

Printed medical information are essential to advance patient safety

While MLPS supports the ongoing efforts of the Commission to fully implement an EU wide digital transformation, we firmly believe that printed pharmaceutical literature remains the primary source of information for patients and healthcare professionals to guarantee a safe and accurate delivery of medication information.

Harnessing innovation-led solutions, such as digitization, as the backbone of a smart and dynamic future is essential. However, such innovation must guarantee positive results for all EU citizens, especially for sensitive and more vulnerable individuals, such as patients using drugs to preserve their health.

Thus, MLPS supports the availability of medication information in electronic form when this complements information on paper. As a matter of fact, the Members of the European Parliament's committee on Energy, Industry and Research (ITRE), recently highlighted the need to keep package information leaflets on products, stating that electronic product information should not replace paper leaflets, but rather complement it¹.

In order to prevent digital solutions from becoming a misnomer that could potentially lead to regrettable consequences, MLPS calls for:

- Clear and unambiguous rules ensuring the highest level of patient safety, that must mandate the use of accessible, relevant and understandable printed medical information for drug products;
- Provisions that clearly identify the complementarity of printed and electronic information, where electronic pharma leaflets (ePI) can improve patients experience, ease caregivers' burdens and liabilities by complementing printed leaflets.

Who we are

MLPS – Medical Leaflets = Patient Safety – a subgroup of ECMA – the European Carton Makers Association – represents the printers of regulated pharmaceutical information, including Package Inserts (PIs), Medication Guides (MedGuides), and Patient Package Inserts (PPIs), advocates for patient safety and risk communication.

Safety first!

Pharmaceutical product leaflets are crucial to provide accurate and accessible information to all patients, promoting the correct use of pharmaceutical products and reducing health risks linked to misuse. The indications provided by caregiver professionals in combination with the detailed description of the characteristics of drugs (e.g. posology, collateral effects, indication of chemical components, etc.), which are always available to patients and consumers, help ensuring the appropriate use of medical products which in turn means increased patient safety.

¹ European Parliament (ITRE committee), ITRE [opinion](#) on a pharmaceutical strategy for Europe (2021/2013(INI)), 30 September 2021.

Printed literature is inclusive and readily available for all patients

Digital solutions are welcome when they can provide additional benefits and enhance the quality of life of the sensitive and more vulnerable individuals.

For this reason, we believe that electronic access to drug information should complement on the benefits of printed leaflets; they should be seen as part of a broader and comprehensive health promotion and disease prevention strategy available to all citizens.

The majority of pharmaceutical products users are elderly people. The available statistics show that the proportion of the EU population using prescribed medicines is lowest in the age group 15–24 and highest in the oldest age group (75 years and over)².

Often elderly people are those most challenged by novelty technologies, including digital access and literacy. When it comes to digital skills, there are significant differences between the young and the older population: while 96% of 16-24 olds are regular internet users, according to Eurostat³, only 57% in the 55-74 age group use the internet regularly. Importantly, besides cognitive challenges, elderly people are more likely to experience difficulties with (small) smart tools because of declining dexterity⁴.

Also, the crucial information on pharmaceutical use must easily reach those living in areas where connectivity is only partially or not accessible. Despite advancements over the last years, internet access and broadband connections are still highly fragmented across Europe. In 2018, Eurostat⁵ found that 11% of the EU population have never used the internet. Moreover, in 2018, 15% of rural households did not have access to the internet compared to 9% in cities and 11% in towns and suburbs⁶. The urban-rural divide is particularly strong in southern countries (e.g. Greece, Portugal, Bulgaria, and Romania), where there is a lower overall level of internet access than the EU average.

Lastly, smartphone ownership is less widespread than expected: according to market research from 2017⁷, 77.3% of Danish consumers own a smartphone which is the highest in the world. That still leaves one out of five Danish consumers without a connected device. Smartphone ownership in other European countries is likely much lower⁸. Further to this, the needed use of connected devices to access product information also presumes that consumers must always bring their devices to the relevant shop, that the device is charged, that mobile subscriptions are functional, etc. – none of which should be taken for granted.

² Eurostat. [Medicine use statistics](#) . 2014 (Update information expected for December 2021).

³ Eurostat. [Digital economy and society statistics - households and individuals](#). June 2019.

⁴ Beuc (The European Consumers Organization). [Why Moving Essential Product Information Online Is A No-Go](#) . February 2021

⁵ Eurostat. [Digital economy and society statistics - households and individuals](#). June 2019.

⁶ Eurostat. [Digital economy and society statistics - households and individuals](#). June 2019.

⁷ Berlingske. [Danmark har flest smartphones i hele verden](#). 6 December 2017.

⁸ According to Eurostat, for example, 69% of Europeans aged 16 to 74 used mobile devices to connect to the internet in 2018. The most common mobile devices for internet connections were mobile or smartphones, but also laptops and tablet computers. See Eurostat. [Digital economy and society statistics - households and individuals](#). June 2019.

For these reasons, any modification should not marginalize those with limited access to digital devices and digital infrastructure or exclude digitally low-skilled and users⁹.

Therefore, we believe that they must be equipped with easy and immediately accessible tools to help guaranteeing their wellbeing. To this end, printed leaflets are crucial for health and risk minimization while increasing regime adherence to deliver better patient outcomes.

Risks of cyber attacks could jeopardise safe delivery of care

Digital tools are deeply changing our society. New services have been created, making it easier for all to access new information wherever we are. The Covid19 pandemic has demonstrated how useful such tools are and the importance of being connected at all times.

However, in parallel with the growing use of online data and need to access digital services, there has been an increase of cyber-attacks on both the private sector and public institutions.

Cyber-attacks are unwelcome attempts to steal, expose, alter, disable or destroy information through unauthorized access to computer systems.

Criminal organizations, state actors and private persons can launch cyber-attacks against enterprises to disrupt and damage business. This damage has high costs which include discovering and responding to the violation, the cost of downtime and lost revenue, and the long-term reputational damage to a business and its brand.

Most importantly, in the case of compromised important information, it can lead to a loss of customer trust, regulatory fines, and even legal actions.

More specifically, accurate, verified and protected information about any pharmaceutical products is critical for any patient or care provider. As such, any threat to ePI could lead to the increase of the risks linked to the use of medicines. Risks range from a partial change to a text, to a complete shut down of servers where the information is saved. The safe delivery of care must be the utmost priority.

The availability of information on the use of pharmaceuticals via paper leaflets eliminates these risks and ensures the continuous availability of information aimed at securing the appropriate use of medicines.

Misuse of drugs could lead to increased societal costs

The good state of healthcare systems is a primary concern for all citizens in the EU. Printed literature is critical in preventing the misuse of drugs and medical products, thus avoiding costs and additional burden for caregivers caused by the admission of patients that are victims of adverse drug events.

Managing multiple prescriptions can be complicated. Printed leaflets enable patients and their caregivers to easily and quickly digest critical information to avoid preventable errors and increase compliance with prescribing instructions.

For this reason, changing the current rules regarding the use of paper leaflets for medical products must undergo a thorough cost-benefit analysis based on a thorough risk-assessment.

This should appraise indirect costs triggered by the potential increase of healthcare assistance caused by adverse drug events. This can create pressure on our society, specifically on healthcare systems. On the other hand, more of the healthcare resources and budget can be devoted to patients with chronic pathologies or other conditions.