EAEP Position Paper on the Public Consultation Regarding the Revision of General Pharmaceutical Legislation.

Brussels, 15 December 2021

The European Association of E-Pharmacies (EAEP) would like to use the opportunity given by the European Commission to provide input on the revision of general pharmaceutical legislation. As the association of leading e-pharmacies, it is our aim to provide better access for more than 20 million customers and patients in eleven European countries to medicines and pharmaceutical advice. We stand for the highest quality standards to ensure (a) patients receive their medication properly, (b) patients are treated professionally and (c) data are securely stored, next to implementing both EU and national legislation in the correct way. Although both Directive 2001/83/EC[1] and Regulation (EC) No 726/2004[2] have been revised, the EAEP sees a need for further improvements. Directive 2001/83/EC is especially vital for e-pharmacies to conduct our business in a proper way. Since the Directive is outdated and does not fit well anymore in an era in which healthcare is increasingly and rapidly digitalising, we herewith provide suggestions for improvements to Directive 2001/83/EC. In this context, we reply to the four objectives as set out in the inception impact assessment[3]:

1. **Ensure access to affordable medicines for patients and address unmet medical needs.**
   - European citizens are increasingly using the Internet for online shopping[4] - a shift that was further accelerated by COVID-19. All kinds of products have been bought, but in many European countries, the sale of products in the category ´pharmacy, personal care & hygiene´ have grown by an average of 21% in 2020 compared to 2019[5]. The digitalisation of healthcare has sped up due to COVID-19[6], but there are a range of national limits and opportunities for patients´ access to affordable and high-quality medicines across Europe. Currently, Article 85c of Directive 2001/83/EC states that "Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services…", but that conditions can be set regarding the retail supply of medication justified on grounds of ´public health protection´. In the current digital era, there are many healthcare providers, such as E-pharmacies and increasingly platforms that bring together healthcare services on a single platform. The list of online providers of medications as defined by the EU Common Logo currently only lists pharmacies and does not allow to consider an EU Common Logo for platforms with only EU Common Logo holders as their participants. Given the development of platforms and the services they offer, the EAEP would be in favour of adapting Directive 2001/83/EC in such a way that it also allows for platforms to be included as reliable medication provider platforms.
   - The EAEP would also like to see clarity regarding the use of website addresses. In some Member States, such as Italy, online providers cannot use one and the

[1] Directive 2001/83/EC on the Community code relating to medicinal products for human use
[2] Regulation (EC) No 726/2004 on the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
[3] https://ec.europa.eu/info/law/better-regulation/
[4] https://ecommerce-europe.eu/wp-content/uploads/2021/09/2021-European-E-commerce-Report-LIGHT-VERSION.pdf
[5] Idem footnote 3
[6] https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-shaping-the-future-of-european-healthcare.pdf

same website address when registering for the EU Common Logo. A more flexible approach would allow platforms and marketplaces to sell their products online with multiple companies using one website address.

- The EU Common Logo is only available in the language where the medication provider´s website address is established and linked to the website listing all the medication providers in that given country. The EAEP proposes that the national authority provides the Common Logo to the online provider in the language of each relevant market to which the website it will be directed instead of only in the language of the country where the online provider is based. Furthermore, given that customers from all over the EU can order in that given country, the EAEP would like to see one integrated EU website listing all the online providers of medications that bear the EU Common Logo. This would enhance transparency, quality and understandability for anyone ordering products abroad.
- Currently, an explicit legal base does not exist to enable healthcare providers to channel/forward orders either from a platform provider to a pharmacy or from a pharmacy to another pharmacy in order to offer the best service to the customer/patient. This should be made possible, of course with the customer always retaining his or her freedom of choice. According to the EAEP, Directive 2001/83/EC would be the fitting legal foundation to provide for such a legal basis.
- The members of the EAEP have continuously proven to be safe and reliable providers of medications, as guaranteed by the EU Common Logo. Unfortunately, we are still unjustifiably perceived as non-reliable pharmacies to work with by many different stakeholders. These false claims are not in the least place fostered by the fact that many falsified medicines are still in circulation in the EU. We would like to underline the importance of more forcefully enacting Article 85d of Directive 2001/83/EC, which is to conduct or promote information campaigns, both carried out by the Member States and the EU, aimed at the general public on the dangers of falsified medicinal products.
- At present, the members of the EAEP feel that the EU Common Logo is still very unknown among EU citizens. The Alliance for Safe Online Pharmacy (ASOP EU) and the European Alliance for Access to Safe Medicines (EAASM), for example, raise awareness about increasing the public awareness of fighting fake medicines[7]. Under Directive 2001/83/EC, both the EU Member States and the European Commission have a legal obligation to raise awareness about the risks of buying medicines online. By means of for example online and billboard campaigns, the EU audience should be made aware of the EU Common Logo and what it stands for.

2. **Enable innovation for the development of high-quality, safe, effective medicines, harnessing the benefits of digital and emerging science and technology while reducing the environmental footprint**
   - As digital pharmacies, we suggest to make use of what digitalisation can offer patients in terms of product literacy. Currently, Directive 2011/83/EC requires that all medicines authorised within the EU are obliged to have a package information leaflet (PIL) and a Summary of Product Characteristics (SmPC). Article 11 of Directive 2011/83/EC describes the information that is required to be included in the SmPC and the PIL. The EAEP supports the outcomes of the ´Study on the Package Leaflets and the Summaries of Product Characteristics of Medicinal

[7] https://buysaferx.pharmacy//wp-content/uploads/2018/06/Fighting-Fakes-By-Member-States-report-2018-updated-May-30-2018.pdf

Products for Human use[8] (2014) to use electronic media to enhance patients´ understanding of the information of a medication. The EAEP would even like to go further and adapt the legislation by adding that both the PIL and SmPC should be made available digitally in all EU languages in an understandable way, easy to find and which fosters the possibility of actively updating new information in the digital PIL and SmPC, since adjustments may be made to the product over time. The EC, together with the MS, should take care of an active communication campaign to point people towards the digital availability of such information.

- Next to the advantages of digitalising the PIL and SmPC for updating information, we believe that additional gains can be achieved in terms of reducing paper waste. The healthcare sector, as many other sectors, can become even more sustainable. This presents a rather easy way to reduce paper use while still safeguarding security and quality of information.

3. **Enhance the security of supply of medicines and address shortages**
   - Under current pharmaceutical legislation, pharmaceutical companies and wholesalers must, within the limits of their responsibilities, ensure a continued supply of medicines once they are placed on the market in the EU. Companies must also notify national authorities at least two months before an expected shortage or planned market withdrawal. The EAEP is of the opinion that one cannot ask companies to have safety stocks, since this would not be in par with having a sustainable approach towards medicines: The risk then exists that if these stocks are not being used, a surplus of the medications stocked is created, which leads to extra costs and the waste of unused medicines. In addition, the risk exists that more and unnecessarily, medicines are nearing their expiry date/shelf life, and according to the GDP[9], they should be withdrawn immediately from saleable stock either physically or through equivalent electronic segregation.
   - We also believe it is within the remit of the company itself to set agreements with cooperation partners themselves, and to not require them to diversify the number of key suppliers. This would harm the principle of freedom of choice as to whom the company works with and would not increase the quality of the products. In fact, a mandatory diversification of supply chains can lead to less quality, thereby endangering peoples´ lives.

4. **Reduce regulatory burden and provide a flexible regulatory framework**
   The EAEP believes that legislation is needed to provide just frameworks for its members and other actors to play by the same rules. Such regulations and legislations should be clear, to the point and easy to understand and implement. Better interfaces should be made between legislation that has an overlap with Directive 2011/83/EC and Regulation EC No 726/2004, such as the EU Cross Border Healthcare Directive 2011/24/EU and the Falsified Medicine Directive 2011/62/EU.

[8] https://ec.europa.eu/health/sites/default/files/files/committee/75meeting/pil_s.pdf
[9] Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)

About the EAEP

The European Association of E-Pharmacies (EAEP) represents the interests of e-pharmacies on the European continent. More than 20 million customers and patients across Europe are currently being supplied by our members and on top of that, our online pharmacies and their more than 4,000 employees are currently active in eleven European markets.

Founded in February 2021, 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.

Do you want to learn more about what we do? Find out more on https://www.eaep.com/en/ and get in touch with us by email: info@eaep.com