EUROPEAN ASSOCIATION OF E-PHARMACIES

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POSITION PAPER ON THE EU PHARMACEUTICAL LEGISLATION

ONLINE PHARMACY SECTOR'S VIEWS ON THE REVISION OF THE EU PHARMACEUTICAL LEGISLATION

The European Association of E-Pharmacies (EAEP) acknowledges the importance of continually updating and revising EU legislation to ensure the safety and efficacy of the pharmaceutical sector in Europe. As e-pharmacies play an increasingly significant role in providing accessible medicines and healthcare services, we present this position paper to address the specific concerns and demands of our members and patients in light of the proposed revision to the EU General Pharmaceutical Legislation, with a particular focus on the revision of Directive 2001/83/EC and Directive 2011/62/EC.

INTRODUCTION

Online pharmacies operate in the EU on the basis of the legal framework formed by Directive 2001/83 – Community Code and subsequent Directive 2011/62 – Falsified Medicines Directive, and based on the "EU Common Logo" introduced in 2014, a legal requirement which vouches for the authenticity of the websites and guarantees the safety of the medicines[1]. In this sense, e-pharmacies play by the exact same rules and standards set for brick-and-mortar pharmacies, while contributing to ensuring the secure supply of Over-the-Counter (OTC) medicines and prescription (Rx) medicines (the latter where allowed) for Europeans everywhere.

The e-pharmacy sector has witnessed rapid growth over the past 20 years, not in the least place accelerated due to Covid, providing patients and consumers with safe and convenient access to a wide range of pharmaceutical products and healthcare services. The proposed revision of the EU Pharmaceutical Legislation aims to adapt to the evolving landscape of the pharmaceutical industry and, as stated by Commissioner for Health Stella Kyriakides at the 2024 High-Level Conference on the Future EU Health Union, "create a true Single Market for medicines, to ensure universal access for patients". The EAEP welcomes the EU's commitment to ensuring patient safety and strengthening the integrity of the healthcare system.

While the European Commission's proposal overall establishes a sound basis, the EAEP believes that specific elements of the current text deserve to be further examined and subsequently adapted with a view to make the rules fit for purpose and therewith fit for the future to fully meet expectations and demands of both patients across Europe and to provide an answer to rising healthcare costs by means of digitalisation.

First and foremost, the revision of the current framework should recognise and embrace the transformative potential of digital health. It is crucial that the new rules further encourage and support the adoption of digital health solutions to improve patients' access to healthcare as well as health outcomes. As highlighted by different e-health organisations in the "2024 Digital Health Manifesto"[2], ensuring better access to healthcare through transformative digital solutions, including across borders, will ultimately improve access, quality and continuity of care offered to all European citizens, no matter where, and reduce healthcare costs.

[1]https://health.ec.europa.eu/medicinal-products/eu-logo-online-sale-medicines_en
[2]https://www.eaep.com/uploads/digital-health-manifesto-pages.pdf?_cchid=0f23520d957852fa615385a64dc39ee1

SALE AT A DISTANCE OF MEDICINAL PRODUCTS

The EAEP underlines the need for a clear, harmonised legal framework for the sale at a distance of medicinal products. Currently, Art. 85c of Directive 2011/62/EC lays down that Member States have the right to decide whether to allow the sale at a distance of prescription (Rx) medicines by registered pharmacies (the sale of Over-the-Counter medicines online is already allowed everywhere in the EU by law)[3]. This article (new Art. 172 in the Commission's proposal) remains substantially unchanged. While over the past 20 years more and more Member States have adapted their regulatory framework to allow patients to purchase their medication online, the text of the updated legislation states that national legislation may still limit online access of Rx[4].

Importantly, such provision prevents various categories of patients, such as those living in rural or remote areas, with mobility issues, or chronic conditions, from safely obtaining their prescription medicine at home through registered pharmacies operating online. This conflicts with the objectives of the European Commission to ensure the **availability, accessibility, and affordability of medicines for patients** in Europe, and therefore denies many citizens access to healthcare using existing safe, legal, and convenient digital tools, leading to inequitable access to healthcare or discriminatory treatment in some cases.

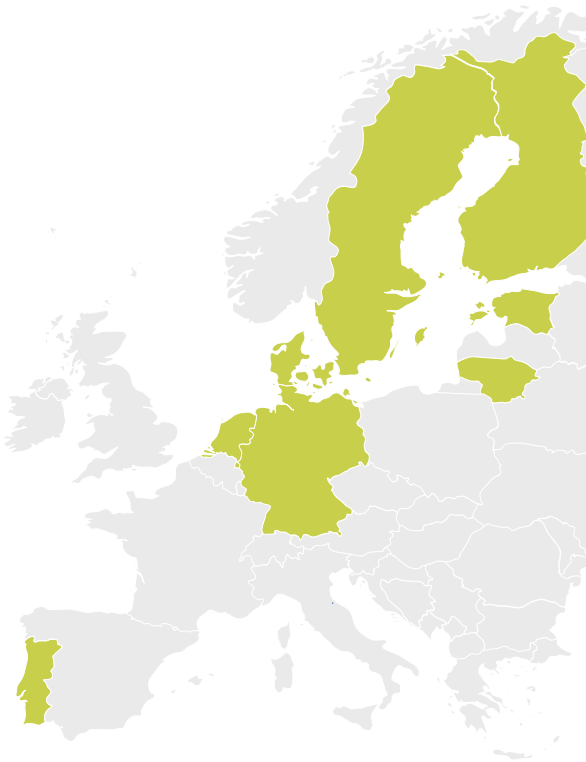
As a proof of its safety, convenience for patients, and substantial contribution to the overall healthcare system, eight Member States already allow, in their national legislation, patients to obtain their prescription medicines online, including Denmark, Estonia, Finland, Germany, the Netherlands, Lithuania, Portugal, and Sweden.

Recent data[5] clearly showcase the wide and diverse amount of benefits for patients living in these countries:

The quest for online access to prescription medicines comes from patients who have the highest burden going to the pharmacy i.e., those suffering from chronic conditions and those living far away from physical pharmacies or struggling with opening hours.

A substantial share of chronic patients, from Member States that allow online access, think that **online access (34%) and delivery (48%) benefit their adherence to treatments**. If we consider replies from chronic patients who tried online access, the shares are significantly higher and **correspond to 57% and 66% respectively.**

Convenience benefits that would come from the EU-wide removal of restrictions range from **EUR 1.3bn in the short run to almost EUR 2.3bn in the long run**.



[3]The online sale of medicines is envisaged at the EU level by different pieces of legislation. Directive 2011/62 – Falsified Medicines Directive – addresses the online sale of Over-the-Counter (OTC) medicines and sets out principles and rules to limit the spread of falsified medicines and keep the patients safe. In parallel, Directive 2001/83 – Community Code – details the minimum criteria and standards for the online sale of medicines, both OTC and prescription medicines (Rx), establishing the legal framework for online pharmacies to operate in Europe.
[4]https://www.eaep.com/uploads/eaep-paper-on-online-sale-of-rx-1.pdf?_cchid=44dd1d5e1b46ce0c692421617f71196f
[5]https://copenhageneconomics.com/publication/unlocking-the-benefits-of-online-access-to-prescription-medicines-across-the-eu/

When considering patients living in countries where the option to purchase Rx online is still not allowed by the national legal framework – including France, Poland, and Spain[6], a recent survey commissioned by the EAEP showed that:

90 % of respondents believe that online pharmacies should be permitted to deliver prescription medicines.

85 % of respondents would buy prescription medicines online if allowed.

On the other hand, in Germany, Sweden, and UK, where obtaining prescription medicines online from registered pharmacies is already permitted,

64 % of respondents declared to have purchased through this channel more than once,

41 % of them buying both over-the-counter and prescription medicines.

Also, the Austrian patient organisation Chronisch Krank has come to a similar conclusion based on a questionnaire[7] run among its members in March 2023. It concludes that:

65 % of chronically ill people would like to be able to order their prescription medication online.

70 % assume that digitalisation in the area of medication supply will improve the service for patients.

Enabling pharmacies to deliver prescription medicines to their patients, using digital means, is of utmost importance to ensure access, adherence, and continued support to patients. This will ultimately establish an EU level playing field to avoid any discriminatory treatment against patients and pharmacies operating online.

RECOMMENDATIONS

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 availability, accessibility, convenience, affordability, and patient empowerment.

PROPOSAL:
The Member States' right to limit the online sale of medicines based on "public health grounds", as spelled out in draft Art 172.2 *"General requirements for sale at a distance"*, should go hand-in-hand with the **obligation to provide evidence** supporting such claims (e.g. risk assessment). Indeed, existing data from several EU/EEA/UK countries[8] where the online sale of prescription medicines is allowed show that the latter contributes to the overall safe access to medicines as well as functioning and sustainability of healthcare systems.

[6]https://www.eaep.com/uploads/survey-on-citizens-appreciation-rx-online.pdf?_cchid=d152fe42751f6b5afc59b5f354229492
[7]https://chronischkrank.at/umfrage-digitalisierung-im-oesterreichischen-gesundheitssystem/
[8]Denmark, Estonia, Finland, Germany, the Netherlands, Lithuania, Portugal, Sweden, Norway, UK.

LEGAL ASSESSMENT:
Recent CJEU case law[9] emphasises that governments of Member States must possess **clear evidence of a significant public health threat** and demonstrate that less restrictive measures cannot achieve the same objectives to justify prohibiting online sales of prescription medicines. Indeed, the general argument according to which the online sale of prescription medicines allegedly might constitute a threat to public health does not constitute a sufficient and relevant legal basis anymore for governments to bluntly put forward a prohibition of such option for patients in the EU. Therefore, the current language of Directive 2001/83/EC is redundant and no longer fit for purpose, and it fails to reflect the latest CJEU case law highlighting clear conditions and limitations for Member States when considering restrictive measures.

ELECTRONIC PRODUCT INFORMATION (ePI)

As innovative healthcare providers operating online, EAEP members acknowledge and appreciate on a daily basis the great potential offered by digitalisation of healthcare to patients and healthcare systems as a whole. We truly believe that, as stated by the European Commission[10], the envisaged use of the electronic Product Information (ePI) will lead to improved accessibility, searchability, multilingual capabilities and especially up-to-date information. The EAEP therefore supports the approach taken by the Commission in the proposed Directive, which will ultimately also contribute to reducing administrative costs for stakeholders along the supply chain. Nonetheless, we see a unique opportunity for co-legislators to improve the current text by clarifying specific elements which remain unaddressed in the Commission's proposal.

RECOMMENDATIONS

The new framework should **include in the outer packaging of the product a digitally readable QR code** or similar, directing patients to the electronic version of the package leaflet, which should be available in all EU languages.

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 e-PI** in a trusted way.

The **source used for the e-PI should be clarified** in the text.

Lastly, the **patient's right to receive a printed copy of the ePI**, as currently foreseen in the Commission's proposal, **should not create a burden on healthcare providers**, as ultimate interlocutors with patients. In this sense, it should be clearly stated in the final text of the Directive that such responsibility should always lie with the marketing authorisation holder.

PROPOSAL:
We call on co-legislators to adapt the wording of Art. 63 "General principles on package leaflet" **to make sure that the ePI is easily accessible to all patients** while **clarifying crucial characteristics and elements of the future ePI structure**.

[9]"It should be noted that the existence of a genuine risk to human health must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research (see, to that effect, judgment of 14 July 1994, van der Veldt, C 17/93, EU:C:1994:299, paragraph 17). Such general conjecture made in that regard does not in any way suffice to prove that the possibility for the consumer to seek to acquire prescription-only medicinal products at lower prices poses an actual risk to public health" (Case C 148/15 – Deutsche Parkinson) https://curia.europa.eu/juris/document/document.jsf?text=&docid=184671&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=804514
[10]https://eur-lex.europa.eu/resource.html?uri=cellar:bfcb9e00-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF

CONCLUSION

The EAEP calls for the active involvement of the e-pharmacy sector in the policy making process, with a view to ensuring a fair representation of the full spectrum of stakeholders. Collaboration between industry, regulatory bodies, patients, and healthcare professionals will result in regulations that are practical, effective, and responsive to the challenges faced by patients in accessing healthcare.

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.

WE STRENGTHEN THE EUROPEAN HEALTHCARE SYSTEM

by ensuring better access to medicines, providing expert professional advice and care for people across Europe.

WE ARE PATIENT-CENTRED HEALTHCARE PROVIDERS

to enhance the quality, safety and efficiency of healthcare for Europeans through high-quality data and strong digital infrastructure across borders.

WE HAVE A EUROPEAN DNA

being active in 11 European markets, serving more than 20 million customers and employing more than 4,000 people in Europe.

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