PRESS RELEASE

# DIGITAL LEAP: Industry Proposes Phased Rollout of ePI for Patient Safety and Environmental Sustainability

*AESGP, EFPIA and Medicines for Europe publish joint recommendations*

**Brussels, January 8, 2025** – In a significant stride towards further modernizing patient care, regulatory efficiency, and environmental sustainability, Pharmaceutical Industry Associations (AESGP, EFPIA, and Medicines for Europe) have launched a new series of position papers advocating for the implementation of electronic Product Information (ePI) and improvement of the patient leaflet content.

By transitioning to ePI, patients, healthcare professionals (HCPs), and civil society will benefit from the most up-to-date, accessible medicinal information, ensuring safer use of medicinal products.

**KEY HIGHLIGHTS:**

1. **ePI Phasing-In, Paper Phasing-Out**: The gradual phasing in of ePI is proposed to be fully operational within 4 years after entry into force of the revised General Pharma Legislation and will precede the phasing out of paper leaflets. This will ensure patients have continuous access to critical medicinal information via secure, harmonized digital platforms. Existing ePI platforms such as National Competent Authority and Industry websites and compendia could be used as solutions to initiate the transition before ePI becomes fully available on the EMA/HMA portal.
   Phasing out paper in self-administered products will be more gradual than for HCP-administered products due to individual needs, administrative capabilities and product specific requirements.
2. **Improving PIL**: Patient information leaflets would greatly benefit from layout and readability improvements. There are several proposals to benefit correct safe use of medicinal products, by delivering clear information to level up health literacy.
3. **Patient Safety and Digital Access**: With 90% of EU citizens regularly accessing the internet[1], ePI will allow for availability of up-to-date leaflets, interactive elements, personalized content, and more accessible formats such as large print or multimedia. However, alternatives for those without internet access will be retained to guarantee inclusivity.
4. **Safeguarding Availability in Small Markets**: Multi-country packs, which are simplified by the use of ePI, language exemption and harmonised labelling requirements, will improve the availability of medicines across Europe particularly in smaller markets, reducing logistical burdens and fostering greater supply chain agility.
5. **Enhancing Regulatory Efficiency**: The ePI platform is designed to streamline regulatory processes, reducing administrative burdens for both pharmaceutical companies and health authorities. The centralized EMA portal will serve as a single source of trustworthy information, fostering transparency and regulatory efficiency across the EU.

**INDUSTRY CALL TO ACTION**

Pharmaceutical Industry is urging regulatory bodies across Europe to adopt a harmonized implementation of ePI. This transition is critical not only for advancing patient care but also for enhancing regulatory operations and addressing environmental challenges.

[1] Eurostat datasets : Statistics | Eurostat (europa.eu). Consulted September 2024.

**LIST OF PAPERS:**

The documents outline a strategic shift from current paper leaflets towards a more patient-centric content and accessible, environment-friendly digital alternative, designed to optimize pharmaceutical operations while keeping patient safety at the forefront.

1. Phasing in of Electronic Product Information and Phasing Out of the Paper Package Leaflet
2. Alternative Ways of Providing the Printed Package Leaflet of Medicinal Products
3. "Key Information Section" in the Package Leaflet
4. Removal of the Name and Address of the Manufacturer in the PIL
5. Adding Disposal Information on the Labelling of Medicinal Products.
6. Facilitating Medicines Availability and Environmental Benefits Through Language Exemptions and Electronic Product Information (ePI).
7. Proposals to Support Multi-Country Packs and Simplify Supply Chain
8. Overview of Potential Obstacles for Using Multi-Country Packs caused by the proposals for the revised Pharmaceutical legislation.
9. Awareness Cards for Antimicrobials in the EU Pharmaceutical Reform

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