AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

Accompany enhanced data sharing with necessary (digital) literacy programs

AESGP reply to European Commission's proposal for a regulation of the European Parliament and of the Council on the European Health Data Space

AESGP welcomes the European Commission's proposal for a regulation on the European Health Data Space and its ambition to support innovation, take advantage of digital technology developments and deliver concrete results to improve healthcare in Europe. It is indeed key to support innovation to position the European Union as a leader in the area and build stronger and more resilient health systems.

AESGP recognises the social-economic and individual healthcare benefits of this initiative.

Empowering individuals to control their health data is essential, but helping them better understand that data is also a cornerstone of success and trust

AESGP agrees that "*today's EU health sector is rich in data, but poor at making it work for people and science*"[1] and that health data can help deliver more effective, better, safer and more personalized care, and help improve healthcare delivery.

But AESGP believes that the Health Data Space can aim to be more person-centered, in the sense that it must take into consideration the needs of patients and their personal contributions. It shouldn't circumscribe the European Commission's assessment of professional, governmental or administrative views of healthcare.

For example, we believe that the entire population not only needs better access to their data, but also needs to be able to understand and use it correctly. Personalized self-care requires people to be better informed about prevention and how to better monitor and take proper actions regarding any illness they may have.

Building a stronger and more resilient health system will also require increased efforts in prevention, self-care and agile regulatory systems

AESGP agrees that *digital health products and services have become part of everyday care delivery*[2] *and welcomes the inclusion of wellness apps for primary and secondary data use*[3].

[1] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on A European Health Data Space: Harnessing the power of health data for people, patients and innovation, 03.05.2022 COM (2022). 196 final.

[2] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on A European Health Data Space: Harnessing the power of health data for people, patients and innovation, 03.05.2022 COM (2022). 196 final.

[3] Proposal for a REGULATION OF EUROPEAN PARLIAMENT AND OF THE COUNCIL on the EUROPEAN HEALTH DATA SPACE. 03.05.2022. COM (2022) 197 final.

AESGP
7 avenue de Tervuren
1040 Brussels, Belgium
Tel : + 32 2 735 51 30
Fax : + 32 2 735 52 22
info@aesgp.eu
www.aesgp.eu

There is indeed a pool of valuable data impacting healthcare that is currently unstructured – such as sleep, eating and physical activity patterns, as well as behavioural records and recording of transient symptoms or episodes – which could, under voluntary data recording and/or data submission, be useful for personal care. There are also data that are not routinely captured in electronic health records, such as the intake of non-prescription medicines, self-care medical devices and food supplements. To encourage and enable research into Real-World Data (RWD), it should be recorded to enable a more holistic view of self-care.
The ability to retrospectively collect data from pharmacy dispencing dataset proved valuable to build understanding of patient groups using a drug in Germany[4]. This example of RWD demonstrates the value of accessing and utilising such data at a national level. We are in the opinion data collected at a regional or EU Community wide level would be equally valuable.

AESGP welcomes the Commission's approach on how to further regulate new technologies mentioned in its European Strategy for Data and agrees an agile approach is needed. The regulatory framework will need to adapt much faster in the coming years so that citizens can benefit from digital advances in a timely manner. Technological acceleration must be coupled with forward-looking regulation to ensure their timely availability to market without safety or security concerns.

Benefits of Real-World Data – accelerating new ways to provide evidence

The challenges of collecting, storing, using, and re-using health data (including self-care data in Electronic Medical Records (EMRs) and Electronic Health Records (EHRs)) are understandable, as is the need to address them under a common set of rules that serve best the interests and rights of citizens. 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, such as the opportunity for collection and analysis of Real-World Data (RWD).

Real-World Data hold the promise for significantly increasing the effectiveness and efficiency of all processes across the entire chain of development, authorisation and marketing of healthcare products and solutions in the very near future. RWD can provide additional data to support the decision-making process also in population groups not typically covered by clinical trials[5]. The use of RWD should ensure that health products, innovative technologies and therapies meet patient needs and lead to favourable health outcomes[6]. This objective, supported by the European Commission, should become a reality, and the use of this data is expected to increase in the years to come.

Responsibilities and access – European Health Data board and proposal for a cyber resilience act

AESGP agrees that *the healthcare sector and relevant cybersecurity authorities should consider cybersecurity as a key factor in ensuring the resilience and availability of key healthcare services*[7].

Europe must ensure a fit for purpose regulatory framework so that people can safely benefit from the advantages brought by digital transformation and new technologies. The proposal for a European Health Data Space is a step in the right direction, but we strongly recommend that a continuous and appropriate application be put in place. Additionally, we should recognize that many recent successes in novel drug applications involving real-world data have leveraged matching primary clinical study data to secondary real-world data (i.e. external control

[4] PHARMACY DISPENSING RECORDS FOR TOPICAL DICLOFENAC AND CONCOMITANT MEDICINES IN GERMANY: A RETROSPECTIVE ANALYSIS OF REALWORLD DATA. D.Deutsch et al. World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO-IOF-ESCEO 2021): Poster Abstracts. Osteoporos Int 32, S311 (2021). https://doi.org/10.1007/s00198-021-06125-9.

[5] Csoke, E, Landes, S, Francis, MJ, Ma, L, Teotico Pohlhaus, D, Anquez-Traxler, C. How can real-world evidence aid decision making during the life cycle of nonprescription medicines? *Clin Transl Sci*. 2022; 15: 43– 54. https://doi.org/10.1111/cts.13129

[6] 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

[7] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on A European Health Data Space: Harnessing the power of health data for people, patients and innovation, 03.05.2022 COM (2022). 196 final.

arms) and ensure that the European Health Data Space allows, at a minimum, for securely bringing primary clinical study data into the environment to continue and expand upon such approaches.

Finally, AESGP believes that industry, regulators, legislators and society at a whole must work together to accelerate the effort if Europe is to become a leader in the digital health space.

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