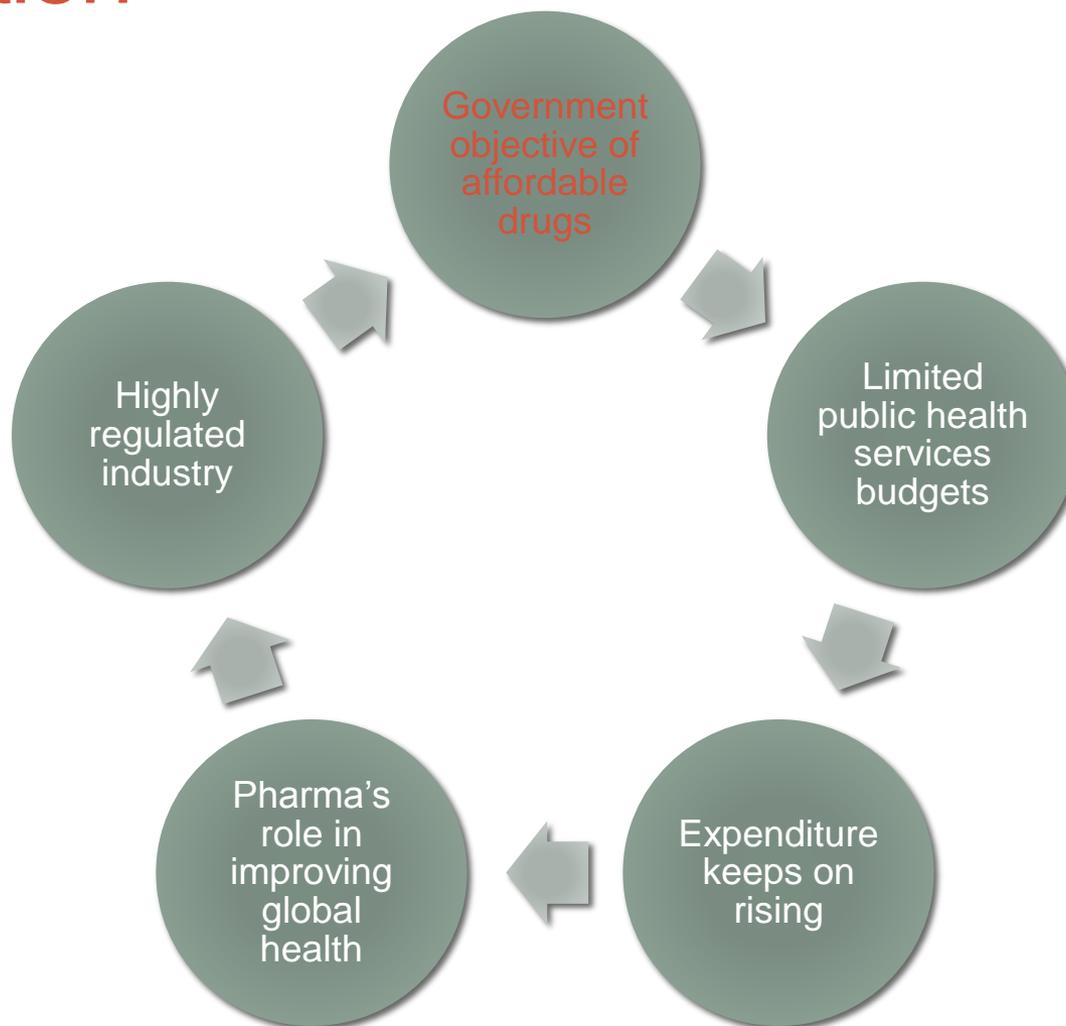


THE REGULATION/COMPETITION INTERACTION IN PHARMACEUTICALS: THE CASE OF PARALLEL IMPORTS

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The Vicious Circle of Drug Price Regulation



Regulatory Objectives & Techniques

- The State acts as **both** the **purchaser** and the **regulator** of drugs
- Pharmaceutical regulation attempts to correct **market failures**:
 - A. Demand Side:**
 - Low elasticity of demand
 - Information asymmetry
 - Lack of decision-making by consumers in prescription drugs
 - B. Supply Side**
 - Market power in the supply of branded drugs
 - Patents to reward R&D **but may restrain innovation**
 - High entry barriers; limited substitutability of medicinal products
- **Regulatory Techniques**
 - Vary substantially from country to country thus resulting in **price discrepancies**
→ perfect conditions for the proliferation of Parallel Trade.
 - Regulation: reimbursement schemes, guidance to physicians; price control

Goals of the Russian Authorities in the pharmaceuticals sector

- **Russian market characteristics**
 - A large market for pharmaceuticals, population of 140 million; state procurement system; prices amongst the **highest** in the world; recipient of innovation
- **FAS key priority** (2009 Report; 2014 Sector inquiry) + **'Roadmap' for developing competition** in the medicinal drug market + **Code of Fair Practices** in the Pharmaceutical Industry
 - Improving the law on IP protection
 - Increase the share of medicines and medical products manufactured locally and develop exports
- **Tools:**
 - A. Introduction of parallel import**
 - B. Compulsory licensing**
 - **Reduce the price** for certain foreign medicines
 - **Facilitate the access** of Russian population to **foreign** medicines

Parallel imports

- **Definition**

- Parallel import: a mechanism under which a medicine is marketed in one country by its patent and/or trademark owner (or with its authorization) and imported into another country (destination country) **without** its authorization, i.e. outside the manufacturer's or its licensed distributor's formal channel
- **Inevitable consequence of state regulation** of pharmaceuticals and **price differentiation** of drugs among countries
- The **only form of competition** for **patented drugs (intra-brand competition)**
- Based on the 'exhaustion' principle (national, regional, international)
- **EU**: a lawful activity based on two fundamental EU Principles: i) free movement of goods and ii) the principle of community exhaustion of industrial and commercial property rights
 - Usual parallel exporters: countries with low drug prices (Greece, Spain); usual importers: countries with high level drug prices (UK, Netherlands, Scandinavian)
- Effect on prices; market integration; promotion of competition

A view from the EU

- **Conditions for parallel imports of medicines within the EU:**
 - **Article 76(3) of Directive 2001/83/EC** of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use (as amended)
 - Obligation of any distributor, not being the marketing authorization holder and importing a medicine from another Member State, to notify the marketing authorization holder and the competent authorities of the member state in which the medicine will be imported.
 - If the medicine has not obtained a EU marketing authorization, this notification shall be without prejudice to local additional procedures in the Member State.

Parallel trade: A source of controversy

- **A regulation-driven arbitrage?**
 - Pharma: parallel traders act as free riders on the R&D efforts → reduce incentives → lead to shortages
 - Measures against parallel trade: Stock allocation or supply quota schemes; sale conditions with dual pricing provisions (CJEU, *GSK Spain and GSK Greece*)
 - European Commission: parallel trade is as an effective tool for the realization of the single market of pharmaceuticals; competition law applies
- **Need for repackaging regulations**
 - Reputation risks
 - Counterfeits risks
 - EU: Directive 2011/62/EU defines strict repackaging conditions: i) A manufacturing authorization holder, which repackages medicines (i.e. a parallel importer), should be liable for damages; ii) A manufacturing authorization holder, which is not the original manufacturer of the medicines, should only be permitted to remove, replace or cover safety features under strict conditions.

The application of Competition Law

- Pharma attempts to limit parallel trade:
 - refusal to deal/prohibition of exports
 - vertical integration
 - adoption of quota systems and dual pricing schemes
- EU default position
 - *The right of a manufacturer faced ... with an event harmful to his interests [such as parallel trade] to adopt the solution which seems to **him to be the best is qualified by the Treaty provisions on competition only to the extent that he must comply with the prohibitions referred to in Articles [101] and [102].** Accordingly, provided he does so without abusing a dominant position, and there is no concurrence of wills between him and his wholesalers, a manufacturer may adopt the supply policy which he considers necessary, even if, by the very nature of its aim, for example, to hinder parallel imports, the implementation of that policy may entail restrictions on competition and affect trade between Member States. Case T-41/96, *Bayer AG v. Commission*, para. 176.*
 - **But** See further **GSK Greece and GSK Spain**

Open questions for Russia

- **Which medicines**
- Should parallel trade be required for all medicines **or** only for those purchased or reimbursed to the patients by public authorities?
- Criteria according to which medicines' subject to parallel trade would be considered as lawfully marketed in their country of origin
 - Marketed by an authorized party
 - Under a compulsory licence?
- **What scope for competition law?**

Thank you!

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