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EU law enforcement against counterfeit medicine products: digital ecosystem, right to health and MEDICRIME Convention

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Abstract

The counterfeiting and substandard medical products constitutes a growing threat to public health and regulatory governance in the European Union. Beyond its industrial and economic implications, this phenomenon violates the right to health recognized in Article 12 of the International Covenant on Economic, Social and Cultural Rights and Article 35 of the Charter of Fundamental Rights of the EU, which impose positive obligations on States regarding the availability, accessibility and quality of medicines.

The European regulatory framework, based on Directive 2011/62/EU and Delegated Regulation (EU) 2016/161, has strengthened traceability and verification mechanisms in the traditional pharmaceutical supply chain. However, the emergence of Very Large Online Platforms (VLOPs) has highlighted its limitations by facilitating the cross-border marketing of counterfeit medicines outside legal channels.

In this context, the Digital Services Act (DSA) of 2022 introduces enhanced diligence and traceability obligations for VLOPs, under the direct supervision of the European Commission. The AliExpress case - examined for potential infringements linked, among other issues, to the online availability of counterfeit or otherwise illicit medicinal products- illustrates both the opportunities and the limitations of the emerging regulatory framework, particularly when viewed through the lens of the transition from traditional command-and-control mechanisms to more responsive regulation approaches.

Also, the complementarity with the Council of Europe's MEDICRIME Convention, which establishes a common criminal framework and mechanisms for international cooperation, is essential for shaping a comprehensive model of multi-level digital health governance

Keywords:

Counterfeit medicines; Digital Services Act (DSA); Very Large Online Platforms; AliExpress; MEDICRIME Convention.

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I. Introduction

The circulation of counterfeit medical products is an increasingly worrying public health problem as it jeopardizes patient health and the integrity of the internal market in many countries around the world. The World Health Organization (WHO) has estimated that one in ten medical products circulating in low- and middle-income countries is substandard or counterfeit, generating an annual global cost of more than $30.5 billion[2]. Its proliferation is due to the fact that the medical products and medicines sector has become a target for criminal organizations because of high demand and the enormous profits it generates[3]. In 2025, the Organization for Economic Cooperation and Development (OECD) points out that pharmaceutical products are among the top 20 categories of counterfeit products destined for the EU[4].

The WHO has worked on classifying spurious medicines, distinguishing between: substandard medical products -known as out of specification, these are authorized medical products that do not meet quality standards or specifications-; unregistered/unlicensed medical products -those that have not been evaluated or approved by the national or regional regulatory authority for the market in which they are marketed, distributed, or used, subject to the conditions permitted by national or regional regulations and legislation- and, finally, counterfeit medical products -those that deliberately or fraudulently misrepresent their identity, composition, or source.[5]. For the purposes of this paper, the term "counterfeit or substandard medical products" includes medicines for human or veterinary use whose composition, dosage or packaging does not correspond to what is stated, as well as active ingredients and excipients that are adulterated or of poor quality, manipulated or sell for different or non-compliant medical devices, as well as components, accessories, packaging materials, containers, labels and leaflets that are counterfeit or do not meet the required standards. This term therefore covers all elements of the supply chain which, by being intentionally altered or manufactured without complying with quality and safety standards, put public health at risk and undermine confidence in the pharmaceutical and healthcare system[6].

Article 12 of the International Covenant on Economic, Social and Cultural Rights recognises "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"[7]. The Committee on Economic, Social and Cultural Rights, in its General Comment No. 14, has elaborated on the normative content of this right, highlighting the fourfold guarantee: availability, accessibility, acceptability and quality8. For its part, the United Nations Human Rights Council has repeatedly emphasised that access to medicines is an integral part of the right to health, particularly for vulnerable populations[9].

Understanding why people resort to online purchases is essential to contextualize an appropriate regulatory response[10]. Despite national health systems -or because of their weakness- the high prices of treatments, sometimes subject to patents, remain a significant barrier to access in many States; on the other hand, family's

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[2] WHO, Substandard and Falsified Medical Products (WHO Fact Sheet, 2022). https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products.

[3] Martínez Navarro, José Antonio, 'Los medicamentos espurios y su venta online en tiempos de pandemia' (2022) 27 *Revista Digital de Derecho Administrativo* 261–294 https://www.redalyc.org/journal/5038/503872656009/html/.

[4] OECD/EUIPO (2025), Mapping Global Trade in Fakes 2025: Global Trends and Enforcement Challenges, Illicit Trade, OECD Publishing, Paris, https://doi.org/10.1787/94d3b29f-en . The presence of counterfeit automotive parts and pharmaceutical products, ranked 10th and 12th respectively, is also a significant concern due to the high safety risks they pose to consumers (p. 18 and 36).

[5] WHO Assembly Document, Member State mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit medical products. A70/23. 20 March 2017. Appendix 3 to Annex. https://apps.who.int/gb/ebwha/pdf_files/wha70/a70_23-en.pdf

[6] Ashraf, Ahmed R, Mackey, Tim K, Vida, Róbert G, Kulcsár, Gábor, Schmidt, Judit, Balázs, Orsolya, Domián, Bálint M, Li, Jing, Csákó, István and Fittler, Andrea, 'Multifactor Quality and Safety Analysis of Semaglutide Products Sold by Online Sellers Without a Prescription: Market Surveillance, Content Analysis, and Product Purchase Evaluation Study' (2024) 26 *Journal of Medical Internet Research* e65440, doi:10.2196/65440.

[7] International Covenant on Economic, Social and Cultural Rights (1966) 993 UNTS 3 art 12.

[8] UN CESCR, General Comment No 14: *The Right to the Highest Attainable Standard of Health* (2000); On this issue, *see* Seuba Hernández, Xavier, *La protección de la salud ante la regulación internacional de los productos farmacéuticos* (Marcial Pons 2010) 69.

[9] UN Human Rights Council, Resolution 12/24: *Access to Medicine in the Context of the Right to Health* (2009).

[10] Nuryunarsih, Dewi Nurul, 'Counterfeit Medicines in Socioeconomic Perspective' (2017) 11(4) *Kesmas* 153–162, 157, doi:10.21109/kesmas.v11i4.1440 https://scholarhub.ui.ac.id/kesmas/vol11/iss4/1..

interest in and expenditure on health products has increased in recent years. Furthermore, price disparities encourage patients to seek cheaper sources online, especially in the case of chronic patients with recurring expenses[11]. Not forgetting, of course, that it is an attractive option for consumers due to the speed and convenience of its transactions and the frequent absence of a prescription requirement. At the same time, geographical barriers, such as the absence or closure of rural pharmacies or the limited availability of specialised medicines in pharmacies, prevent patients from accessing them in a timely manner; not to mention consumer profiling and ad personalization techniques that encourage purchasing. In these contexts, online purchases open and alternative market as a temptation[12]. On this sense, Europe is not an exception[13].

The European Court of Human Rights has never ruled directly on counterfeit medicines, but it has recognised the positive obligations of States to ensure access to essential medical treatment under Articles 2 and 8 of the European Convention on Human Rights[14]. For its part, the Court of Justice of the European Union in the *Deutscher Apothekerverband vs. DocMorris* Case recognized that the sale of medicines online is compatible with freedom of establishment, provided that consumer protection and public health safeguards are maintained[15]. Within the European Union (EU), despite the existence of a sophisticated regulatory framework, counterfeit medicines continue to be offered to consumers; the European Commission has noted an upward trend in the distribution of counterfeit medicines, identifying the online environment as a particularly vulnerable sector[16]. Similarly, Europol has reported seizures of counterfeit medicines worth more than €11 million in coordinated operations in Member States (MS), highlighting the transnational dimension of the problem[17]. The connection between health and medicines has often been addressed from the perspective of access, but much less so from the perspective of service quality and safety.

This paper advances the hypothesis that enforcement model of European law structured around multiple approaches, alternative to the traditional command-and-control model, can enhance the State's effectiveness in preventing and combating the online trade of falsified medicines and medical products. A secondary objective is to examine how such enforcement model action may be strengthened through the ability of Member States to combine the European Union's normative framework with the ratification and enforcement of international instruments, thereby generating a more coherent, robust, and adaptive regulatory environment, capable of addressing the transnational dynamics of illicit digital markets.

This paper is divided into four sections: after this introduction setting out some preliminary definitions, such as the indissoluble link between medicines and the right to health as established by public international law, and how the sale of counterfeit or substandard medical products is a matter of concern for international organizations and must be prosecuted by States, the first section sets out the European Union's set of acts regulating the controls in the sale of medicines. Next, in the second part, in relation to the proceedings brought by the European Commission against AliExpress, the enforcement model established by the Digital Services Regulation is

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[11] Syed, Imran U and Milburn, Thomas W**,** 'Rethinking Counterfeit Medical Supply Chains: A Critical Review of the Current Literature' (2024) 3 *Health Care Science* 203–210, doi:10.1002/hcs2.97..

[12] Funestrand, Helena**,** Liu, Rui**,** Lundin, Sara and Troein, Margareta, 'Substandard and Falsified Medical Products Are a Global Public Health Threat: A Pilot Survey of Awareness Among Physicians in Sweden' (2019) 41(1) *Journal of Public Health* e95–e102, e95, doi:10.1093/pubmed/fdy092..

[13] See European Board for Digital Services, First Report of the European Board for Digital Services, in cooperation with the Commission, pursuant to Article 35(2) of the Digital Services Act, on the most prominent and recurrent systemic risks as well as mitigation measures, 18 November 2024, available at: https://ec.europa.eu/newsroom/dae/redirection/document/121707; see also, Gutorova, Nataliia; Pashkov, Viacheslav and Soloviov, Oleksandr, 'Illegal Internet Pharmacies as a Threat to Public Health in Europe' (2021) LXXIV(9 pt 1) *Wiadomości Lekarskie* 2173, doi:10.36740/wlek202109125 https://wiadlek.pl/wp-content/uploads/archive/2021/WLek202109125.pdf

[14] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR) arts 2 and 8. https://www.echr.coe.int/documents/d/echr/convention_eng

[15] Case C-322/01 *Deutscher Apothekerverband eV v DocMorris* NV [2003] ECR I-14887 ECLI:EU:C:2003:664. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62001CJ0322.

[16] DG Sante (2023) *Study supporting the report to the European Parliament and to the Council on trends in the falsification of medicinal products and measures provided according to Directive 2011/62/EU.* https://health.ec.europa.eu/publications/study-supporting-report-trends-falsification-medicinal-products-and-measures-provided-according_en.

[17] Europol, ´Europol warns consumers to be mindful about fake medicines offered online´ (Press Release, 2023). https://www.europol.europa.eu/media-press/newsroom/news/europol-warns-consumers-to-be-mindful-about-fake-medicines-offered-online.

critically examined; in the third section, the possible complementary regime between the DSA and the 2011 Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health is discussed. Finally, evaluative conclusions are presented regarding the enforcement procedure adopted by the DSA.

I. Legal Framework

The fight against counterfeit medicines is a prime example of shared competence between the EU and the MS. The Treaty on the Functioning of the European Union clearly defines this model: Article 4 recognises that the internal market and the protection of public health are areas in which both the EU and the MS can legislate and adopt legally binding acts[18].

In the field of public health, Article 168 TFEU states that the Union's action is limited to supporting, coordinating and supplementing national policies. However, paragraph 4(c) of the same article introduces a fundamental exception: the EU may adopt measures setting high standards of quality and safety for medicinal products and medical devices[19]. Since the beginning of the century, the EU has made use of its harmonising and unifying powers to develop a robust regulatory framework against counterfeit medicines, which basically consists of three instruments:

- Directive 2011/62/EU establishing a Community code relating to medicinal products for human use, with regard to the prevention of the entry of falsified medicinal products into the legal supply chain, introduced controls on active ingredients, recognising that falsification does not only affect the finished product, but can originate at the very basis of the medicinal product. Thus, active ingredients can only be introduced into European territory if they have been manufactured in accordance with manufacturing practices equivalent to those required by EU legislation. It also imposed on European importers and manufacturers the obligation to verify compliance with these conditions and to carry out regular audits of manufacturers and distributors, even when manufacturing takes place within the EU (recognized as, Know Your Customer -KYC-)[20].

- Delegated Regulation (EU) 2016/161 established the European system for verifying medicines based on unique identifiers and anti-tampering devices[21]. At the same time, Regulations (EU) 2017/745[22] and 2017/746[23] on medical devices and in vitro diagnostic medical devices strengthened traceability by requiring the inclusion of a unique device identifier and consolidated the obligation to report incidents and carry out post-market surveillance.

For their part, MS are responsible for authorising medicines –in collaboration with the EMA– inspecting manufacturers and distributors, controlling active substances entering their territory, monitoring the market and penalising infringements; national medicines agencies are also responsible for verification, auditing and control of the supply chain. Criminal penalties for counterfeiting medicines are also a national competence.

Broadly speaking, the end result consists of a unique identifier and a tamper-proof device; a common EU logo, with a hyperlink to national registers so that consumers can verify their legitimacy; a European Medicines Verification System (EMVS) supervised by the European Medicines Verification Organisation (EMVO) and

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[18] Treaty on the Functioning of the European Union [2016] C202/1, art 4. https://eur-lex.europa.eu/eli/treaty/tfeu_2016/art_4.
[19] TFEU [2016] C202/1, art 168. https://eur-lex.europa.eu/eli/treaty/tfeu_2016/art_168.
[20] Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products [2011] L174/1. https://eur-lex.europa.eu/eli/dir/2011/62.
[21] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use [2016] L 32/1, https://eur-lex.europa.eu/eli/reg_del/2016/161.
[22] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] L117/1, https://eur-lex.europa.eu/eli/reg/2017/745.
[23] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] L117/176, https://eur-lex.europa.eu/eli/reg/2017/746.

implemented at national level by National Medicines Verification Organisations (NMVOs). Inspections of manufacturers and distributors and customs controls are carried out to monitor the entry of active ingredients into the territory by national medicines agencies, which impose administrative penalties for infringements and may order the withdrawal of affected products and the closure of illegal distribution channels. In the MS, the classification of conduct related to counterfeit medical products is heterogeneous: some states have established specific offences against public health that directly punish the production or distribution of counterfeit medicines and devices; in others, such conduct is usually subsumed under general criminal offences of fraud, swindling or document forgery, without a specific autonomous offence. Not to mention those that have traditionally addressed it through trademark or patent infringement, considering it more of a commercial infringement problem than an attack on public health, reserving criminal proceedings for cases of aggravated intent or direct risk to life (Germany, Denmark, the Netherlands or Finland).

These classic measures for the verification and traceability of medicines adopted by the EU, although advanced, have become insufficient with the advent of VLOPs because they were designed for the classic authorised pharmaceutical chain: medicines travelled from laboratories to distributors and from there to pharmacies or hospitals; in general, the commercial channel was mapped out and controllable, while everything else was illegal and therefore traceable. However, in global digital marketplace environments, sellers are not subject to pharmaceutical regulations and physical traceability mechanisms are rendered ineffective, as it is not possible to verify the unique code at the point of sale. Furthermore, consumers no longer buy from physical pharmacies, but directly from remote sellers, often outside the EU, who offer products outside the legal channels. While the classic model acted against counterfeiting in the supply chain within the EU, on global platforms, many sellers are in third countries outside the jurisdiction of MS. We must not forget that the Internet is not a new paradigm for law, but it is an additional element of a new paradigm that requires a renewed legal logic that emphasises the vulnerability of human beings subject to the system, as well as the fragility of the system itself[24].

The EU has enshrined the right of access to preventive healthcare and medical treatment in accordance with national laws and practices in Article 35 of the Charter of Fundamental Rights of the European Union[25]. This provision places pharmaceutical regulation within a rights-based paradigm, ensuring that the EU's action in the field of public health is not merely a matter of regulatory technique, but also of the protection of fundamental rights. Of course, the issue of counterfeit or substandard medical products is a problem that can be extrapolated to many sectors, but in the case of counterfeit medicines, it constitutes a fundamental rights issue. Therefore, the right to health provides not only a normative basis but also a practical justification for stricter regulation of the digital pharmaceutical market.

To address the digital issue, the EU adopted Regulation 2022/2065 on the Digital Services Act (DSA)26, which imposes systemic risk management obligations, trader traceability and mechanisms for the swift removal of illegal content the DSA could become a central tool for the EU to control the circulation of illegal medical products in the digital environment, by imposing obligations of diligence, traceability, and control on online platforms, and by projecting these standards beyond Europe through the Brussels Effect[27], which reinforces its global impact. DSA is aligned with EU's interest to influence global health governance part of the strategic trajectory initiated by the 2010 Communication on the EU's role in global health, in which the Union set out to act as a responsible global player in promoting robust enforcement models, mitigating transnational risks, and protecting public health beyond its borders. Thus, the DSA operates as the digital dimension of that ambition, positioning the EU as a player in the fight against counterfeit or substandard medicines and in the construction of global health safety standards in online channels.

The issue of enforcing restrictions on the online sale of counterfeit or substandard medical products is an interesting question from the perspective of choosing an enforcement model. In order to address this issue, it is necessary to consider the intended objective of the legislation, whilst also taking into account the evolution in

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[24] Sorel, Jean-Marc, 'Internet et le Droit International: un étrange ballet sans chorégraphe' in *Société Française pour le Droit International*, *Colloque de Rouen: Internet et le Droit International* (Pedone 2014) 484.

[25] Charter of Fundamental Rights of the European Union [2012] C 326/391, art 35. https://eur-lex.europa.eu/eli/treaty/char_2016/art_35.

[26] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act) [2022] L 277/1. https://eur-lex.europa.eu/eli/reg/2022/2065.

[27] *Vid.* Bradford, Anu, *The Brussels Effect: How the European Union Rules the World* (Oxford University Press 2020).

the way counterfeit or substandard products – including medicines – have become a means of distributing medicines. Conventionally, the purpose of legislation has been to prevent, detect, punish and eliminate the manufacture, distribution, marketing and fraudulent introduction into the legal supply chain of counterfeit or substandard medicines, with an emphasis on traceability and action against manufacturers, distributors and pharmacies. This approach was adopted in Western European states, where enforcement was based on a classic model of "command-and-control enforcement". This model combined public administrative enforcement and criminal enforcement in the most serious cases, with an almost total absence of private enforcement, except for complaints of intellectual property infringement. This enforcement model facilitated a high degree of institutional coherence and centralised public authority in the states, which guaranteed uniformity of criteria, democratic legitimacy and direct control of the public interest. Furthermore, a preventive approach was promoted on the basis of prior marketing authorisation, laboratory approval and the granting of distribution licences. This approach limited the access of unauthorised products to the market and created an effective enforcement barrier against counterfeiting in a highly professional sector subject to strict standards of responsibility and professional ethics. The physical presence of the pharmacist, the control of prescriptions and sales in authorised establishments, and the generation of trust between the patient and the "health state" all act as verification and health filter mechanisms. Conversely, national medicines agencies and inspection services have coercive powers to withdraw products, revoke licences or impose sanctions. This deterrence-based approach to law enforcement is fundamentally based on the position that penalties must be of such a nature and magnitude that the anticipated costs for the perpetrator outweigh the anticipated benefits[28]. However, the "command and control" approach, in which the state is highly interventionist[29], suffered from national fragmentation and limited cross-border cooperation. Moreover, with the advent of e-commerce, the available resources were limited, the number of inspectors was small, and the technological tools were more oriented towards the role of dispensing control systems than as a primary source of data for analysis.

The advent of e-commerce, the dematerialisation of the sales channel and the platformization of e-commerce have precipitated a shift in the objectives that legislation must address. It is incumbent upon online retailers to adopt effective measures to prevent, detect and eliminate the supply, promotion or sale of counterfeit or substandard medicines and medical products in their services, ensuring that consumers have access only to standard-quality products at competitive prices that can be dispensed through virtual channels. In addition, online retailers must ensure patient information is preserved and public confidence is maintained in the digital ecosystem and health authorities. Furthermore, online retailers must protect the right to health against the risks arising from illicit online trade and promote health education. In light of these considerations, it would be prudent to re-evaluate the efficacy of the command-and-control enforcement model in this particular scenario.

Enforcement model literature has developed alternative models that seek greater efficiency, adaptability and cooperation between actors. Among the most significant of these is the concept of "responsive regulation", a term coined by Ian Ayres and John Braithwaite in their seminal work "*Responsive Regulation: The present study transcends the discourse surrounding the deregulation debate*"[30], proposing a tiered compliance system that is predicated on two fundamental tenets. Firstly, the system is based on initial cooperation with regulated entities. Secondly, it is predicated on the progressive application of sanctions, only in the event of persistent non-compliance. This approach was superseded by more complex models, such as tripartite enforcement or the "tripartite model", which was conceptualised by Robert Baldwin and Julia Black[31]. In this model, regulatory compliance is coordinated between public authorities, regulated entities, and interested third parties (civil society, professional associations, or consumers) within a framework of shared governance. Digitalisation has given rise to the use of technological or algorithmic enforcement, whereby enforcement is transferred to automated detection, filtering or traceability systems. These systems integrate the principles of "regulation by design"[32] and

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[28] *Vid.* Voermans, Wim, 'Motive-Based Enforcement' in Sergey Kabyshev and Luzius Mader (eds), *Regulatory reforms – Implementation and Compliance* (Nomos 2014), doi:10.5771/9783845244228.

[29] *Vid.* Aalders, Maarten and Wilthagen, Ton, 'Moving Beyond Command-and-Control: Reflexivity in the Regulation of Occupational Safety and Health and the Environment' (1997) 19(4) *Law & Policy*, doi:10.1111/1467-9930.t01-1-00034.

[30] *Vid.* Ayres, Ian and Braithwaite, John, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press 1992) https://johnbraithwaite.com/wp-content/uploads/2016/06/Responsive-Regulation-Transce.pdf.

[31] *Vid.* Black, Julia and Baldwin, Robert, 'Really Responsive Risk-Based Regulation' (2010) 32(2) *Law & Policy* 181–213, doi:10.1111/j.1467-9930.2010.00318.

[32] *Vid.* Lessig, Lawrence, *Code and Other Laws of Cyberspace* (Basic Books 1999).

"data-driven compliance"[33], with technology becoming a direct instrument of enforcement, investigation and verification of non-compliance and compliance respectively.

Despite the prevailing legal doctrine that categorically insists on demonstrating the ineffectiveness of alternative models compared to the classic command-and-control model for achieving compliance, certain aspects seem to reinforce its suitability in some aspects of the fight against counterfeit and substandard medicines. To this end, firstly we must define as an effective enforcement model the integrated set of institutional, technological, and operational measures aimed at preventing, detecting, interrupting, and punishing the digital circulation of products that compromise the safety, health, and rights of patients or consumers, while ensuring the protection of the rights of legitimate owners and the preservation of integrity and reliability in the pharmaceutical market.

The ensuing section undertakes an analysis of the enforcement procedure applied by the DSA in relation to counterfeit or substandard medical devices and medicines in VLOPs.

II. Enforcement procedure

The DSA entered into force on 16 November 2022 and has been fully applicable since 17 February 2024. It establishes a horizontal framework of due diligence obligations for intermediary service providers, ranging from mere conduits to hosting and online platforms, with responsibilities graded according to size and social impact. It constitutes a special law applicable to VLOPs, defined as having more than 45 million users in the EU, which are subject to enhanced obligations. This is a very interesting point for two reasons: Firstly, because we are faced with a partial regime that establishes a model for addressing the health risks posed by counterfeit or substandard medicines and products exclusively found on VLOP, while in the rest of the digital environment, the regulation model differs[34]; secondly, because we know that regulation tend to displace non-compliers to unregulated spaces, which means that the DSA will probably cause a shift of counterfeit medicines from VLOP to smaller platforms.

In terms of institutional design, it has been observed that the European legislator opts for a design based on networks of national authorities when seeking a good level of expertise on the ground, and that this model tends to work when the EU's regulatory powers are highly developed but its operational capacities are particularly weak[35]; it has also been observed that execution and enforcement powers are more appropriately placed at national level. Enforcement of the DSA follows a multi-level model: national digital services coordinators oversee compliance at ME level, while the European Commission retains enhanced powers over VLOPs. This seems to be in line with the health rationale behind the DSA regime, according to which, given the magnitude of the social, economic and health impact of these platforms, supranational oversight is necessary to ensure uniformity in the application of the rules and to strengthen health protection and trust in pharmaceutical market.

The procedure begins with the assessment of information obtained from both routine monitoring and reliable sources, including mandatory transparency reports that platforms must publish periodically, independent audits and complaints received through the complaints system set up by the DSA itself. This first phase is not merely descriptive but forms the basis on which the Commission assesses whether there are indications of non-compliance that warrant stricter control. In October 2023, the Commission exercised these powers for the first

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[33] The notion of data-driven compliance comes from formulation of algorithmic regulation (*Vid.* Yeung, Karen, 'Algorithmic Regulation: A Critical Interrogation' (2018) 12 *Regulation & Governance* 505–523, doi:10.1111/rego.12158.) insofar as it applies the same data-intensive and continuously monitored architectures to internal compliance processes. While algorithmic regulation operates as a general model for influencing behaviour through algorithmic systems, data-driven compliance translates this logic into organizational compliance practices, aimed at anticipating risks and ensuring conformity with applicable norms.

[34] Outside the VLOP regime, action against falsified or substandard medicines and medical products sold online is articulated through a fragmented and essentially national regulatory framework, based on Directive 2001/83/EC (as amended by Directive 2011/62/EU), Regulations (EU) 2017/745 and 2017/746, Regulation (EU) 2019/1020 on market surveillance and the complementary use of criminal law (including the MEDICRIME Convention), without equivalent obligations for systemic risk assessment and structural mitigation measures, and whose implementation depends largely on the capacities and practices of the competent national authorities, generating significant asymmetries between Member States; As a result, their attractiveness is only outweighed by VLOPs, given their larger size, to the extent that they do not effectively implement the regulation provided for in the DSA.

[35] Van Kreij, Laurens, 'The Choice of EU Agencies or Networks of National Authorities: Exploring the Relevance of Regulated Industry Characteristics' in Miroslava Scholten (ed), Research Handbook on the Enforcement of EU Law (Edward Elgar 2023) ch 11, 167–184, doi:10.4337/9781802208030.00020.

time, sending requests for information to several VLOPs, underlining the preventive importance of the instrument and its potential for sanctions in the event of resistance or concealment[36].

Providers of very large online platforms shall diligently identify, analyse and assess any systemic risks in the Union stemming from the design or functioning of their service and its related systems, including algorithmic systems, or from the use made of their services but also preventive and mitigation plans (Art. 34 and art. 35 DSA). It is certainly questionable whether responsive regulation is the best route the EU could have taken to ensure compliance with the requirements of article 34 DSA regarding any actual or foreseeable negative effects in relation to the protection of public health considering the size and influence of the regulated targets, and we will certainly encounter passionate opposition from believers in the command-and-control model. Nevertheless, some aspects are interesting to consider for debate:

- The doctrine has identified a lack of awareness and knowledge among patients and healthcare professionals regarding the risks associated with substandard and counterfeit medicines as a significant obstacle, also the trend towards self-diagnosis and self-treatment. It indicates that education on the dangers is a fundamental tool for saving lives and preventing harm. While the command-and-control model has required the industry to include informational messages on certain products -a good example would be warnings about side effects in medicine leaflets or about the consequences of tobacco use on cigarette packets- the results of its educational campaigns have been costly, limited and questionable. However, a responsive regulation model requiring compliance with information measures prior to online medical product purchases, developed by patient associations, the pharmaceutical industry, universities, or the state itself, could be useful in prevent ion efforts. This would be reinforced by the fact that VLOPs would indirectly benefit from such actions.
- New and existing technologies can be integrated into frameworks to strengthen patient protection, especially in light of criminals' ability to exploit systemic flaws. Although tools such as accreditation seals for e-pharmacies were conceived as safeguards built into the very design of the digital ecosystem, evidence shows that these mechanisms have been exploited to confer an appearance of legitimacy on sites that do not meet security standards, taking advantage of consumer trust, online anonymity, the ease of replicating sites and accounts after closures or suspensions, and the inadequacy of automated verification systems. Technologies such as blockchain[37], intelligent traceability systems, and data-driven analytical models are considered tools that will enable enforcement controls to be integrated directly into the architecture of the online supply chain, enabling continuous monitoring based on behaviour patterns, risk signals, and predictive analytics. This shows that no single approach is sufficient and that a coordinated combination of “command-and-control” regulation with “regulation by design” and “data-driven regulation” is required.
- The use of medicines for off-label purposes and access to medicines without the required medical prescription has experienced an unprecedented boom in recent times, increasing the use of unauthorised products for online sale, substandard products or products of unverified quality in VLOPs. Self-regulated verification solutions -through the uploading of certificates- are proving insufficient, opening up the possibility of an enforcement model in which European professional bodies and medical associations but also national are invited to perform guarantee, monitoring, and control functions. It is hoped that this combination of actors will provide a more effective model from a prevention perspective.

This corresponds closely with the first-order regulatory model put forward by Ayres and Braithwaite, which promotes direct interaction between regulators and the addressees of regulation in order to promote compliance through the least intrusive response that is feasible and acceptable. If such a response fails to achieve the desired results, the regulator should progressively escalate toward more intrusive measures. In this sense, the requests for information provided for in Article 67 DSA are one of the most relevant investigative mechanisms. They are not limited to gathering data but are a real instrument of enforcement pressure: Article 74(2) DSA provides that, in the event of incomplete, incorrect or misleading responses, the Commission may impose penalties of up to one per cent of the infringing platform's global annual turnover[38]. This framework was designed to ensure that large

[36] European Commission, *Digital Services Act: Commission sends first requests for information to VLOPs and VLOSEs* (Brussels, October 2023). https://digital-strategy.ec.europa.eu/en/news/commission-sends-requests-information-17-very-large-online-platforms-and-search-engines-under

[37] Jiang, Jiahua and Chen, Jian, ‘Managing the Product-Counterfeiting Problem with a Blockchain-Supported E-Commerce Platform’ (2021) 13 *Sustainability* 6016, doi:10.3390/su13116016.

[38] Regulation (EU) 2022/2065 on a Single Market for Digital Services (Digital Services Act) [2022] OJ L277/1, art 74(2).

platforms could not trivialise the obligation to cooperate or delay the provision of information essential for supervision.

Although not immediate, the failure of the addressee to provide a diligent response triggers a logic of regulatory escalation in accordance with the model developed by Ayres and Braithwaite. This involves the regulator moving from cooperative mechanisms towards progressively more restrictive institutional arrangements and governance principles, thereby gradually reducing the margin of freedom of the regulated entity. Ultimately, command-and-control frameworks are approached if non-compliance persists. From a preventive perspective, this model remains effective provided the addressee of the regulation understands the need to adopt clear and decisive compliance measures. In the health sector, this means demonstrating a genuine willingness to comply with obligations promptly and proactively, in order to avoid the need for more intrusive enforcement measures.

The practical application of this scheme is clearly seen in the case of AliExpress, designated as a VLOP on 25 April 2023[39]. Pursuant to this designation, the company submitted a risk assessment report in accordance with Article 34 DSA, the purpose of which was to identify the systemic risks arising from the dissemination of illegal content, threats to public health and possible manipulations of its service. However, after reviewing it, the Commission considered that the report was insufficient, as it did not accurately or comprehensively reflect the extent of the risks identified. In the same year, the Commission opened preliminary investigations into several digital platforms for alleged infringements related to the sale of counterfeit goods.

With regard to AliExpress, on 6 November 2023, the Commission activated Article 67 DSA and sent a formal request for information regarding the measures taken against the marketing of illegal products, including counterfeit medicines and vitamin supplements. The warning was explicit: failure to respond adequately could result in penalties under Article 74 DSA. This step is representative of how the procedure combines prevention and enforcement: the Commission does not merely demand passive cooperation but imposes on VLOPs the obligation to show verifiable results in the detection and mitigation of risks.

If, after these preliminary stages, the Commission suspects that there has been a breach, it is empowered to open a formal investigation, deploying all its powers of control. This may include interviews with company officials, additional requests for information, physical inspections of premises, or even requests for direct access to algorithms and internal systems. In the case of AliExpress, a formal procedure was opened on 14 March 2024 under Article 66 DSA[40]. The investigation focused specifically on the systemic risks associated with the dissemination of illegal products and the presence of counterfeit and unauthorised medicines, unsafe food supplements and other non-compliant consumer goods on the platform.

The case against AliExpress covered a wide range of possible regulatory violations: systemic risk management and mitigation (Articles 34 and 35 DSA), content moderation and reporting system obligations (Articles 14–17), internal redress mechanisms (Articles 20–21), transparency in advertising and recommendation systems (Articles 24 and 27), traceability of traders (Article 30), and access to data for investigators (Article 40)[41]. In this way, the Commission sought to analyse not only whether AliExpress complied with specific obligations, but also whether it had failed to build a structural compliance ecosystem, which was the spirit of the DSA.

At the procedural level, the objective of these investigations is to gather consistent evidence to determine whether there has indeed been a breach of the regulatory framework. However, the DSA grants the Commission additional powers: if it considers that there is urgency due to the risk of serious harm to users, it may adopt provisional measures (Art. 70 DSA), which must be proportionate and temporary[42]. These may include immediate adjustments to recommendation systems, the establishment of enhanced keyword controls, or the issuance of specific orders to remove illegal content.

Once the investigation phase is complete, if there is still evidence of non-compliance, the Commission is empowered to initiate formal proceedings, guaranteeing the VLOP in question the right to be heard on the preliminary findings, in accordance with Article 79 DSA. At this point, the supervisory authority must balance

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[39] European Commission, *Commission designates AliExpress as Very Large Online Platform under the DSA* (Brussels, 25 Abril 2023). https://digital-strategy.ec.europa.eu/en/news/commission-designates-very-large-online-platforms-and-search-engines-under-digital-services-act.

[40] European Commission, *Request for Information to AliExpress under the Digital Services Act* (Brussels, 6 November 2023). https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5678.

[41] DSA Regulation Arts 14–17, 20–21, 24, 27, 30, 40. https://eur-lex.europa.eu/eli/reg/2022/2065.

[42] Regulation (EU) 2022/2065 on a Single Market for Digital Services (Digital Services Act) [2022] OJ L277/1, art 70.

the principle of proportionality with the need to preserve the effectiveness of the rule, ensuring that decisions are based on solid evidence and that penalties have a deterrent effect.

On 18 June 2025, the Commission published its preliminary findings regarding AliExpress, concluding that the platform had failed to comply with its obligations under the DSA to address systemic risks[43]. The report argued three specific shortcomings: first, AliExpress did not adequately enforce its sanctions policy against merchants who repeatedly published illegal content; second, its content moderation systems had structural flaws that made them vulnerable to manipulation by malicious actors; and third, it had underestimated the risks associated with illegal products by allocating insufficient resources to its moderation systems, thereby reducing its ability to prevent the spread of such products.

It should be noted that one day earlier, on 17 June 2025, AliExpress submitted a package of commitments under Article 71 DSA, which was accepted by the Commission and made binding[44]. The measures committed to included: strengthening verification, monitoring and detection systems to counter risks related to "hidden links" leading to illegal products (including medical products); increasing the effectiveness of internal sanctions against sellers who repeatedly violated the platform's policies; improving transparency in advertising and recommendation systems; strengthening the traceability of merchants; facilitating researchers' access to relevant public data through APIs, customised datasets and authorised scraping; improving “notice & action” mechanism and the internal complaints system; introducing additional external controls carried out by specialised third parties; and creating a monitoring framework with an independent Monitoring Trustee, responsible for issuing regular reports for at least five years.

The Commission's acceptance of commitments does not imply the end of the formal procedure. In the absence of official information on the holding of the hearing provided for in Article 79 DSA, it must be understood that the adversarial phase is still ongoing. In any case, the DSA establishes a severe and graduated penalty regime. In the event of an infringement, the Commission may impose fines of up to six per cent of the annual global turnover of the infringing platform (Art. 74.1), penalty payments of up to five per cent of the average daily global turnover for each day of delay in implementing measures (Art. 76), and, in extreme cases, even request a national court to temporarily suspend the service within the EU (Art. 82)[45].

The determination of penalties requires an assessment of a number of factors: the nature and gravity of the infringement, the provisions infringed and their relevance to the protection of public health, safety, fundamental rights and consumers; the duration of the infringement, since Article 74 DSA establishes that persistence is an aggravating factor; the geographical scope and number of users affected; and the attitude of the platform during the proceedings, distinguishing between active cooperation -such as the submission of commitments in accordance with Article 71- or obstructive behaviour, such as the concealment of information or recidivism. The economic capacity of the company is also taken into account, in so that the six per cent cap seeks to ensure proportionality and a deterrent effect based on the size of each operator[46].

However, a careful analysis of the commitments communicated by AliExpress in the context of the formal investigation opened by the European Commission reveals significant limitations in relation to the circulation of counterfeit or non-compliant medical products. Among the most notable shortcomings is the absence of quantifiable metrics to verify the number of illegal product removals in the healthcare sector, which makes it difficult to assess the real impact of the measures. Furthermore, the platform did not establish an automatic penalty system for repeat offenders specialising in the distribution of counterfeit medicines, maintaining broad discretion that weakens the deterrent function of the regulations. Nor did it commit to integrating European trader traceability systems under KYC standards, which are essential for tracing the origin of active ingredients and pharmaceutical batches. Similarly, no structured cooperation with EU drug regulatory networks or the EMA was envisaged,

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[43] European Commission, *Commission makes AliExpress' commitments under the Digital Services Act binding* (Brussels,18 June 2025) https://digital-strategy.ec.europa.eu/en/news/commission-makes-aliexpress-commitments-under-digital-services-act-binding.

[44] European Commission, *Commission accepts commitments offered by AliExpress under the DSA* (Brussels, 17 June 2025) https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1551.

[45] Regulation (EU) 2022/2065 on a Single Market for Digital Services (Digital Services Act) [2022] OJ L277/1, arts 74–76 y 82. https://eur-lex.europa.eu/eli/reg/2022/2065.

[46] Regulation (EU) 2022/2065 on a Single Market for Digital Services (Digital Services Act) [2022] OJ L277/1, arts 74. https://eur-lex.europa.eu/eli/reg/2022/2065.

depriving the system of a formal channel for exchanging safety alerts. Finally, no timetable for implementation was set, which reduces the ability to monitor the effectiveness of public health commitments.

These limitations are part of the broader framework of information asymmetries that characterise the application of the DSA. The regulation relies heavily on self-declarations by platforms and on the compliance reports they produce themselves, which creates the risk of insufficient transparency. Although Articles 51–67 of the DSA confer investigative powers on the Commission -including requests for information, audits, and access to systems- in practice, operators often restrict or modulate access, which can make oversight a partial exercise if effective technical control is not ensured. In this context, the AliExpress case offers a relevant nuance: the package of commitments accepted by the Commission on 18 June 2025 expressly included a commitment to offer "access to public data for researchers", to enable a dedicated API for eligible researchers and to create customised datasets on request[47]. These elements aim to enhance transparency in research on systemic risks, but they do not replace the need for verifiable data on the removal of counterfeit medicines.

In the absence of verifiable metrics, authorities lack a solid empirical basis for measuring the real impact of measures to withdraw illegal medicines. The lack of automatic sanctions for repeat offenders undermines the deterrent effect and encourages the repetition of illegal behaviour. The failure to integrate KYC systems makes it difficult to trace traders who reopen accounts with fictitious identities, weakening compliance with Article 30 DSA. The lack of cooperation with agencies such as the EMA deprives the Commission of real-time access to pharmacovigilance alert databases and trends in the counterfeiting of active ingredients. Furthermore, the refusal to open algorithmic or advertising systems limits the ability to detect sophisticated concealment practices, such as hidden links that redirect to illegal products, reducing the value of the supervision provided for in Articles 51–67 DSA. Taken together, these shortcomings compromise the practical effectiveness of digital control in an environment marked by the rapid circulation of products and the ease of replicating fraudulent identities.

This situation has two main consequences. Firstly, even if the system is based on an alternative model to command and control, providing for a progressive escalation of sanctioning measures, it is essential to maintain focus on optimising the factors that allow for the most effective achievement of the ultimate objective of health protection. While the analysis of these factors and the behaviour of the different actors involved has been addressed in general terms by scientific doctrine and in some specific sectors[48], it seems necessary for future research to further investigate the particularities of action against counterfeit or substandard medicines and medical products marketed through VLOPs. Secondly, it is advisable to provide the system with additional instruments that allow progress to be made in mitigating the health risks associated with these products. This should include the intervention of criminal law in a manner that does not conflict with the chosen institutional design. These additional instruments should address spaces outside the strictly regulated sphere, both from a preventive perspective and in the face of possible displacements of illegal actors towards platforms not qualified as VLOPs, as mentioned above. They should also communicate to regulated -and reluctant[49]- subjects the existence of a firm political conviction capable of reinforcing and multiplying the effects of the prevention and mitigation measures required of them.

The following section will address the adoption of complementary and parallel mechanisms to the DSA as a countermeasure against counterfeit and substandard medicines, in particular the MEDICRIME Convention.

III. Complements to DSA regulation: MEDICRIME Convention.

In September 2025, the EMA and some national authorities warned of a significant upturn in the online sale of illegal medicines marketed -not specifically mentioned on AliExpress- as GLP-1 receptor agonists -including semaglutide, liraglutide and tirzepatide- commonly used for weight control and diabetes and frequently found on the WHO's lists of counterfeit medicines[50].

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[47] European Commission, *Commission makes AliExpress' commitments under the Digital Services Act binding* (18 June 2025) https://digital-strategy.ec.europa.eu/en/news/commission-makes-aliexpress-commitments-under-digital-services-act-binding.

[48] Scholten, Miroslava, 'Challenges and Successes of Enforcement of EU Law' in Miroslava Scholten (ed), *Research Handbook on the Enforcement of EU Law* (Edward Elgar 2023) ch 33, 525–538, doi:10.4337/9781802208030.00043.

[49] Gorwa, Robert; Lechowski, Grzegorz; Schneiß, Daniel, 'Platform lobbying: Policy influence strategies and the EU's Digital Services Act' [2024] 13(2) Internet Policy Review, p. 3. Available at: https://doi.org/10.14763/2024.2.1782.

[50] EMA, *Warning about sharp rise in illegal medicines sold in the EU* (3 September 2025). https://www.ema.europa.eu/en/news/warning-about-sharp-rise-illegal-medicines-sold-eu.

Counterfeit medical products advertised on VLOP usually enter the European market through cross-border e-commerce, taking advantage of gaps in the control of low-value parcels. In practice, sellers based mainly in Asia publish offers that are sometimes camouflaged by "hidden links" or misleading descriptions, and shipments reach the end consumer in fragmented, small packages that often pass-through customs without inspection thanks to undervaluation or false product categories. In other cases, intermediate warehouses within the EU (fulfilment centres) are used, which speeds up redistribution and makes it difficult to trace batches.

The DSA is a new-generation regulatory framework whose effectiveness depends on its ability to interconnect functionally and normatively with other EU and EM instruments. In this context of connection with other instruments of judicial and police cooperation, the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (MEDICRIME)[51] takes on renewed relevance.

MEDICRIME represents a milestone in the international criminal codification of the right to health. Its development responded to the need to provide the European area with a binding legal instrument to combat the transnational phenomenon of counterfeit medical products -it does not cover unsafe food supplements-. Adopted in 2011 and in force since 2016, the Convention establishes a comprehensive framework for judicial, police and health cooperation aimed at harmonising the criminal laws of the States Parties, strengthening the traceability of medical products and closing existing jurisdictional gaps.

The main objective of MEDICRIME is to ensure the protection of public health by criminalising the most serious offences related to the counterfeiting, manufacture or illegal distribution of medical products -The Convention obliges States Parties to criminalise the manufacture, supply and offering of counterfeit medical products, to incorporate procedural and victim protection measures, and to establish an advanced system of international cooperation covering extradition, mutual legal assistance and the exchange of information between national authorities and international organisations such as the WHO and Interpol.

Despite its substantive relevance , the Convention has been ratified by only 23 States, of which only six are Member States (Spain, Hungary, Belgium, France, Portugal and Croatia); however, eight others MS have already sign it[52]. Among the reasons for this limited adherence are the perception of overlap with EU regulations, the technical difficulties of criminal legislative adaptation[53] and the low political visibility of the phenomenon, although the latter aspect could change when the data extracted from the VLDP' APIs begin to be analysed.

MEDICRIME's potential as a complementary instrument to the DSA is significant: *Firstly*, because MEDICRIME promotes a uniform framework for criminalization that does not yet exist in all MS' domestic legal systems, closing gaps in the regulatory landscape. *Secondly*, because while the DSA focuses on the responsibility of digital platforms and the establishment of risk management, traceability and cooperation obligations (Articles 34–35, 30 and 40 DSA)[54], the MEDICRIME Convention provides MS with a common criminal law instrument to prosecute sellers and manufacturers operating within or outside the EU[55]. This would strengthen the effectiveness of the digital framework, ensuring that the moderation and removal obligations provided for by the DSA can be accompanied by sanctions against fraudulent actors. *Fourthly*, because it would promote international cooperation in judicial and police in health matters (Articles 22–26 MEDICRIME), facilitating the exchange of information with third countries -and with organizations such as the WHO- which is essential given the cross-border nature of sales on platforms[56]. Fifthly, because MEDICRIME has potential to expand criminalization of counterfeit medicines to another regions -especially center and south America area-. Finally, because aalthough MEDICRIME was not specifically designed as an instrument of cybercrime law, technological developments and

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[51] Council of Europe, *Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (MEDICRIME Convention)* (CETS No 211). https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=211.

[52] Council of Europe, *Status of signatures and ratifications of the MEDICRIME Convention* (updated 2025).

[53] Frolova, Olga, 'Circulation of Falsified Medicinal Products and Medical Devices under the Medicrime Convention: Problems of Defining the Concept and Scope of Application' (2023) 2(2) *Political and Legal Studies* 103–109, 107, doi:10.15804/CPLS.2023208.

[54] Regulation (EU) 2022/2065 on a Single Market for Digital Services (Digital Services Act) [2022] OJ L277/1, arts 34–35, 30 and 40. https://eur-lex.europa.eu/eli/reg/2022/2065.

[55] Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention) (CETS No 211), arts 8–9 https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=211

56 Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention) (CETS No 211), arts 22–26 https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=211

the digitisation of the illicit trade in healthcare products have made cyberspace the main operational arena for the crimes covered by the Convention. MEDICRIME not use the term cybercrime, but it anticipated a technological dimension by imposing in Article 17 the obligation to adopt effective investigation and evidence-gathering measures, including data preservation and cooperation with service providers. This provision is similar to the Budapest Convention on Cybercrime[57], particularly Articles 16–21 concerning the preservation of computer data and cross-border cooperation. The convergence between the two treaties allows us to interpret that MEDICRIME complements the Budapest Convention in the health sector, providing a specialised substantive criminal framework, while the Budapest Convention provides the procedural and digital cooperation instruments necessary for its effective implementation. On this way, the sale of substandard insulin analogues or GLP-1 receptor agonists on unauthorised place sited outside EU on a VLDP could be preventive and regulatory sanctioned by the DSA, punished by ES criminal jurisdiction prosecuted by MEDICRIME (Articles 5–8), while investigation techniques and inter-state cooperation are covered by Budapest Convention.

Although the EU cannot directly ratify the MEDICRIME Convention, as it is a Council of Europe treaty open only to states, it could play a key role in promoting it among MS through soft law instruments, politically encouraging their accession and highlighting its consistency with the European acquis in the areas of public health, the internal market and the fight against counterfeiting. This would make it possible to partially overcome the limitations of the purely digital regime of the DSA, creating a comprehensive framework for digital health governance that combines regulatory control and coordinated criminal prosecution.

IV. Conclusion

Access to medicines is not explicitly recognised as an autonomous right within the international human rights protection system. Nevertheless, various treaty instruments, as well as the interpretative and monitoring acts of specialised bodies, have affirmed its inseparability from the right to health. This broad interpretation means access to medicines can be considered a key part of achieving the highest possible standard of physical and mental health. It also means regulatory action in this field is a particularly important area for analysis in terms of models for enforcement European law.

The international system has specified the qualitative characteristics that medicines must meet, particularly emphasising quality, safety, efficacy and availability — indispensable parameters in accordance with WHO standards. Nevertheless, contemporary developments reveal mounting tensions between these requirements and current market dynamics, with rising prices and decreasing accessibility — particularly for vulnerable populations and patients requiring long-term treatments — continuing to test the limits of traditional, rule-based enforcement mechanisms.

Counterfeit medicines not only violate intellectual property rights, but also threaten public health through the circulation of substandard or adulterated medicines, altered or absent active ingredients, placebo products and non-compliant medical devices. For this reason, acting against such products is an instructive case study for evaluating the effectiveness of different models for enforcement European law. This reveals the limitations of traditional command-and-control strategies and the potential of responsive, data-driven and hybrid approaches, particularly from a preventive perspective.

The emergence of very large online platforms (VLOPs) has radically transformed access to products, purchasing decisions and consumption patterns. While this transformation affects all economic sectors, it generates heightened and differentiated risks in the health sector that require enhanced forms of oversight. Digital platforms have strong economic incentives to host medical products due to their high demand and capacity to generate secondary consumption flows. In this context, data-driven monitoring, algorithmic risk assessment and iterative compliance tools can meaningfully complement traditional models.

Against this background, the DSA is the EU's regulatory response to a pharmaceutical verification and traceability system that has been overtaken by digitalisation and global e-commerce. Since its entry into force, the European Commission has initiated enforcement actions against several large platforms, most notably proceedings against AliExpress for hosting counterfeit medicines and nutritional supplements. This pilot case illustrates the operational logic of enforcement under the DSA, with procedures centred on requests for information, independent audits, proportionate sanctioning powers and negotiated compliance commitments. This reflects an approach to

[57] Council of Europe, *Convention on Cybercrime (Budapest Convention)* (CETS No 185, 2001) https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=185.

the enforcement of European law that deliberately moves beyond strict command and control, while seeking to maximise preventive capacity and systemic correction.

Considering its transformative ambition, the DSA's effectiveness in addressing counterfeit medicines could be enhanced by the shared competences of the Union and Member States in internal market and public health matters. Consequently, the decentralised and cooperative implementation of its control mechanisms requires structured coordination with national health authorities and criminal enforcement bodies.

In this respect, it is essential for the DSA to strengthen its interaction with other regulatory and institutional instruments at EU and Member State levels. The Council of Europe's MEDICRIME Convention, which aims to promote harmonised criminal classifications and enhanced international cooperation among judicial and law enforcement authorities, acquires renewed relevance in this context. Despite its limited ratification to date, the Convention represents a paradigmatic example of institutional coherence and complementarity in the implementation of European law within a multilevel legal framework. It illustrates how Union law, together with international and national instruments, can produce mutually reinforcing effects that strengthen preventive action and the protection of fundamental rights in the fight against counterfeit medical products.

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