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Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

PGEU Position Paper on the Digital Services Act package

The Pharmaceutical Group of the European Union (PGEU) welcomes the review of the current regulatory framework to deepen the Internal Market for Digital Services under the Digital Services Act Package. We recognise the need to update and clarify the rules established by the e-Commerce Directive and harmonise the responsibilities and obligations of digital services providers, including online platforms and reinforce the oversight and supervision of digital services in the EU.

It is expected that the impact of digitalization on health, healthcare delivery and health systems, can and will likely be profound, according to the Opinion of the European Commission Expert Panel on Health[1]. In particular, health services have already undergone digital transformation which impacts healthcare delivery.

The European Commission *Companion Report*[2] to the *State of Health in the EU 2019* finds out that digital transformation of healthcare – and in particular of health promotion and disease prevention – is one of the 5 biggest trends in the national health systems of EU Member States.

Given the focus of our professional practice, our response will focus on the online provision of medicinal products (including non-prescription medicines and prescription medicines) and healthcare products, which is growing, as well as on patient safety and consumer protection aspects.

The online sale of non-prescription medicines is allowed at EU level by Directive 2011/62 (Falsified Medicines Directive) which contains a range of measures aimed at preventing falsified medicines entering the supply chain and reaching the hands of patients. Directive 2001/83 (the Community Code) establishes the minimum requirements for the sale at a distance of human medicines to the public. It clearly states, however, that Member States remain competent to allow or prohibit the online retail supply of prescription medicines (POMs). Additionally, Member States are entitled to impose additional restrictive conditions, justified on grounds of public health protection, for the online retail supply on their territory of medicinal products to the public.

We take the opportunity to raise community pharmacists' concerns with regard to the impact of the diversity of legal frameworks applying to the provision of online pharmacy services across Member States on their quality and the level of consumer protection. We also would like to highlight some recent illegal practices that have illustrated the vulnerability of consumers vis-à-vis the illegal provision of medicines online and other unfair commercial practices in respect of such products. Finally, we will focus on the importance of strengthening cooperation between Member States and ensuring an effective enforcement of harmonised rules in connection with cross-border online provision of medicines.

[1] https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/022_digitaltransformation_en.pdf
[2] https://ec.europa.eu/health/state/companion_report_en

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1. Guiding principles

We strongly support the principle of "what is illegal offline is also illegal online", as well as the principles of consumer protection should become guiding principles of the future regulatory framework, as it has been highlighted in the draft IMCO report on a *"Digital Single Act: Improving the functioning of the Single Market".* In addition, such a regulatory framework should guarantee the safety, efficacy and quality of medicinal products offered to EU patients online.

We also share the view, expressed in such a draft report, that a level playing field in the internal market between the platform economy and the "traditional" offline economy, based on the same rights and obligations for all interested parties - consumers and businesses - is needed. The level of regulation applied for ''traditional'' offline economy shall be valid for the online platform economy as well.

2. Diversity of legal frameworks across Member States

As authorised by European law, Member States have adopted different approaches regarding the conditions for the online provision of non-prescription medicines, according to the specific realities and needs of populations in their territory.

Nevertheless, at least half of EU countries consider safer to allow online pharmacy services only as complementing the usual brick and mortar pharmacy activity or are registered and subject to the same requirements than high street pharmacies. In principle, this makes the Internet sale of NPMs through such pharmacies subject to the same requirements applicable to the offline sale thereof at national level (for instance, a responsible pharmacist is required to supervise the sale of medicines both online and offline, the same storage conditions apply, etc.).

Despite differences, we firmly believe that, as noted by several national regulators across EU countries, the legal principles and regulatory standards aimed at guaranteeing safe outcomes for patients and people who use pharmacy services must still be met, regardless of the (online or offline) form pharmacy services are delivered (3).

Given the different regulatory framework across Member States, it cannot be ensured that patients are granted the same level of protection when purchasing medicines online across EU Member States. Also, as it is illustrated by recent EU case-law[4] there is some legal uncertainty on which rules apply to the online provision and advertising of medicinal products to patients/customers based in a different Member State from the one where the online pharmacy service provider is established. The Advocate General Opinion in this case indicated that the country of origin should apply in principle to the online advertising of such products. However, this would mean that patients face a different level of

[3] UK General Pharmaceutical Council 'Guidance for pharmacies providing services at a distance, including on the internet'

[4] See Advocate General Opinion of 27 February 2020, in case C-649/18 concerning a preliminary question referred by a French court on the applicability of French rules to a Dutch-based online pharmacy supplying medicines at a distance to French customers.

protection when acquiring medicinal products online than the one granted by brick-and-mortar pharmacies.

Furthermore, online pharmacies benefit of the possibility of choosing to be established in the territory of a Member State with a favourable regime (i.e. subject to less regulation) while having no limits on the country of destination they supply their goods to (other than supplying products that hold a market authorisation in the country of destination). They will therefore compete with local pharmacies in the country of destination which are subject to stricter rules and take advantage of the situation. This situation undermines national health protection standards and stands in complete contradiction with Member States' competence to tailor the level of protection of public health to the needs and realities of their territory.

In light of the above, the rule of the country of destination should prevail, in our view, in respect of the cross-border online provision of non-prescription and prescription medicines across the European Union to guarantee patient safety and quality of care according to the level of protection determined by the country where the consumer/patient is established. Indeed, patients must be able to rely on the fact that the laws and consumer protection rights of their home country are respected. The European legislator as well as the Court of Justice have both repeatedly recognized the special nature of medicinal products whose therapeutic effects distinguish them substantially from other goods, and that it is for the Member States to determine the degree of protection that they wish to afford to public health and the way in which that degree of protection is to be achieved.

In addition, a harmonised definition of illegal content is needed in order to ensure a consistent level of consumer protection across Member States.

3. Ensuring consumers/patients safety and protecting public health

In addition, PGEU believes the Digital Services Act should first and foremost tackle unsafe and illegal products available online, including medicinal and healthcare products, as these are increasingly present online and clearly threaten consumers, as it is shown with some recent examples below.

In June 2018, the General Pharmaceutical Council (GPC), expressed its concerns about easy online access of certain medicines in the United Kingdom[5]. The regulator stated that it was aware of situations where patients have been put at risk because of the inappropriate sale and supply of medicines on the internet. The GPC also called on online pharmacy owners to make appropriate checks, such as the identity of the patient, and to identify possible risks to patients, such as identifying multiple orders to the same address.

In 2019, the Italian consumer organization conducted mystery-shopping on online pharmacies which has resulted in the delivery of over-the-counter medicines to Italian citizens of medicines with a packaging which does not comply with the packaging rules of the Community Code. Indeed, the packs and package leaflets of such OTCs were not displayed in Italian which is a mandatory requirement for

[5] https://www.chemistanddruggist.co.uk/news/stop-selling-opiates-asthma-inhalers-gphc-online-pharmacies

medicines to be sold in Italy. In addition, in 2019, the Dutch consumer organisation published the results of a mystery-shopping conducted in the Netherlands which revealed that a number of online websites (based in EU and non-EU countries) were supplying prescription medicines to Dutch customers in breach of the law. The research targeted 12 online websites and 20 prescription medicines were ordered and delivered without a doctor prescription which is contrary to Dutch law. Such medicines included antibiotics, sleeping pills, sedatives, and cancer drugs. The study showed that almost all medicines supplied contained a different quantity of active ingredient than the stated on the packaging[6].

In addition, several recent (some of them underway) investigations of illegal conduct by online operators targeting Italian consumers have shown the vulnerability of consumers vis-à-vis deceptive and misleading practices concerning medicines sold online. This includes misleading advertising of prescription-only medicines claiming beneficial effects in the treatment of Covid-19, without holding a marketing authorisation[7], as well as the finding of fake pharmacy websites, which operated in the Italian market without the necessary authorization to sell medicines online. Indeed, in April 2020, Italy's competition and consumer protection authority required search engines and browsers to remove fake pharmacy websites from their search results. They identified 60 illegal pharmacies, which offered prescription-only drugs without authorization while claiming beneficial effects in the treatment of COVID-19[8]. The same competition authority also opened two investigations into e-commerce platforms Amazon and eBay for allowing individual market players the online supply of coronavirus-related products at exorbitant prices and by providing misleading descriptions. Protecting public health also means ensuring the availability of and access to medicines. It is worth noting that in a context of shortages of medicines, online sales can prevent patients from having access to medicines they need. Indeed, during the COVID-19 pandemic, France imposed a temporary ban on online sales of paracetamol, ibuprofen and aspirin in order to prevent people to acquire large quantities of these products which were getting scarce. [9]

Illegal practices regarding the online provision of medicines have also been identified in other EU countries including France, Greece[10], Denmark and Bulgaria. For instance, in France some individuals used big platforms to sell their prescription medicines. In Denmark, several foreign websites giving the wrong impression of being Danish pharmacies offered medicines prescribed at an online consultation at the website, such online consultation is forbidden in Denmark. In Bulgaria, big online social media

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[6] https://www.consumentenbond.nl/nieuws/2019/kinderlijk-eenvoudig-zware-medicijnen-bestellen-zonder-doktersrecept

[7] https://www.agcm.it/media/comunicati-stampa/2020/3/PS11733-PS11735?utm_source=POLITICO.EU&utm_campaign=c8f57c279a-EMAIL_CAMPAIGN_2020_03_31_04_58&utm_medium=email&utm_term=0_10959edeb5-c8f57c279a-190547999&utm_source=POLITICO.EU&utm_campaign=4245772282-EMAIL_CAMPAIGN_2020_04_21_12_02&utm_medium=email&utm_term=0_10959edeb5-4245772282-190359449

[8] https://www.agcm.it/media/comunicati-stampa/2020/4/PS11746

[9] Article 6 of arrêté du 23 mars 2020, https://www.legifrance.gouv.fr/affichTexteArticle.do;jsessionid=F284C452428768772D12B3F2C26F1A23.tplgfr42s_1?idArticle=LEGIARTI000041866997&cidTexte=LEGITEXT000041748109&dateTexte=20200710

[10] In the last three to four years, there have been several reports issued by the Hellenic Drug Authority (EOF) recalling a number of non-approved medicines sold through internet occasionally, containing prescription-only active substances. In addition, it was reported that certain non-prescription medicines, which are prohibited by the Greek law to be sold via e-shops, were available on certain digital platforms.

platforms such as Facebook are used by individuals to offer and deliver to patients by postal services prescription medicines, including drugs containing narcotic substances or powerful sedatives. Some medicines distributed through Internet are not registered for use in Bulgaria. Ongoing police investigations encounter difficulties to establish the identity and/or geographical location of the sellers.

We also support broadening the scope of the e-Commerce Directive for this to apply to suppliers established outside the Union that sell products, including medicinal products, online to European consumers which do not comply with Union rules on safety and consumer protection. This should also apply to large online platforms established in a third country which are able to leverage their position on the market to get access to personal data of European citizens. We elaborate on this in the below section.

Furthermore, a recent report published by the OECD and the European Union Intellectual Property Office (EUIPO)[11], warned that the Covid-19 crisis underscored the need to address trade in counterfeit pharmaceuticals worldwide. This highlights the treat to patient safety and protection that could be generated via the sale of illegal goods through online platforms.

4. Ex ante regulation of systemic platforms

Big online platforms are seeking to exploit opportunities arising from digital transformation in the healthcare sector. Indeed, since at least three years now, tech giants have been building their health divisions. New technologies and broader use of e-health as well as e-prescription tools could contribute to a growing online pharmacy market in Europe.

A clear example of this trend has been an incident recently reported by the Polish Chamber of Pharmacists where it was found that a large online platform and a high tech company had access to patient data through access to e-prescription data used and processed by a pharmacy chain operating in this country. This created the risk that online platforms were able to profile patients on the basis of such sensitive data. The Polish Chamber of Commerce has already communicated this conduct to the Data Protection Authorities and the Pharmaceutical Inspectorate Authorities[12],[13], [14], [15].

In particular, and taking into consideration the abovementioned cases, PGEU supports the introduction of ex-ante rules for very large online platforms with significant network effects acting as gate-keepers in the EU's internal market. In this respect, we consider the approach proposed by the European Commission in 'option 2' as outlined in the Roadmap as the best way forward.

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[11] https://www.oecd.org/governance/trade-in-counterfeit-pharmaceutical-products-a7c7e054-en.htm
[12] Complaint before the Polish Data Protection Authority: https://uodo.gov.pl/pl/138/1581
[13] Press release (EN)
https://www.reddit.com/r/europe/comments/hijm14/gdpr_polish_pharmacy_chain_gemini_caught/
[14] MP question to the MoH
http://www.sejm.gov.pl/Sejm9.nsf/InterpelacjaTresc.xsp?key=BRCC3T&view=5
[15] Reply from the MoH to the MP question
http://orka2.sejm.gov.pl/INT9.nsf/klucz/ATTBS2HTU/%24FILE/i08532-o1.pdf

5. Governance and enforcement

The above-mentioned cases illustrate the importance of the early detection and the speedy removal of illegal products, particularly medicines, to ensure patient safety and public health. Furthermore, this shows strong cooperation among Member States is crucial to identify and tackle such illegal practices which may affect more than one Member State given online platforms operate across EU countries. We therefore support the need to introduce effective cooperation and enforcement procedures for cross-border issues in the regulation and oversight over digital services.

We take the opportunity to stress that the provisions of the E-Commerce-Directive which oblige the country of destination to notify to the Member State where the online services provider is established and the European Commission before taking any legal action against such services providers (when infringing the rules of the country of destination) constitute a huge procedural burden that may jeopardise the protection of public health. In our view, this notification procedure could prevent Member States from exercising their competence to ensure the level of health protection established in their own legislation is maintained. This is shown, for example, in the above mentioned case-law (C-649/18) where the Advocate General indicated that French authorities were only entitled to require internet pharmacies based in another Member State to comply with French dispensing rules provided that, firstly, France had previously asked the Member State of origin (i.e. The Netherlands) to take measures to implement them. Then, if the Member State of origin did not take such measures or these were considered inadequate, France would need to notify the European Commission and the Member State of origin its intention to take the due legal actions against the Dutch online services provider.

With regard to online pharmacy websites, the common EU logo intended to prove the authenticity of the website needs to be complemented by essential communication from the authorities in collaboration with pharmacists organizations and awareness messages as to how to distinguish illegal sites as well as active prosecution of market places that do not respect regulations and legal requirements by the competent authorities.

Measures as the reinforcement of patient awareness of falsified medicines must be one of European and national authorities' main concerns, assuring that patients only use online pharmacy approved services offered by the authorised pharmacies. Overall, PGEU supports the DSA package objective to provide a modern legal framework for digital services, strengthening the Digital Single Market and ensuring that digital service providers present in the Union act responsibly to mitigate risks emanating from the use of their service, respecting Union rights and values, and protecting fundamental rights.