DG Enterprise and Industry Studies on Distribution Channels

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Directives on medical devices

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices

Recently amended by Directive 2007/47/EC

- Directive 98/79/EC In vitro diagnostic medical devices

Directive

- Addressed to the Member States
- Obligation to transpose into their national law
- Obligation to enforce the national law
- Must be communicated to the Commission
- Incorrect transposition or failure to transpose is a breach of Community law

Premarketing
Medical Device on the Community market

- Definition of medical device
- Classification
- Conformity assessment procedure
- Declaration of conformity
- Affixing CE marking

Postmarketing
Medical Device on the Community market Member States

- Vigilance reporting

Addressed to the (other) Member States

- Corrective actions

Safeguard clause, particular health monitoring clause and wrongly affixed CE marking

Postmarketing
Medical Device on the Community market
Manufacturers

- Institute and keep a systematic procedure updated to review experience gained from devices in the post-production phase
- Implement appropriate means to apply any necessary corrective action
- Notify the Competent Authorities of the incidents falling into the criteria defined in the Directive immediately on learning of them

Securing the supply chain

"Track and trace requirements" at Community level for the regulation of medical devices

E.g. Annex I point 13.3, the label must bear the following particulars: […]

(d) Where appropriate, the ***batchcode,*** preceeded by the word LOT, or serial number"

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DG Enterprise & Industry Activities

Study on distribution channels:

For medicines launched in 2006
- Part I : combating counterfeit medicines
- Part II: safe medicines in parallel trade

For medical devices launched in 2007
- Part I : combating counterfeit medical device
- Part II: safe medical devices in parallel trade

Counterfeit medical devices

- Condoms
- Lenses
- Blood Glucose Strips
- Non-absorbable mesh to repair hernias
- Intra-aortic pumps
- Stethoscopes
- Blood pressure meters

Combating counterfeit medical devices

Severe implications → adverse health implications for consumers.

potentially lethal consequences as products have been found :

- non-sterile
- of poor quality
- consisting of wrong materials and questionable effectiveness.

In addition:

- distorts competition
- damages legitimate producers' interests and their brand names, undermines employment
- reduces tax income.

Objective & Steps

To develop a strategy for possible further action

- to combat counterfeit products
- concerning safe products in parallel trade

based on an assessment of possible social, economic, environmental impacts

Steps:
1) Analysis
2) Policy options
3) Impact Assessment
4) Summary

Four Key Areas of Interest

1. Legislation re.
   - legitimate supply chain
   - avoiding illegitimate supply chain

2. Supervision/ Enforcement

3. Cooperation/ Communication

4. Awareness Raising

Medical Devices: Activities

	Part I Counterfeit	Part II Parallel Trade
Fact finding missions NL, DE, UK	10-11-2007	
Consultation MS & stakeholders	10-11-2007	
Draft analysis	02-2008	
Policy options and impact	03-2009	

Part I: Counterfeit medical device

Key topics:

- Number and type of identified counterfeits
- Identification of (and enforcement of) anti-counterfeit measures
- National legislative framework surveillance
- Technologies (track and trace requirements)
- Remedies/penalties
- Cooperation structures/ networking/ databases
- awareness-raising

Part II: parallel trade medical device

Key topics:

- Numbers (and type) of parallel traded medical devices
- National legislative framework on parallel trader/distributor
- Repackaging/relabelling
- Track and trace requirements
- Reporting obligations (vigilance)

Track and Trace requirements medical devices

- Are there national practices/legislation on the topic?
- Specific needs for different categories of medical devices?
- Which technology for which medical device?
- Expectations for harmonised track & trace provisions for the future?

etcetera…

Medicinal Products: Activities

	Part I Counterfeit	Part II Parallel Trade
Consultation MS & stakeholders	04/2007	03/2007
Draft analysis	End 2007	09/2007
Fact finding missions NL, DE, UK	10 - 11/2007	
Policy options and impact assessment	2nd half 2008	End 2007

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Medicines - Part I: Counterfeits

Key topics:

1. Definitions
2. Number of identified counterfeit products
3. Traceability, technologies (e.g. RFID, 2D barcode)
4. Internet Trade
5. Laboratory testing campaigns
6. Cooperation structures/ networking/ databases
7. Awareness-raising
8. ....

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Medicines - Part II: Parallel Trade

Potential areas of in-depth review:

1. Parallel import licenses
2. Compliance with notification provision for PD
3. Obligations for parallel traders
4. GMP requirements for repackaging and relabelling
5. Traceability requirements for wholesalers/ distributors
6. Control reports (CoA) to accompany each batch in intra-Community trade
7. Correleation with extent of surveillance practices and high number of batches proceeded
8. Aspects of official retesting (OCABR) in parallel trade

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Traceability - Current Position

Director Heinz Zourek on 14 May 2007:

„… as a first step I think it is important to define which objectives should be achieved. Different products and regions may need different technical solutions. However, joint activities of various services on RFID and other track and trace solutions are meant to already prepare today for the options of the future…"

WHO IMPACT
DG ENTR supports…

- IMPACT Working Groups: Participation and/ or coordination of EU input
  - Legislative and Regulatory Infrastructure
  - Regulatory Implementation
  - Enforcement
  - Technologies
  - Communication

Development of principles and elements for legislation aimed at, inter alia, Combating Counterfeit Medical Products
(Medicinal products & Medical devices)