# Digital Healthcare Advancements in Germany and Europe: Boosting Competitiveness in the Global Pharmaceutical Market?

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## BACKGROUND

This paper provides an overview of the status quo of e-health developments in Germany and Europe, addressing the paramount flaws (confusion between actors, lack of cross-boundary data sharing, missing interoperability) within the domestic and European contexts and linking those to the promising establishment of the European Health Data Space (EHDS).

The EHDS is set to become a vital tool to increase cross-boundary exchange of healthcare data between member states, to spur research and development into new medicines thanks to the available secondary healthcare data and to further improve health literacy among patients. In a time when Europe's competitiveness is a reason for concern and debate, the EHDS can contribute to more attractive conditions for pharmaceutical companies to increase their investments; and for Europe to ultimately remain in the top-tier for innovative medical manufacturing sites.

For its successful implementation, beyond European co-legislation, technical features, such as ensuring the cybersecurity of the infrastructure, but also legal features, such as a precise definition of the scope of the secondary use, are crucial to gain patients' support and backing.

## INTRODUCTION

Digital healthcare tools and apps such as electronic patient records, electronic medication plans, a symptom tracker, or the cross-boundary processing of healthcare data and patients' medical histories in the German and European context have been at the centre of many discussions in the past years; however, their respective implementation to yield tangible benefits for patients is a different story. Some attribute this to the decentralised nature (federal structure) within the German

context, where each state has its own Data Officer or even the lengthy political decision-making processes and disagreements between the various actors in the German healthcare sector. In particular, the question as to whether the industry (pharmaceutical companies) should be given the right to access anonymised secondary healthcare data to conduct research for innovative medicines was a contentious issue that now seems to have been addressed adequately. With the European Commission's legislative proposal for the "European Health Data Space" in 2022 and subsequent German policies enacted in the past year, a direct link between Germany's digitalisation efforts and the European Union's Health Union is on its way.

For Germany these digitalisation efforts refer to the establishment of secure networking in the healthcare system (telematics infrastructure, TI), the introduction of the electronic health card (eGK) with its applications, the introduction of the electronic patient file (ePA) and the electronic prescription (e-prescription), the new range of digital health applications (DiGA) and digital care applications (DiPA) for insured persons as well as telemedicine services allowing for the instant issuance of electronic certificates of medical leave.

For the European Union (EU), the European Health Data Space (EHDS) fits into the broader picture of building a "European Health Union", where interlinkages between the EHDS and the EU's pharmaceutical strategy or its newly established Health Emergency and Response Authority (HERA) are created, banking extensively on the availability and use of healthcare data.

## GERMANY – COVID-19 AS A REMINDER OF THE SLOW PROGRESS ON DIGITALISATION

The coronavirus pandemic has revealed a number of deficits and flaws in the German healthcare system, most notably: a poor data situation, unclear competences between the actors in a federal system (federal, state, municipal, district), a lack of coordination, inadequate communication, little intersection across medical disciplines and an unequal distribution of risks and burdens within the population.

Take the delayed reporting of new COVID-19 infections to the Robert Koch Institute (Germany's version of a public health institute) or the slow contact tracing as examples. Former Federal Minister of Health Jens Spahn initiated a number of far-reaching projects during his time as minister, such as the electronic prescription and the electronic patient record, which are now gradually becoming a centrepiece of the German healthcare system. However, this should not obscure the fact that Germany's healthcare system and structures require further digitalisation. Among

other things, interoperability for the "Telematikinfrastruktur" (telematics infrastructure for safe and interoperable communication) between various players in the healthcare sector (doctors, pharmacists, health insurance providers) needs to run smoother and become better established as well as accepted.

With the new coalition coming into power, the three parties (Social-Democrats, Greens and Liberals) have agreed to "advance" the digitalisation of Germany, not only in the healthcare sector but also in the sphere of public administration (government services). At the beginning of his term of office, Federal Health Minister Karl Lauterbach (Social Democratic Party of Germany, SPD) promised a "new start in digitalisation".[1] In addition to the already agreed e-prescription model, he advocated for a new edition/overhaul of the electronic patient file (ePA), which is to be introduced in 2025. The proposed "Digital and Health Data Utilisation Act" adopted an "opt-out" approach, whereby individuals covered by statutory and private health insurance will automatically receive an electronic patient file unless they choose not to.

Since January 2024, prescriptions must be issued electronically, meaning a transition from paper-based drug prescription to an electronic format. According to the recent "E-Health Monitor" by McKinsey, every second prescription is currently issued electronically.[2] Furthermore, the figures from the federal telematics organisation Gematik show that patients have received 49.8 million e-prescriptions as of the 28th of January.[3]

During the pandemic, there was a lot of misinformation circulating on online platforms such as YouTube. Within its digitalisation initiatives, Germany is also trying to increase the "health literacy" of its citizens by providing crucial health information on its National Health Portal, where scientifically sound, neutral and easy-to-understand information on selected health topics, clinical pictures and treatment options can be found. This serves as an enabler to making informed decisions. Through the National Health Portal a direct contribution to a patient's journey (from diagnosis, to treatment to recovery and secondary prevention) and patient sovereignty (considering more available information, weighing treatment options, ability to make informed decisions) could be created. In addition to information on illnesses, care services and patient rights, the portal also explains digital

1. (https://www.handelsblatt.com/politik/deutschland/e-rezept-wie-gut-klappt-die-digitalisierung-im-gesundheitswesen/100008222.html).

2. Ibid.

3. (https://www.faz.net/aktuell/wirtschaft/e-rezept-was-apotheken-von-dem-neuen-system-halten-19480392.html).

healthcare services such as the aforementioned ePA, DiGAs and telemedicine. The Health Portal therefore facilitates the people's understanding of digital healthcare tools and services vis-à-vis showing the benefits of those innovations.[4]

## PRIMARY VERSUS SECONDARY HEALTH DATA

Every day, vast amounts of health data are generated, processed and stored, when a patient undergoes medical consultations, blood collection, magnetic resonance imaging (MRI) tests and medicine prescription. Ideally, this data (results, treatment options, medications) would be stored on his personal electronic patient record so that it can be used during his next medical consultation at home or abroad. Possessing an electronic file of the patient's journey could therefore avoid duplicate tests, reduce the necessity to recall the medical history and give doctors a solid overview of the patient's status quo, helping pharmacists to rule out the side-effects of poly-medications and so on. In a nutshell: time and efficiency gains. Yet it often remains difficult for citizens to access their own health data electronically as different institutes (e.g., hospitals, clinics) have stored the results locally, or the electronic file is simply not available yet. By extension, researchers at university hospitals or in public health institutes also share an interest to use the samples of health data to improve diagnosis and treatments. For further debates and understanding, below is a brief summary of the differences between primary and secondary health data.

**Primary health** data refers to the data that is collected during a patient's medical journey, such as in the above-mentioned scenario (check-ups, consultations, patient's journey, MRI scans). The patient owns the information and can make his health data available to a health professional of their choice, including when abroad and ideally in the same language of the health professional. Needless to say, the patient can decide what information to share and with whom. In the case of psychological treatment, the patient may not share this information with another health practitioner, let alone his health insurance provider. There are debates on whether "opt-out" (it is presumed that patients want their electronic patient file issued, issuance by default) or "opt-in" (patients actively need to give their consent for the issuance) should apply in creating the electronic patient file. In Germany, the former approach is adopted.

4. (https://www.bundesgesundheitsministerium.de/themen/digitalisierung/digitalisierung-im-gesundheitswesen.html).

All these primary health data, once generated, processed and stored, could then be used as **secondary health** data for research purposes on rare diseases, development of new medicines and enhancing patient safety (e.g., comparison of similar treatment cases, as in same chronic disease with a similar patient population). For that matter, the personalised primary health data will have to be made anonymous so that patients' personal information (name, address, occupancy, etc.) is not traceable. Usually this is done by a "trustee" or a "data steward" responsible for pseudonymising and anonymising primary health data. In Germany there is a dedicated "Forschungsdatenzentrum" responsible for that task, where interested parties can request to obtain these anonymised data for research purposes or public health policies. There are discrepancies in policymaking regarding who should be allowed to access the secondary health data and for what purpose.

The European Commission in its proposal sums up the differences insightfully: primary use of health data relates to "electronic health data in the context of healthcare" while the use of secondary health data "would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities".[5] The following is an overview of how Germany and the EU approach the use of health data.

## DIGITAL HEALTH TO BECOME A CENTREPIECE IN GERMANY'S HEALTHCARE SYSTEM

The acceleration of Germany's digitalisation efforts can in part be explained by the dissatisfaction of large pharmaceutical companies conducting research and development (R&D). Notwithstanding the high degree of persistent bureaucracy, the difficulty in accessing secondary health data (anonymised and pseudonymised) especially has been a major complaint in relation to hindrance of their R&D activities and innovation. German pharmaceutical giant Bayer's announcements in early 2023 of its intention to shift the focus of its pharmaceutical business more towards the United States (US) and China in the future and BioNTech's decision to establish a R&D centre for cancer therapy and personalised mRNA immunotherapies in the United Kingdom (UK) instead of Germany have put the perception of Germany as

5. (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197) and (https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en).

a seemingly attractive location for innovation and investment into question.[6] With that in mind, the "Health Data Utilisation Act" (GDNG) was approved by the German parliament in December 2023, aiming to enhance the use of health data for research purposes. According to the Ministry of Health, the establishment of a central data access and coordination centre for the use of health data will reduce bureaucratic hurdles and facilitate access to research data.[7] Approval is no longer determined by who is applying (formerly only universities are allowed but not the pharmaceutical industry), but for what purpose. The decisive factor is hence the purposes of use in the public interest. The Research Data Centre can link pseudonymised data with data from legally regulated medical registers if this is necessary for the research purpose in accordance with the application and only if the interests of the insured persons are sufficiently protected.

With the GDNG in effect, the pharmaceutical industry will now have comprehensive access to (secondary) health data; while at the same time the policy establishes the foundation for a connection to the European Health Data Space.

## THE OVERARCHING FRAMEWORK – THE EUROPEAN HEALTH DATA SPACE (EHDS)

Extending beyond Germany, Europe's competitiveness in the pharmaceutical sector also does not remain unchallenged. The European Health Data Space (EHDS) aims to ensure Europe remains a prime location for pharmaceutical companies and innovation centres. The EHDS in particular addresses the limited use of digital health data in the EU, a situation that arises due to different standards among member states; in other words: improving the currently limited interoperability. The EHDS therefore provides a much-needed regulation for information-sharing between member states, providing rules and guidelines on the usage of primary and secondary healthcare data by setting out a common framework for the whole bloc.[8]

The EHDS within the wider framework of the European Health Union, initiated by Commission President Ursula von der Leyen in September 2020, intends

6. (https://www.tagesschau.de/wirtschaft/pharmaindustrie-forschung-biontech-101.html) and (https://www.manager-magazin.de/unternehmen/bayer-verlagert-pharma-fokus-in-usa-und-nach-china-europa-ist-innovations-unfreundlich-a-79cb82fa-bf06-4387-9263-4f94c814c7b1).

7. (https://www.bundesgesundheitsministerium.de/themen/digitalisierung/digitalisierung-im-gesundheitswesen.html).

8. For more, see: (https://www.european-health-data-space.com/).

to address the deficits resulting from the experiences of the COVID-19 pandemic (lack of member states coordination with regard to COVID-19 policies at first, border closures, slow contract-tracing, low stock of certain medical equipment and medicines) to now "improve protection, prevention, preparedness, and response to human health hazards at EU level".[9] The EHDS can play an important role here, as representatives at the Konrad-Adenauer-Stiftung's EU Data Summit in December 2022 unequivocally confirmed.[10]

Access to research data (secondary health data) for the industry in Germany and Europe is currently still poor, let alone sufficient in terms of available datasets, although research data on tumour diseases, rare diseases, personalised medicine, clinical studies, new drug therapies and generally for R&D reveal enormous potential.[11] As aforementioned, in Germany, this was previously due to research companies' ineligibility to apply to the research data centre established for this purpose on the one hand, and to a still inadequate digitalisation of the public healthcare system (ePA, ePrescription), on the other – which is still to some extent valid.[12]

Whether the EHDS will become operational from 2025 as planned by the EU Commission is to be seen. It is more likely to be a learning system that is gradually improved. At its core, the EHDS enshrines that digitalisation will be essential for the future of healthcare. Over 810 million euros will be funded for the implementation of the EHDS, bringing together the health data of 430 million citizens, which, according to Health Commissioner Stella Kyriakides, could "mak[e] the EU a global leader in data-driven technologies".[13]

9. (https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_de).

10. (https://www.youtube.com/watch?v=D66dDropRuE) (from minute 1:20:27 - Keynote: The EHDS Proposal).

11. (https://www.encepp.eu/events/documents/Discussionpaper.pdf), (https://theodi2022.wpengine.com/wp-content/uploads/2021/09/Secondary-use-of-Health-Data-In-Europe-ODI-Roche-Report-2021-5.pdf) and (https://www.mdpi.com/2227-9032/10/9/1629).

12. The Research Data Centre makes it possible to access the billing data of all people with statutory health insurance in Germany.

13. (https://ec.europa.eu/commission/presscorner/detail/fr/speech_23_4947) and (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A52022DC0196).

## LEVEL OF MEMBER STATES READINESS IN THE EHDS

The healthcare systems of the member states already generate, process, and store a large volume of data. Yet, access to health data (digital patient record, e-medication plan) is still not guaranteed for many EU citizens.[14] An immediate priority for the Commission is therefore to address the inconsistent level of digitalisation across member states and to harmonise patient information systems. Such systems can vary significantly at both the state and regional levels, complicating agreements on common standards.[15]

The success of the EHDS relies on member states' levels of interoperability and ultimately readiness. Not surprisingly, the European Commission resorted to a regulation, hence "a legal act of the European Union that becomes immediately enforceable as law in all member states simultaneously".[16]

According to a recent Surfshark survey, within Europe, the Nordic countries lead while Eastern Europe lags behind in terms of healthcare sector digitalisation and readiness (e.g., patient files, electronic prescriptions, booking of doctor's consultations). Not all member states have set up systems to exchange electronic health records and there are significant deficiencies in the interoperability of the systems. Patient summaries and e-prescription services exist in two-thirds of all member states and are most frequently accessed via an online portal, but only in a few member states can they be sent or received across borders. Furthermore, eleven member states are still using paper printouts for prescriptions. Only ten member states support access to patient summaries or e-prescriptions via MyHealth@EU.[17]

Based on *the Assessment of the EU Member States' rules on health data in the light of the GDPR*, some 81 per cent consider that the use of different GDPR legal basis makes it difficult to share health data. Even if data processing is allowed due to GDPR, the doubts, misunderstandings, and fears of the consequences create altogether an invisible blockage impacting the overall acceptance for opening up the

14. (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A52022DC0196).

15. In addition, a large divergence in the digitalisation of healthcare systems between the EU member states is evident – this is also mentioned several times in the legislative proposal on the EU Health Data Space. (https://prod.ucwe.capgemini.com/wp-content/uploads/2022/07/eGovernment-Benchmark-2022-1.-Insight-Report.pdf).

16. (https://commission.europa.eu/law/law-making-process/types-eu-law_en -:~:text=Regulations%20are%20legal%20acts%20that,be%20transposed%20into%20national%20law).

17. (https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf).

data for secondary use.[18] For instance, when a research centre wanted to access and process data, it was required to send requests to all individual data controllers.

The uneven implementation and interpretation of the GDPR by member states creates considerable legal uncertainties, resulting in barriers to secondary use of electronic health data.

## USE OF SECONDARY HEALTH DATA IN THE EHDS

Even for research in the second step, after health-related data has been anonymised or pseudonymised, it is difficult to harness this data to improve diagnosis and treatment.

The EU Commission describes this fact in its legislative proposal as follows: "EU health sector is rich in data, but poor in making it work for people and science".[19]

According to the Commission, the new legal framework would enable stakeholders such as researchers, decision-makers, and member states to access electronic health data so as to promote better diagnosis, treatment, and patient well-being, as well as attaining an optimised and well-defined policy. What is more, the EHDS aims to drive the harmonisation of provisions on an internal market basis for digital health products and services, thus increasing the efficiency of healthcare systems.[20] It is in Europe's interest and against the background of the far-reaching GDPR to also become something like a global standard setter for digital health.

In this context, there is much talk about European digital sovereignty, which entails processing the anonymised and pseudonymised data of EU citizens to develop new innovative approaches in the pharmaceutical sector. This, in turn, means that data or AI-based solutions from China or the US could be renounced, hence increasing European independence in the use of secondary healthcare data, providing a boost to its own research activities in personal medicine or innovative drugs altogether.

In the meantime, the European Parliament has adopted the Commission's proposal to create the EHDS, "aimed at improving access to personal health data

18. Ibid.

19. IMMC.COM%282022%29196%20final.ENG.xhtml.1_EN_ACT_part1_v8.docx (europa.eu).

20. Ibid.

across EU states and bolstering secure data sharing for research".[21] Now it will be between the European Council and the Parliament to form the final legislation.[22]

In contrast to the Commission's proposal, the Parliament proposed an opt-out system for secondary data use and mandatory explicit consent for sensitive data like genetic information. Furthermore, the Parliament seeks to broaden the ban on secondary uses in sectors like labour and finance, highlighting the need to get patients' trust and backing of the far-reaching regulation before enactment.

## POSITIVE SPILL-OVER EFFECTS INTO R&D ACTIVITIES IN EUROPE

Positive examples of interactions between the EHDS and other EU-led initiatives include, for instance, the European Plan to Combat Cancer and the EU-wide "Beyond 1 Million Genomes" project.[23] The development and expansion of data registers (tumour register, spine register, prostate cancer register) is also being promoted.[24] This can improve understanding as well as early detection, diagnosis, treatment, and monitoring of cancer by enabling health service providers in the EU to access and share health data across borders. The more high-quality data can be used, the greater the benefit for research and development as well as diagnosis.[25] This would appear logical as accessing data from a wide patient pool is essential for comprehensive insights into therapy and drug tolerability. The establishment of the EHDS is therefore vital for strengthening Europe's position as a pharmaceutical location and its research innovative landscape, which would also benefit Germany subsequently.[26]

In the global competition to attract foreign direct investment (FDI) or multinational companies or simply to safeguard their own supply chains, innovative

21. EU Parliament agrees position on digitalising health data – Euractiv.

22. Check the status of the EHDS regulation in the legislative train: Carriages preview | Legislative Train Schedule (europa.eu).

23. (https://b1mg-project.eu/ see also: https://www.kas.de/de/web/die-politische-meinung/artikel/detail/-/content/gene-und-genome-1 and https://www.kas.de/de/einzeltitel/-/content/genomsequenzierung).

24. Michaela Hempel. 2021. Strategy for the industrial healthcare sector: Anchor in times of crisis and growth driver of the future. In Federation of German Industries.

25. Ibid. and (https://www.tagesschau.de/wissen/forschung/medikamentenentwicklung-101.html).

26. (https://www.kas.de/documents/252038/22161843/Europe+as+a+Pharmaceutical+Location+%E2%80%93+Strengthening+Resilience+and+Competitiveness.pdf/f5e9c4bd-a0d4-8644-c550-923b98ccee4b?version=1.4&t=1685461444085).

biopharmaceuticals, such as cancer treatments, are still being primarily produced in Europe and North America. But China is catching up in the race. To this end, the European Chamber of Commerce in China writes: "China finds itself at a critical juncture, as the country is currently transforming from a generic drugs manufacturer to a supplier of primary drugs."[27] Strengthening the industrial healthcare sector and Europe's competitiveness as a scientific and research location thus largely depends on access to research data as part of the EHDS. For this reason, it is necessary to establish quality-assured databases, such as for patient data, including genomic data. This requires adequate funding and standardisation, as well as statutory regulations for data protection-compliant access that is research- and application-friendly at the same time.

By the same token, it is also noteworthy to look into R&D efforts in the EU, which are not only linked to the EHDS but also facilitated through the new framework: Pharmaceutical research into new and innovative drugs is growing rapidly, especially in China (from imitator to innovator) and to a smaller extent in other emerging markets such as India, while the gap with the EU and the US is narrowing.[28] Between 2017 and 2020, R&D spending on pharmaceuticals in China increased by an average of 12.9 per cent per year, compared to just 8.5 per cent in the US and only 4 per cent in Europe.[29] Of the 95 new substances launched on the global drug market in 2021, 35 came from the US, 19 from Europe and 18 from China. This means that China will not only continue to be an important supplier of pharmaceutical raw materials and inexpensive drugs in the future, but also a serious competitor in the pharmaceutical high-tech segment with growing R&D performance and effective implementation in new products, taking a lead on data-driven healthcare technologies.[30]

In general, pharmaceutical R&D in Europe benefits from a good research infrastructure and an efficient science and university system which produces well-trained scientists for the labour market and is available as a cooperation partner for research companies. Regarding the pharmaceutical industry, there is a division of labour between publicly funded research at universities and research institu-

27. (https://www.euractiv.de/section/gesundheit-und-verbraucherschutz/news/europas-abhaengigkeit-von-medikamenten-importen/ and https://www.handelsblatt.com/unternehmen/industrie/arzneimittel-pharmabranche-warnt-vor-abhaengigkeit-von-fernost-eu-will-mit-neuer-arzneistrategie-reagieren/28363374.html).

28. (https://economictimes.indiatimes.com/small-biz/sme-sector/budget-2023-pharmacy-of-the-world-has-a-chinese-achillean-heel/articleshow/97046291.cms?from=mdr).

29. (https://pharma-fakten.de/grafiken/pharmazeutische-forschung-und-entwicklung-in-europa-oder-anderswo/).

30. Ibid.

tions and companies. Publicly funded institutes mainly conduct basic research, for example, identifying basic substances that could have a useful pharmaceutical effect. The pharmaceutical industry often takes these results from basic research, develops them further and, in positive cases, ultimately incorporates them into clinical research.[31]

New regulations,[32] with the introduction of the Clinical Trials Information System (CTIS),[33] under the pharmaceutical strategy are also improving the clinical testing of new drugs in Europe. For instance, organisations that intend to carry out clinical trial assessments in several EU countries now only need to submit a single Clinical Trial Application (CTA) application that is then valid in up to 30 European Economic Area countries. So, for example, if a company wants to conduct a clinical trial within six member countries, they can do so with a single CTA. The new regulation helps to further streamline the clinical trial process and data sharing within Europe.[34]

The Horizon 2020 Framework Programme for Research and Innovation lists 2,347 research projects in the field of pharmacology and pharmacy that have been carried out in recent years.[35] The new Horizon Europe funding programme also provides intensive support for health-related research, notably for digital healthcare, digital tools, and health apps. A total of 8.2 billion euros has been earmarked.[36] The urgent need for research into diagnostics, vaccines, antibiotics and pharmaceuticals is emphasised.[37]

The pharmaceutical strategy for Europe also focuses on promoting research and development of "high-quality, safe, effective and environmentally friendly

31. (https://www.kas.de/documents/252038/22161843/Europe+as+a+Pharmaceutical+Location+%E2%80%93+Strengthening+Resilience+and+Competitiveness.pdf/f5e9c4bd-a0d4-8644-c550-923b98ccee4b?version=1.4&t=1685461444085).

32. (https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32014R0536&from=EN).

33. (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system).

34. (arkivum.com/what-is-ctis-and-what-are-its-benefits/).

35. (https://cordis.europa.eu/search?q=%2Fproject%2Frelations%2Fcategories%2FeuroSciVoc%2Fcode%3D%27%2F21%2F35%2F159%27&p=1&num=10&srt=/project/contentUpdateDate:decreasing).

36. (https://op.europa.eu/en/publication-detail/-/publication/1f107d76-acbe-11eb-9767-01aa75ed71a1).

37. (https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/3c6ffd74-8ac3-11eb-b85c-01aa75ed71a1), p. 35.

medicines".[38] Many other funding programmes, such as for cancer[39] or coronavirus research,[40] are aligned with EHDS, making Europe an interesting research location for the pharmaceutical industry. The European Medicines Agency (EMA)[41] performs key tasks at the interface between R&D and commercial use. Further harmonisation of the approval of new pharmaceuticals, including orphan drugs (drugs for rare diseases where the patient population is small, like diseases affecting 1 in 100,000 people)[42], would make Europe even more attractive as a pharmaceutical location. The European Health Emergency Preparedness and Response Authority (HERA) is also developing research activities with a view to future pandemic situations, which will benefit the pharmaceutical industry, while concurrently and most importantly relying on available healthcare data on infection clusters (e.g., prevalence of the flu) or the quantity of prescribed medicine in Europe to navigate demand.[43]

## OUTLOOK

The COVID-19 pandemic has revealed the urgent need and the high potential for interoperability and harmonisation. Germany looked repeatedly at other states with much more pronounced data collection experience, such as Israel, Denmark or the UK, when it came to public policies (e.g., school closing, lockdowns, transmission ways). Even though digitalisation in Germany has long been a subject of debate, its implementation due to the decentralised structure has always proven to be difficult. Germany is at times too occupied with its attention and debate to even the smallest details, delaying important policies altogether in this regard (instead of opting for a learning and gradually improving system), while at the same time confusion arises between the different actors (health insurance providers, doctors, patients, pharmacists) on how to best approach digital innovations. Another

38. (https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_de).

39. (https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en).

40. (https://research-and-innovation.ec.europa.eu/research-area/health/coronavirus_en, https://research-and-innovation.ec.europa.eu/system/files/2020-04/ec_rtd_era-vs-corona.pdf).

41. (https://www.ema.europa.eu/en).

42. To learn more about Orphan Drugs and Rare diseases, refer to: (https://www.ema.europa.eu/en/human-regulatory-overview/orphan-designation-overview#ema-inpage-item-11930). Orphan drugs come with high treatment costs for patients as the R&D efforts and expenses must be recouped from a small number of patients.

43. (https://health.ec.europa.eu/system/files/2021-09/hera_2021_comm_en_0.pdf).

factor is the diverging views between the Federal Data Protection Commissioner and the 17 state authorities towards the design and implementation of certain policies, whenever it concerns data protection, data safety or data use. With two new policies and the strong start of the e-prescription project this year, the digitalisation initiative finally seems to have gained some steam in Germany. At the EU level, the "Digital and Health Data Utilisation Act" is also an important step forward in connecting the overarching European Health Data Space that was put forward by the EU Commission in May 2022. Once this regulation is approved by the Parliament and Council, it will be fully applied across the European Union.

The proposal intends to address the limited use of digital health data in the EU due to different standards among member states and the limited interoperability. The EHDS provides a much-needed regulation to harmonise and spur information-sharing between member states. As the European Union only has a "supporting competency" in the healthcare sector, a full-fledged European Health Data Space within the European Health Union will certainly spark debates as to whether it interferes with national competencies.

A fact that should not be overlooked in Germany's and the EU's policies is the people's trust in bringing together healthcare data and their willingness to share data in the first place. Therefore, not only technical features, such as ensuring the cybersecurity of the infrastructure, but also legal features, such as a precise definition of the scope of the secondary use, need to be fleshed out and implemented. Ideally, digital literacy should be enhanced to allow the empowerment of EU citizens, as regards the use of their own health data.[44]

In order for Europe to maintain a leading position in the global pharmaceutical competition, research and development for new and high-quality pharmaceuticals must be promoted. One major building block to accomplish this constitutes the European Health Data Space and, deriving from that, the digital framework condition within EU member states.



44. (https://www.europarl.europa.eu/legislative-train/spotlight-JD22/file-european-health-data-space?sid=6801).

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