

January 2025

# EAEP FEEDBACK TO THE SINGLE MARKET STRATEGY 2025

The **European Association of E-Pharmacies** (EAEP) welcomes the opportunity to contribute to the European Commission's consultation on the Single Market Strategy 2025. We applaud the European Commission's commitment to further integrate the Single Market, reduce fragmentation, and enhance cross-border trade in goods and services, especially as outlined in the consultation document and the 2024 Annual Single Market and Competitiveness Report, as well as in the European Council conclusions of April 2024 and the Draghi and Letta reports.

As the organisation representing online pharmacies across the EU, which in the majority of cases are SMEs in itself, we firmly believe that **establishing a seamless and harmonised Single Market for health products and digital health services** is a critical component of this strategy.

We encourage the European Commission to include the following urgent and concrete actions in the upcoming Single Market Strategy 2035:

### 1. Addressing fragmented pharmacy regulations

- Despite efforts to harmonise rules for online services, the European health sector remains one of the most fragmented domains within the Single Market. Outdated EU legislation, national prohibitions and discriminatory rules undermine the provision of both national and cross-border digital health services (such as online pharmacies and telepharmacy/telemedicine services), preventing consumers' safe, affordable, and convenient access to medicines and health services. In this sense, a true European Digital **Health Union** is still far from being established. This has been particularly stressed by Letta, calling for the EU to take decisive action to foster integration and ensure sustainable access to healthcare for all citizens.
- Specifically, in 19 Member States, patients are unable to obtain their prescription medicines online, while 8 Member States the Netherlands, Sweden, Denmark, Germany, Portugal, Lithuania, Estonia, and Finland have successfully offered this service, in some cases for over 15 years. This disparity highlights not only a regulatory gap but also a market inefficiency, resulting in a two-tier pharmacy system. In countries with a second-tier system, both pharmacies (on the supply side) and patients (on the demand side) are deprived of the enhanced access, availability, and affordability that a well-regulated online system for prescription medicines complete with secure and reliable home delivery could provide. This goes against the objectives spelled out by the European Commission in the European Health Data Space (EHDS) Regulation, which obliges all Member States to





implement the e-prescription infrastructure and make it interoperable across borders for patients to redeem their prescription medicine conveniently in another country – the infrastructure is thus already there.

- The sheer convenience of being able to access prescription medication online is desired by the public and most importantly for the most vulnerable, e.g. those who have a chronic condition, mobility impairment, those who have a carer (thus saving precious time), and also those living in remote rural areas. This was clearly documented in a recently-published Copenhagen Economics report title "Unlocking the Benefits of Online Access to Prescription Medicines Across the EU"<sup>1</sup>, for which 5000 patients were surveyed in 5 countries.
- Based on the Copenhagen Economics report's findings, removing such barriers could:
  - Enhance patient safety by improving access to licensed medicines from regulated healthcare providers.
  - **Promote affordability** by increasing price transparency and competition.
  - Ensure continuity of care for mobile EU citizens and expatriates.
  - Make it attractive for pharmacies to develop digital solutions and thus provide greater choice for their patients.

Therefore, the EAEP, together with the <u>OnHOME Alliance</u> – a group of patient organisations and healthcare stakeholders determined to advocate for all Member States to allow their patients the choice to obtain their prescription medicines online and get them delivered at home by registered pharmacies – **urge the Commission to prioritise reforms that remove these obstacles, ensuring EU citizens benefit from equal access to health services irrespective of their country of residence**. This could be achieved by **amending**<sup>2</sup> **Article 172** "General requirements for sale at a distance" of the proposal for revision of the EU General Pharmaceutical Legislation<sup>3</sup>, to encourage Member States to permit online access to prescription medicines through authorised pharmacies, in line with the laws and regulations of the Single Market and in according with the most recent case law of the European Court of Justice<sup>4</sup>.

<sup>&</sup>lt;sup>1</sup> https://copenhageneconomics.com/publication/unlocking-the-benefits-of-online-access-to-prescription-medicines-across-the-eu/

<sup>&</sup>lt;sup>2</sup> https://www.eaep.com/uploads/eaep-position-paper-pharmaceutical-

legislation.pdf?\_cchid=632b0442d20c0b206c72da2ff88aec7e

<sup>&</sup>lt;sup>3</sup> <u>Proposal</u> for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

<sup>&</sup>lt;sup>4</sup> "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=Ist&dir =&occ=first&part=1&cid=804514



# 2. Harmonising policies for cross-border reimbursement of digital healths services

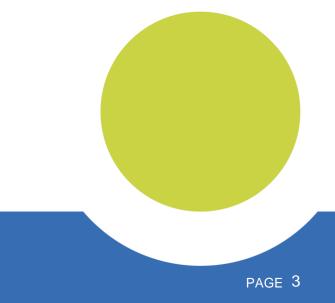
• To harness the full potential of digital health, it is important to recognise the vital role of reimbursement for digital health/pharmacy solutions within statutory health insurance. To date, reimbursement policies prioritise physical care, ultimately preventing patients from fully benefiting from remote consultations, which is important especially in rural areas. Concrete best practices across Europe should be replicated to foster harmonisation among Member States. Future EU legislation in this domain should, first and foremost, enable equitable access to the best quality of digital health innovations and services across Europe for patients and healthcare providers. Future legislation should also acknowledge and promote the importance of fostering a level playing field for healthcare stakeholders when it comes to (cross-border) reimbursement policies. This strategic approach directly addresses challenges in healthcare delivery and access (especially across borders), while also serving as a catalyst for innovation, all the while safeguarding patient privacy.

### 3. Preventing medicine shortages through simplified cross-border regulations

- Medicine shortages are a growing concern across Europe, affecting both common and lifesaving medications. The EAEP recognises the profound impact these shortages have on patients and the overall healthcare system. By further strengthening the Single Market, digital solutions could play a pivotal role in mitigating these shortages by:
  - Facilitating cross-border access: Harmonised regulations would enable patients to source medications from a broader range of online pharmacies across the EU, bridging gaps between supply and demand.
  - Streamlining regulatory processes: Simplified cross-border regulations on imports and compounding regulations (e.g. leaflets in different languages) can expedite the distribution of essential medicines across borders, ensuring timely access for patients in need.
  - Enhancing supply chain transparency: Implementing interoperable digital platforms can provide real-time data on medicine availability, allowing for proactive management of potential shortages.

### 4. Ensuring a non-discriminatory environment for pharmacies across Europe

 Apart from the points mentioned above, the EAEP witnesses that the EU free movement of goods and services is far from fully recognised. On EU Member State level, online pharmacies established in one country and delivering their services to another EU Member



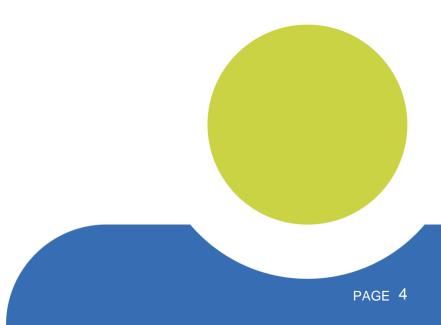


State, are e.g. still prevented to participate in medication plans and to grant bonuses to prescription medicine, although in the latter example, EU case law from the past (*Deutsche Parkinson Vereinigung*, case <u>C-148/15</u>) is still valid, as was recently confirmed in a conclusion by advocate-general Szpunar (in the case <u>C-517/23</u> *Apothekerkammer Nordrhein*). We therefore call upon the European Commission to be more vigilant and to firmly enforce existing single market rules, where necessary also through infringement procedures against EU Member States wo do not uphold the principles of the free movement of goods and services.

### 5. Improving conditions for cross-border commuters

- Furthermore, the EAEP advocates for the full realisation of the principle of the free movement of people. Currently, employees who do not carry out their work in their Member State of residence, especially cross-border commuters, in many cases face financial disadvantages and a complicated tax regime.
- The positive developments that the increased use of mobile working has brought in recent years - less commuting time, a better work-life balance, especially for young families, a better environmental footprint, etc. are being thwarted. The EAEP underlines that the conditions for working home need to be improved, reflecting the reality of flexible and mobile working models.
- In order to fully live up to the principle of free movement of people, a solution on European level needs to be implemented swiftly ensuring that no European employee is suffering from financial disadvantages for working and living not in the same Member State.

The Single Market for Healthcare should be a reality today. We have experienced painfully the uncoordinated action at country level during the COVID pandemic and hopes deriving from the EU COVID certificate and EU vaccine action plan have vanished. Excessive fragmentation at country level is depriving patients and citizens across EU from convenient and sometimes timely access to their treatments impacting their health outcomes, their wellbeing and their daily lives. Additional measures to fully integrate the Single Market in the healthcare (and e-commerce) domain are therefore urgently needed.





# ABOUT US

The <u>European Association of E-Pharmacies</u> (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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