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Direct-to-consumer advertising of medicines

Do we need more regulation?

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The issue is not whether medicines advertising should be unregulated

BASELINE



Maintain the EU prohibition on DTC advertising of Rx medicines

The prohibition reflects the EU policy choice that decisions concerning Rx medicines should remain professionally mediated

REFORM



Implement the Pharma Package proportionately

The agreed reform clarifies important issues, but some provisions may increase classification risk or lead to differences in national implementation

ENFORCEMENT



Direct resources towards illicit digital activity

Unauthorised sellers, deceptive accounts and falsified products operate outside the compliance systems applied to legitimate companies

The EU and US start from fundamentally different regulatory models

EUROPEAN UNION

Rx medicines DTC advertising is prohibited



- Public advertising of Rx medicines is prohibited
- OTC medicines may be advertised subject to safeguards
- Communication about Rx medicines is therefore directed primarily on healthcare professionals

UNITED STATES

Consumer advertising of Rx medicines is permitted



- Advertising of Rx medicines aimed at consumers is permitted within a separate disclosure and content framework
- Consumer-facing promotion is therefore a substantial channel of pharmaceutical communication

Directive 2001/83/EC creates a comprehensive advertising framework



Article 86

What counts as advertising?



Articles 87–88

What is prohibited or required?



Articles 89–90

What rules apply to permitted public advertising?



OTC advertising to consumers: allowed – within clear limits

ALLOWED (ART. 87–88)

- OTC medicines may be advertised to the public
- Rx and psychotropic/narcotic medicines banned, except approved vaccination campaigns
- Authorised products only; claims consistent with the SmPC
- Rational use: objective, not exaggerated, not misleading

MANDATORY (ART. 89)

- Clearly recognisable as advertising of a medicine
- Product name (and active substance, if it is a single-ingredient medicine)
- Information needed for correct use
- Express invitation to read the leaflet / packaging

PROHIBITED (ART. 88(6), 90)

- Suggesting consultation is unnecessary, or that health improves by taking / suffers by not taking the product
- Guaranteed effects, no side effects, or superiority/equivalence to another treatment
- Targeting mainly children; scientist, HCP or celebrity endorsements
- Presentation as food/cosmetic, or as safe or effective because “natural”
- Risk of erroneous self-diagnosis; improper, alarming or misleading recovery claims or images
- Direct distribution of medicines to the public for promotion

CJEU case law distinguishes product promotion from pharmacy promotion

C-190/20 DOCMORRIS



The prize competition promoted pharmacy choice

Participation required submission of a prescription, but the promotional message was directed at choosing the pharmacy rather than choosing or consuming a specific medicine

C-649/18 A



Online pharmacy advertising also engages e-commerce law

The case concerned a cross-border online pharmacy campaign and national restrictions on measures such as mass advertising, discounts and paid referencing

EUROAPTIEKA and C-517/23 DocMorris

C-530/20 EUROAPTIEKA



Advertising may concern unspecified medicinal products

The Court held that Article 86 may cover communications encouraging the purchase of medicines even where no specific product is identified

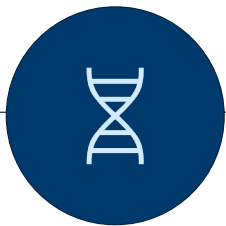
C-517/23 DOCMORRIS



Different benefits receive different legal treatment

- Immediate price reductions or payments relating only to prescription medicines concerned pharmacy choice and fell outside Article 86
- Vouchers for later OTC purchases could constitute medicines advertising
- The legal classification depends on what the incentive promotes: pharmacy choice or additional medicine consumption

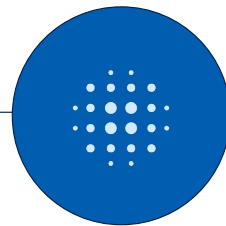
The information–advertising boundary is substantive and fact-specific



LOWER RISK

Neutral disease awareness

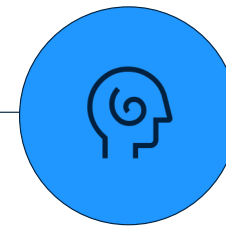
Objective information on symptoms, prevalence and treatment options, with no product preference and a direction to consult a healthcare professional



BORDERLINE

Indirect steering or branded cues

A specialist-finder tool, product-associated visual language or selective treatment framing may connect nominally unbranded content to a commercial objective

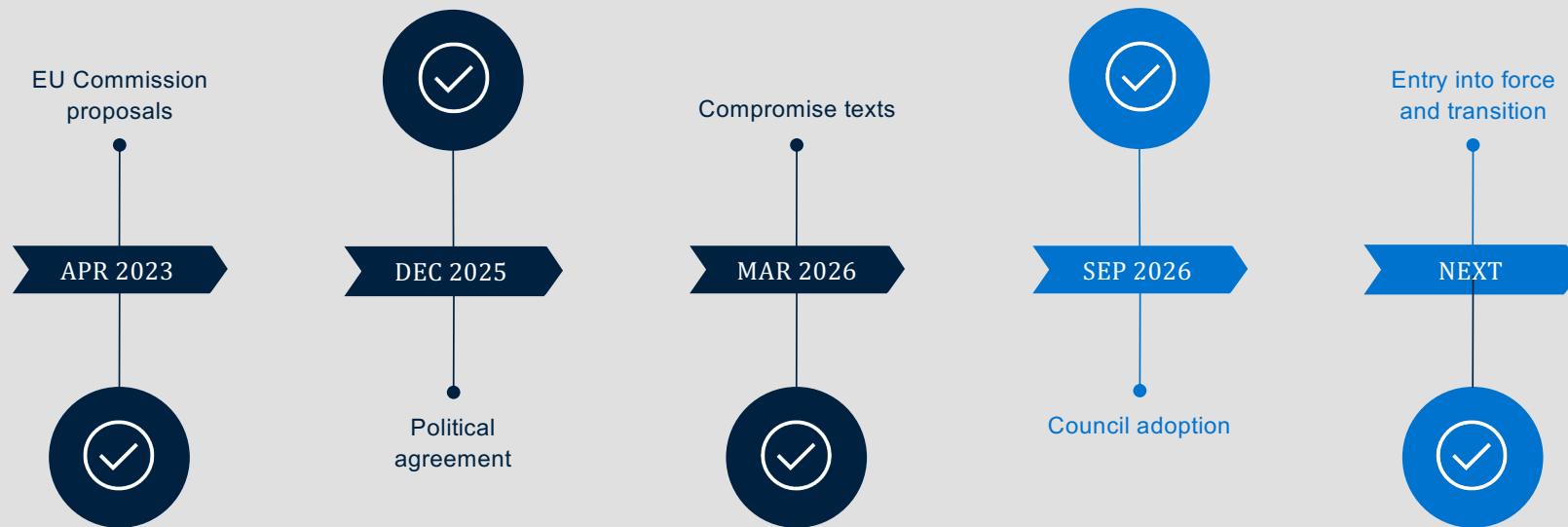


HIGHER RISK

Product-aligned education

Content that consistently mirrors one product's indication, dosing or mechanism may promote that product even without prominently naming the brand

The EU Pharma Package: legislative status



The reform expressly codifies advertising of unspecified medicines

REGULATORY SCOPE

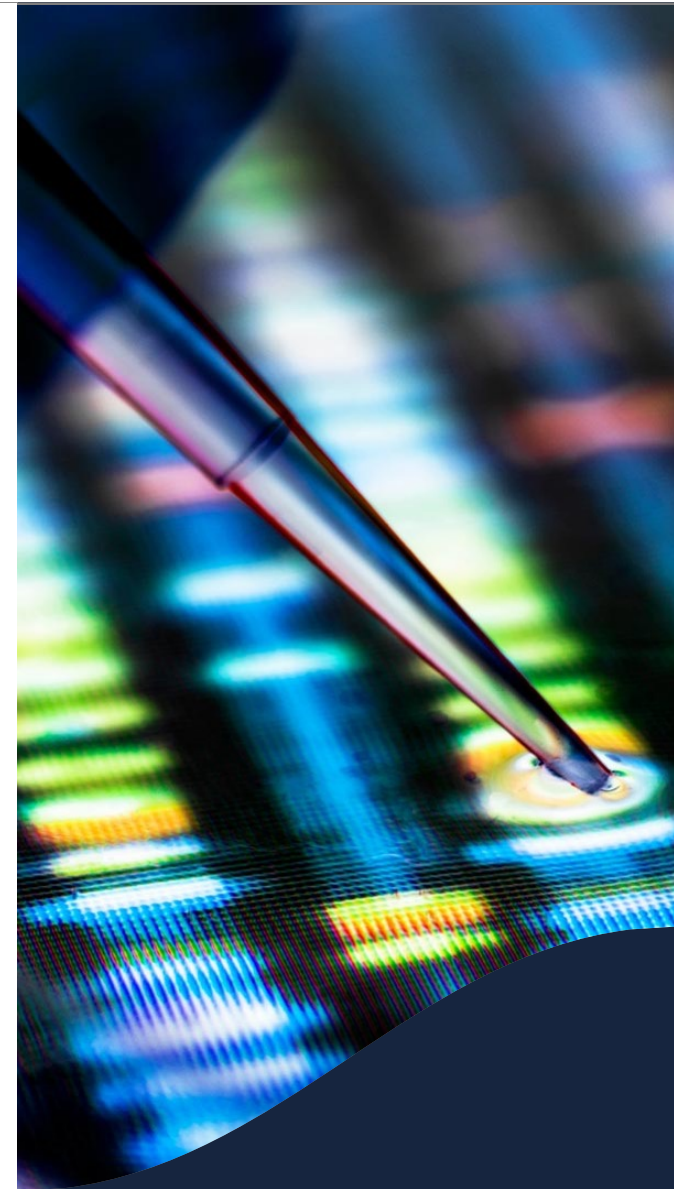
A named medicine is not required

- Category-wide and range-wide promotions may fall within the advertising regime where the communication encourages purchase or consumption of medicinal products
- This makes the treatment of unspecified medicines explicit in the package text

LIMITS OF THE REFORM

Health communication is not automatically advertising

- Disease-awareness, patient-support and general health information still require analysis of promotional purpose, product linkage and presentation
- The reform does not make every unbranded communication promotional



The broader HCP definition reflects multidisciplinary healthcare delivery

CURRENT MODEL



Prescribe or supply

- The existing framework focuses principally on persons qualified to prescribe or supply medicinal products
- This can exclude professionals who play an important role in administering complex treatments

AGREED REFORM



“Administer” may also qualify

- The new definition may include persons authorised and qualified to administer medicines
- Certain nurses, paramedics or other professionals may therefore fall within the professional audience, but only where their actual legal qualifications support that status

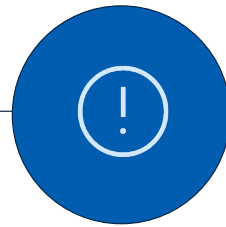
Comparative advertising becomes more closely tied to approved product information



LEGAL DIRECTION

Objective and unbiased comparison

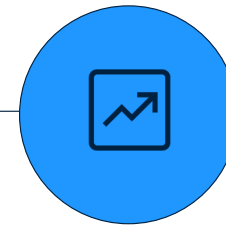
The package restricts negative highlighting of competing products and unsupported claims that the advertised medicine is “safer” or “more effective”



PRACTICAL CONSEQUENCE

New evidence may have limited immediate promotional use

Head-to-head evidence not reflected in the relevant approved product information may be harder to use in promotional communications



POTENTIAL BUSINESS IMPACT

Possible effect on research incentives

A possible concern is that delayed promotional use of new comparative evidence may reduce its immediate commercial value. The actual effect on incentives to fund head-to-head research remains uncertain

Vaccination campaigns and medicine shortages require different legal explanations

VACCINATION CAMPAIGNS

Article 88(4) of Directive 2001/83/EC already recognises the exception

Current law already allows Member States to permit industry vaccination campaigns approved by competent authorities

MEDICINE SHORTAGES

Advertising may be restricted during shortage conditions

- The reform may allow Member States to suspend advertising of a medicinal product where continued promotion could aggravate an identified shortage
- Implementation should define evidence, scope, duration, proportionality and procedural safeguards to reduce inconsistent or discriminatory use



A balanced assessment of the Pharma Package identifies both modernisation and risk

POSITIVE CHANGES



Modern care and clearer communication rules

The broader HCP concept better reflects multidisciplinary practice. Express treatment of unspecified medicines can improve legal clarity

CONCERNS



Classification, comparative claims and differences in national implementation and enforcement

The reform may increase uncertainty at the information–advertising boundary, constrain comparative promotion and permit divergent national shortage measures.

Influencer marketing is governed by overlapping rules rather than a single EU statute

UCPD

Commercial intent, hidden advertising and misleading practices

DSA

Online-ad transparency and platform systems

AVMSD

Audiovisual commercial communications and video-sharing platforms

GDPR

Health data, profiling and targeted communication

PHARMA LAW

Product category, audience, content restrictions and mandatory warnings

The available evidence shows disclosure problems, but must not be overstated

BEUC MONITORING



A broad influencer-transparency problem

Between March and September 2025, 14 consumer organisations from 12 countries monitored approximately 650 posts and videos across TikTok, Instagram, YouTube or Snapchat

The monitoring focused on unhealthy food and fast fashion and found widespread hidden advertising practices

DIGITAL FAIRNESS ACT



Broader reform is still under preparation

The initiative has been announced, with a Commission proposal planned for Q4 2026

Influencer marketing, dark patterns, addictive design and unfair personalisation are under consideration; exact duties remain to be proposed and negotiated

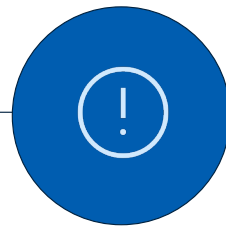
OLG Köln 6 U 118/24 applies audiovisual medicines-advertising duties to an Instagram Reel



FACTS

An 18-second paid Reel advertising a medicine

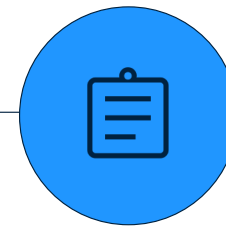
The statutory short-form risk warning was not displayed or spoken in the Reel itself. A longer text and linked account were available outside the video



HOLDING

The warning had to appear inside the Reel

The Reel was audiovisual advertising. A caption or link did not substitute for the statutory short warning. In the paid partnership, the influencer could be treated as the company's agent



LIMITS

“Known person” depends on the individual facts

The court did not create an automatic rule for all influencers or a fixed follower threshold. It also did not require every detailed product particular to appear inside the Reel

Compliant and illicit actors face different enforcement exposure

REGULATED PHARMACEUTICAL COMPANIES



Identifiable, reviewable and accountable

Legitimate companies maintain legal, medical and regulatory review, operate under product-specific restrictions and face established enforcement channels. Influencer partnerships create direct corporate compliance exposure

ILLICIT OR EVASIVE ACTORS



Temporary, cross-border and harder to reach

Unlawful sellers may use disposable accounts, fraudulent sites, disguised wellness or nutrition content, and cross-border fulfilment

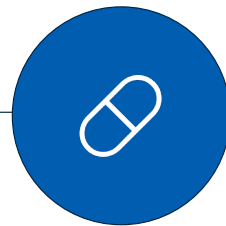
Official operations show the scale and persistence of illicit pharmaceutical trade



ECONOMIC ESTIMATE

EUR 16.5 billion in lost EU sales

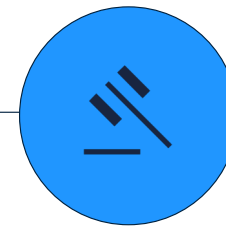
The 2020 OECD/EUIPO study estimated annual lost sales of EUR 16.5 billion and an employment impact affecting more than 80,000 jobs in the EU pharmaceutical sector



SHIELD IV

April to October 2023

More than EUR 64 million in seizures, over 12 million tablets and pills, 1,284 persons charged or under prosecution, 92 websites closed and four underground laboratories dismantled



SHIELD V

April to November 2024

Preliminary results included seizures above EUR 11.1 million, 418 persons arrested, charged or under prosecution, 52 organised crime groups investigated and more than 4.68 million tablets and pills

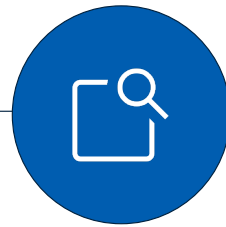
The GLP-1 market illustrates how digital demand is exploited by illicit sellers



VISIBILITY

Reach consumers through ordinary digital channels

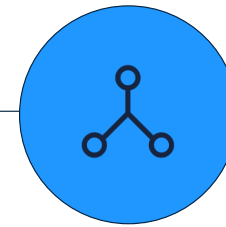
Search promotion, social-media content and marketplace listings place illegal offers alongside legitimate health information



DECEPTION

Create an appearance of authenticity

Fraudulent sites may misuse official logos, imitate brands, use fake profiles and publish false endorsements. The objective is to look authorised and trustworthy



FULFILMENT

Complete transactions across dispersed networks

Websites, messaging applications, postal services and couriers enable cross-border transaction and delivery. Enforcement must disrupt the network, not only remove one advertisement

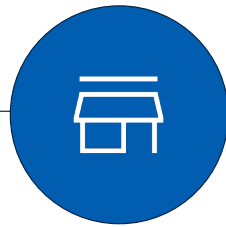
Trademark enforcement supports patient safety, but the legal concepts must remain precise



IMITATION

Marks and packaging create apparent authenticity

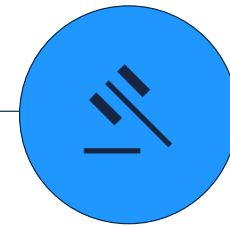
Illicit sellers may copy pharmaceutical trademarks, product names, packaging, domains and social-media identities to persuade consumers that a product or seller is genuine



ATTRIBUTION

Harm may be attributed to the legitimate manufacturer

Where a copied brand appears on an ineffective or unsafe product, consumers may blame the genuine manufacturer, damaging trust and brand reputation



LEGAL DISTINCTION

Falsification is broader than trademark infringement

WHO defines falsified products by deliberate misrepresentation of identity, composition or source

Case studies: examples of pharmaceutical brand exploitation

ALFLUTOP

Grey-market brand exploitation

ALFLUTOP was reportedly sold through illegal Ukrainian websites in unregistered packaging

The example shows how grey-market sellers exploit established pharmaceutical brands to build consumer trust in potentially unsafe products

COUNTERFEIT BOTOX

Brand and patient-safety risk

Operation SHIELD IV uncovered counterfeit botulinum toxin products distributed for cosmetic procedures in Greece

Imitation branding made products of unknown composition and sterility appear genuine, creating both patient-safety and reputational risks

FAKE GLP-1 PRODUCTS

Demand-driven trademark misuse

Counterfeiters exploited the recognition of Ozempic and Wegovy to market products containing incorrect doses, substituted or missing active ingredients, and unidentified contaminants

The resulting patient harm may also undermine trust in the legitimate brands

The enforcement priorities

RECOMMENDATION 1

Target unauthorised online supply

Use timely risk-based monitoring, improve cross-border investigation, streamline lawful removal of clearly illicit offers and prioritise criminal enforcement against organised or high-risk conduct

RECOMMENDATION 2

Create permanent EU coordination

Build on the SHIELD model by connecting medicines regulators, customs, law enforcement, digital authorities and relevant EU bodies through structured intelligence-sharing and joint action

RECOMMENDATION 3

Strengthen intermediary and rights-holder cooperation

Improve notice-and-action, repeat-infringer responses, domain measures, authentication support and cooperation with search and platform services, subject to applicable safeguards

Questions?