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Proposal for a Directive on Medicinal Products for Human Use – the essential role of package leaflets

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The European Commission's proposal on medicinal products for human use of 26 April 2023 presents a revolutionary approach to package leaflets that accompany the medicinal product (Article 63). The proposal grants the flexibility to Member States to remove the leaflet from the packaging to rely only on the information made available online (via the electronic product information – ePI).

Package leaflets provide vital information to patients, including the posology, the route of administration and the suspected adverse reactions. It is fundamental that all patients have access to accurate and comprehensive information about their medication.

The proposal foresees the possibility to receive the paper leaflet upon request from the patient. Not only does this approach represent a potential risk to patients' safety, but it also gives rise to concerns regarding its practical implementation.

1. Accessibility and patients' safety

Article 63.3 of the Commission's proposal states that

> *"it should be ensured that the information in digital format is easily accessible to all patients".*

This objective is laudable but unachievable. According to the European Commission's own **statistics**, 70.7% of Europeans have only basic, low or no digital skills. Moreover, on average 7.5% of European households have no internet access and 8% have either never used internet or not used for more than one year[1].

Relying on digital access to medication information goes **against the principle of inclusion**. The removal of the paper leaflet will penalise many patients, mainly the most vulnerable ones – those excluded because of age, lack of skills or lack of resources.

2. Patient's right to printed leaflet

Article 63.3 of the Commission's proposal states that

> *"if the package leaflet is only made available electronically,*
> *the patient's right to a printed copy of the package leaflet should be guaranteed*
> *upon request and free of charge".*

The patients' right to a printed copy has merit but **cannot be implemented in practice**. The proposal does not provide a practical solution for Member States to implement this provision. Moreover, the **Impact Assessment** does not address the technical and economic feasibility of this provision.

[1] Eurostat 2023 (indicators: levels of digital skills, level of internet access and internet use)

We understand the proposal suggests the supply of a printed copy could be handled at the point of sale, ie by pharmacists.

The printing of pharmaceutical leaflets is an **industrial process** monitored by strict operating procedures (from the selection of the paper, the designing phase to the printing and packing phases). The process is handled by trained workers and governed by very strict specifications and conditions set by the pharmaceutical industry itself.

How can it be expected that pharmacists or any other operators could supply leaflets that meet the technical specifications and appropriate level of security required for the production and handling of medical leaflets? Print on demand cannot provide the same level of quality and safety as industrial-level printing.

Additionally, the patients' right to a printed copy shifts the burden to access the medication information from the pharmaceutical company to the patient, increasing the **risk of oversight** by the patient and the **risk of errors** when handling printed copies of several leaflets referring to different medications.

3. Addressing the issue of small markets

Solving the shortage and accessibility issues of medicines in small European markets through the possibility to remove the paper leaflet is a disproportionate solution.

Leaflet manufacturers are innovative and flexible companies. If pharmaceutical companies cooperate, leaflet manufacturers can provide **practical solutions**, like supplying small quantities of leaflets, to any European market.

4. Complementarity

Electronic paper information (ePI) may increase the possibilities to access the information on medicines but it should not replace the paper leaflet accompanying the medicines. They complement themselves. The exclusive use of ePI should only be considered in exceptional circumstances, when medicines are delivered by a medical professional (for instance to in-hospital patients).

The development of ePI has merits but it should **not lead to Europe implementing a 'digital only' approach** to its healthcare system. The move to a digital transition should stop when it leads to exclusion of a significant part of the population, in particular the most vulnerable ones, and puts their safety and health at risk.

Intergraf calls for maintaining leaflets in the package of medicinal products and therefore calls for the removal of Article 63.3 of the proposal for a Directive on the Union code relating to medicinal products for human use.

Intergraf is the voice of the European printing industry in Brussels. We represent 22 national printing federations in 21 countries in Europe. The printing industry provides jobs to 610,000 Europeans active in over 110,000 companies and generates a turnover of approximately € 70 billion. The industry throughout Europe consists mainly of small companies, as 90% of them employ fewer than 20 persons.
Intergraf is a supporter of MLPS – Medical Leaflet = Product Safety, which regroups specialist and regulated healthcare packaging producers.