



*Making Medicines Affordable*

**Counterfeiting of Medicines:  
Perspective of the  
EU Generic Medicines Industry**  
“Conference on Industrial Property Rights  
in the Internal Market”

**Strasbourg 17 October 2008**

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# Counterfeit : What are We Talking About ? - Problem of Definitions





# EC Customs Regulation 1383/2003 is clear but not applied in debate

Article 2. 3 types of infringing an IP right:

- Counterfeit goods that infringe trademarks
- Pirated goods that infringe copyrights and designs
- Other goods that infringe patents or SPCs

Distinction Clear: Patents are Not Counterfeited

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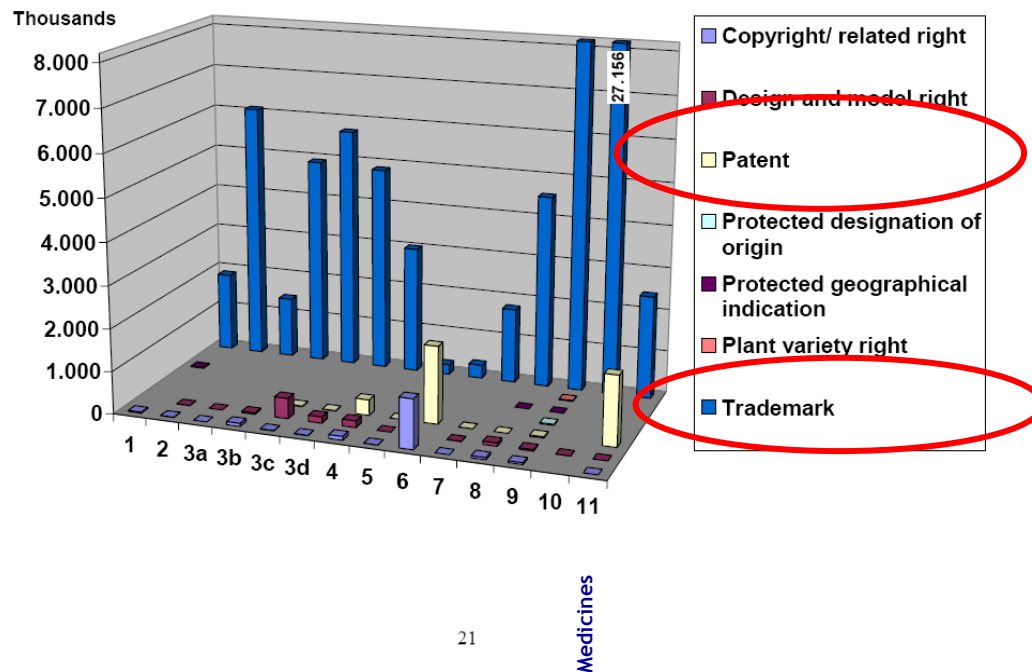
# How the Lack of a Single Definition is Causing Major Confusion



European Commission — Taxation and Customs Union



Annex 5 Overview of infringed IP rights in articles per product category



Source: REPORT ON COMMUNITY CUSTOMS ACTIVITIES ON COUNTERFEIT AND PIRACY RESULTS AT THE EUROPEAN BORDER - 2007

 Different definitions lead to wrong conclusions



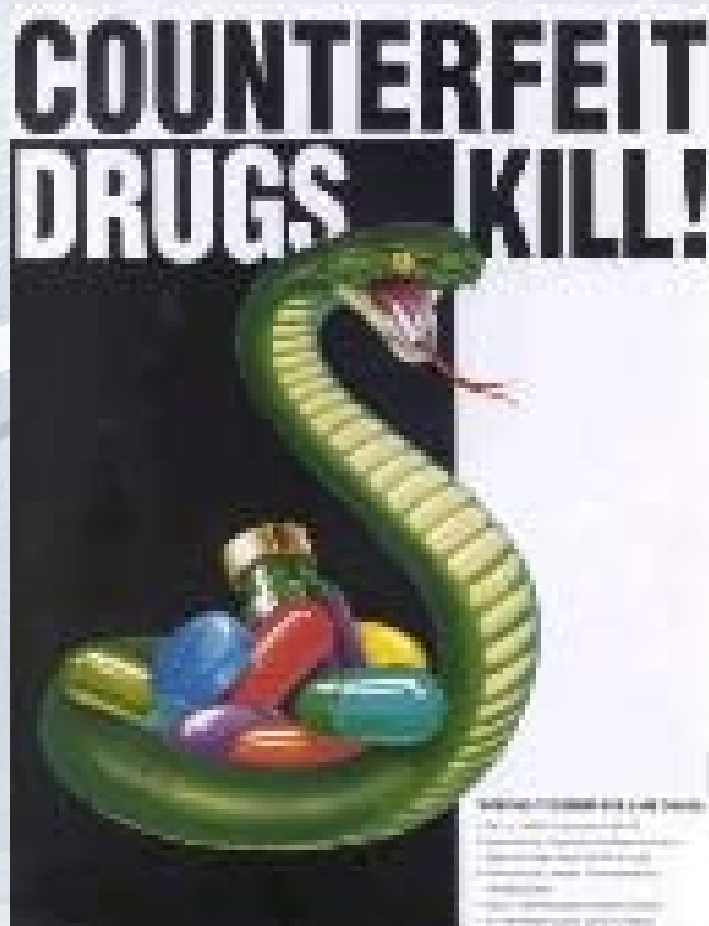
**Annex 4 Overview per product sector of countries of origin**

2007									
Breakdown of number of articles seized expressed as % by provenance and by product type									
1. Foodstuff, beverages	45,92% Turkey	37,35% China	5,06% Italy	3,10% Georgia	1,50% Belize	1,11% Bulgaria	1,04% USA	0,97% Vietnam	3,95% Others
2. Cosmetics, personal care products	32,11% Georgia	28,68% Turkey	15,86% China	5,67% Singapore	4,34% Korea	3,55% Unknown	2,27% UAE <sup>2</sup>	2,01% Algeria	5,50% Others
3a) sportswear	55,62% China	19,44% Turkey	9,83% Unknown	4,60% Bulgaria	3,21% Algeria	0,97% Romania	0,95% Poland	0,71% Thailand	4,68% Others
3b) other clothing (ready to wear)	62,58% China	10,32% Turkey	4,63% Unknown	4,51% Vietnam	2,66% Italia	2,40% Syria	1,79% Bangladesh	1,77% UAE	9,33% Others
3c) clothing accessories	57,16% China	17,54% Italia	11,65% Turkey	4,66% Unknown	2,55% Bulgaria	1,41% Hungary	1,02% Algeria	0,65% Tunisia	3,38% Others
3d) shoes	79,67% China	7,08% Algeria	2,35% Italia	1,81% Unknown	1,24% Turkey	1,07% Russia	1,00% Spain	0,87% Malaysia	4,91% Others
4. Electrical equipment	35,21% Unknown	30,73% China	12,58% Algeria	10,06% Hong Kong	2,57% Italia	2,40% UAE	1,59% Liechtenstein	1,17% Turkey	3,69% Others
5. Computer equipment	47,61% China	14,15% Italia	11,86% Hong Kong	5,41% San Marino	4,41% USA	3,57% Algeria	3,06% Unknown	1,98% Japan	7,94% Others
6. CD, DVD, cassettes	75,07% China	6,53% Unknown	3,31% Poland	3,21% Hong Kong	2,65% UAE	2,13% Italia	1,72% Syria	1,26% Ukraine	4,12% Others
7. Jewellery	52,21% China	36,15% Italia	5,70% Hong Kong	1,90% Unknown	1,04% Netherlands	0,63% Japan	0,60% Thailand	0,28% Liechtenstein	1,50% Others
8. Toys, games	41,59% China	36,19% Tunisia	7,35% Italia	4,73% Hong Kong	2,39% USA	1,50% Unknown	0,92% Croatia	0,61% Canada	2,36% Others
9. Other	71,14% China	8,79% Hong Kong	6,26% Unknown	3,28% Italia	2,35% Tunisia	2,12% Ukraine	1,74% Turkey	0,78% Pakistan	3,54% Others
10. Cigarettes	55,05% China	18,01% Unknown	7,30% UAE	4,78% Bulgaria	2,81% Turkey	2,41% Belgium	1,57% Greece	1,27% Poland	6,80% Others
11. Medicines	39,21% Switzerland	34,60% India	14,70% UAE	3,88% China	3,28% Hong Kong	2,66% Unknown	0,52% Mauritius	0,30% USA	0,84% Others

<sup>2</sup> UAE – United Arab Emirates



# Counterfeit of Medicines is a Public Health Issue not IP issue





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# WHO Counterfeit Definition

- « a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products and may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. »



**No reference to patent infringement**

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# Supporting Statements

At the 13th International Conference of Drug Regulatory Authorities (ICDRA):

- Hans Hogerzeil, director of WHO Essential Medicines and Pharmaceutical Policies: “*one of the major worries of the intellectual property sector on drugs is counterfeit*”. However “*the real concern is about safety and not IP.*”
- Yves Juillet, counsellor to the president of Leem, agreed, saying “*IP is not the issue, it’s fraudulent misrepresentation that cheats the patients who purchase the drug*”.

Source | *IP Watch: Kaitlin Mara*

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# EP's Resolution 12 July 2007

- Point 16. The European Parliament:  
“Recalls that counterfeiting of medicines is not a patent issue as such; stresses that measures to tackle counterfeiting need to be taken in the area of criminal enforcement (penal sanctions) and drug regulation by reinforcing the regulatory capacity of the national authorities and not by increasing levels of intellectual property protection”;



# Focus Fight on Counterfeit Medicines

- Fighting counterfeiting of pharmaceuticals focus on trademark issues and securing supply chain
- The fight against counterfeiting cannot be used as an excuse to justify:
  - Patent extensions or increases of data exclusivity
  - Harsher civil sanctions to enforce patents
  - Criminal sanctions to punish patent infringementsThis would be ineffective as well as unjustified.



# IP Enforcement EU and Outside

- *IP Enforcement 1 (civil) - Art. 3.2 of Directive 2004/48/EC - measures must be applied in such a manner as to avoid the creation of barriers to legitimate trade. In addition, safeguards are provided against any abuse of these measures.*
  - *Proposed IP Enforcement II (criminal)- Patents excluded from criminal sanctions in EP first reading.*
  - EU's external policy should also reflect this approach and agreed definitions
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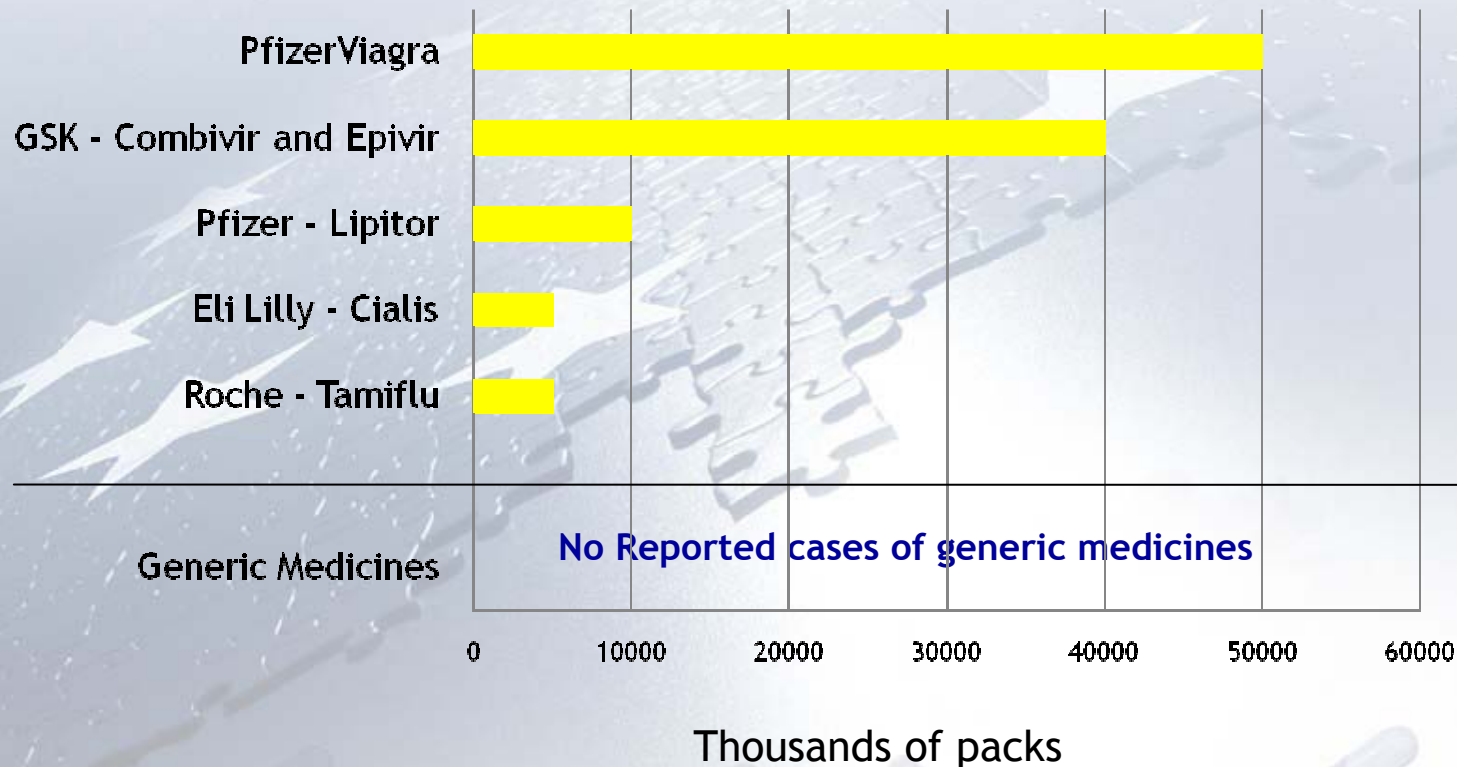


# Counterfeit Medicines in the EU



# Examples of Reported Cases of Counterfeited Medicines

## Examples of Report Cases of Medicines

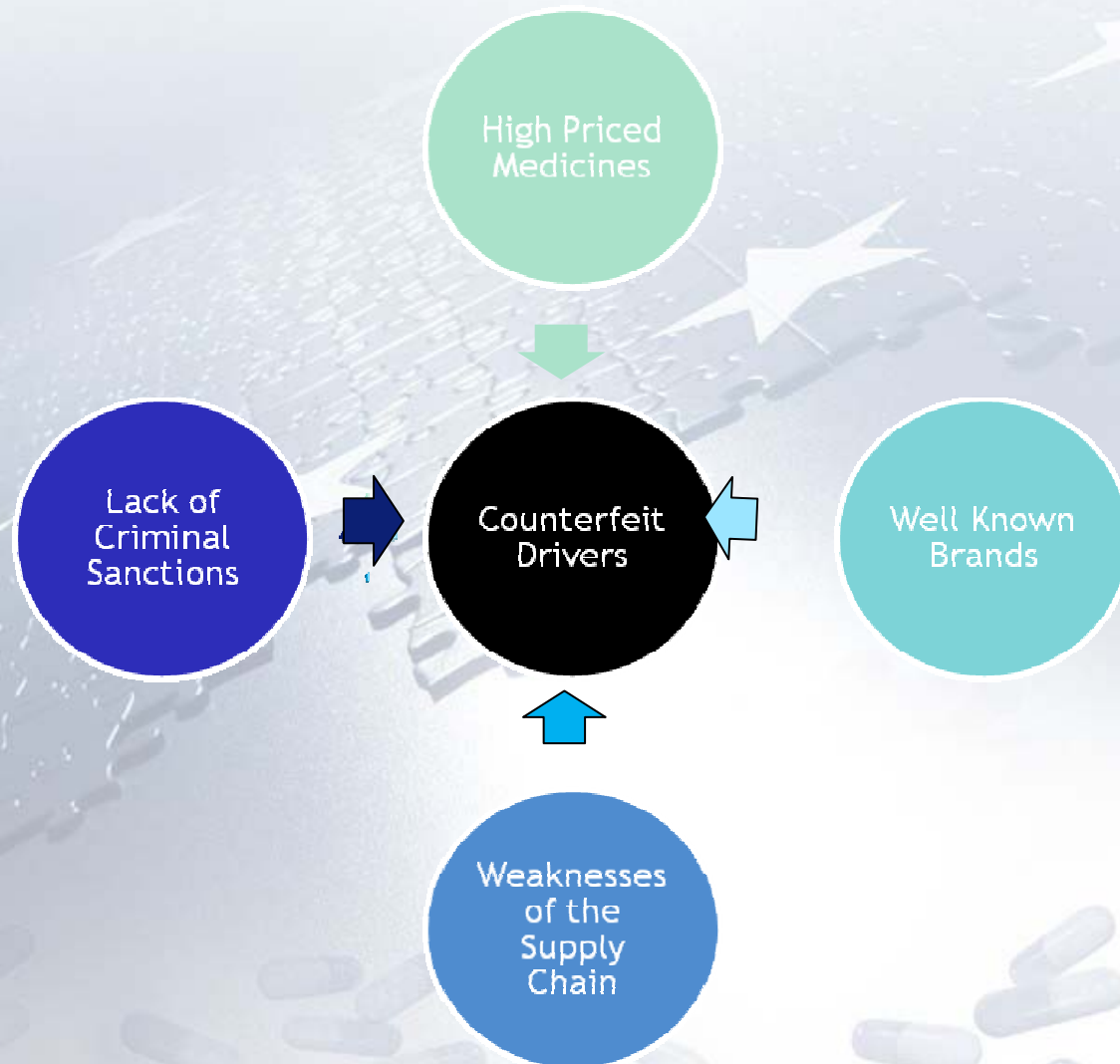


Source:  
WHO Fact  
Sheet N275,  
Council of  
Europe  
Report  
2006,  
AEGATE



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# What is Driving Counterfeiting?





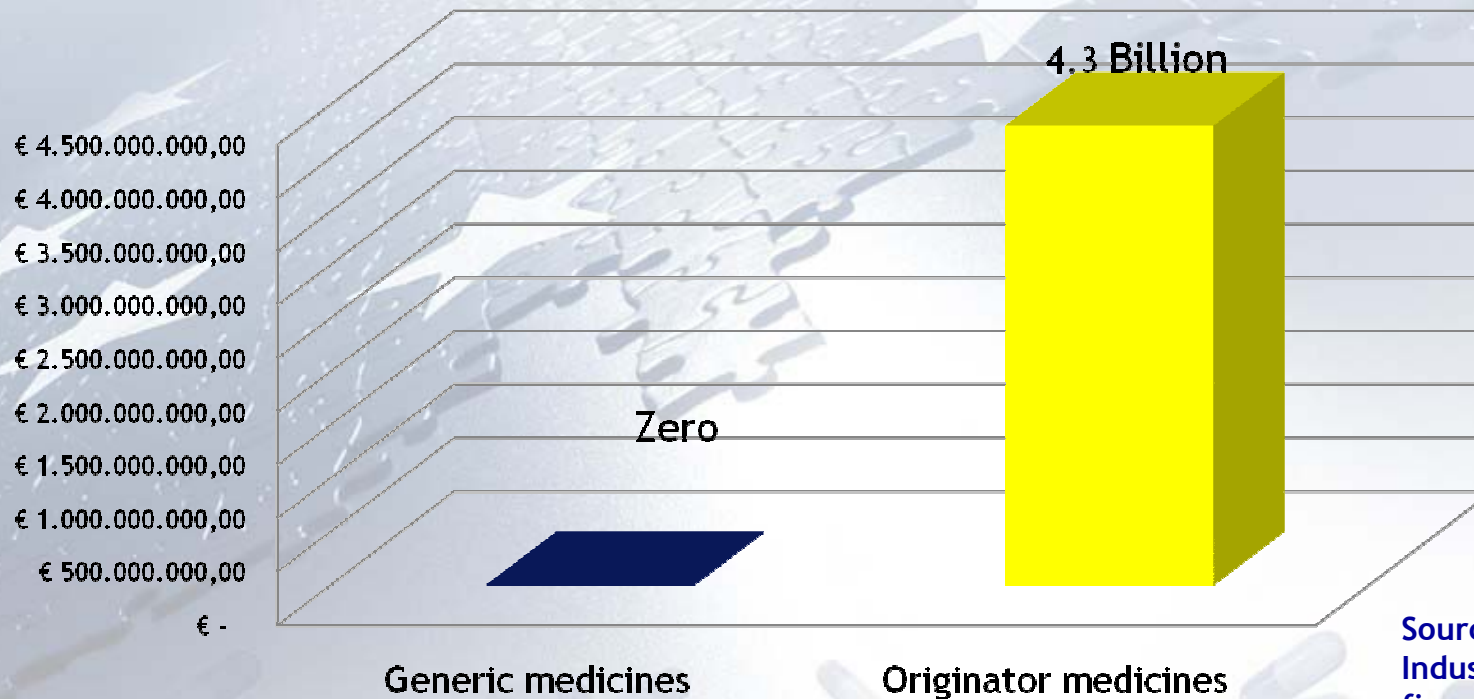
# Price of Generic Medicines Uninteresting for Counterfeiters

## Generic Medicine Prices

	Reimbursement price per October 1, 2008		Distribution per pack (Fee Wholesaler)	
Omeprazol 20mg	€	1.34	€	0.35
Simvastatin 20mg	€	0.74	€	0.35
Amlodipine 5mg	€	0.84	€	0.35
Fluoxetine 20mg	€	0.73	€	0.35
Captopril 25mg	€	0.50	€	0.35
Enalapril 20mg	€	0.58	€	0.35
Lisinopril 10mg	€	0.66	€	0.35
Metformine 500mg	€	0.41	€	0.35
Tolbutamide 500mg	€	0.61	€	0.35

# Price of Generic Medicines Uninteresting for Parallel Traders

## Parallel Trade of medicines in Europe



Source: EFPIA  
Industry in  
figures2008



# Within EU Focus Actions on where Problems Arise.

- Strengthen legitimate supply chain
    - Manufacturers (GMP) wholesalers & parallel importers (GDP) pharmacists (GPP)
  - Technological measures - applied to 'commercially interesting' medicines (flexible and focused approach)
  - Strict monitoring of internet sales (50% counterfeit)
  - Strong criminal punishment of counterfeiting of health and food goods
  - EU law on anti-counterfeiting awaited 21/10
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