AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

Let the knowledge contained in data open doors to the future of healthcare

AESGP reply to European Commission's Roadmap on Health Data Space

AESGP welcomes the European Commission's Combined Evaluation Roadmap and Inception Impact Assessment on A European Health Data Space, under the European Strategy for Data, and its ambition to introduce innovation, to take advantage of digital technology developments and to deliver concrete results to improve healthcare in Europe.

AESGP supports to the social-economic and individual healthcare advantages of this initiative expected to *increase cost-effectiveness for patients and healthcare systems by shortening time of diagnosis, optimising treatment options, avoiding duplication of tests and efforts, reducing medical errors, reducing inefficiencies in healthcare, facilitating personalised medicine, improving the effectiveness of prevention programmes, improving the monitoring of medicinal products and medical devices effectiveness and safety and facilitating epidemiological surveillance*.

However, a Health Data Space should aim to be more person-centric, in the sense that it needs to take into consideration the patients' needs and their personal contributions, and not circumscribe the European Commission's assessment to professional, governmental or administrative views of healthcare. Only with patient generated data will the EHDS achieve an added value that proves successful. There is a pool of valuable data with impact on healthcare that is not currently structured – such as sleeping, nutritional and physical activity habits, as well as behavioural records and registration of transient symptoms or episodes – which could, under voluntary data submission, prove useful for personal care. There is data which already fails to be routinely captured in electronic health records, like non-prescription medicines' and food supplements' intake. In order to encourage and enable Real World Data research, these should be recorded in order to enable a more holistic view of what individuals take.

AESGP would like to highlight that, due to new technologies (wearables and other bio-sensors), the number of potential sources of data has increased. AESGP welcomes the Commission's approach regarding the way to further regulate new technologies mentioned in its European Strategy for Data and agrees that there is a need for an agile approach. Individuals have an easily accessible overview of which data is collected where and can opt-out for specific purposes. Regulatory framework will require much quicker adaptation in the coming years so that people can have a timely benefit from digital progress. Technological acceleration needs to be paired with future-gazing regulation to ensure their on-time availability on the market without safety or security issues.

Usable data needs to be quality data – going beyond interoperability

Although there is a commendable focus on interoperability in the European Commission Roadmap, AESGP believes that this effort should be paired with investigation on the quality of data. Data capture is a key element that should only be performed by validated tools which can, in turn, be evaluated and guarantee data comparability. Therefore, high harmonised standards for data collection should be developed and, to be a part of the Health Data Space, ultimately enforced. Additionally, even if

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intellectual property is respected and ensured, transparency on how the data has been collected and used is essential.

From data storage to custody – responsibilities and access

AESGP calls for more harmonization in terms of data storage responsibility and access while welcoming the vision and willingness from the European Commission to create a common European Health Data Space. AESGP would also highlight the need to take advantage of the various initiatives already undertaken like the EHDEN project[1]. Working step-by-step and to set reasonable goals and expectations will be key for success in this area. AESGP further calls for more support of the legislation in data sharing and Industry access to anonymized data under defined conditions.

Real World Data benefits – translating potential evidence to favourable health outcomes

It is understandable the challenges posed by the collection, access, storage, use and re-use of data in healthcare, as well as the need to address it within a common set of rules that best serve citizens' interests and rights. But it is also very relevant that the regulatory framework for a European Health Data Space makes data-sharing ecosystems work, while harnessing the potential for favourable health outcomes, like the opportunity for Real World Data (RWD) collection and analysis.

RWD hold the promise for substantially increasing effectiveness and efficiency of all processes in the whole chain of development, authorisation and marketing of healthcare products and solutions in a very close future. RWD can provide additional data to support the decision-making process also in population groups that are usually not covered by clinical trials. The use of RWD should ensure that healthcare products, innovative technologies and therapies meet patients' needs and lead to favourable health outcomes[2]. This aim, supported by the European Commission, should become a reality, and it is expected that the use of such data will increase in the years to come.

AESGP deems it would be valuable to reach a harmonised definition on "secondary data use" versus "primary data collection". The lack, thereof, may sometimes lead to situations where it remains unclear as to where primary use ends and secondary use starts.

The secondary use of patient level Real-World Data (non-clinical, per se, from registries or a database) is often left to interpretation with regards to GDPR and there may be different views of the legal basis, and specific challenges as to whether data may be viewed as personal data, like in the case of pseudonymized data. There is currently a lack of consistency concerning data sources such as registries or genomic or microbiome datasets, causing complexity, in particular, when a consent mechanism would be unfeasible due to, for instance, a large data volume, unreachable patients or retrospective use of large data sets.

Empower people's health and digital literacies for a better future

As a general principle, AESGP believes that there is a tremendous opportunity for health data to be used to foster personalised care in order to empower people to take an active role in the management of their own health.

If general population is more informed on the added value of healthcare data for individuals and society, it could be more prone to register and use data while, consequently, increasing data quantity and quality. Information on the rights, duties and possibilities granted by the use of healthcare data will create more competent and confident citizens in dealing with digitization. The prerequisites must, therefore, be met for individuals to be the responsible owners of their data and to enact this sovereignty.

[1] EDHEN available at https://www.ehden.eu/
[2] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 25.4.2018 COM(2018) 233 final

The need to build digital workforce capacity is already well recognized[3]. AESGP would highlight the fact that there are important needs in the training of both healthcare and digital experts, so that the ability to work cross functionally is enhanced. AESGP believes that it is important to train people specialized in the field of artificial intelligence or data science, as well as to give basic training to the general population. Having everyone digitally and data literate will not only ensure responsible and adequate use of the digital tools, but build trust in the system as well.

When it comes to self-care and healthcare, the authorized data usage for research purposes, for product improvement or for evaluation of personal needs is rather limited. While welcoming some of the initiatives already taken by the regulators, AESGP would like to call for more data applications to unleash the potential of this massive amount of data while guaranteeing the safety and security of European citizens.

Europe must ensure a fit for purpose regulatory framework so that people can safely enjoy the benefits brought by digital transformation and new technologies. AESGP believes that Industry, regulators, legislators and society at large have to work together to accelerate the effort if Europe is to become a leader in the digital health space.

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[3] Building digital workforce capacity and skills for data-intensive science
Available at http://www.oecd.org/publications/building-digital-workforce-capacity-and-skills-for-data-intensive-science-e08aa3bb-en.htm