

Honourable Members of the European Council

Digital Services Act: The current proposal if approved will not meet the ambition set by the European Commission which includes the statement “...to create a safer and more open digital space.”

It is an undisputed fact that EU citizens are put in harm's way as the sale of falsified and substandard medicines is rampant and growing on the Internet¹. This is clearly recognised by the European Commission in its Impact Assessment for the Falsified Medicines Directive², which clearly states that the Internet is a major source of falsified and substandard medicines. According to the WHO, in over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit. Similarly, a study conducted under a strict protocol by the European Alliance for Access to Safe Medicines, found that 62% of medicines purchased from sites found by way of common search engines were substandard or counterfeit.³

Similarly, according to the non-profit independent National Association of Boards of Pharmacy of the 35,000 of websites selling medicines, more than 96% are operating illegally.^{4 5}

Unscrupulous operators prey on citizens' fears, especially during the COVID-19 pandemic which have created opportunities for cyber criminals to capitalize on increased demand for COVID-19 cures and preventatives. In fact during March 2020, at least 100,000 new domain names were registered containing terms like “covid,” “corona,” and “virus”, plus more domains registered to sell items such as medical masks.⁶ Other domains have been registered and used to spam out advertisements for COVID-themed scams.

The catalogue of patient harm and deaths due to falsified and substandard medicines bought online is well documented⁷.

Article 5 of the e-Commerce Act is not effective in ensuring business entities identify themselves

It is very important to note that in the 2000 legislation introduced an obligation on businesses to identify themselves on their websites (see Article 5 of the e-Commerce Directive (ECD)). Unfortunately (and unsurprisingly) businesses that have the intention of making a profit out of illegal content **do not comply with this obligation and do not suffer consequences.**

1 OECD/EUIPO report Illicit trade – Trade in Pharmaceutical products <https://euiipo.europa.eu/ohimportal/en/web/observatory/trade-in-counterfeit-pharmaceutical-products>

2 2.10.2015 SWD(2015) 189 final COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document COMMISSION DELEGATED REGULATION (EU) - supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use. https://ec.europa.eu/smartregulation/impact/ia_carried_out/docs/ia_2015/swd_2015_0189_en.pdf

3 The Counterfeiting Super Highway EAASM report <https://eaasm.eu/wp-content/uploads/CtCreport2012.pdf>

4 Internet Drug Outlet Identification Program, National Association of Boards of Pharmacy, 2016

5 The Internet Pharmacy Market in 2016, LegitScript and the Center for Safe Internet Pharmacies, January 2016

6 Don't Panic: COVID-19 Cyber Threats." Palo Alto Networks Unit 42 blog, 24 March 2020, at: <https://unit42.paloaltonetworks.com/covid19-cyber-threats/>

7 Examples of patients harmed by medications purchased online <https://buysaferx.pharmacy/wp-content/uploads/2020/06/Patient-Harms-Tracker-6-4-2020.pdf>

Article 22 of the DSA Proposal should apply to all online Intermediaries to prevent their customers from engaging in criminal activity online and harming EU citizens

The current DSA proposal is primarily focused on online marketplaces. This limitation in scope which excludes all other Internet Intermediaries (who are involved in selling and administering the domain names that enable a website to be set up, hosting the website, providing payment services to the website, promoting the website online, etc.) will mean that criminals will continue to be free to conduct illegal business

This means that the DSA will not meet its objectives and will, in effect continue the current situation where the European citizen will be put in harm's way due to criminal and illegal online activities selling falsified and substandard medicines.

With regard to KYBC obligations, the sections relating to this are commendable and include the provision to ensure the traceability of traders in Article 22. Whilst this is an improvement, **the Commission's proposed Article 22 only introduces KYBC obligations in the context of online marketplaces. Such a limited approach means that criminals still have the opportunity to conduct their illegal business and circumvent Article 22, thus continuing to endanger the lives of EU patients and consumers. Criminals knowing that online market places in general have policies to monitor illegal activity and have their own security policies, will set up their own websites and use domain names totally independent of market places.**

We believe that there are solutions to this situation. To transact business online the entity is required to buy a domain at very small cost. Hence criminals will buy 1000s of domains at one time which is to the detriment of a safe and trustworthy online environment and has facilitated the use of infrastructure by completely anonymous commercial entities that intentionally make available or distribute illegal content and products.

It is essential therefore that all the Intermediaries having a direct working relationship with the business entity (registries, registrars, hosting companies, advertisement and payment services, proxy services, etc) are held accountable to identify to whom they are selling the domain name.

The Digital Services Act is an opportunity for the European Parliament to be in the vanguard across the world in addressing the clear need for those using the Internet to be easily identifiable and thus can be monitored with the same visibility that exists for the off line environment.

We would therefore request that the scope of the DSA is expanded to address these shortcomings of the current proposal.

We therefore urge you to **ensure that all intermediaries – not just online marketplaces – are included in the scope of the DSA and so the KYBC principle can be incorporated.**

We thank you for your attention and would welcome the opportunity to discuss this issue with you further.

Kind regards,

Please contact Mike Isles if you wish to discuss this further mike.isles@asop.eu

Signatories

Alliance for Safe Online Pharmacy in the EU



Commonwealth Pharmacists Association



European Alliance for Access to Safe Medicines



European Parkinson's Disease Association



Irish Patients' Organisation



Irish Patients' Association

Ketotic Hypoglycemia International



Self-Care in Europe

SCiE