AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

AESGP Position Paper

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

Excerpt — Data, Real-World Data And Real-World Evidence

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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 (1), **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.

(1) 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 (2) 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) (3).

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 (4).

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 (5), a Danish academic study, performed by Kristian Kragholm et al. (6) 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.

(2) 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.

(3) 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.

(4) 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.

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

(6) 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 (7). **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." (8) 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."* (9)

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).

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

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

(9) 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** (10). 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 (11).

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.

(10) 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.

(11) 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."* (12) *"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."* (13)

(12) 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

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

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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