

## Position Paper

of the German Medicines Manufacturers' Association (BAH) on

### European Health Data Space (EHDS)

- Expectations and requirements of the medicines manufacturers -

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## 1. Introduction

The European Commission (EC) started a process in early 2021 with the objective of drawing up a legislative proposal for the creation of a legal framework for a European Health Data Space (EHDS). This dataspace is to facilitate cross-border exchange and use of data from electronic health records, genomic information and patient registries. The EC outlines the following objectives:

- Ensuring access, sharing and optimal use of health data for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, timely, transparent and trustworthy way, and with an appropriate institutional governance;
- Fostering a genuine single market in digital health, covering health services and products, including tele-health, tele-monitoring and mobile health;
- Enhancing the development, deployment and application of trustworthy digital health products and services, including those incorporating Artificial Intelligence in the field of health.

The EHDS is an important module of the European digital strategy and particularly the further development of the European health system connected with it. The EC recognises the necessity of achieving these targets to make Europe's economy more competitive, to enable further product innovations, to secure access to health and to improve people's health care.

The BAH welcomes the EC's initiative and states its expectations and requirements below. It would like to contribute to Europe becoming a leading place for secure and innovative health care for the population.

## 2. Recording the status quo

The health systems of most European countries considerably differ from one another. Particularly on the provisions side, regulations (inter alia on reimbursement and pricing) differ greatly. This concerns data with a view to their structure and their storage locations as well as the competent authorities and involved stakeholders. As a result, data already recorded today neither can be matched technically or with a view to their contents, nor with legal effectivity and efficiency.

Not rarely, politic and economic interests of the individual players form a large hurdle. For example, compilation of settlement data in provisions of medicines in Germany with the data

of the medical treatments is still an extensive and time-consuming process. The use of this data for healthcare research and on particular for drug development drags a long way behind the expectations and necessities.

The EC should therefore obtain a specific overview of the individual countries and about essential obstacles for a joint dataspace, to align the legal framework and measures legitimated by it as precisely and efficiently as possible and, if applicable, also learn about approaches to solutions which have already succeeded. Particular attention should be paid to instruments such as the electronic health record. In this context, the current initiative for the set-up of an electronic Patient Summary (Act for the Digital Modernisation of Care and Nursing – DVPMG) is to be emphasised.

In addition, obstacles resulting from various transformations of European requirements to national law should be detected (see e. g. General Data Protection Regulation – GDPR).

### 3. EHDS in the context of the European health infrastructure

On a European level alone, data and data infrastructure in an EHDS affect a series of stakeholders, authorities and institutions as well as various legal texts. Therefore, attention should be paid to conflicts of objectives, overlaps of competence and contradictory allocations of tasks from the outset in the creation of the legal framework for an EHDS. In this context, thrifty dealings with regulations may be helpful ("less is more"). Inflationary involvement of authorities and institutions have to be avoided at all costs.

Up to now, digitalisation of the healthcare system not only affects companies and stakeholders established on the highly regulated healthcare market. Instead, globally active digital companies are entering this market. The EHDS should guarantee that fair competition conditions exist for all the players in the generation and use of data.

In Europe, standardised and transparent rules should apply to data recording and access for research purposes. This is the only way in which the value of the EHDS as an entirety can win.

At the same time, binding legal regulations for liability, but also for protection of intellectual property are necessary. It requires a clear allocation of the product, the change process caused by Artificial Intelligence (AI) and the application or the operation of the product as the liability of an individual must not necessarily relate, for example, to all the elements stated. This is an essential requirement to extend a consumer-orientated single market for digital health, observing the national competences for reimbursement and prices, and thus being able to contribute to the growth of the European health economy.

Digitalisation of the healthcare system is a process which permanently accelerates. The agencies to be involved must strategically and operatively adjust to this. The dynamic development has to be taken into account with flexible reactions and fast decisions. To enable this, Europe needs suitable structures, rules and political processes. As a result, the existing decision-making structures in the EU are to be reformed as quickly as possible. An agile approach must be developed, to be able to survive in competition, for example with China and the USA.

#### 4. EHDS – space for data generation and use

The development of medicines up to market maturity is essentially done in commercial companies. For research of new therapies and further development of known active ingredients, it is essential not to leave the existing data on substances and therapies from clinical development, but also from everyday provisions in hospitals, treatment centres and medical surgeries unused or even ignore them. Instead, they should be available to institutions and companies committed in research and development to be used for the intended marketing authorisations and the necessary generation of evidence. This requires a regulated, secure and protected storage, processing and output of the data.

For the fastest and most efficient use of the existing data from various sources in the Member States, health data on a national level should be provided and processed such that it can be provided relative to the occasion in pan-European consented structures, formats and additionally anonymised via a central European hub. Research institutions and companies would have to declare and apply for their development projects with the hub, organisationally located at the European Medicines Agency (EMA). Therefore, the hub should have a coordinating function, but not store any data itself. As a further requirement, standardised handling of the generation and provision of the data in Europe from publicly institutional, clinical sources, from individual patient records and comparable sources is to be fulfilled. It would be counterproductive and a distortion of competition if such data were available to certain institutions and companies in some countries, but not in others.

In addition, health data stored in the private therapy-accompanying area, as well as vital data of obviously healthy people, contain an enormous wealth of knowledge that should be used.

Overall, the EHDS must be filled with life, i. e. data, in a way that allows this data to be used in a meaningful way in the sense of health research, but also in health care. This means that people who automatically obtain this data or who generate it within the framework of their tasks or actions must demonstrate the willingness to provide the data for further purposes of use. They themselves could have an interest in receiving this data in conjunction with other data for their own future development projects. The outcome of this is thinking about a general solidary

incentive model which motivates people, companies and institutions to provide data on the one hand and to use them on the other hand. In this context, this should ideally be less of a monetary and more of a knowledge-based system. It has to be avoided that data becomes a sales product. This is not contradicted by the fact that there must be payment for the efforts of data recording, processing and issue for the purpose of financing. However, a data donation may never be made under pressure on the individual (patients, physicians...). Instead, an intensive public debate and information about the chances and the risks of a data donation are necessary.

An EHDS offers the unique chance of raising a great potential of knowledge across national boards. "Big Data" relies on the people in Europe to obtain knowledge for their benefit. In this space and under the intended conditions, Real World Evidence can be generated in a quantitative and qualitative extent which could never be achieved in a single state. The larger and better this initial basis is, the more reliably and securely Artificial Intelligence (AI) can be applied.

Creation of an EHDS is not a project which is limited with a view to time. Instead, it is a large task on a long-term basis which has to be fulfilled in an iterative, agile process without losing sight of the holistic approach. To this extent, a specific order of subprojects should be stipulated and implemented within the framework of the overall strategy. For example, a first subproject could be the creation of a dataspace with a view to cancer registry data. This would support the efforts of the EU to combat cancer disorders and could act as a database for research of new cancer therapies.

## 5. EHDS – added value for the patients

When it comes to health care and its further development, patient-centred care should always be thought and addressed. Provision, benefit and protection of the patients are in the centre of attention. The EHDS can secure the following freedoms for people:

- freedom of communication
- freedom of movement
- freedom of choice

Alongside improvement of effectivity and efficiency of health care for people in Europe, digitalisation and more extensive data from real provisions additionally open up chances for purposeful and direct information about health services and possibilities of therapy for all those involved in the healthcare sector and in particular for patients. The information is however not a "one-way-road". Instead, digitalisation offers individual support ("coaching" and "monitoring") as well as communication independent of place and time with therapeutic and nursing

agencies. This presupposes that healthcare providers such as medicine manufacturers have the possibility of obtaining data as a basis for research and information.

Europeans appreciate the freedom of being able to travel, to work and to live within the EU. These freedoms may not be thwarted in the field of health by national borders. This particularly affects people with specific diseases. They ought not to be bound to one place. Instead, they should have the possibility of feeling safe and obtaining provisions at any place inside Europe, despite or possibly even because of their health handicap, as they always have their health data "at hand" and therapeutic professions can read their data. In this way, treatments are made possible and double examinations are avoided.

This freedom is to be guaranteed independent of the fact that the reimbursement and pricing systems are justifiably subject to the national regulations as a result of the great differences in the Member States' social systems.

Patients will make use of the freedoms they have chosen if they feel competent in dealings with digitalisation and have trust in the corresponding systems. Accordingly, requirements must be fulfilled so that patients are the sovereign of their data and can also manage it in practice like that. At the same time, European and national institutions must inform citizens about chances and risks and explain the options of a data donation. This transfer of knowledge increases competence and creates the necessary trust. At this point, the significance of school education, in particular the STEM subjects (Science, Technology, Engineering, Mathematics), becomes clear, as it is an essential requirement for understanding digitalisation and health.

## 6. EHDS – infrastructure

In an EHDS, all data structures, key systems and nomenclatures should be aligned to internationally acknowledged standards. An EHDS can only develop its effect if speaking is done "in one language", i. e. if interoperability is guaranteed on the various levels. This also means that future national procedures have to take the EHDS and its structures into due account.

Experience in Germany has shown that digitalisation in operative implementation has been given a great thrust by the highly capable "gematik" ([www.gematik.de](http://www.gematik.de)). The institution creates a specific implementation framework and tools for digitalisation of the healthcare system. It pays attention to transparency and interoperability. The extent to which Europe needs such a regulating institution to implement the EHDS needs to be checked.

An EHDS can only be developed in a suitable technical environment. Therefore, the efforts for the extension of robust networks must be increased. In order to maintain a digital infrastructure,

the personnel resources must also be extended.

## 7. EHDS – secure to the outside and the inside

By definition, an EHDS is an area relevant and sensitive to security.

For the companies of the pharmaceutical industry, the institutions in the healthcare sector and for each individual patient, IT security and data protection are of maximum, sometimes existential importance. In this regard, the EHDS must do justice to the highest of requirements and should therefore be designed from the outset such a way that it can keep pace with ongoing technical progress but is also a step ahead of the criminal threateners who permanently learn.

To the extent necessary for analysis and research, provision data needs anonymisation, if not at least pseudonymisation without traceability to the individual being possible. Security also means that data is transferred exclusively via specifically secured connections. Institutions and companies which collect, manage or use data for research purposes must take all the technically possible measures for data protection and security.

## 8. Improving healthcare with Artificial Intelligence in the EHDS

The EHDS is also to serve development and secure application of Artificial Intelligence (AI).

AI as an integral part bears a great potential for better, more intelligent products and thus for a secure and individual medicine therapy. AI particularly takes effect if data sets from highly differing sources/structures are to be matched with one another, e. g. laboratory results, image-based or textual descriptive findings, each from completely different institutions, cohorts or technical units (e. g. differing MRI appliances), and a high number of cases are to be taken into account. In this way, AI enables the earliest possible detection of disorders, including concomitant disorders and sequences of disorders, as well as development of predictive models with a view to illness risks. All told, AI strengthens research of innovative products and is gentle on clinical resources. Strain on patients is avoided in this way. In addition, AI permanently influences production, logistics and distribution of health products, in the end the entire value-added process.

Against this background, a data access right for medicine manufacturers is essential. They must concern themselves with AI on various levels. AI means a great challenge for the companies technically, ethically and as a result of the immanent inherent dynamism. The regulations valid up to now were created for comparatively rigid areas. These regulations do

not match up with the permanent further development of AI in many cases. It is most important for companies to become familiar with a legal framework which does justice to this new technology and within which they can undertake new added value. Therefore, the regulations of (ethical) responsibility and liability have a high significance. Protection of intellectual property forms a particular challenge with a view to the inherent dynamism of AI which has already been addressed.

In conjunction with epidemiological, but also socio- and geographical-economic data, AI with additional information can contribute to an efficient, sustainable and equitable provision of the people in Europe.

For a sensible and secure application of AI, quality-assured data, interoperability and secure structures are essential. The EHDS should form the basis for this. The patient is at the centre of all ideas and measures, even in AI. AI will only successfully serve people if they have trust in the benefits and the security of it.

## 9. Conclusion

People in Europe should be able to live and work in freedom. This needs suitable political and economic framework conditions. But, as the current pandemic sadly shows, it also needs suitable conditions for good and well interlinked health care. This is the basis for growth and prosperity. However, this can only be achieved if the possibilities of digitalisation are recognised and used - for both people and for society. But digitalisation also needs a regulatory and legal framework to avert dangers, to avoid risks and to make use of the chances.

The EHDS should be an important brick in this – with ...

- ensuring of cross-border interoperability,
- secure and efficient data generation, donation and use,
- use rights for medicine manufacturers,
- freedom of communication and movement for people,
- secure data exchange between authorities, citizens and further stakeholders (amongst others, companies),
- ensuring of maximum ethical and technical standards and citizens' sovereignty,
- creation of consciousness and provision of information to the citizens and to individual players in the healthcare sector (e. g. physicians).

The EHDS will be able to develop its effect when Europeans develop an awareness for the societal and individual value of health data and when they can recognise and experience an individual benefit. A matching trust must be built up. Then, the EHDS will make its contribution

in Europe for ...

- a prospering health economy,
- a legally secure single market,
- a competitive digital location

and particularly **for a more effective, more efficient, more sustainable and more equitable provision of patients.**

The BAH is ready at any time for discussions on the further development of digitalisation in general and of the EHDS specifically and looks forward to the dialogue with the partners in the healthcare sector.