

Regulating Online Pharmacies: International & EU Law

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Outline

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Introduction

- What are online pharmacies?
- Types of online pharmacies:
 - Traditional online pharmacy
 - Prescribing-based site pharmacy
 - Rogue pharmacy
- Benefits of Online Pharmacies:
 - Convenience
 - Availability
 - Privacy
 - Price competition

Dangers of some types of Online Pharmacies

- Illegal pharmaceutical industry is growing
 - Consumer's difficulty distinguish legal/rogue pharmacy
 - Consumers have easy access to low-quality, expired, counterfeit, unapproved medicines
 - No limits on quantity bought; possibility of increased antibiotic resistance arising from their misuse;
 - Risks consumers' privacy violations when dealing with online pharmacies
 - Medicines purchased from foreign sites may have incorrect and dangerous labelling and packaging
 - There may not be a patient-physician relationship
- Examples:
 - Obtaining weight loss medication from online pharmacy by inputting the information of a seven-years-old child into the website;
 - Obtaining Viagra for a cat from online pharmacy (castrated)

Ezafun

Legal Challenges Online Pharmacies

- National level: Diversity regulatory systems
- Deficiency in effective regulation: websites and suppliers can be located in different countries from customers (jurisdictional limits)
- Need for international action

Jurisprudence Online Pharmacies EUCJ: *DocMorris* case (C-322/1, 2003)

- The case concerned the provision of prescription and non-prescription pharmaceuticals in Germany by the DocMorris company, which was established in the Netherlands but did much of its trade in Germany. DocMorris was taken to the EU Court of Justice following an accusation of illegal practice by the German Association of Pharmacists. Pharmaceuticals could be ordered from the company in several ways, including telephone, fax and online. Some products offered by the company were ‘prescription-only’ in either Germany or the Netherlands.
- EUCJ: “Member States may not prohibit the sale of *non-prescription* medicines (OTC medicines) on the Internet“
- Thus, the court notes that a Member State may prohibit the distance selling of *prescription* medicines: diverse picture in 28 MS

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Legal Framework Online Pharmacies: EU Law

- Art. 168(7) TFEU
- EU free movement principles (EU Treaty)
- Directive 2011/24/EU on CBC
 - Art. 11: ePrescriptions
 - * Mutual recognition CB prescriptions
 - * Exceptions
 - * Reimbursement
- Advantages: accessible to health providers, patient and HIF; Information & comparing prescription behaviour; fully operational in Scandinavian countries
- Interoperability ePs (Directive 2012/52/EU)
- Cross-border sale of medicines; towards an open EU online market?

Latest Developments: Fighting Counterfeits

- Track and trace system (Tackle counterfeiting life-saving medicines: Directive 2011/62/EU)
- Buying medicines online: common EU logo (Art 85c, Reg. 699/2014)



- Online retailers registered with national authorities EU MS (Dir 2011/62/EU)
- eCommerce Directive (online contracting, eg medicines)

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International Approaches: WHO and Counterfeits

- WHO's "soft-law" tools:
 - WHO Guidebook *Medical Products and the Internet*
 - International Medical Products Anti-Counterfeit Taskforce ('IMPACT') presenting 'guiding principles for model legislation'

A stylized, handwritten-style logo for Erasmus, featuring a large, flowing 'E' followed by the word 'Erasmus' in a cursive script.

International Approaches (2): INTERPOL

- Law enforcement agencies
- INTERPOL & the fight of counterfeit medicines
- Pharmaceutical crime as a global problem
- Primary trend: increased use of illicit online pharmacies operated by transnational criminal groups
- INTERPOL's Response: Operation Pangea IX (2016)

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Council of Europe: “Medicrime Convention” No. 211 (2011)

- 1-1-2016
- First international criminal law instrument to oblige States Parties to criminalise:
 - the manufacturing of counterfeit medical products;
 - supplying, offering to supply and trafficking in counterfeit medical products;
 - the falsification of documents;
 - the unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements.
- Framework for national and international co-operation
- Foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties
- Limited ratifications so far (8)

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Discussion

- Diversity regulatory and policy mechanisms online pharmacy
- Need for cohesive international legal framework enforcing this domain
- Towards a UN Framework Convention on Internet Pharmacy
- Content of the Framework Convention:
 - Global instrument (“Medicrime Convention”)
 - Differentiate types of online pharmacies, targeting ‘rogue pharmacies’
 - Setting standards for prescription medicines online (COMPACT)
 - Registration
 - Central Database
 - Disclosure essential information website
 - Reporting ‘dangerous substances’ dispensed
 - In-person doctor-patient examination required
 - International enforcement mechanisms

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Conclusions

- Online pharmacy: Important phenomenon going that is continuing to spread, despite partial regulation
- Deficiencies in (inter)national regulations
- Accordingly, patients not adequately protected
- Need for cohesive international action: EU, WHO, CoE & Interpol
- Implementing a comprehensive international regulatory regime (Framework Convention)

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