AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

AESGP Position Paper

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

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Contents

Abbreviations

AI	Artificial Intelligence
CPME	Standing Committee of European Doctors
EMA	European Medicines Agency
EC	European Commission
ePI	electronic Product Information
GDPR	General Data Protection Regulation
HCP	Healthcare Professional
HMA	Head of Medicines Agencies
ICT	Information Communication Technology
MD	Medical Device
PGHD	Patient/Person Generated Health Data
RCT	Randomised clinical trials
RWD	Real-world data
RWE	Real-world evidence

EXECUTIVE SUMMARY

Executive Summary

AESGP welcomes the various initiatives undertaken at European level (EU Digital Strategy, Pharmaceutical Strategy for Europe, European Health Data Space, EMA Big Data Task Force…) aiming at providing a framework for the upcoming digital innovations while ensuring trust and safety from the European citizens. Digitalisation bears a lot of hopes but is certainly a complex topic.

AESGP is committed to helping define a fit-for-purpose and proportionate regulatory framework.

Hence, this AESGP position paper on digital strategy is highlighting some points of main importance for the self-care sector regarding data, real-world data (RWD), real-world evidence (RWE), Artificial Intelligence (AI), product and disease information, the building of the digital workforce capacity and eCommerce.

1. Data, Real-world data and Real-world evidence

◊ While welcoming and strongly supporting some of the initiatives (GDPR, the European Strategy for Data, the HMA-EMA Big Data Task Force work…) already launched by the regulators, AESGP would like to call for **more authorised data applications and infrastructure developed and run in the EU to unleash the potential** of this massive amount of data while guaranteeing the safety and security of European citizens.

◊ When it comes to self-care and healthcare, the authorised data **usage for research purposes**, for tool **improvement** or for **evaluation of personal needs** is rather **limited**.

◊ As a general principle, AESGP believes that **health data should be used to foster personalised care in order to empower people** to take an **active role** in the management of their own health.

◊ RWD and RWE are of **particular interest for the self-care area** and non-prescription products. The additional insights provided could:

- **Help substantiate the switch from prescription to non-prescription medicines**
- **In addition to their usage in safety evaluation and monitoring, they could support the efficacy evaluation of products.**
- **Support product development, authorisation of new indications and discovery of new populations**
- **Support the positive benefit-risk ratios of "older" non-prescription medicines.**
- **Generate insights to better understand people behaviours and treatment needs.**

2. Artificial Intelligence (AI)

◊ In the self-care sector, AI can help 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.

3. Product and disease information

◊ 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. Of course, a paper version of the product information should remain available in case of need.

4. Building digital workforce capacity

◊ AESGP believes that **it is important to train people specialised in the field** of Artificial Intelligence or data science to operate in a regulated healthcare environment, **as well as to give basic training to the general population** on using digital solutions.

◊ Encouraging digital literacy in healthcare will not only ensure a responsible and adequate use of the digital tools but will also build trust in the system.

5. eCommerce

◊ Raise awareness of rules applicable to online medicine retailers

◊ Further enforce food rules applicable to online sales

◊ Ensure that only compliant EU MD apps are available on the market and to ask for the removal of those that are not placed on the market as MDs but should be.

A Call for Action

	Asks	Enablers
Data, Real-World Data and Real-World Evidence	• User-focused data, foster personalised healthcare • Agile framework to foster innovation • Consider every useful source of data (not only health registries) for decision-making purposes • Foster RWD/RWE usage in addition to the data generated in traditional clinical trials • Authorise a broad variety of data sources to generate real-world data and real-world evidence • Interoperability in databases (health registries, e-prescription), regulations • Overall harmonisation	• Regulatory framework fit for purpose • High-quality and interoperable databases • Trustworthy algorithms • Appropriate and continuous funding • Digital health-literate professionals • Continuous involvement of all the stakeholders
Artificial Intelligence	• Ethical Trustworthy AI • Risk-based approach • Fair and horizontal regulation • Clearly defined accountabilities and liabilities	
Product and Disease Information	• Availability of electronic Product Information • Well-being and treatment follow-up apps	
Building Digital Workforce Capacity	• Invest in training and development of specialised workforce • Critical need to increase basic knowledge of the general population	
E-Commerce	• Raise AWARENESS of rules applicable to online medicine retailers • Further ENFORCE food rules applicable to online sales • Ensure that only compliant EU MD apps are available on the market and to ask for the removal of those that are not placed on the market as MDs but should be.	

PAVING THE WAY FOR THE DIGITALISATION OF THE SELF-CARE SECTOR

Introduction

The creation of a **Europe fit for the digital age** is in the European Commission priorities for **2019-2024**.

> *"The Commission is determined to make this Europe's "Digital Decade". Europe must now strengthen its **digital sovereignty and set standards, rather than following those of others** – with a **clear focus on data, technology, and infrastructure"** (1).*

The EU's digital strategy aims to make this transformation work for people and businesses, while helping to achieve its target of a climate-neutral Europe by 2050.

AESGP (2) welcomes this statement and recognises the **need and urgency** to develop **Europe capabilities** in **the digital space.** Due to the economic situation and more recently the **COVID-19 crisis**, it is even clearer that Europe must be at the **forefront of the digital development**. An unexpected consequence of the COVID-19 pandemic is that governments everywhere have to rethink the role of innovation and digital technology for health and well-being. It has brought accelerated change in the way companies in our sector have approached their digital adoption strategies in response to increased consumer needs.

Digital solutions can help **people take ownership of their health**, make it easier for them to **self-diagnose** a condition or a symptom, change a health habit or behaviour to reach a goal, enable compliance with a course of treatment thanks to electronic Product Information, or interact with their community of care providers or fellow individuals with similar health concerns. **Today, technology itself can be a wellness or treatment option.**

For industry, digital technology helps to speed up processes and to have real-time access to an increased amount of data. These help to monitor not only the various stages of research and development but post-market surveillance and quality control as well. It ultimately increases **operational efficiency** and **manufacturing readiness**. Information technology is transforming regulatory science and allowing for a **better use of available resources** and an improvement in the quality and extent of harmonised information available to support marketing authorisation, among other advantages.

Concerning COVID-19 specifically, there is evidence that the usage of data helps to get a better understanding about the virus. Artificial Intelligence (AI) was used to identify targets for vaccine development (3), relieve pressure on national health systems and create remote solutions to easily connect with healthcare professionals – when in-person contact is discouraged – through, for example, chatbots. The various tracing applications have helped people to take further protective measures when in contact with infected people. COVID-19 **strongly highlighted the need for practicing responsible self-care** which helped to alleviate pressure from already strained health systems and to **prevent** illness in the first place. In that regard, digital means proved to be of tremendous help as recognised by the European Commission (4).

(1) A Europe fit for the digital age. European Commission website [Internet]. Available at https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age_en. Consulted October 22nd 2020

(2) 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 selfcare medical devices in Europe, an area also referred to as consumer healthcare products.

(3) Keshavarzi Arshadi A, Webb J, Salem M, Cruz E, Calad-Thomson S, Ghadirian N, Collins J, Diez-Cecilia E, Kelly B, Goodarzi H and Yuan JS (2020) Artificial Intelligence for COVID-19 Drug Discovery and Vaccine Development. Front. Artif. Intell. 3:65. doi: 10.3389/frai.2020.00065. Consulted January 29th 2021.

(4) European Commission. Digital Solutions during the pandemic. Available at https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/digital-solutions-during-pandemic_en. Consulted January 29th 2021.

Allowing to harness the potential of new technologies in the **self-care area** will facilitate the shift towards more efficient and **preventive healthcare systems** and bring an **overall reduction of the costs and improve access**. It will also allow for the creation of a **tailored experience** for people, **empowering them and increasing their compliance**.

In its 2018 communication on Digital Health and Care, the Commission (5) identified three pillars to achieve:

- **Pillar one:** Secure data access and sharing.
- **Pillar two:** Connecting and sharing health data for research, faster diagnosis and improved health.
- **Pillar three:** Strengthening citizen empowerment and individual care through digital services.

One can argue that we are unfortunately far away from the concrete implementation of the above pillars. **Tremendous benefits** are foreseen for healthcare but, to achieve them, there is a **clear need to collaborate** and **streamline efforts**.

To that end, AESGP has developed this position paper on digital strategy for self-care that focuses on the regulatory aspects of digital transformation. This paper is displaying several requests and enablers, from the self-care Industry standpoint, aiming to stimulate the necessary regulatory changes and initiatives around digitalisation in healthcare and regulatory science.

This position paper contains 5 sections that highlight Industry's key interests, namely:

1. **Data, real-world data / real-world evidence (RWD/RWE)**
2. **Artificial intelligence (AI)**
3. **Product and disease information**
4. **eCommerce**
5. **Building digital workforce capacity**

AESGP thinks 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. AESGP would also like to emphasise that, while useful, **written public consultations are not always the best stakeholders engagement options**. AESGP would like to further encourage the **organisation of workshops and brainstorming sessions** to exchange ideas and points of view more easily. The European Union has the potential to be successful in the data-agile economy. It already has the knowledge and expertise, state-of-the-art technology, and a highly-skilled workforce. However, competitors to the EU – for example China and the US – are already innovating rapidly and shaping their own concepts of access to data and its use across the globe. In order to compete on the global stage, the European strategy must be able to pragmatically balance the flow and wide use of data, while preserving privacy, security, safety and ethical standards, and yet be agile and responsive. A rigid and static regulatory framework will stifle innovation and global competitiveness, and prevent the EU's digital economy from thriving.

Europe must ensure **a fit-for-purpose regulatory framework** so that people can **safely enjoy the benefits brought by digital transformation and new technologies.**

(5) SWD (2018) 126 final. 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. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018SC0126&from=EN. Consulted October 22nd 2020.

Data, Real-World Data And Real-World Evidence

The last decade has not only seen the **explosion of the number** of data **captured, shared** and **stored** but has **also witnessed a shift on the way data is processed**. According to some numbers provided in the European Data Strategy (6), **in 2018**, data processing was performed at 80% by centralised computing facilities and 20% by smart connected objects. **In 2025**, so not so far from now, it is expected that we are going to see the opposite. So, **20%** processing performed by **centralised computing facilities** and **80%** performed by **smart connected objects!**

Nevertheless, when it comes to self-care and healthcare, the authorised data **usage for research purposes**, for tool **improvement** or for the **evaluation of personal needs** is rather **limited**. While welcoming and strongly supporting some of the initiatives (GDPR, European Strategy for Data, the HMA-EMA Big Data Task Force work…) already launched by the regulators, AESGP would like to call for **more authorised data applications and infrastructure developed and run in the EU to unleash the potential** of this massive amount of data while guaranteeing the safety and security of European citizens.

KEY SELF-CARE INDUSTRY ASKS FOR DATA USE TO ADVANCE SELF-CARE

1. User-focused data, foster personalised healthcare

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

In the examples below, there are potential applications of user-focused data.

Nicorette® Stop smoking app developed by J&J

Nicorette® QuickmistSmartTrack™ combines the authorised medicine Nicorette® mouth spray with a behavioural support app. Nicorette® QuickmistSmartTrack™ leverages near field communication (NFC) technology to allow consumers to track their NRT usage with a simple tap to the Nicorette® stop smoking app downloaded to their smartphone. The behavioural support app allows users to set a personal quit plan in the app, track their progress & product usage towards their quitting goals and receive motivational tips to help them stay on track.
Nicorette® QuickMistSmartTrack™ is only available in the UK at this time.

Flu Tracker® GSK

GSK launched Flu Tracker microsites across several markets to forecast where and when people could contract the flu so they could better protect themselves against it. The initial launch was in 2017 in Russia, followed by Hungary, Poland, Sweden and South Africa in 2019. Multiple data sources were used to forecast which regions of the country are at highest risk for contracting the flu. The data is converted into a flu score for each region and forecasts are delivered to people as a heat map.
Important point to note: No first party data is captured by the app.

(6) The European Data Strategy available at https://ec.europa.eu/commission/presscorner/detail/en/fs_20_283

2. Agile framework to foster innovation

AESGP welcomes the Commission's approach regarding the way to further regulate new technologies (like AI or Blockchain) mentioned in its European Strategy for Data (7) and agrees that **there is a need for an agile approach**. New technologies are indeed evolving so fast that there is a need to carefully (re-)think the **way such products are regulated** to ensure their on-time availability on the market without safety issues.

It is clear that if the regulation is not proportionate and fit for innovation, very few products – with limited functionalities – will be marketed and buy-in from the general population will be small.

AESGP also welcomes the proposal of a regulation of the European Parliament and of the Council on European data governance (Data Governance Act) (8).

Finally, AESGP would like to highlight the need to ensure free movement and interoperability of data format across borders in respect of the requirements.

A. Data availability

The quantity of data we collect increases over the years. Yet, we were unable to fully utilise these data to bring benefits for individuals and society. We believe that **EU legislation should support more data access for healthcare purposes.**

Even if AESGP acknowledges the need to have a regulatory framework in place to limit data usage to specific cases, there are a number of benefits that could be brought by with more data sharing.

For example, the **COVID-19 pandemic highlighted the need to share data** and to have **good remote solutions** in place. The development of COVID-19 tracing apps and the encouragement from the various countries in Europe does show that such tools can be useful, for example, in the context of a pandemic. The usage of telemedicine and remote solutions has clearly increased during the COVID-19 global pandemic when personal contact was discouraged (9).

B. Data quality

Data quality is essential for obvious reasons and every action possible that can improve the quality of the data processed should be undertaken. Even if intellectual property should be respected and ensured, transparency on how the data has been collected and used is also a must. Furthermore, AESGP believes that data capture is a key element that should only be performed by validated tools. In addition to good quality data, the various sources used should provide data that is easily comparable. Therefore, harmonised standards for data collection should be developed and enforced.

COVID-19 has also unfortunately again shown the damage that can be caused through the spread of misinformation by non-trustworthy sources. For example, some false hasty/erroneous statements were issued on the fact that it was dangerous to take ibuprofen if you had COVID-19. Fortunately, thanks to a good quality population-wide health database (10), a Danish academic study, performed by Kristian Kragholm et al. (11) was able to determine that there was no significant association between ibuprofen prescription use claims and aggravation of severe COVID-19. The use of this database allowed the inclusion of COVID-19 positive individuals managed in the community, rather than hospitalised patients only.

(7) Brussels, 19.2.2020 COM (2020) 66 final. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. A European strategy for data. Available at https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf. Consulted October 30th 2020.

(8) Brussels, 25.11.2020 COM(2020) 767 final 2020/0340 (COD) - Data Governance act available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767. Consulted December 10th 2020.

(9) Mann DM, Chen J, Chunara R, Testa PA, Nov O. COVID-19 transforms self through telemedicine: Evidence from the field. J Am Med Inform Assoc. 2020 Jul 1;27(7):1132-1135. doi: 10.1093/jamia/ocaa072. PMID: 32324855; PMCID: PMC7188161. Consulted December 9th 2020.

(10) https://www.healthcaredenmark.dk/the-case-of-denmark/personalized-medicine/big-data/.Consulted October 30th 2020.

(11) Kragholm K, Gerds TA, Fosbøl E, Andersen MP, Phelps M, Butt JH, Østergaard L, Bang CN, Pallisgaard J, Gislason G, Schou M, Køber L, Torp-Pedersen C. Association Between Prescribed Ibuprofen and Severe COVID-19 Infection: A Nationwide Register-Based Cohort Study. Clin Transl Sci. 2020 Sep 24:10.1111/cts.12904. doi: 10.1111/cts.12904. Epub ahead of print. PMID: 32970921; PMCID: PMC7537121. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7537121/pdf/CTS-9999-na.pdf. Consulted October 30th 2020.

C. Data capture

AESGP believes that the regulatory framework **should take into account the numerous new ways of collecting data** (e.g., wearables, pharmacy records…). The means of capturing data have been strongly modified in the last decade, particularly in recent years. The arrival on the market of smartphones, smart watches and a plethora of other wearables disrupted the ways in which we capture data. Legislation should take these decentralised ways of data collection into account.

It is also foreseen that the regulatory framework will require **much quicker adaptation in the coming years** so that patients can have a **timely benefit** from digital progress in a secured way.

D. Data storage and health data space

AESGP calls for more harmonisation in terms of data storage and welcomes the vision and willingness from the European Commission to create a common European health data space. AESGP would also highlight the **advantages of the various initiatives already undertaken** like the EHDEN project (12). **Working step by step** and setting **reasonable goals** and **expectations** will be the key to success in this area.

E. Data ownership and dissemination

Personal health data ultimately belongs to the individual. It is key to put high safeguards in place for data protection and the proper implementation of the GDPR is critical in that regard. For clinical trials, the usage of electronic personalised informed consent should be explored. Regarding AI, algorithms **need to be tested and trained using quality datasets to be able to generate improved outcomes including lowering risk more reliably**. This is also clearly stated in the white paper "On Artificial Intelligence - A European approach to excellence and trust" published by the European Commission, where improving access to and the management of data is considered fundamental. "Without data, the development of AI and other digital applications is not possible." (13) AESGP calls for more support of the legislation in data sharing to improve the datasets used by AI algorithms and improve industry access to anonymised data under defined conditions.

3. Consider every useful source of data (not only health registries) for decision-making purposes

The HMA-EMA Big Data Task Force, which has been in existence since 2017, is defining big data in the following terms:

> *"Extremely **large datasets** which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations. In general, big data sets require advanced or specialised methods to provide an answer within reliable constraints."* (14)

From these large Real-World Data (RWD) pools some evidence can be extracted which can support the decision-making process for the approval of new drugs – Real-World Evidence (RWE).

(12) EDHEN available at https://www.ehden.eu/. Consulted October 22th 2020.

(13) Available at https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf. Consulted October 30th 2020.

(14) Big data - EMA website available at https://www.ema.europa.eu/en/about-us/how-we-work/big-data. Consulted October 30th 2020.

AESGP would like to highlight that, due to new technologies (wearables and other (bio)sensors), the **number of potential sources of data** has increased. There are increasingly more literature publications on the potential applications of real-world data/real-world evidence (RWD/RWE). Also, the findings of the EMA and the co-chairs of the HMA -EMA Big Data Task Force point out the need to **go beyond the current framework for decision-making purposes** (15). However, the usage of RWD and RWE is still relatively limited in Europe. The lack of clear guidance makes any submission of such data difficult. **Framing the data regulatory acceptability criteria is of key significance for both Industry and Regulators**. On a positive note, this topic has already been identified in the European Medicines Agency's (EMA's) Regulatory Science Strategy to 2025 as one of the key priorities (16).

RWD and RWE are of **particular interest for the self-care area** and non-prescription products. The additional insights provided could:

- **Help substantiate the switch from prescription to non-prescription medicines.**
- **In addition to their usage in safety evaluation and monitoring, they could support efficacy evaluation of products.**
- **Support product development, authorisation of new indications and discovery of new populations.**
- **Support the positive benefit-risk ratios of "older" non-prescription medicines.**
- **Generate insights to better understand people behaviours and treatment needs.**

4. Foster RWD/RWE usage in addition to the data generated in traditional clinical trials

Usage of RWD and RWE help provide **new insight** in self-care product use during the entire lifecycle and **improve the decision-making process**. Randomised clinical trials (RCT) traditionally have been the determining factor to evaluate the efficacy and safety of new drugs. While RCT are the gold standard, they also pose some disadvantages such as underrepresenting the impacts of actual use scenarios in a wider population or cost, especially for small digital start-ups. Even if traditional clinical trials should obviously not be overlooked, RWE can provide additional data to support the decision-making process also in population groups that are usually not covered by clinical trials. Normalising the use of RWE data to complement a smaller RCT results would improve the time to public access to new products and technologies, especially digital technologies which can iterate quickly, and encourage innovation developed by smaller companies.

In addition, considerations should be given to the situations where RWD and RWE could serve as standalone in the assessment of a product.

(15) Eichler HG, Pignatti F, Schwarzer-Daum B, Hidalgo-Simon A, Eichler I, Arlett P, Humphreys A, Vamvakas S, Brun N, Rasi G. Randomized Controlled Trials Versus Real World Evidence: Neither Magic Nor Myth. Clin Pharmacol Ther. 2020 Oct 16. doi: 10.1002/cpt.2083 (https://doi.org/10.1002/cpt.2083). Consulted November 2nd 2020.

(16) EMRN strategy available at https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf. Consulted November 2nd 2020.

5. Authorise a broad variety of data sources to generate RWD and RWE

Data on non-prescription medicines can partially be found in the same places as prescription (Rx) medicines but it can also be found in different data sources such as:

- National Health Surveys
- Patient/Consumer Surveys
- Consumer Behaviour Research studies
- Patient/Person Generated Health Data (PGHD)

Since some non-prescription products have been used for many years, there is plenty of real-world data available. Anecdotal evidence from social media can help researchers identify ways to acquire more robust data via the methods mentioned above.

6. Interoperability in databases (Health registries, e-prescription), regulations

Interoperability among different official health databases is absolutely necessary to ensure the success of the various initiatives. **Not only between countries but also inside the same country**. Again, the COVID-19 pandemic has unfortunately shown the need to have interoperable systems and databases as much as possible. The **inclusion of non-prescription medicines and other self-care products in medical and pharmacy records** in a harmonised way would bring great benefits to the people (such as the potential follow-up of their treatment when travelling) as well as improve patient safety (such as medicines' use compatibility). Additionally, interoperability of databases would facilitate patient treatment journey between the various healthcare professionals (Doctor, Pharmacist, Kinesitherapist…) and improve quality of care.

7. Overall harmonisation

Data is a powerful tool and can bring tremendous benefits when used in an organised way. Hence the reason for AESGP to call for more standardisation and harmonisation, not only in terms of interoperability (as mentioned above) but **also in terms of cooperation among Member States, and coordination with the European Commission and EMA**. The risk of a fragmented approach is recognised in several documents published by the European Commission:

> *"Fragmentation between Member States is a major risk for the vision of a common European data space and for the further development of a genuine single market for data."* (17) *"If the EU fails to provide an EU-wide approach, there is a real risk of fragmentation in the internal market, which would undermine the objectives of trust, legal certainty and market uptake."* (18)

(17) Brussels, 19.2.2020 COM (2020) 66 final. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. A European strategy for data. Available at https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

(18) Available at https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf. Consulted October 30th 2020.

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… (19)
        - 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 (20)
- **Mental Wellness apps with AI**
    - Woebot: uses cognitive behaviour therapy (CBT) and intelligent mood tracking. Provides mediation techniques and COVID-19-related information to help handle the social impact of distancing restrictions. (21)
    - Happify: AI coach to guide the user through interactive games and exercises using language recognition in order to reduce stress and overcome negative emotions. (22)
    - 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. (23)

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

(20) 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.

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

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

(23) 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.

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 (24) - 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 (25) - 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.

(24) SmartBP. Available at https://apps.apple.com/be/app/smartbp-smart-blood-pressure/id519076558. Consulted January 29th 2021.
(25) 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.** (26)

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

Building Digital Workforce Capacity

The need to build digital workforce capacity **is already well recognised** (27). AESGP believes that **it is important to train people specialised in the field** of artificial intelligence or data science to operate in a regulated healthcare environment, **as well as to give basic training to the general population** on using digital solutions. Encouraging digital literacy in healthcare will not only ensure a responsible and adequate use of the digital tools but also build trust in the system.

KEY SELF-CARE INDUSTRY ASKS REGARDING DIGITAL WORKFORCE CAPACITY

1. Invest in training and development of specialised workforce

As recognised by the European Commission, there is a shortage of highly skilled and qualified professionals in the digital area (Information and communications technology (ICT) professionals, data scientists, etc). The deficiency crosses society, regulatory, industry and healthcare professionals.

At the regulator level, the current **lack of national health system digitalisation** and the **lack of digital capabilities within health authorities** demonstrates that there is an urgent need for greater competences in this area, resolvable by recruiting and training more people with expertise in data science and ICT. Additionally, as regulators and industry are driving several **ambitious initiatives in this area**, it is expected that the need for **skilled workforce in the ICT and data areas will increase.**

Besides, healthcare professionals (doctors, pharmacists, nurses…) will need to adapt and integrate digital technology education and training as a foundation requirement, as well as develop skills using distinct new technologies (e.g. AI for diagnosis, various diagnostic, monitoring, and treatment apps). In fact, the Standing Committee of European Doctors (CPME) has already released a Policy on Digital Competencies for Doctors (28) which details the necessary digital competencies for current and future doctors.

2. Critical need to increase the basic knowledge of the general population

The lack of digital skills in the general population is also of concern. According to numbers shared by the European Commission, the percentage of the population having basic digital skills in 2018 was around 57% (29). In 2025 it is expected that this number will increase to 65%.

There is a clear need to improve digital skills so that everyone can take advantage of digital transformation and specific efforts should be made to help the elderly learn to use digital tools. Considerations should also be given on how access to digital solutions could be improved. Finally, specific training on GDPR and GDPR data management would also be really helpful.

(27) 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. Consulted October 30th 2020.

(28) Available at https://www.cpme.eu/index.php?downloadunprotected=/uploads/adopted/2020/11/CPME_AD_Board_21112020_100.FINAL_.CPME_.Policy.Digital.Competencies.for_.Doctors.pdf. Consulted December 9th 2020.

(29) The European data strategy fact sheet available at https://ec.europa.eu/commission/presscorner/detail/en/fs_20_283. Consulted October 22th 2020.

SPECIFIC ENABLERS

1. Awareness campaigns

The lack of information or knowledge **is often paired with fear and distrust**. To bring the population onboard the digital journey envisioned, **awareness campaigns are required**. Some basic explanations **as to how these new technologies work and are used in healthcare should be provided**. Information on efforts and measures that protect personal data should be an integrated part of communication campaigns.

2. Open-source resources (webinars, podcasts, online courses)

Awareness campaigns should be supported by **good quality** user-friendly resources on the digital topics. These resources should be open-source and available **on government-run platforms**. Healthcare providers should be encouraged to refer patients to these resources to foster patients' self-education of their conditions and reinforce methods for both disease prevention and health management.

3. Continuous professional development

As healthcare professionals are going to be "first in line" to use the various new technologies and **asked to provide advice**, extensive trainings should be provided to them and be part of their mandatory professional development as well as foundation training.

E-Commerce

E-commerce of self-care products including non-prescription medicines is allowed in the EU and there is a harmonised approach to registering e-Pharmacies, including requiring the registered sites to display an EU common logo. However, national governments take different approaches across which product classes can be sold online, which entities can sell which product class, as well as the requirement for e-Pharmacies to have a physical presence or not.

The most frequently cited reason for people to buy self-care products online is affordability and convenience (30). The COVID-19 global pandemic, for obvious reasons, has increased the popularity of e-commerce including to purchase self-care products.

KEY SELF-CARE INDUSTRY ASKS REGARDING E-COMMERCE

1. Raise AWARENESS of rules applicable to online medicine retailers

European regulators and governments are already working to educate people regarding the safe online purchase of self-care products and promote the use of the logo for registered e-Pharmacies. Unfortunately, this does not prevent fake websites from using the logo or legitimate websites from appearing without the logo. We believe more can be done in collaboration with industry and retailers to ensure that people who choose to buy online have the necessary knowledge to recognise legitimate sellers of self-care products.

2. Further ENFORCE food rules applicable to online sales

Official controls on internet offers and sales need to be strengthened. AESGP welcomes the Commission's initiatives on coordinated control plans on eFood (31). Competent authorities need to increase cooperation at European level in order to ensure the proper application and enforcement of the relevant EU rules for food products (including food supplements) marketed via the Internet which are very often traded cross-border. Innovative mechanisms such as direct contacts between control authorities and eCommerce platforms, social media, credit card brands and payment service providers should be further developed to efficiently remove non-compliant products from the online market.

3. Online sales of medical devices

Adequate resources should be engaged to ensure that only compliant EU MD apps are available on the market and to ask for the removal of those that are not placed on the market as MDs but should be.

(30) Available at https://www.iqvia.com/en/library/white-papers/e-pharmacy-and-the-new-consumer-whitepaper. Consulted December 9th 2020.

(31) COMMISSION RECOMMENDATION of 24.7.2017 on a coordinated control plan on the official control of certain foods marketed through the Internet and annexes 1 to 3 - Available at https://ec.europa.eu/transparency/regdoc/rep/3/2017/EN/C-2017-4986-F1-EN-MAIN-PART-1.PDF ; https://ec.europa.eu/transparency/regdoc/rep/3/2017/EN/C-2017-4986-F1-EN-ANNEX-1-PART-1.PDF. Analysis of the main outcome of the implementation of the Commission Recommendation on a coordinated control plan on the official control of certain foods marketed through the Internet available at https://ec.europa.eu/food/sites/food/files/oc_oof_analysis_main_outcome_en.pdf. Consulted December 10th 2020.

4. Positioning eCommerce execution to regulators

Although eCommerce is indeed allowed in the EU, regulators need to understand how, in some respects, eCommerce is different to selling through "traditional" stores and notably, understand the different mechanics of an eCommerce "digital shelf" and particularly the importance of retailer search algorithms. This is why for example:

1) product titles can be used that are different from the product name;

2) optimised images can be used in place of a genuine pack shot.

SPECIFIC ENABLERS

1. Collaboration between regulators, law enforcement authorities and digital companies

Collaboration between regulators, law enforcement authorities, eCommerce platforms, social media, credit card brands and payment service providers within and outside the EU/EEA are needed in order to ensure that illegitimate sellers of self-care products have no chance to operate online.

2. Regulators should dedicate more resources to securing online space

AESGP is aware that there are only limited resources available to regulatory authorities regarding the oversight of online space as well as cross-border cooperation on these matters. As the online channel continues to gain popularity, it is important to ensure that adequate resources are allocated so that people who choose to buy their self-care products online can do so safely.

Conclusion

AESGP welcomes and supports the various initiatives undertaken at European level and is committed to playing its role in building an innovative digital health for Europe while ensuring the protection of the citizens' data. To that end, AESGP has developed this position paper that identifies some regulatory gaps and highlights several asks for improvements. It also proposes some enablers.

Digitalisation is a tremendous opportunity to improve the well-being of the European citizens and help them through their treatment journey. But to guarantee its integration in our health systems, trust must be ensured and maintained over time. That's why educating and informing the whole population about this constantly evolving environment will be key.

AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

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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