



PRESS RELEASE

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INTERGRAF CALLS FOR THE RETENTION OF PAPER LEAFLETS IN MEDICINAL PRODUCTS

Intergraf takes a stand in defence of consumer rights, particularly those related to medicinal products for human use. Intergraf urges the European Union to reconsider Article 63.3 of the proposed Directive on Medicinal Products, emphasizing the essential role of medical leaflets in pharmaceutical packaging.

Accessibility and patients' safety

The legislative proposal under consideration aims to ensure the accessibility and safety of patient information in a digital format. While this goal is commendable, Eurostat 2023 data point out the stark reality that 70.7% of Europeans possess only basic, low, or no digital skills, whereas 7.5% of European households have no internet access. Thus, the reliance on digital access to medication information risks excluding many patients, particularly those who are vulnerable due to age, lack of digital skills, or limited resources. The advancement of the digital healthcare system should not result in the exclusion of a significant part of the population; it is crucial to prioritize the safety and health of all patients.

Patient's right to printed leaflet

Article 63.3 proposes that patients can request free printed copies of digital-only package leaflets. However, this idea lacks practical implementation solutions. **Pharmacies cannot meet the rigorous printing standards and security requirements for medical leaflets, unlike industrial-level processes in the pharmaceutical industry.**

Printed and digital leaflets are not mutually exclusive

Intergraf underscores the importance of complementarity between electronic product information (ePI) and paper leaflets. **ePI enhances access to medication information for some demographics but cannot replace paper leaflets accompanying medicines**. The exclusive use of ePI should only be considered in exceptional circumstances, such as when medicines are administered by medical professionals, like in-hospital patients.

In light of these concerns, Intergraf calls for the mandatory retention of paper leaflets in the packaging of medicinal products.

Intergraf's position paper on the proposal is available here.

Intergraf is a supporter of <u>MLPS – Medical Leaflet = Product Safety</u>, which regroups specialist and regulated healthcare packaging producers.

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Notes to editor

The European graphical sector is made up of some 112,000 printing companies (95% SMEs), which employ 640,000 people, and generate a combined turnover of €82 billion (EU27 + UK, Switzerland, and Norway).

Intergraf (www.intergraf.eu) is the European printing industry association, representing employers in the graphical sector. We are a Brussels-based umbrella federation with 22 members from 21 countries and 17 Associate Members from across Europe. Our primary goal is to represent and advocate for Europe's printing industry, working with European Union to support the sector's competitiveness through advocacy, information-sharing, networking, social dialogue, and European projects.

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