



AESGP Position Paper

Paving the way for the digitalisation of the self-care sector

Excerpt — Product and Disease Information

February 2021



Product and Disease Information

To possess good product and disease information is absolutely key for people to properly manage their health status. The development and public use of electronic product information (ePI), self-diagnosis and self-monitoring apps could really help individuals to get easy access to reliable sources of information.



KEY SELF-CARE INDUSTRY ASKS REGARDING PRODUCT AND DISEASE INFORMATION

1. Electronic product information (ePI)

- An agreed binding roadmap for a consistent and coherent implementation of the ePI project in all EU Member States, covering all pharmaceutical and medical products.
- Start an open dialogue with all stakeholders as soon as possible, to ensure the ePI project is well aligned with the telematics ecosystem, and to identify and mitigate gaps.
- A future EU implementing guideline elaborating the concept of ePI-associated structured, unstructured, and re-usable elements should be provided by EMA.
- ePI interoperability by design should be a successful criterion for its coherent implementation.
- Recognise the value of additional resources like video instructions, supporting apps, etc.

2. Well-being and treatment follow-up apps

In self-care, apps are developed in diverse therapeutic and wellness areas that could bring benefits for individuals, contribute to support product safety and responsible use of products. However, suitable incentives and a fit-for-purpose regulatory framework are sometimes lacking for self-care products. Recently, Germany released a new digital healthcare act that allows for the reimbursement of prescribed digital health applications.

SmartBP (1) - Smart Blood Pressure on the App Store (apple.com) SmartBP is a Blood Pressure management app that allows patients to record, track, analyse and share their Blood Pressure information with their HCPs with an overall goal of improving their blood pressure.

MYAPOTECANATURA (2) - This application, available online and on mobile devices, helps in treatments follow ups and wellbeing. It allows people to save and monitor their health data, to set drug reminders, to improve their eating habits taking into consideration specific health needs, to count their steps and to receive personalized healthcare advices.

(1) SmartBP. Available at <https://apps.apple.com/be/app/smartbp-smart-blood-pressure/id519076558>. Consulted January 29th 2021.

(2) MYAPOTECANATURA. Available at <https://www.apotecanatura.it/my-apoteca-natura/>. Consulted January 29th 2021.





SPECIFIC ENABLERS

For the e-product and e-disease information to become a standard, there is a need for:

1. **Clear regulatory framework that incentivises the development of ePI and supporting tools**
2. **Definite governance structure (including industry representatives) with set accountabilities and ownership of the ePI project**
3. **Necessary resources at regulatory level**
4. **Involvement and buy-in of Healthcare Professionals and the general population**
5. **Health literacy campaigns to raise awareness of the ePI and support its appropriate use**
6. **Continuous collaboration of all stakeholders (individuals, healthcare professionals, industry, regulators) to define how the content of the Product Information can be further improved**
7. **Availability of trusted well-being apps on government websites would be of clear benefit for the public. These apps would have been assessed as clinically safe and secure for use. The NHS in the UK for example already possesses such a platform. ⁽³⁾**

⁽³⁾ NHS apps library available at <https://www.nhs.uk/apps-library/>. Consulted January 29th 2021.





About

The **Association of the European Self-Care Industry (AESGP)** is a non-profit organisation which represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, an area also referred to as consumer healthcare products.

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