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October 2024



The Digital Services Act: Implications for brand owners in the pharmaceutical industry

AGENDA AND OUTLINE

DSA: Implications for Brand Owners in the Pharmaceutical industry

- Legislative and Regulatory Pressure Intensifying
- Making Europe fit for the Digital Age
- The Graduated Approach to Regulation
- Key Obligations which help Pharmaceutical Rights Owners
- Landmark Legislation – or is it ?
- Questions?



Legal and Regulatory Shift: Pressure Intensifying



SHOP SAFE Act
INFORM Consumers Act



The Digital Services Act ("the DSA")
The European Artificial Intelligence Act (the AI Act)



The Online Safety Act



"Congress must create accountability to prevent hazardous items from infiltrating the homes of millions of Americans."

"Europe must be fit for the digital age. What is illegal offline must also be illegal online".

Making Europe Fit for the Digital Age



“Europe must be fit for the digital age: what is illegal offline should also be illegal online”

Ursula Von Der Leyen, European Commission President



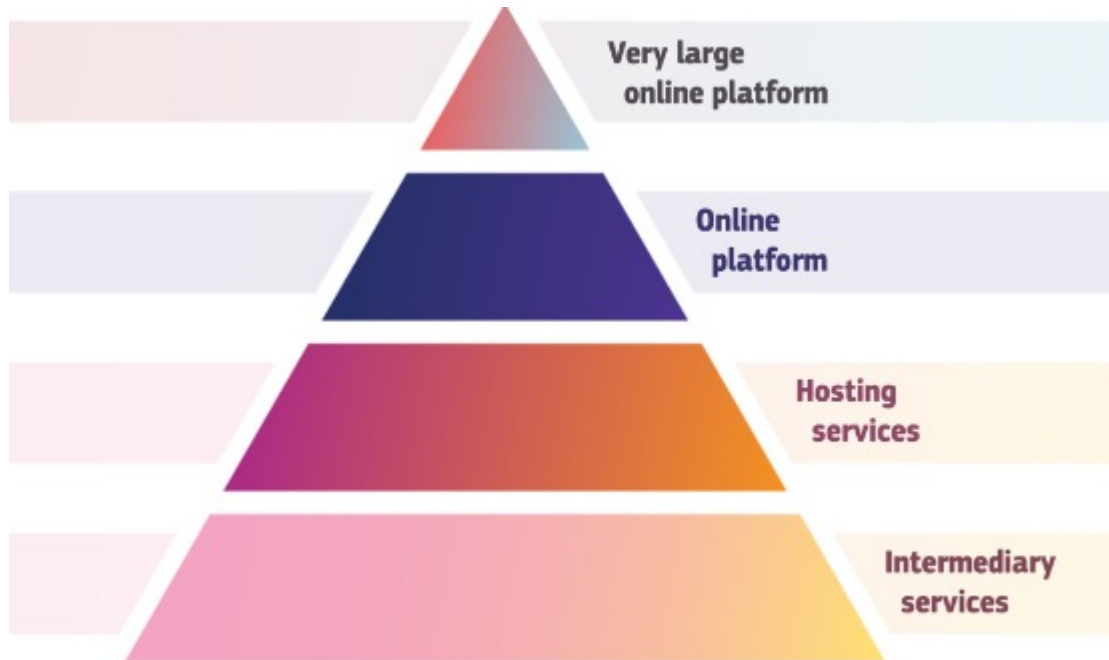
“ the DSA regulates online intermediaries and platforms such as marketplaces, social networks, content-sharing platforms. Its main goal is to prevent illegal and harmful activities online and the spread of disinformation. It ensures user safety, protects fundamental rights, and creates a fair and open online platform environment....”

www.commission.europa.eu

The Graduated Approach to Regulation



Establishes four tiers of 'service providers' with obligations applying cumulatively (the 'graduated approach' to regulation)



Very large online platforms and search engines pose particular risks in the dissemination of illegal content and societal harms. Specific rules are foreseen for platforms reaching more than 10% of 450 million consumers in Europe

Online platforms bring together sellers and consumers such as online marketplaces, app stores, collaborative economy platforms and social media platforms.

Hosting services such as cloud and web hosting services (also including online platforms).

Intermediary services offering network infrastructure: Internet access providers and domain name registrars (also including hosting services).



Key Obligations: Is the Burden of Policing and Enforcing IP shifting ?

Platforms now have to do more and may face substantial penalties for non-compliance

- **Notice and Action** mechanisms for **fake medicines** (*sets the position under E Commerce Directive*)
- Suspension for **Repeat Infringement**
- **Trusted Flaggers**
- Seller **Verification/Authentication** – driving consumer confidence
- Article 15: **Transparency Reporting**
- Article 18: Notifying criminal Offences (incl. **illegal online pharmacies**)
- Article 25 Compliance by **Design**
- Article 54: **Compensation**

In addition:

- DSA applies with ‘extra-territorial’ scope – including providers with substantial connection to or “targeting” the EU”
- Directly applicable across all member states. Not directly enforceable in the UK

Recidivism: Suspension for Repeat Infringement

Article 23 – Measures to protect against misuse

- 1) Providers of online platforms shall suspend, **for a reasonable period of time** and after having issued a prior warning, the provision of their services to recipients of the service that frequently provide manifestly illegal **content**.

- 3) When deciding on suspension, providers of online platforms shall assess, **on a case-by-case basis** and in a timely, diligent and objective manner, whether the recipient of the service, the individual, the entity or the complainant engages in the misuse referred to in paragraphs 1 and 2, **taking into account all relevant facts and circumstances** apparent from the information available to the provider of online platforms. Those circumstances shall include at least the following:
 - (a) the **absolute numbers** of items of manifestly illegal content or manifestly unfounded notices or complaints, submitted within a given timeframe;
 - (b) the **relative proportion** thereof in relation to the total number of items of information provided or notices submitted within a given timeframe;
 - (c) the **gravity of the misuses**, including the nature of illegal content, and of its consequences;
 - (d) where it is possible to identify it, **the intention of the recipient of the service**, the individual, the entity or the complainant.

Recital 12 – the concept of ‘illegal content’ should be defined broadly to cover information **relating to illegal content, products, services and activities**... examples include... **sale of non-compliant or counterfeit products**

Authentication: stopping sellers re-offending

Article 30 – Traceability of Traders

- 1) Providers of online platforms allowing consumers to conclude distance contracts with traders shall ensure that traders can only use those online platforms to promote messages on or to **offer products or services to consumers located in the Union** if, prior to the use of their services for those purposes, they have obtained the following information, where applicable to the trader:
 - (a) **the name, address, telephone number** and email address of the trader;
 - (b) a copy of the identification document of the trader;
 - (c) **the payment account details of the trader**;
 - (d) where the trader is registered in a trade register or similar public register, the trade register in which the trader is registered and its registration number or equivalent means of identification in that register;
 - (e) **a self-certification by the trader committing to only offer products or services that comply with the applicable rules of Union law.**



Landmark Legislation – or is it... ?

- DSA is the most sweeping reform to tech regulation in Europe in 20 + years
- Most rights owners cautiously welcome these developments
- DSA reflects growing legal and political momentum around the world towards enhanced platform accountability
- Clear benefits for pharmaceutical rights owners
- Platforms have to do more !



HOWEVER...

- Core liability framework is unchanged – burden continues with rights owners
- Opportunity missed to regulate through proactive monitoring + sanctions
- New and broadly untested law
- Election year and impact





Thank you!

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