

# **Counterfeit Medicines - The (Unknown?) Threat with many Faces**

**EUROPEAN SECURITY CONFERENCE INITIATIVE &  
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**Panel: Actual Risk vs. Felt Security – Cases and Conclusions**

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# More people were killed by counterfeit medicines than by terrorist incidents in the last 40 years

- Terror > 65.000

***“Over the last 40 years, more than 65,000 people have been killed or injured in transnational terrorist incidents,***

Counterfeit medicines:  $n * 10.000 - n * 100.000$  p.a.

***while estimates of deaths caused by fake medicines range from tens of thousands to hundreds of thousands annually. In China, almost 200,000 individuals died in a single year from fake medicines” :***

**Ronald K. Noble, INTERPOL Secretary General,  
Opening Remarks IPC workshop Nairobi, 2008**

# Awareness?

- Third World
- Europe
- Organized crime
  - Perfect structures, well trained specialists...
  - Big business:
    - Up to 75 billion US dollars by 2010
    - an increase of more than 90 per cent in just five years
- Low risk of detection – high proportion of unreported cases
  - medical doctors, health authorities,

# What are counterfeit medicines?

- **The definition of the WHO:**
- Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source.
- Counterfeit medicines may include products with
  - **the correct ingredients**
  - **or with the wrong ingredients,**
  - **without active ingredients,**
  - **with insufficient or**
  - **too much active ingredient,**
  - **or with fake packaging.**
- **Use of counterfeit medicines can result in treatment failure or even death.**
- **Public confidence in health-delivery systems may be eroded following use and/or detection of counterfeit medicines.**
- **Both branded and generic products are subject to counterfeiting.**
- **All kinds of medicines have been counterfeited, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines**

the Heparine Case...  
a problem of lacking awareness?  
...where safety meets security...

- FDA: 81 deaths related with heparine in 2007/8 in US
- Whereas reports from the EU have mentioned only three side-effects and no deaths,
  - the EU could have been equally affected

## Counterfeit cases:

exerpt from the EU COM SEC(2008) 27674

- Please refer to the document of the EU Parliament

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2674:FIN:EN:PDF>

Have a look on the table of page 12 :

**„Counterfeit medicines: Examples of cases reported in 2006/07,  
potential threats and players involved“**

and have also a look on the pie chart of page 1 of the WHO document:

<http://apps.who.int/medicinedocs/pdf/s4921e/s4921e.pdf>

**and see the big range of counterfeit medicines including  
block busters as well as hormones....**

**Potential sources of counterfeit products in the LEGAL SUPPLY  
CHAIN**

from EU COM SEC(2008) 27674

- Please refer to the schemes of
- the infiltration of the legal supply chain
- and the complexity of the distribution chain
- on page 18 of the document of the EU parliament:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2674:FIN:EN:PDF>

# The problem of grey and re-imports

- a problem:
- Capping of selling prices for pharmaceuticals and
- no cap of selling prices for pharmaceuticals
  - increases the rate of (cheaper) re-imports from countries with a cap on selling prices
  - increases the probability of infiltration with counterfeit products into the legal supply chain
  
- Should be scrutinized
  - re-import by regulation in Germany:
  - **according § 129 para. 2 SGB V**
  - **within a framework agreement pharmacists are obliged to fulfill an import quota of 5% for cheap pharmaceuticals by e.g. internet sales**



# Which countermeasures exist- what should be done?

- EU initiatives
- EU Call: Tackling counterfeit medicines and related criminal networks
- The so-called wholesalers
- EFPIA-study in Sweden
- DIN & ISO/ TC 247 project "Fraud countermeasures and controls"
- EHIBCC & DIN: Unique ID Mark DoD&NATO
- Public Awareness Campaigns: Sweden, Germany



**Counterfeit medicine: a crime with multiple causes –  
there never will be one and only single technical measure  
to cover all aspects for all times**

- Any protection (technical countermeasure) causes only a delay in time
- Our holistic approach from University of Hamburg  
for a sustainable success:
- Short term – mid term – long term measures  
by
- Prevention/Protection – Verification – Criminological Research/Public  
Awareness
- Short term: Increasing Public Awareness
- Mid-term: Prevention by adequate authentication system  
– high level parameters and diagnostics
- Verification: by means of automatic identification + data base access  
e.g. UIM-Datamatrix & measurable physical criteria  
technical developments for the interface pharmacy/patient
- Deterrence: field measurements
- Mid - long term: technological developments for customs, wholesalers
- and legal Aspects

## interesting to read:

- **COMMISSION STAFF WORKING DOCUMENT. SEC(2008) 2674**  
***Accompanying document to the: Proposal for a***  
**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**
- **Counterfeit medicines; Survey report: © Council of Europe, January 2006; ISBN 92-871-5863-0,**
- **WHO /EDM/ QSM/ 99.1 : Counterfeit drugs (Guidelines for combat)**
- **WHO/EDM/2003.2: Effective medicines regulation: ensuring safety, efficacy and quality**
- **„Fälschung auf Rezept“: Der Spiegel, 30/2003**
- **Europaweiter Versandhandel mit gefälschten Lifestyle-Pillen from „ Die Kriminalpolizei“, Dezember 2007:**  
**[www.kriminalpolizei.de/articles,europaweiter\\_versandhandel\\_mit\\_gefalschten\\_lifestylepillen,1,171.htm](http://www.kriminalpolizei.de/articles,europaweiter_versandhandel_mit_gefalschten_lifestylepillen,1,171.htm)**

**Thank you for  
your kind attention!**

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