

Association of the European Self-Care Industry

PRESS RELEASE

Trust and safety are needed to reap benefits of eHealth:

AESGP proposals for successful accomplishment of self-care digital transition

Position Paper on Paving the way for the digitalisation of the self-care sector

AESGP has released an in-depth analysis on how digital tools are applied to healthcare, particularly by manufacturers of self-care products, building on successful examples, proposing necessary policy adjustments, advising on regulatory well-balanced requirements and recommending essential enablers.

AESGP has welcomed the various European-level initiatives aiming at providing a framework for upcoming digital innovations and the digital transition of healthcare, while ensuring trust and safety from the European citizens (such as the EU Digital Strategy, European Health Data Space, EMA Big Data Task Force, 2030 Digital Compass and, ultimately, the Pharmaceutical Strategy for Europe).

AESGP believes that, if Europe is to become a global leader in the digital health space, regulators, policy-makers, industry, and society at large have to work together to accelerate the effort of digital transition. AESGP agrees that a solid legal and regulatory framework needs to be in place to protect consumers and bring further trust in innovative digital tools. However, such a framework needs to be flexible enough to harness the full potential of digital tools and bring further opportunities to health systems by increasing accessibility and cost-effectiveness of care.

To that end, AESGP has developed <u>a position paper</u> on *Paving the way for the digitalisation of the self-care sector* that identifies regulatory gaps and highlights several requests for improvement. The paper also proposes essential enablers that will leverage a successful accomplishment of digital self-care, making sure Europe is not holding back in this area.

The goal of this paper is to help define a fit-for-purpose and proportionate regulatory framework and to stimulate the necessary regulatory changes and initiatives around digitalisation in healthcare and regulatory science.

The Position Paper examines 5 areas that highlight Self-Care Industry's key interests:

- Health Data, Real-World Data / Real-World Evidence (RWD/RWE)
- Artificial intelligence (AI)
- Product and disease information
- Building digital workforce capacity
- <u>eCommerce</u>.

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The Association of the European Self-Care Industry (AESGP) is the voice of the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, also referred to as self-care / consumer healthcare products.



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