

## POSITION PAPER ON THE DIRECTIVE ON MEDICINAL PRODUCTS FOR HUMAN USE ON ELECTRONIC PRODUCT INFORMATION (EPI)

MLPS (Medical Leaflet = Patient Safety), a subgroup of the European Carton Manufacturers Association, would like to express our concerns regarding the Commission's proposed Directive revising **the medicinal products for human use Directive concerning the use of electronic product information (ePI)**.

Article 63 of the proposal allows Member States to replace paper medical leaflets with ePI by leaving the possibility to choose between paper and ePI. If implemented, this would **leave millions of vulnerable Europeans without guaranteed access to crucial medical information, increasing the risk of misdosing medication**. Patient safety must always be the priority and therefore we argue for a complementary approach, taking the best from ePI and paper leaflets. Please find our main recommendations below.

### 1. Accessibility to medical information must be guaranteed for all

The Commission's proposal gives Member States the discretion to remove the mandatory paper leaflet from the medicinal packaging. This means if a Member State decides to replace paper leaflets with ePI, crucial medical information will only be available to those with sufficient digital literacy and access to a smartphone.

A large share of European citizens does not have uninterrupted access to the digital tools and services necessary to guarantee access to ePI. Even in countries with high smartphone usage such as Denmark, up to 25% of the population are not in possession of a smartphone.<sup>1</sup> Across the EU, these statistics becomes even more stark when looking at the oldest age group, which have the highest need for prescribed medicines.<sup>2</sup> According to Eurostat, only 57% of people in the 55-74 age group use the internet regularly.<sup>3</sup>

The Commission's proposal clearly states that ePI **should always guarantee equal or better quality of information to all patients**.<sup>4</sup> This requirement directly contradicts what is included in this Article 63. **Ensuring accessibility to all patients requires a 100% level of digital literacy and accessibility at all times**. Currently, this level of accessibility cannot be guaranteed in any Member State. We note the Commission has not conducted an assessment on the impact of removing paper leaflets on patient safety. We must put patient safety first and legislate based on evidence before introducing such changes with an enormous impact on patient safety.

To ensure no patient gets left behind, we strongly urge retaining the mandatory paper leaflet and implementing a complementary approach between ePI and paper leaflets.

### 2. Print on Demand is not a viable alternative to paper leaflets

Article 63(3) of the Directive stipulates that, in cases where paper leaflets have been removed, patients should be guaranteed a paper leaflet upon request. This policy, known as 'Print on Demand' (POD), is proposed to mitigate the lack of digital accessibility of many patients.

However, POD would be an unworkable alternative to the current system of paper leaflets. It is unclear on how POD will be interpreted or implemented. If POD is implemented through pharmacies, it would require pharmacists to print the full product information leaflet for the patient whereas their role in administering medicine is vital in ensuring the patients' health and wellbeing. Printing the leaflet requires additional time and resources, potentially increasing the cost for pharmacies which can present logistical and financial challenges. Furthermore, as the leaflet

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<sup>1</sup> Thomas Breinstrup, "Danmark har flest smartphones i hele verden", *Berlingske*, 2017.

<sup>2</sup> Eurostat, "Medicine Use Statistics," *European Commission*, 2022.

<sup>3</sup> Eurostat, "Internet access and use statistics - households and individuals," *European Commission*, 2022. s

<sup>4</sup> Directive proposal, Recital 127, 128, 129 and Article 63(3)

must be 100% accurate 100% of the time, industrial level printers have been manufactured, calibrated, and are maintained precisely for printing medicinal leaflets. Desktop printers used by pharmacies are subject to a risk of character substitution, possibly altering the content and meaning of the pharmaceutical leaflets. This can lead to severe health risks for the patient, in which case the pharmacy would be held liable. By printing the product information separately, this increases the chance of the product information getting lost or separated from the medicine during transport. Therefore, we urge the removal of POD as a real alternative to paper leaflets.

### **3. The leaflet industry can cater to the specific language needs of smaller Member States**

Allowing accessibility to medical information is the core of our business. We recognize that in certain specific contexts, full accessibility may not always be possible. In smaller Member States with lesser used languages, not all necessary translations may always be available. This is an issue that does indeed need to be addressed, but removing paper leaflets is not the solution.

The complementary approach would offer the benefits of a wider array of languages digitally for these Member States, while removing the risk of leaving less digitally literate patients behind. At the same time, the leaflet printing industry is ready to offer specific support for smaller Member States. If the pharmaceutical companies cooperate on this, leaflet printers can execute shorter print runs (from 1000) to supply paper leaflets in specific languages where necessary.

### **4. Keeping the option for patients to follow their medical instructions fully offline is crucial to making good on their right to access and privacy.**

We would also like to express concerns around the security and use of patients' data. Especially today, when much criminal action has moved into the cyberspace, online health data is at risk of cyber-attacks. In particular, patient's medical data is highly confidential. It is not clear when a patient scans the ePI where this data will be stored, for how long, and who will be responsible for keeping the information safe. As such, with a digital by default approach their right to privacy cannot be assured with certainty. Besides such overtly malicious attacks, tracking through cookies and third-party systems pose a risk to patient's confidential online medical data. To ensure patient privacy, patients must be given the alternative to access any critical information offline. A complementary approach would allow patients to opt out of ePI over privacy concerns.

### **5. The proposed delegated act mandating ePI should allow sufficient transition time and retain complementarity**

Article 63(5) of the Directive empowers the Commission to adopt delegated acts mandating ePI and POD. In light of the issues with a digital by default approach as outlined above, we believe that this delegated act retains the paper leaflet through a complementary approach as long as it is necessary. Furthermore, taking into account vulnerable Europeans and the lack of digital literacy specially among older people, we believe the proposed transition time of five years following the entry into force of the Directive is far too short to mandate a harmonized ePI.

*MLPS, Medical Leaflet = Patient Safety, is a subgroup of ECMA (TR: 948591610750-02), the European Carton Makers Association, and represents the printers of regulated pharmaceutical information, including Package Inserts (PIs), Medication Guides (MedGuides), and Patient Package Inserts (PPIs).*

*The manufacture of pharma paper information leaflets by MLPS members employs over 3100 people in 14 countries, contributing around €150 million directly to the European economy per annum in employee costs and additional expenditure on paper, inks and equipment of more than €147 million*