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CPME, PGEU, BEUC, AGE, HOPE, AIM, EFN, EAHP, EPF
Joint Statement on Electronic Product Information (ePI)

Doctors, nurses, community and hospital pharmacists, hospitals and healthcare services, consumers, older people, health insurance funds and not-for-profit health mutuals, patients call on legislators to maintain paper package leaflets, and use electronic leaflets as a complementary tool.

Ahead of the future co-legislators' interinstitutional negotiations on the European Commission's Proposal for a revised pharmaceutical legislation in the European Union,[1] the signatory organisations appeal for inclusive provisions that leave no one behind and are respectful of privacy and personal data protection.

We call upon the co-legislators to:

Contribute to an inclusive society, without enacting discriminatory rules that increase the digital divide and limit individuals' choice

We call on the EU to guarantee the right to use digitalisation for those who wish to do so, and maintain the paper leaflet for those who do not,[2] or cannot. We also alert to the risks of imposing the use of a mobile device to access basic health information. An exclusive ePI implies possessing a smartphone or a tablet, sufficient connectivity, an internet data plan, and to have those devices at hand at the time of need. The ePI imposes a level of digitalisation without considering those who do not want to use a smartphone/tablet, or cannot, due to age, geographical location, disability, health, income, religion or social situation. The ePI is also disproportionate to what the paper alternative could offer in a simpler way.

Recognise the importance of the package leaflet as a key tool for information accessibility

We highlight that the package leaflet is a vital component of the information provided to patients on the safe and effective use of the medicines they take, which is a consideration under the benefit/risk analysis. It is furthermore a tool to improve health literacy. Paper leaflets offer immediate access to approved, complete and unbiased information that helps the patient to make an informed decision. Changes that make access to such information and its storage more difficult place the burden of seeking information on the patients. For example, studies conducted in other fields show that a low level of consumers scan product information made available through a QR Code[3].

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[1] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023)193 final, and a Proposal for a a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, COM(2023)192 final, 26 April 2024.

[2] European Parliament resolution of 13 December 2022 on the digital divide: the social differences created by digitalisation (2022/2810(RSP)), OJ C 177, 17.5.2023, p. 57–62, point M.

[3] Rehm J, Ferreira-Borges C, Kokole D, Neufeld M, Olsen A, Rovira P, Segura Garcia L, Tran A, Colom J. Assessing the impact of providing digital product information on the health risks of alcoholic beverages to the consumer at point of sale: A pilot study. Drug Alcohol Rev. 2023 Sep;42(6):1332-1337, accessed on 24 October 2024: https://pubmed.ncbi.nlm.nih.gov/37132168/

Balance the advantages and disadvantages of ePI

Due to its semi-structured and accessible format and design, ePI, developed in close collaboration with patients and healthcare professionals, offers opportunities to improve readability and meet specific patients' needs, such as of those with impaired sight. However, the possible attractiveness of ePI presentation material or speed of access to a medicine's latest information are not sufficient arguments to undermine the fundamental rights of individuals. A pilot conducted in Belgium and Luxembourg acknowledged that access to the internet, even in a hospital setting, was not always possible[4]. We further underline situations where internet can affect medical device usage and it needs to be turned off, or rooms where the connection is slow or out of range, making it impossible to provide the healthcare service to patients in such locations. At present, providing the paper leaflet in the medicine packages is a key regulatory responsibility of pharmaceutical companies, who also bear the costs. If the paper leaflets are removed from the packages, the burden, practicalities and costs (time, paper, printer, ink, internet connection, etc) of printing an ePI would fall on the pharmacist or on the patient.

Protect patients' privacy and guarantee that the information is not used for commercial purposes

Even if the ePI leaflet is introduced as a complementary tool and does not replace the paper version, it is of utmost importance to guarantee patients' privacy and data protection when accessing the online leaflet. It should be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine, which could potentially lead indirectly to promotional activities. At the same time, it must be clarified how software, apps or websites will process and store citizens' data when searching for a medicine's ePI – be it a search query or by scanning a medicine's barcode linking to the ePI. The appropriate application of European and national data protection legislation should be guaranteed and closely monitored in these third-party applications or websites at all times.

It is also important to ensure that the ePI leaflet provides approved information only, and that it is not used to deliver promotional information. It should always be published as open data, freely accessible for use and reuse. To ensure that ePI remains a source of trusted and non-promotional information, it will be crucial that patients are directed to the ePI leaflet stored by independent and official sources such as the European Medicines Agency and National Medicines Agencies' websites.

Listen to patients and other end users as an evidence-base for action

Even if a phase-out period was established to allow an improvement of individual digital skills[5], evidence shows that 79% of consumers think paper leaflets should be available inside the package, even if there is a QR code alternative on it[6]. Survey respondents felt this would otherwise disadvantage older people (81%) and would make society too dependent on the internet (70%). In 2023, only 55.6% of people in the EU aged 16 to 74 had at least basic digital skills, and by 2030 the estimation is of 59.8%, falling short by more than 20% from the target[7]. We insist on the need to offer a non-digital solution to maintain a proportionate playing field between the online and offline world. The scaling up of ePI to the whole population, with the disparities that it entails, is a burdensome change the success of which is not evidence-based.

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[4] The pilot advocated as a good example by the pharmaceutical industry was limited to highly qualified professionals (hospital pharmacists) and in a hospital setting, <https://pharma.be/sites/default/files/2022-04/2021_E-PIL%20pilot%20project_one-pager_final.pdf>.

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, State of the Digital Decade 2024, COM(2024)260 final, 2 July 2024 and respective annex 2, p. 5. Overall digital skills refer to five areas: information and data literacy skills, communication and collaboration skills, digital content creation skills, safety skills and problem-solving skills. To have at least basic overall digital skills, individuals must know how to do at least one activity related to each area.

[6] Surveys conducted between June and July 2022 by Altroconsumo (Italy), DECO (Portugal), OCU (Spain) and Test Achats/Test Aankoop (Belgium) as part of the Euroconsumers group, https://www.euroconsumers.org/wp-content/uploads/2023/06/Digital-Rules-Labelling.pdf

[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, State of the Digital Decade 2024, COM(2024)260 final, 2 July 2024 and respective annex 2, p. 5. Overall digital skills refer to five areas: information and data literacy skills, communication and collaboration skills, digital content creation skills, safety skills and problem-solving skills. To have at least basic overall digital skills, individuals must know how to do at least one activity related to each area.

*The **Standing Committee of European Doctors** (CPME) is a European not-for profit association representing 37 national medical associations across Europe, giving voice to over 1.7 million doctors.*

*The **Pharmaceutical Group of the European Union** (PGEU) is the association representing 400,000 community pharmacists in 33 European countries.*

*The **European Consumer Organisation** (BEUC) is the umbrella group for 44 independent consumer organisations from 31 countries.*

***AGE Platform Europe** is the largest European network of non-profit organisations of and for older people. We elevate older people's voices, bringing their experiences and aspirations to the table to celebrate ageing and fight for equality at all ages.*

*The **European Hospital and Healthcare Federation** (HOPE) is a European not-for profit association representing 37 national public and private hospital and healthcare associations and hospital, health and social care services owners.*

*The **International Association of Mutual Benefit Societies** (AIM) is an international umbrella organisation of federations of health mutuals and health insurance bodies counting with 49 members from 26 countries around Europe, Latin America and Africa and the Middle East.*

*The **European Federation of Nurses Associations** (EFN) is a European not-for profit association representing 36 national nurses associations and represents as such 3 million EU Nurses*

*The **European Association of Hospital Pharmacists** (EAHP) represents over 29,000 hospital pharmacists across 36 member countries.*

*The **European Patients' Forum** (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 80 members include disease-specific patient groups active at EU level and national coalitions of patients.*

Resources:

AGE Platform Europe: "Digitalisation and older people: our call to EU policy makers", June 2024.

BEUC: Position on the European Commission's proposal for a revised pharmaceutical legislation, Recommendations for improving access to medicines in Europe, December 2023.

PGEU: Position paper on the reform of the EU Pharmaceutical Legislation and PGEU position on electronic product information.

CPME: Proposed amendments to the Commission's Proposals for the Directive on the Union code relating to medicinal products for human use and the Regulation lying down Union procedures for the authorization and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, Medicine shortages and security of supply, October 2023.

EFN: EFN PS improving frontline nurses' time for direct patient care with digitalisation & responsible AI *(October 2024)* and EFN Policy Statement on EHDS *(April 2023)*