EU Initiative on Combating Counterfeit Medicines

Sabine Atzor
DG Enterprise and Industry, Pharmaceuticals
European Commission, Brussels

• Counterfeit medicines: 2001 – 2005
  • 27 cases in legitimate supply chain
  • 170 cases in illegitimate supply chain
  • focus: lifestyle drugs
    (EU Working Group of Enforcement Officers)

• Less than 1% of medicines in countries with regulatory systems, such as the EU
  (WHO estimates in 2006)
The Problem has reached the EU ...

- 384% increase of seizures of counterfeit medicines at EU customs borders from 2005-2006 (DG TAXUD 2007)
- Cases of fake medicines against
  - Infections
  - Heart diseases
  - Psychiatric disorders
  - Prostate cancer
- No or low level of active substance
There are indications …

- From lifestyle to life-saving drugs
- From illegal to legal supply chain
- Misuse of bonded warehouses
A specific problem: Active Substances

- Asian manufacturers
  - EU Inspections revealed major non-compliances
  - Local control of manufacturers intransparent
- Gentamycins case (beginning of 2000)
  - Numerous deaths and hundreds of side effects
  - Source: faulty manufacture
- Heparin case ????
  - 2008, investigations ongoing
The changed risk profile has consequences for...

<table>
<thead>
<tr>
<th>Public Health</th>
<th>Economy</th>
<th>Internal Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Concrete threats</td>
<td>Negative effects on</td>
<td>• Member States start</td>
</tr>
<tr>
<td>• Loss of confidence</td>
<td>• Pharma Industry</td>
<td>taking action at national</td>
</tr>
<tr>
<td></td>
<td>• Health care systems</td>
<td>level</td>
</tr>
</tbody>
</table>
Time to act ...
Strategies to Combat Counterfeit Medicinal Products

- Protection of Intellectual Property Rights
- Criminal Law Framework
- Pharma Legislation
- International Cooperation
- Customs Action
<table>
<thead>
<tr>
<th>Studies on distribution channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part I: combating counterfeit products</td>
</tr>
<tr>
<td>Part II: safe products in parallel trade</td>
</tr>
<tr>
<td>Medicines</td>
</tr>
<tr>
<td>Launch in 2006</td>
</tr>
<tr>
<td>Results in 2008</td>
</tr>
</tbody>
</table>
Objective:  - develop a strategy for further action
- explore need for specific legal requirements

Steps:   1) Analysis
2) Policy options
3) Assessment of impacts
    - social
    - economic
    - environmental
Combat Counterfeit Medicines

Strategy for Action:

1. Tighten regulatory framework
2. Tighten enforcement
3. Enhance international cooperation
4. Improve awareness
„Principles and Elements for National Legislation Against Counterfeit Medical Products“ (Dec 2007)

address requirements for

– Manufacturers, e.g. of
  • medicinal products, active substances

– Operators of the distribution chain, e.g.
  • wholesalers, traders, brokers, agents

– Export of medicines
1. Prevent manufacturing, importation, exportation and distribution of
   - Counterfeit and sub-standard active substances
   - counterfeit medicines

2. Protect *legal* distribution chain

3. Prevent establishment of *illegal* distribution chains
Policy options
Tighten Pharmaceutical Legislation for:

1. Manufacture, Placing on the Market of Medicinal Products & Inspections

2. Import for Export

3. Manufacture, Placing on the Market of Active Substances & Inspections

„Placing on the market“ also includes importation, distribution
Calls of European Parliament

- Resolution on counterfeit medicinal products (06 Sept 2006)
  - Strengthening of regulatory systems and control
  - Enhanced cooperation at national, EU & international level
  ...

- Declaration on Active Substances (04 Sept 2006)
  - GMP certificates (i.e. Inspections) of/ for all manufacturers...
Bilateral Discussions on Counterfeit Medical Products with

- US
- Canada
- China
- India
- Russia
- ......
1. The risk profile has changed significantly.

2. A legal proposal on pharmaceuticals is a matter of urgency and should focus on aspects of
   • manufacture
   • placing on the market, incl.
     • importation
     • distribution
   • (import for) exportation