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Parallel Distribution – the European Perspective

Contribution to the debate of the Health Committee of the Czech Parliament

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EAEPC – who we are

- **Founded in 1998**
- **70 firms in 21 countries in the EEA**
- **Direct members or national associations**
- **All products handled by EAEPC members have national or EU regulatory approval and are exlusively sourced from and sold to EEA markets**

Parallel distribution is integral part of European medicines supply chain – the ESM

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Parallel distribution: savings to payers and patients

- **Is legal within EEA area of Europe**
- **Is safe and regulated by GMP and GDP rules**
- **Is thus regulated in same way as the research-based pharma industry**
- **Only form of price competition for patented medicines**
- **Lower prices for consumers/patients and health care systems**
  - **€ 500 million direct savings per year**
- **Is supported by EU institutions (case law), and by national authorities via the reimbursement system**
- **ECJ acknowledges consumer welfare from parallel imports; (Glaxo Greece and Spain cases)**

No imports without exports

past

- From South to North
- Limited range of products

Status

Level of parallel trade in Europe stable over 5 yrs, ca. 4 Bio € import sales, less than 3% of pharma market.

present

- Trade across Europe as price differentials become more diverse
- Fluctuations between markets, as currencies, prices and reimbursement may change
- Quota systems limit availability
- Parallel distributor will seek larger portfolio of products, and new source markets

➔ Scrip: all products and all countries can be subject to import or export.

EAEPC takes shortages very seriously – but do we know enough about the causes?

- **Reports about shortage of crucial medicines in US or CH, where no parallel distribution exists**
- **Greece: No shortages in 2007/8 when export levels were >800 mio, and double those of today, but now allegations of shortages appear**
- **Cost control – pricing pressures – margin squeeze in supply chain – reimbursement delays: many turn to export to keep up liquidity**
- **No more buffer stocks in the supply chain (cost of capital)**
- **Quality related medicine recalls lead to scarcity, locally or EU wide**
- **EMA reflection paper on shortages due to manufacturing issues (Nov 2011)**
- **Italy, UK: pharmacies point at quota systems limiting availability**
- **Too simplistic to put blame on trade !**

EU limits to member states' intervention

- **The rules on free movement of goods (Art 34-36) and case law apply!**
  - **The imposition of a notification requirement for imports or exports constitutes a direct and actual restriction of trade by the delay which it involves and the dissuasive effect upon exporters (Dassonville formula, exemplified in Commission vs. France, Judgement of 3 Feb 1977 in Case 68/76)**
  - **A measure addressing export sales without also treating domestic sales equally is considered a distinctively applicable measure, and thus falls under the scope of the prohibition (of restricting exports) laid down in Article 35 TFEU.**

- **Directive 2001/83 establishes full harmonization; some exceptions such as Art. 81 leave some room for national measures but these must observe the limits established in Art. 81/3, ie. must aim to protect public health and must be proportionate, and also in that case the rules on free movement of goods (Art 34-36) must be respected !**

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Commission enforcing treaty rules

- **The proportionality test is broken down into two cumulative sub-tests:**
  - **A "suitability test", i.e. the means must be suitable to achieve the pursued public health objective;**
  - **A "necessity test", which consists in balancing the different interests at stake.**
- **Moreover it is for the MS who claims the measure to demonstrate by evidence the existence of a reason relating to the public interest, the need for the restriction in question and the proportionality of the restriction in relation to the objective pursued.**
- **As an example, Estonia has notified a draft measure for a notification system where the consent of the manufacturer is needed for the agency to approve exports.**
- **This is clear restriction which has been the object of a new Commission infringement proceeding, because the ECJ has in the Lelos case determined that is is alone for the public authorities, not for the manufacturer, to "resolve the situation by taking appropriate and proportionate steps that were consistent with the requirements following from Article 81/3 of the Directive".**

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The Spanish experience

- **The Spanish agency in 2011 introduced a full ex-ante notification obligation on wholesalers for all transactions of every medicine outside its territory. The agency reserved the right to refuse a transaction, but the criteria were not defined and should be developed later. The EAEPC complained at the EU Commission.**
- **The Commission started an infringement procedure. Spain conceded.**
- ✓ **Eventually, the agency introduced a notification obligation on wholesalers for a very limited number of medicines, and the agency has 3 days to respond.**
- ✓ **The list is limited to medicines for which there is no therapeutic alternative available in Spain, and which are in short supply on its market. It contains 8 medicines with 14 presentations.**
- ➢ **The criteria for determining a shortage are still vague, and a test case is ongoing in a national court to identify whether the information provided to the agency by the manufacturer could really justify the listing of the medicine, and the determination that is is really in short supply.**

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Summary

- **Parallel distribution is 100 % legal under EU law. Member States must respect the principles and case law on free movement, and the Article 81, para 2 and 3 of the Directive.**
- **A notification system must be limited to medicines for which there is no alternative therapeutic option available, and which are in short supply. Batch information is irrelevant.**
- **The agency must respond rapidly; a 30 day period is an obstruction.**
- **The criteria for determining a shortage must be objective and transparent. When pharmacies cant get products from the wholesaler, but can turn to direct sales from the manufacturer, this is not a shortage but a case where medicines are in the market but at the wrong place.**
- **A list of "all exportable products" would clearly be a restriction to trade and therefore banned by the TFEU; this is also the conclusion of the French Competition Council, addressing a French legislative proposal; it has been withdrawn.**
- **The measure must be suitable: if shortages result from manufacturing problems, or from manufacturer supply quotas, the manufacturers must be taken to task, who, according to Art. 81 "ensure appropriate and continued supply to pharmacies within the limits of their responsibility".**
- **Member states may be liable for damage caused to private parties due to measures breaching the treaty.**