„Health as the Real Winner“, Sofia

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European Association of Euro-Pharmaceutical Companies

# Limits of national export restrictions

Introduction and legal basis

1. ECJ case law
2. EU Infringement procedures *(and national best practice)*

*Outlook and conclusion*

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# Introduction

All products handled by EAEPC members have national or EU regulatory approval and are exclusively sourced from and sold to EEA markets.

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Parallel distribution is safe, regulated by both GDP and GMP rules: distributors who repackage are regulated like manufacturers and are holders of a manufacturing autorisation (EAEPC part of EMVO)

The number of parallel distributed medicines packages in Europe is estimated around 120-140 million packs p.a. and very stable: **Only form of price competition for patented medicines**

Lower prices for consumers/patients and health care systems: More than € 500 million direct savings per year and **indirect savings much higher (EPR system -> "downward spiral")**

# Introduction

It is supported by EU institutions (case law) and

by national authorities via the reimbursement system

Volume stable, **more products and diverse directions**, **less trade of top products.**

**Recent independent studies**

*Parallel trade of pharmaceuticals: The Danish market for statins, Dr. Susan J.Mendez*

"Banning PI increases profits of manufacturers, increase in health expenditures, decrease of welfare of patients, savings higher than previous studies."

*EU enlargement, parallel trade and price competition: Granlund/Köksal, Gothenburg*

"Drugs facing competition from PI are found to have on average 19-22% lower prices than they would have if they had never faced such competition."

# Legal basis

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Article 81 of Directive of human medicines (2001/83/EC): Public Service Obligation (PSO) for wholesalers and manufacturers

*"The holder of a marketing authorisation for a medicinal product* ***and*** *the distributors of the said medicinal product actually placed on the market in a* ***Member State shall****, within the limits of their responsibilities,* ***ensure appropriate and continued supplies*** *of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered."*

*"the arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning* ***the free movement of goods*** *and competition*".

**European Commission "***Study on the Availability of Medicinal Products for Human Use***" Matrix Insight** page 82
***"obligations relating to manufacturers may not necessarily be transposed at a national level."***

# 1. ECJ case law

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Parallel trade in ECJ case law consistently recognized
Communication from the European Commission 1982 and 2003

**Medicines are goods** with specific characteristics significantly different, yet goods (Delattre C-369/88)

In *Gysbrecht*, the Court ruled that the **adverse effect on exports is sufficient** to declare a measure in breach of Article 35 TFUE: Judgment of 16 December 2008, case C-205/07, *Gysbrechts and Santurel Inter* ECR I-9947

Article 35 TFEU prohibits **any quantitative restrictions on exports and all measures having equivalent effect** between Member States. In its well-known judgment in *Dassonville,* the ECJ defined "measures having equivalent effect" in the following terms (C-120/78 *Cassis de Dijon* and C-267/91 *Keck*)

***„All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions.“***

# 1. ECJ case law




The Public health exception has been interpreted in a very narrow way by the ECJ (COM v.DE, C-141/07, Deutsche Parkinson Vereinigung, C-148/15 or recently in June 2017 **Medisanus, C296-15**). The member state has the **burden of proof** if he wants to derogate (**Art 36 TFEU**) from the fundamental principle of the free movement of goods. Article 168 TFEU is **not** specific reason (COM C141/07)

In the *Lélos* case, **GSK** limited exports because of shortages (par.66)
"there can be no escape from the prohibition laid down in [Article 102 of the TFEU] for the practices of an undertaking in a dominant position which are aimed at avoiding all parallel exports from a Member State to other Member State, practices which, by **partitioning the national markets**, **neutralize the benefits of effective competition** in terms of the supply and the prices that those exports would obtain for final consumers in the other Member States."

"it would not be for the undertakings holding a dominant position **but for the national authorities to resolve the situation**, by taking appropriate and proportionate steps that were consistent with national legislation as well as with the obligations flowing from Article 81 of Directive 2001/83" (emphasis added, par 75)

# 1. ECJ case law

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The existence of a real risk to human health must be assessed, not by general consideration

Such a restriction cannot constitute an arbitrary discrimination or a disguised restriction and has to be proportional (C-434/04 Ahokainen).

Criteria must be based on objective, non-discriminatory criteria known in advance (Hartlauer, C-169-07, Canal Satélite Digital, C 390/99, COM FR C-333/08), not preventing exports per se.

Duration and cost should not deter the operators from the implementation of the business plan, it must be **possible to challenge a refusal in the courts**

# 2. EU Infringement procedures




**EC Infringement procedure**

European Commission (EC) acts as a Guardian of the Treaty

and oversees the application of EU law

(Initial phase, Structured dialogue, pre-litigation phase, ECJ referal)

*-> Most cases are settled before  being referred to the Court*

Public Health exception must be limited in time and scope, **member state has the burden of proof** (DPV, C-148/15).

**„Proportionality test“  (Venturini C-159/12, Sokoll-Sebacher, C-367/12)**

# 3. EU Infringement procedures

**3 types of restrictions: “direct ban”, ex-ante notification, consent of MAH**

Slovakia and Portugal: reasoned opinion of the EC

(old) Cases closed: Spain, Estonia, Greece, Bulgaria (Constitutional Court)
Romania (Official list medicamentelipsa.ms.ro and exports / List of medicines withdrawn)

France has a more balanced approach. Competition authority with 4 conditions for quotas (2007) states that “restrictions on supply should not go beyond what is strictly necessary to ensure reliable and economically-viable supply of product.”

# 3. EU Infringement procedures



France: Article L 5124-6CSP sets down obligation of information, if major therapeutical interest it must collaborate with ANSM

Decree 2012-1096 (PSO, clear and precise **definition of shortages**)

**MAH** needs call centers with QP, MAH needs "**to prevent or manage any shortage situation"**

"These **shortage management plans could**, in particular, provide for medicinal products intended for the **national market to be stockpiled** according to the market share of each pharmaceutical undertaking and of other manufacturing sites for proprietary medicinal products, as well as, where applicable, identify any proprietary medicinal products that might constitute an alternative to the unavailable proprietary medicinal product."

# Outlook

**Excessive pricing without parallel trade**

Oct 2016 ICA fined Aspen for abusing its dominant market position

500% price increase (old drugs and market niches / Aspen wanted to increase the price and to avoid parallel export and price competition)

Aspen has imposed unfair and excessive prices in the form of significant price increases for medicinal products containing the Active Pharmaceutical Ingredients chlorambucil, melphalan, mercaptopurine, busulfan and tioguanine in the EEA Member States except Italy ("the Member States").

The European Commission will also investigate information that to impose such price increases, Aspen has made use of **unfair, abusive negotiation practices with national authorities and/or hindered parallel trade** between the Member States.

See also : Flynn Pharma and CMA in the UK

# Conclusion

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**1. Negative real effects of export restrictions**

Medium/long term negative price effects of protectionism and export restrictions

-> better strengthening (and control) regular domestic supply chain

-> better fighting against black market

**2. Legal limits of export restrictions**

**Full** (!) Implementation of PSO (**wholesaler and MAH**) as less restrictive + more effective mean

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