



AESGP Position Paper

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

Excerpt — Artificial Intelligence

February 2021



Artificial Intelligence

AESGP welcomes the various initiatives undertaken by the Commission on Artificial Intelligence (AI). AESGP also agrees on the need to make Europe a stronger player in the field of AI while ensuring compliance with human rights. AI could bring tremendous benefits to the healthcare sector as a whole and some of **its potential applications are already described in numerous publications**. AI will foster growth of a digital economy and unleash the value of data.

In the self-care sector, AI can help to foster a **personalised self-care approach** and empower people to better manage their health and well-being, especially regarding the prevention and early detection/treatment of potential health concerns. AI, by analysing data shared by consenting individuals, could **support them in practicing self-diagnosis and self-care**.

Some AI-based symptom checkers and mental wellness apps are already marketed. Some examples are listed below.

- **AI-based symptom checkers**

- * Ada

- Ada is an AI-based symptom checker available on the Google Store, the App Store... (1)
- Ada's AI assesses the answers of the user against its medical dictionary of thousands of disorders and medical conditions.

- * Apple Watch uses AI to detect heart arrhythmias (2)

- **Mental Wellness apps with AI**

- * Woebot: uses cognitive behaviour therapy (CBT) and intelligent mood tracking. Provides meditation techniques and COVID-19-related information to help handle the social impact of distancing restrictions. (3)
- * Happify: AI coach to guide the user through interactive games and exercises using language recognition in order to reduce stress and overcome negative emotions. (4)
- * Binah.ai: Real-time, medical-grade vital signs measurements (heart rate, oxygen sat., respiration, stress level, heart-rate variability) using only a smartphone, laptop or tablet camera. (5)

(1) Ada. Available at https://play.google.com/store/apps/details?id=com.ada.app&hl=en_US&gl=US. Consulted January 29th 2021.

(2) Using Apple Watch for Arrhythmia Detection December 2020. Available at https://www.apple.com/healthcare/docs/site/Apple_Watch_Arrhythmia_Detection.pdf. Consulted January 29th 2021.

(3) Woebot. Available at Mental Health Chatbot | Woebot (woebothealth.com). <https://woebothealth.com/>. Consulted January 29th 2021.

(4) Happify. Available at Happify: Science-Based Activities and Games. <https://my.happify.com/>. Consulted January 29th 2021.

(5) binah.ai. Available at [Video-based Vital Signs Monitoring - Binah](#). Consulted January 29th 2021.





KEY SELF-CARE INDUSTRY ASKS REGARDING ARTIFICIAL INTELLIGENCE USAGE

1. Ethical Trustworthy AI

AESGP agrees with the fact that AI systems **need to be human-centric** with the aim to increase individual **and** societal well-being.

2. Risk-based approach

The regulatory framework of AI should take into account the various usages of AI. It is obvious that depending on the application, different risks for the individual are expected. **Therefore, defined risk categories with their specific rules or definitions of clear criteria should be provided.**

3. Fair and horizontal regulation

In the healthcare sector, the pharmaceutical industry is used to working in a highly regulated environment. The various types of products must follow a long procedure of safety testing and extensive evaluations of their benefits before any marketing authorisation is issued by the authorities. Industry actors such as digital developers may be new to this highly regulated environment of traditional healthcare. Without overly limiting access to innovative technologies, regulators must ensure a fair level playing field for all actors by developing and enforcing horizontal regulations across sectors while taking into account the particularities of the healthcare sector respecting the benefit/risk profiles of the products and the data privacy of the patients.

4. Clearly defined accountabilities and liabilities

The development and use of AI-powered tools is subject to different contributors. As the development of the various applications of AI is progressing, the strong **need for accountabilities and liabilities to be clearly defined** is becoming absolutely necessary.



SPECIFIC ENABLERS

1. High-quality and interoperable databases

In order to grasp the benefits of AI, there is the need for well-designed and interoperable databases that can support the increasing amount of data storage needed.

2. Trustworthy algorithms

In order to ensure trust from the various stakeholders, further research on how AI products achieve results and impact decisions in healthcare practice is a must. Extensive explanations and communication between the multiple parties involved (Regulators, Industry, HCPs...) should occur to ensure buy-in and trust from civil society and the wider healthcare system in general.





3. Fit-for-purpose regulatory framework

AI is a good example to show that regulation implementation must be redefined. Due to its many **different applications and its constant evolution**, adopting an **agile mindset** would be very beneficial.

4. Trained professionals

Highly trained professionals (data scientists, policy makers, healthcare professionals, patient advocates...) are **not only required for the development of artificial intelligence solutions or for the development of policies and regulations**. AESGP would also highlight the fact that there are other important needs for skilled professionals. Training experts **to work cross-functionally** will be key to broadly incorporating effective AI solutions in healthcare. **Good communication, education and training that targets both practicing and future professionals in healthcare and technology innovation, their assistants and the population at large** is also essential to accomplish this goal.





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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