspects of the primary use of electronic health data ***without prejudice to the powers of the supervisory authorities pursuant to regulation (EU) 2016/679.*** (2048 Greens, 2049 S&D) ***The written contributions of the EHDS board shall not concern the interpretation or application of rights and obligations under Regulation (EU) 2016/679 or Regulation 2018/175.***
        - (ba) ***to provide guidance and recommendations to digital health authorities; (147 Rapporteurs)***
    - (c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for annual activity reporting, peer-review of annual activity reports and exchange of information;

- (d) to share ***among the Members of the Board*** information concerning risks posed by EHR systems and serious incidents as well as their handling, ***without prejudice to the obligation to inform competent supervisory authorities pursuant to Regulation (EU) 2016/679 (2052 Greens)***;
- (e) to facilitate the exchange of views on the primary use of electronic health data with the ***Advisory Forum referred to in Art 64(a)*** ~~relevant stakeholders, including representatives of patients, health professionals, (148 Rapporteurs), researchers, regulators and policy makers in the health sector~~ ***to support the design of aligned implementation strategies, guidance and standards and to assess the needs for further improvement. In addition, the co-chairs of the advisory forum shall be invited to at least once annually to a meeting of the EHDS Board to present its activities.***

2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:

- (a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;
- (b) to issue written contributions and to exchange 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:
  - (i) implementation of rules for access to electronic health data;
  - (ii) technical specifications or existing standards regarding the requirements set out in Chapter IV;
  - (iii) incentives policy for promoting data quality and interoperability improvement;
  - (iv) policies concerning fees to be charged by the health data access bodies and data holders;
  - ~~(v) the establishment and application of penalties;~~
  - (vi) other aspects of the secondary use of electronic health data ***without prejudice to the powers of the supervisory authorities pursuant to regulation (EU) 2016/679.***
- (c) to facilitate cooperation ***and exchange of best practices (2062 Greens partially)*** between health data access bodies through capacity-building, establishing the structure for annual activity reporting, peer-review of annual activity reports and exchange of information ***pursuant to the obligations laid down in Article 37(1), point (q)***;
- (d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling; ***without prejudice to the obligation to inform competent supervisory authorities pursuant to Regulation (EU) 2016/679 (2052 Greens)***;

- (e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation [...] [Data Governance Act COM/2020/767 final];
- (f) to ~~facilitate the exchange of~~ views on the secondary use of electronic health data with the *Advisory Forum referred to in Art 64(a)* ~~relevant stakeholders, including representatives of patients, health professionals, researchers regulators and policy makers in the health sector~~ *to support the design of aligned implementation strategies, guidance and standards and to assess the needs for further improvement*; (2066 S&D ENVI)
- (fa) *adopt recommendations to facilitate consistent provision of the secure processing environment compliant with the technical, information security and interoperability requirements (151 Rapporteurs)*
- 2a. *The EHDS board shall provide recommendations to the Commission and the Member States on the implementation and enforcement of this Regulation, including cross-border interoperability of health data, and potential mechanisms of funding support to ensure equal development of health data systems across Europe in respect to the secondary use of electronic health data. (152 Rapporteurs), without prejudice to the competences of EDPB, where personal electronic health data are concerned; (146 Rapporteurs, 2045 Renew).*
- 2b. *The EHDS board may commission studies and other initiatives in order to support the implementation and development of the EHDS. (153 Rapporteurs)*
- 2c. *The EHDS Board shall publish an annual report to include the implementation status of the European Health Data Space and other relevant points of development, including with respect to cross-border health data interoperability, and arising implementation challenges. (145 Rapporteurs, 2040 S&D ENVI)*

## COMPROMISE AMENDMENT 67: Article 66

Replacing the following amendments: 2070 NA, 2071 Greens/EFA, 2072 EPP, 2073 RE

### *Article 66*

#### *Joint controllership groups for Union infrastructures*

1. The Commission shall establish two groups dealing with joint controllership for the cross-border infrastructures provided for in Articles 12 and 52. The groups shall be composed of the representatives of the national contact points and other authorised participants in those infrastructures.
2. The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure adopted by those groups.
3. Stakeholders and relevant third parties, including patients', *health professionals', consumers' and industry representatives (2072 EPP, 2071 Greens/EFA (partially))* representatives, may be invited to attend meetings of the groups and to participate in their work.
4. The groups shall elect chairs for their meetings.

5. The groups shall be assisted by a secretariat provided by the Commission.
  6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.
- 6a. *The groups shall consult relevant experts when carrying out their tasks as well as on technical implementing measures related to cybersecurity, confidentiality and data protection, in particular experts from ENISA, EDPB and EDPS. (2073 Renew, 2071 Greens/EFA (partially))***

## CHAPTER VII

### Delegation and Committee

<b>COMPROMISE AMENDMENT 68: Article 67</b>
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Replacing the following amendments: 2073 RE, 2074 Greens/EFA, 2075 RE, 2076 S&D, 2077 EPP, 2078 Greens/EFA, 2079 The Left, 2080 RE, 2081 S&D, 2082 S&D, 2083 S&D, 2084 Greens/EFA, 2085 RE, IMCO 105

#### *Article 67*

##### *Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 5(2), **7(3)**, **9(2)** ~~10(3)~~, **13(3)** 25(3), 32(4), ~~33(7)~~, 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), **52(13)**, 56(4), **63a(2)** shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The power to adopt delegated acts referred to in Articles 5(2), **7(3) (2081 S&D)**, **9(2)**, ~~10(3)~~, **13(3)**, 25(3), 32(4), ~~33(7)~~, **(2079 The Left, 2080 Renew, 2081 S&D)** 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), **52(13)**, 56(4), **63a(2)** 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.
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 Inter-institutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.



6. A delegated act adopted pursuant to Articles 5(2), **7(3)**, **9(2)**, ~~10(3)~~, **13(3)**, 25(3), 32(4), ~~33(7)~~, 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), **52(13)**, 56(4), **63a(2)** shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 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 3 months at the initiative of the European Parliament or of the Council.

#### **COMPROMISE AMENDMENT 69: Article 68**

Replacing the following amendments: 2086 S&D, 2087 RE

##### *Article 68*

##### *Committee procedure*

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. ***Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.***

## **Chapter VIII**

### **Miscellaneous**

#### **COMPROMISE AMENDMENT 70: Article 69 (2088, 2089, 2092, 2090, 2091, 154, IMCO 107, 2093, IMCO 109, IMCO 110, IMCO 111, IMCO 112, IMCO 113)**

##### *Article 69*

##### *Penalties*

Member States shall lay down the rules on *other* penalties applicable to infringements of this Regulation ***in particular for infringements which are not subject to administrative fines pursuant to Article 43a***, and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

#### **COMPROMISE AMENDMENT 71: Article 69a**

#### *Article 69a*

##### *Right to receive compensation*

*Any person who 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 national and Union law. (2097 S&D, 2096 The Left, 2095 The Left)*

#### *Article 69b*

##### *Representation of a natural person*

*Where a natural person considers that their rights under this Regulation are infringed, they shall have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal data, to lodge a complaint on their behalf or to exercise the rights referred to in 11a.*

#### *Article 69c*

##### *Suspension of proceedings*

- 1. Where a competent court of a Member State seized of proceedings against a decision by a digital health authority or health data access body has reason to believe that proceedings concerning the same access to electronic health data by the same health data user, such as for the same purpose for processing for secondary use are brought before a competent court in another Member State, it shall contact that court in order to confirm the existence of such related proceedings.*
- 2. Where proceedings concerning the same subject matter and the same digital health authority or health data access body are pending before a court in another Member State, any court other than the court first seized can stay its proceedings or can, on request of one of the parties, decline jurisdiction in favour of the court first seized if that court has jurisdiction over the proceedings in question and its law permits the consolidation of such related proceedings.*

### **COMPROMISE AMENDMENT 72: Article 70**

Replacing the following amendments: 157-158 Rap., 2098 RE, 2099 Greens/EFA, 2100 S&D, 2101 S&D, 2102 NA, 2103 ID, 2104 The Left, 2105 NA/ID, 2106 RE, 2107 ID, 2108 S&D, IMCO 114, IMCO 115, IMCO 116 and IMCO 117

#### *Article 70*

##### *Evaluation and review*

- 1. By 5 years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to, ~~Chapter II, III and IV, including~~ the possibilities to further extend interoperability between EHR systems and electronic health data access services other than those established by*

*the Member States, the possibility to expand the access to MyHealth@EU infrastructure to third countries and international organisations, the need to update the data categories in Article 33 and the purposes of use in Article 34 the implementation and use by natural persons of the opt-out mechanism in secondary use as referred to in Article 33(5a), and opt-in mechanism in secondary use as referred to in Article 33(5b), the use and implementation of the right referred to in Article 3(9), as well as the application of fees as referred to in Article 42 (2098 Renew, 157 rapporteurs) and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. ~~The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.~~*

- 1a. After two years from the entry into force of this Regulation, the Commission shall carry out an evaluation of the Union funding attributed to the setting up and functioning of the EHDS, notably as to the ability of the bodies established under this Regulation to carry out their tasks and obligations under this Regulation and of Member States to applying the Regulation in a uniform and coherent manner. The Commission shall submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by the necessary measures. (158 Rapporteurs, 2106 RE, 2105 ID)*
2. After 7 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to 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*.
3. Member States shall provide the Commission with the information necessary for the preparation of that report.

### **COMPROMISE AMENDMENT 73: Article 71**

Replacing the following amendments: 2109 The Left, 2110 Greens/EFA

#### *Article 71*

#### *Amendment to Directive 2011/24/EU*

Article 14 of Directive 2011/24/EU is deleted.

#### *Article 71a*

#### *Amendments to Directive (EU) 2020/1828*

*In the Annex of Directive (EU) 2020/1828, the following point is added:*

*(XX) Regulation (EU) XXX of the European Parliament and of the Council on the European Health Data Space.*

## Chapter IX

### Deferred application and final provisions

#### COMPROMISE AMENDMENT 74: Article 72

Replacing the following amendments: 2111 ECR, 2112 ECR, 2113 RE, 2114 ECR, 2115 EPP, 2116 ECR, 2117 EPP, 2118 ECR, 2119 ECR, 2120 S&D, 2121 ECR, 2122 S&D, 2123 ECR, 2124 ECR, 2125 NA

#### *Article 72*

##### *Entry into force and application*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ~~12~~ **24** months after its entry into force. **(2111 ECR, 2112 ECR, 2113 Renew, 2114 ECR)**

However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:

- (a) from 1 year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.;
- (b) from 3 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) (f), **and f(a)** and to EHR systems intended by the manufacturer to process such categories of data;
- ~~(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.~~

Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3 years after date of entry into application.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

