

EAEP feedback to the public consultation on the proposal for a revision of the EU General Pharmaceuticals Legislation

The **European Association of E-Pharmacies (EAEP)**, which represents online pharmacies and their patients on the European continent, welcomes the publication of the revision of the EU's general legislation on medicines for human use, and appreciates the opportunity to provide its feedback. As a key stakeholder in the pharmaceutical supply chain, we believe that our insights can contribute to the development of a robust **medicinal regulatory system framework that ensures patient safety, fosters digitalisation, and promotes equitable and affordable access to medicines.**

As registered pharmacies, EAEP members provide patients with digital access to medications and pharmaceutical consulting services, everywhere in the EU. **Online pharmacies are key to ensuring patients' access to healthcare**, even in special circumstances e.g. COVID19 pandemic, or health or mobility issues.

The proposed Pharmaceutical Package provides for an opportunity to revive the current regulatory framework, which dates back 20 years and no longer fits the current scenario where healthcare is increasingly digitalised. Of key relevance to the online pharmacy sector in Europe¹, the proposed **Directive on the Union code relating to medicinal products for human use**, repealing Directive 2001/83/EC and Directive 2009/35/EC, constitutes the **basis for e-pharmacies to operate**. The EAEP is of the opinion that, while the European Commission's proposal overall establishes a sound basis, the final text of the Directive should further build on two key pillars:

+ Digital health services

The revision of the EU pharmaceuticals legislation should recognise and embrace the transformative potential of digital health. Online pharmacies are at the forefront of leveraging technology to provide innovative services such as e-prescriptions, remote consultations, and medication adherence support, which overall contribute to the EU goals in this field, set out in the Pharmaceutical Strategy². It is crucial that the updated legislation further encourages and supports the adoption of digital health solutions to improve patients' access to healthcare as well as health outcomes. EU legislation in this domain should, first and foremost, acknowledge and promote the importance of fostering a level playing field for healthcare providers when it comes to (cross-border) reimbursement policies.

¹ The number of online pharmacies in each EU country is growing on a yearly basis. So far, recent data count more than 1800 online pharmacies across the EU. Next to this number, many thousands of brick-and-mortar pharmacies also offer digital health services, which are not considered in the 1800 online pharmacies.

² Availability, accessibility, and affordability of medicines

https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

✦ Patients' access to medication

The digital age has revolutionised various aspects of our lives, including the way we access and purchase medicines. In the healthcare sector, the online sale of both Over-the-Counter (OTC)³ and Prescription (Rx) medicines has emerged as a topic of interest especially for patients, accelerated by the COVID19 pandemic where people needed to stay at home as much as possible. Online pharmacies play a crucial role in enhancing patients' access to medicines, especially for those living in remote areas or with mobility issues. The updated pharmaceutical legislation should facilitate the adoption at the Member State level of a regulatory framework that enables patients to obtain their Rx medication online in a safe and secure way. Allowing the online sale of Rx medicines across the EU holds significant potential to enhance accessibility, convenience, affordability, patient empowerment, and informed decision-making. By learning from successful implementation models and best practices⁴, the EU can leverage existing digital technologies and solutions to advance healthcare delivery.

In this context, the EAEP wishes to raise targeted suggestions for improvements, related to five articles (63, 172, 173, 174, 175):

- ✦ **Article 63 – General principles on package leaflet:** the provisions related to electronic patient leaflet (e-PL) need some further clarifications and specifications.
 - It needs to be clarified further who ensures and monitors the necessary quality standards for electronic package inserts. The websites of national authorities should be equipped with secure, dedicated platforms where patients can access all e-PLs in a trusted way;
 - The source used for the e-PLs should be clarified in the text.
 - Lastly, the patients' right to receive a printed copy of the PL, as currently foreseen in the Commission's proposal, should not create a burden on healthcare providers, as ultimate interlocutors with patients. Such responsibility should always lie with the marketing authorisation holder.
- ✦ **Article 172 – 174 – Sale at a distance to the public:** the provisions related to the sale at a distance of medicinal products remain substantially unchanged. While the text of the updated legislation states that national legislation may still limit the online sale to allow the sale OTC medicines, over the past 20 years more and more Member States have adapted their regulatory framework to allow patients to purchase their Rx medication online⁵.
 - The Member States' right to limit the online sale of medicines based on "public health grounds" should go hand-in-hand

³ Regulated by Directive 2011/62/EU
https://health.ec.europa.eu/system/files/2016-11/dir_2011_62_en_0.pdf

⁴ Eight countries in the EU have legal frameworks in place enabling the online sale of Rx medicines (EAEP paper on the online sale of Rx)
<https://www.eaep.com/en/publications>

⁵ See footnote 4.

with the obligation to provide evidence supporting such claims (e.g. risk assessment). Indeed, existing data from several EU/EEA Member States where the online sale of prescription medicines is allowed⁶ show that the latter contributes to the overall safe access to medicines as well as functioning and sustainability of healthcare systems.

- In addition, we see the overall need to prevent special circumstances (as with the COVID19 pandemic) fostering “grey areas” in legislation, where many brick-and-mortar pharmacies delivered medicines at home, including Rx, without proper authorisation or compliance with national legal obligations (e.g. EU Common Logo)⁷.

- ✦ **Article 175 – Definition of advertising of medicinal products:** point ‘h’ of Art. 175 would prevent healthcare providers operating online from conducting regular practices such as marketing activities for the pharmacy and its services to patients and customers using their services, eventually creating an unnecessary burden on the business. We therefore suggest that this sub-paragraph is taken out from the final text of the legislation, or alternatively that its scope would be formulated more precise in Article 177 (1)(a).

Lastly, we wish to emphasise the importance of engaging stakeholders from the online pharmacy sector in ongoing discussions and decision-making processes. Collaboration with industry representatives, patient organizations, healthcare professionals/providers, and regulatory authorities will result in comprehensive and effective legislation that addresses the diverse needs of patients and strengthens the pharmaceutical supply chain.

To know more about the activities of the EAEP in this domain, please check our [publications](#).

ABOUT US

The [European Association of E-Pharmacies](#) (EAEP) represents the interests of e-pharmacies on the European continent. The EAEP voices its interests mainly with political stakeholders, regional and business actors, with the ultimate aim to improve the health of Europe’s citizens and strengthen the European healthcare system. E-pharmacies have digitalised the classical pharmacy, and therefore act at the crossroads of digitalisation, healthcare, e-commerce and sustainability. As pioneers in providing digital solutions and our innovative and secure processes in dealing with health data, offering medicinal products and digital healthcare service while complying with national and EU law, the EAEP members continuously seek for ways to enhance the quality, safety and efficiency of healthcare for Europeans.

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⁶ See footnote 4.

⁷ Online-Apotheken im Kampf um rezeptpflichtige Medikamente (1 April 2020)