Stakeholder Meeting 29 November 2006

DG ENTR Study on Distribution Channels: Part I Combating Counterfeit Medicines

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Recent Anti-Counterfeit Activities

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- WHO:
  - Discussion about a convention (2005)
  - IMPACT International Medical Products Anti-Counterfeiting Task Force (2006)
- Council of Europe Conferences
  - Strasbourg, „Harper Report“ (2005)
  - Moscow (2006)
- US FDA: Counterfeit Drug Task Force (2004)
- OECD

…

WHO Analysis 2006

Counterfeiting is greater in regions with weak regulatory and legal oversight:

- < 1% of market value: Most developed countries with effective regulatory systems and market control (e.g. EU, US, Can, Japan…)
- 10-30 % of medicines: many developing countries of Africa, parts of Asia & Latin America
- 20% of market value: many of the former Soviet republics
- >50 % of cases, when medicines purchased from Internet sites that conceal their address

Counterfeits in the EU

- 1000% increase in counterfeit seizures in general between 1998 and 2004
  (DG TAXUD)

- Counterfeit medicines 2001 – 2005
  - 27 cases in *legitimate* supply chain
  - 170 cases in *illegitimate* supply chain

  (EU Medicines Enforcement Officers Survey)

Press Release: 27 March 2006 Commission warns about fake drugs on the internet

- Unlicensed and counterfeit Rimonabant sold over the internet, fake copies of Viagra[R], Cialis[R], Tamiflu[R]
- Vice-President Günter Verheugen:

„ I am alarmend at the ever increasing number of counterfeit medicines sold via Internet. This represents a real danger to the health of patients.

The Commission is working with European and international partners to do everything possible to ensure legal methods for marketing of medicines are respected and enforced.“

6 September 2006
EP Parliament Resolution: Call for…

1. action to combat piracy and counterfeit medicines (EC, Commission)

2. key role in promoting an international convention to create a specific criminal offence of counterfeiting (EU)

3. greater cooperation at both national and international level between various authorities

- emphasis on importance of preventive measures in action programmes (e.g. structure, cooperation, awareness campaigns)

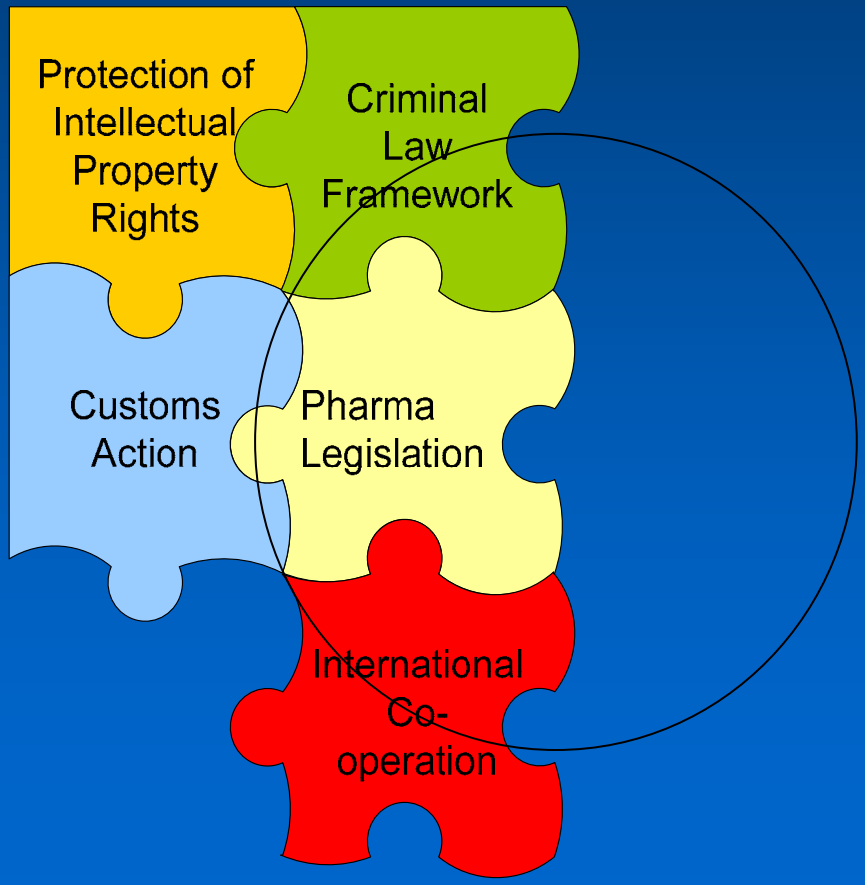
- steps to strengthen the regulatory and quality-control framework in countries with inadequate resources and improve affordable medicines (EU)

Objective of the ENTR Study

To develop a strategy to address possible further action to combat counterfeit medicines

based on an assessment of possible impacts

Areas of action



Four Key Areas of Interest

1. Legislation: Factors

   - supporting legitimate supply chain
   - avoiding illegitimate supply chain

2. Supervision/ Enforcement

3. Cooperation/ Communication

4. Awareness Raising

Four Steps approach

1) **Analysis** of the current situation in four key areas with subtopics
2) Development of **policy options** to fill in possible gaps for each subtopic
3) **Impact assessment** on policy options for each subtopic
4) Development of a **strategy paper** with proposals for next steps (e.g. Commission Communication, legislative proposals)

1. Legislation - Subtopics

Illegitimate supply/ distribution chain

- Definition of counterfeit & pharmaceutical crime
- Import, export, (transshipment)
- active substance control
- Internet (potential to be used for illegal purposes)

Legitimate supply/ distribution chain

- Wholesalers
- Internet
- Packaging, re-labelling activities
- Guideline on GMP, GDP
- Possibility/ requirements for authentication (e.g. markers)
- System requirements for track & trace (e.g. technologies)

2. Supervision/ Enforcement - Subtopics

- Sampling of medicinal products
  - Regulatory requirements
  - National resources for sampling in the legitimate and illegitimate supply chain
  - Coordination activities
- Testing of medicinal products
- Inspection procedures and practices
  - To address counterfeit during GMP/ GDP inspections

3. Cooperation & Communication Subtopics

- National/ Member State level
- European Union level
- International level
- Industry and authorities
- Databases
- Pharmacovigilance reporting
- Rapid Alert System
- Training of regulators

4. Awareness raising

- Analysis of existing programmes/ need for additional programmes for awareness raising of the public (e.g. illegal trade via internet)

Timelines

April 2007	Input from MS and Stakeholders
III Q 2007	Draft analysis and policy options by DG ENTR
beginning of 2008	Europe Economics: input for assessment of impacts
mid 2008	DG ENTR: Strategy paper

Expected Input from Member States

- via nominated experts on counterfeit
- Governments
  - Pharmaceutical Committee
  - Veterinary Pharmaceutical Committee

Expected Input from Member States (1)

- Data on the extent of the problem in MS
- Data on any possible relationship between parallel trade and the occurrence of counterfeit medicines
- Implementation definition on counterfeit medicines and pharmaceutical crime in MS, if any
- Specific national measures to avoid illegal trade via Internet

Expected Input from Member States (2)

- Data, experiences on potential of analytical testing to identify counterfeit medicines, recent approaches and experiences
- National co-operation structures to combat counterfeit medicines (customs, enforcement, pharmaceutical supervision)
- Models of co-operation between stakeholders and regulators
- National Databases on counterfeit medicines (customs, enforcement, pharmaceutical supervision)
- National programmes for awareness raising

Expected Input from Stakeholders

- Data on the extent of the problem for different stakeholders (e.g. incidents, type of products, countries inside and outside EU)
- Models of co-operation to combat counterfeit medicines, i.e. between regulators and stakeholders
- Stakeholder programmes for awareness raising
- Any other data, suggestions, proposals

Summary

- The DG ENTR project will primarily focus on concrete actions for/ from the EU.
- The objective of the strategy is to
  - focus on potential areas for EC regulatory requirements
  - focus on aspects of international cooperation
  - consider any measures to combat counterfeiting in a broader context
- The DG ENTR project builds on existing information (WHO, CoE, US-FDA etc.)

Your questions ?