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Fighting online pharmacies

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Structure

- Falsified medicines: setting the scene
- Why do people buy medicines online?
- Risks for the patient
- Mapping of online pharmacies in the EU and European legislation
- Existing initiatives
- Developing and strengthening cooperation
- Close-up of Belgium

Falsified medicines



- Growing threat to public health and safety in Europe
- Falsified medicines may:
 - Have fake packaging or the wrong ingredients
 - Have no active ingredient at all
 - Have their identity or source deliberately mislabelled
 - Contain low quality ingredients or the wrong doses

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Setting the scene (1)



- 27.5 million items of counterfeit medicine seized at the outer border of the EU in 2011 (24% of the total)



- NABP: 96% of 6,000 websites reviewed not in compliance with state and federal laws and/or pharmacy practice and patient safety standards



- WHO: 50% of medicines purchased over the Internet from illegal websites that do not disclose their physical address are counterfeit

Setting the scene (2)

- UCSD: largest illegal online medicine sellers may generate between \$1 and \$2.5 million in sales every month
- US CBP: seizures of counterfeit pharmaceuticals have increased by 200% and seizures occurring at express consignment/mail facilities have risen by 84% since 2007
- EU Customs: intercepted shipments have doubled compared to 2010; 82% increase of postal traffic detentions; 36.5 % of articles seized from postal traffic are medicines

Setting the scene (3)

- Interpol: Pangea IV (September 2011)
 - Seizure of 2.4 million potentially harmful medicines, valued at \$6.3 million
 - 13,500 websites engaged in illegal activity down
 - 45,500 packages inspected
 - 8,000 packages seized and 2.4 million individual doses confiscated
 - 48 different countries identified as source
 - Antibiotics, steroids, anti-cancer, anti-depression and anti-epileptic pills, as well as slimming aids or food supplements.



Why do people buy medicines online?

- Elderly, disabled and people unable to visit a pharmacist during normal working hours
- Speed and convenience
- Too embarrassed to discuss their condition with a healthcare professional
- Discretion from family/employer/authorities
- A doctor might be reluctant to prescribe them a particular medicine
- Alleged low price
- Etc.



A growing online threat*



- 62% of medicines purchased online are fake or substandard
- 95.6% of online pharmacies researched are operating illegally - 94% of websites do not have a named, verifiable pharmacist
- Over 90% of websites supply prescription-only medicines without prescriptions
- More than 8 out of 10 online pharmacies do not “physically exist”



** Based on research carried out by the EAASM*

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The important role of patient safety stakeholders bypassed via illegal online medicine sellers



Doctors

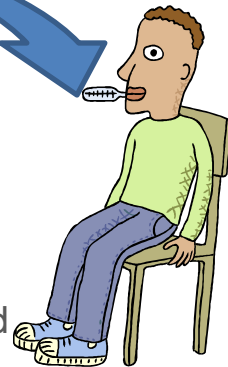
- Prescribe appropriate dosage
- Monitor for intentional abuse of prescription medicines
- Prevent intentional abuse of prescription medicines
- Coordinate patient care and use of other medicines

Pharmacists & Pharmacies

- Review prescription and contact prescriber if indicated
- Provide dispensed medication
- Monitor for medicine interactions and contact prescriber as indicated
- Monitor for intentional abuse of prescription medicines

EU and National Regulators

- Oversee pharmacists and pharmacies
- Oversee doctors
- Oversee medicine manufacturers
- Prevent counterfeit & substandard medicines



What is known: common characteristics of illegal online medicine sellers

- No prescription required
 - Prescription medicine abuse increasing
 - No medical supervision by doctor or pharmacist
- Unregulated/unapproved prescription medicines
 - Counterfeits, adulterated, expired, substandard
 - May be dangerous and/or ineffective
- Lack of valid / required pharmacy licences
 - Not really a pharmacy (warehouse or house)
 - Lack of supervision
 - Copied certificates from regulatory authorities and false statements relating to licence status and professional affiliation



European legislation - ECJ "DocMorris" judgement of 11 December 2003

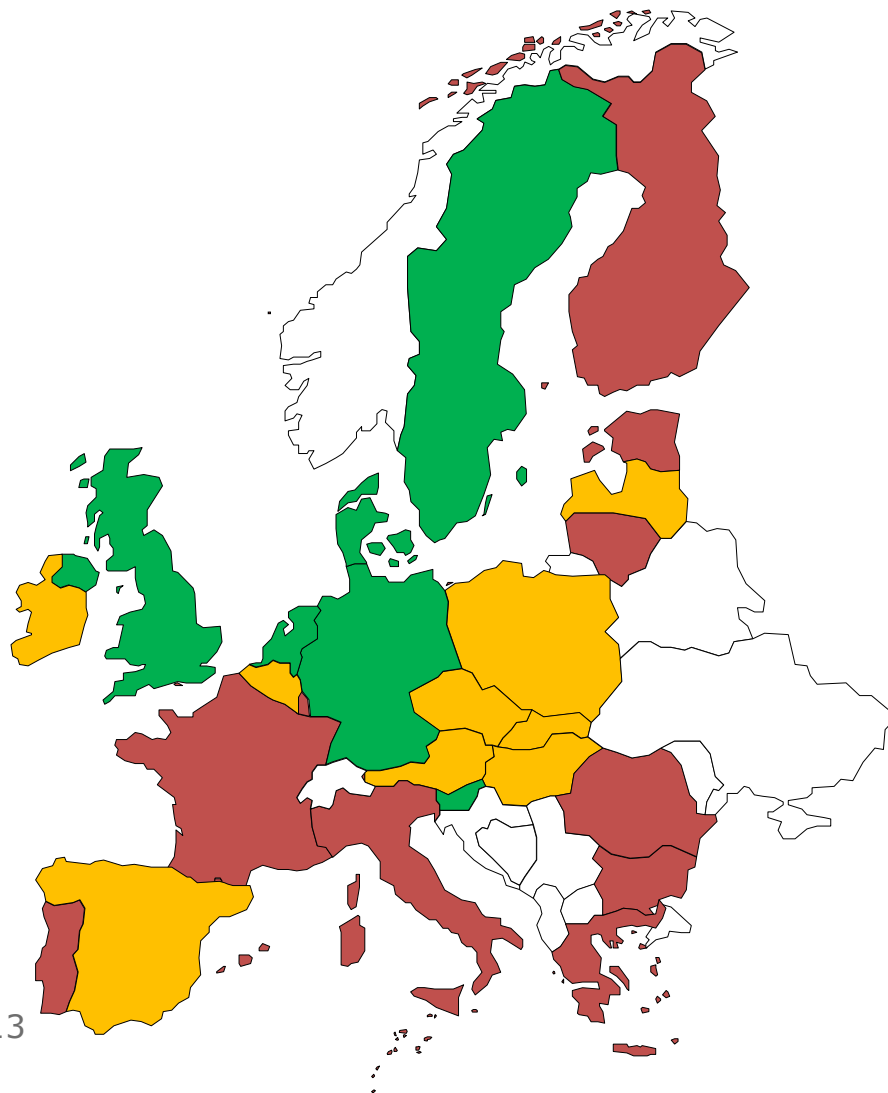
- Crossborder electronic commerce of medicines



- ECJ Position

- $><$ Sale on the Internet of medicines that are unauthorised in the destination country
- In favour of electronic commerce if there are no health risks or not on prescription
- In favor of pharmaceutical monopoly: websites can only operated from existing pharmacies = virtual extension of authorised pharmacies in supplier's MS

Online pharmacies in the EU



- 6 Member States allow online sales of OTC and prescription-only medicines
- 9 Member States allow online sales of OTCs

Both OTC and prescriptions allowed

Only OTCs allowed

No online sales allowed

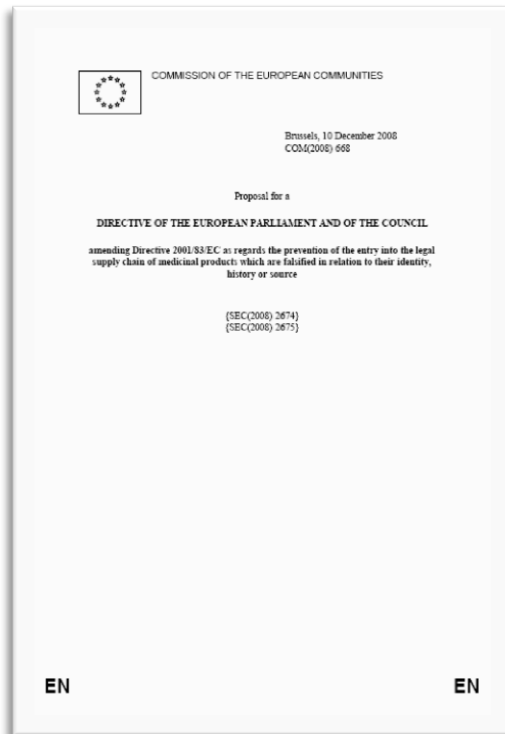
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Mosaic of regulations and cultures in the EU and beyond → Impossible for the industry to recommend one model rather than another



But in the fight against counterfeit medicines, the industry's paramount concern and focus is to protect patient safety and public health

European legislation - Falsified Medicines Directive 2011/62/UE (art 85 quater directive 2001/83/EU)



1. Respects national legislations (NLs) prohibiting remote prescription sales to the public
 - From authorised pharmacies only;
 - Accreditation
 - Respect for NLs of destination MS;
 - Obligations of information in and of Directive 2000/31/EC
2. Respects specific MS-justified conditions
3. Community logo and identification of MS from which the offer is emanating
4. Minimum info on MS websites
5. EMA website + links to MS websites
6. Sanctions

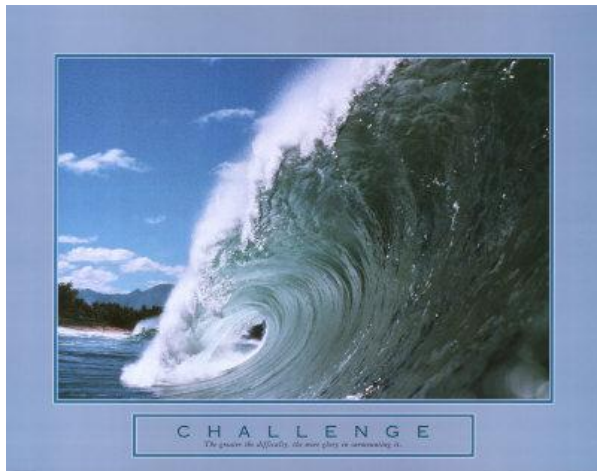
Existing initiatives relevant for online sales of counterfeit medicines

- **EU Falsified Medicines Directive**
 - Mandatory registration of legitimate online pharmacies and use EU logo
- Other relevant **EU Initiatives**
 - Stakeholder Dialogue / MoU on online platforms (May 2012)
 - Consultation Clean Open Internet (N&A) (September 2012)
 - Consultation Common logo (FMD) (October 2012 ?)
 - Review of IPR Enforcement Directive
 - Strengthening European Observatory
 - Proposal for new Customs Regulation
- **EFPIA Dialogues**
 - Search engines (Google, Yahoo) in order to eliminate advertising by illegal online pharmacies
 - Domain name registrars (Nominet)
- **Official Agencies**
 - Customs seizures; trafficker/seller prosecutions; shutting down illegal websites, etc.



Despite the range of measures already taken, the vast majority of illegal online pharmacies is continuing to operate with impunity

A challenge to all stakeholders



- Online sale of medicines:
 - Ease of use by the patient
 - Specifics patient safety issues
- Actions
 - Tackle illegal websites working with Internet service providers and other portal administrators
 - Patient education and awareness
 - On-going work with European and International organisations
 - Etc.

Developing and strengthening cooperation



Cooperation in fighting counterfeits



- Memorandum of Understanding against the sale of counterfeit online goods coordinated by the European Commission
- Charter to fight counterfeiting on the Internet coordinated by the French government
- Alliance for Safe online Pharmacies (ASOP) US and Center for Safe Internet Pharmacies (CSIP)

➔ **Combating counterfeit medicines through voluntary cooperation between all stakeholders**

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First steps Alliance for Safe Online Pharmacy (ASOP EU)

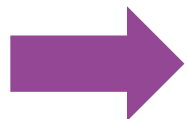
- Launch 11/2012
- Approaches the issue from the patient safety perspective
- An informal multi-stakeholder coalition involving representatives from patient organisations, pharmaceutical companies, pharmacists, wholesalers, parallel distributors, and online intermediaries
- Aligned with ASOP US (global outlook) but adapted to EU context and targeted on EU stakeholders



ASOP EU is looking at replicating US initiatives



- Setting-up EU-based CSIP with online intermediaries
- Advocating a Europe-wide protocol for licensing online pharmacies, the introduction of “White Lists” (.pharmacy domain suffix) and GtLD registrars action
- Developing common methodologies for reporting and removing illicit online pharmacies
- Advocating - when needed - legislative changes
- Conducting pan-European awareness campaigns in order to educate patients



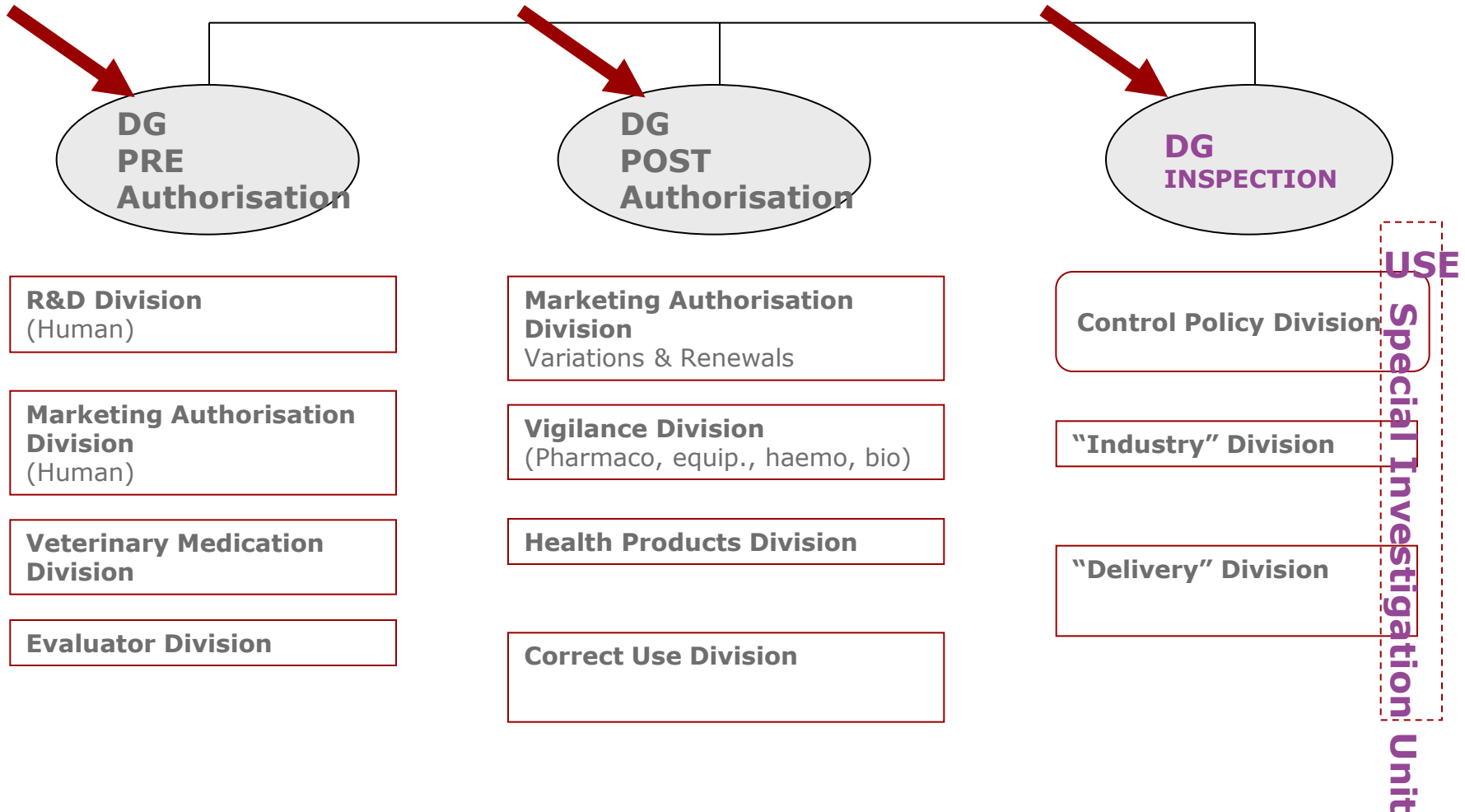
Voluntary & cooperative action

Close-up on Belgium



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FAMPH: 3 Pillars or General Directorates



Close-up on Belgium



Are you putting your health in danger by buying medicines on the Internet?



Surf to
www.medicaments-par-internet.be
[pharma.be]



Médicaments
par internet ?
Ne surfez pas
avec votre santé !



PANGEA IV Operation



- Target = online sale of medicines
- Interpol, World Customs Organisation (WCO), Permanent Forum on International Pharmaceutical Crime (PFIPC), Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO), pharmaceutical industry and electronic payment providers
- 81 countries are involved, including Belgium
 - Federal Public Service Finances, General Administration of Customs and Excise Duties and the Federal Agency for Medicines and Health Products (FAHMP)

Belgian legislation: main features (1)



- Delivery of medicines in pharmacies remains the basic principle
- Exemption envisaged by Article 29 of the [RD of 21/01/2009](#) conveying instructions for pharmacists
- Allows, **only pharmacies open to the public and authorised in Belgium, to sell by the Internet, under very strict conditions, medicines authorised for human use and not subject to medical prescription, and certain medical devices**

Belgian legislation: main features (2)

- Website = virtual extension of the dispensary
- Medicines not subjected to medical prescription
- Possible reservation for prescriptions
- Delivery rules in dispensary officines apply
- From the pharmacy, on the pharmacist's entire responsibility and following good dispensing practices
- Respects the patient's protection of privacy rights
- Website designed so as to encourage rational use
- Website must contain administrative dispensary data (pharmacist and dispensary names , addresses, etc.)
- FAMPH publishes list of authorised online pharmacies
- Notification to FAMPH and Order of Pharmacists, via appropriate form (1 month)
- FAMPH recommends clear link to its website



A real need in Belgium?



- Extensive network of dispensaries open to the public (5,000 dispensaries open to the public; 11M inhabitants; 30,500 km²)
 - 1 dispensary per 2,200 inhabitants and per 7.3 km²
 - Great geographical availability for the patient
- Closed and secure regular distribution chain
- 8 Belgians out of 10 have a fixed pharmacist, in particular in terms of advice and retail outlet (Dimarso)
- In NICT context: sale of OTC medicines via Internet can constitute **additional channel** for certain patients provided that:
 - Patient protection is assured
 - Same service guaranteed

Limited development in Belgium



- List of online pharmacies consultable on FAMPH website
- About 170 registered websites



Sufficient sanctions?

- Without prejudice to criminal penalties:
Article 16 of the Medicines Law of 25 March 1964



- Imprisonment of 1 month to 1 year and/or fine of EUR 200 to EUR 15,000 (X 5,5)
- Consumers: warning system before possible sanction
- Shippers: complex legal procedure, practically impossible to carry out since shippers operate from abroad

In conclusion

- Focus on the safety of patients
- Raise patient awareness
- Supervise, control and sanction
- Develop and strengthen cooperation at every level





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attention!

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