ASCENSIA
Diabetes Care

AGREEMENTS RESTRICTING PARALLEL TRADE AND EU COMPETITION LAW

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TOPIC OF TODAY

Agreements Restricting Parallel Trade, or:

What Healthcare Companies have to consider from a Competition Law perspective when Dealing with Parallel Trade

BACKGROUND

- **Parallel Trade:** Buy a Product (incl. Medicinal Product/Medical Device) in one Member State and sell it in another at a higher price

- **Member States** influence the price at which Healthcare Products sold or reimbursed, which results in price differences between the countries

- **Healthcare Companies** may apply different product/pricing strategies in different territories

  => **Opportunity for Parallel Traders**: Buy a product in a “cheap” market, sell it at a higher price in a “expensive” market

OPPORTUNITIES FOR PARALLEL TRADE WITH PHARMACEUTICALS

- **Relevant Geographic Area for Parallel Trade:** EEA (EU, Norway, Iceland, Liechtenstein)

Important export markets are supplemented with new export sources
- GB
- Greece
- CZ, SK, the Baltic states, and
- other Eastern European countries

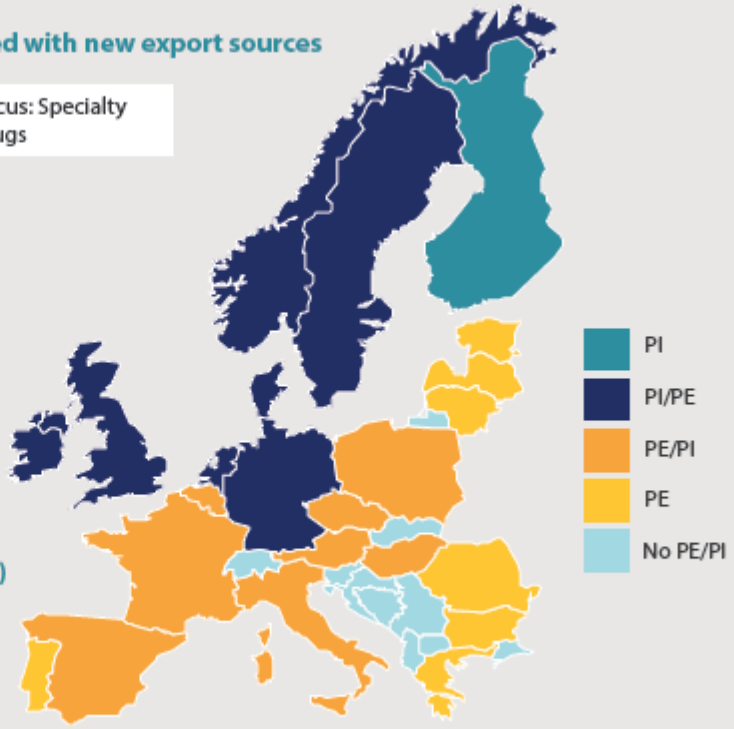
Focus: Specialty drugs

Further export markets:
- Spain
- Italy
- Portugal
- France
- Austria
- Belgium and the Netherlands

Significantly more parallel exports
- Greece
- Eastern Europe

Significant target markets (size and growth)
- Germany (size)
- Sweden (growth)

"These trends will continue to change as price corridors adjust."



Source: IMS Senior Management Review

(IMS Whitepaper Parallel Trade, 2015)

FACTORS INFLUENCING PARALLEL TRADE

- Price Differences per Product per Country
- Legal Guidelines
- Currency Exchange Rate Fluctuations
- Socio-Cultural Factors

POSITIONS

- Healthcare Companies' View on Parallel Trade:

efpia
European Federation of Pharmaceutical Industries and Associations

The Pharmaceutical Industry in Figures
Key Data * 2016

* The fragmentation of the EU pharmaceutical market has resulted in a lucrative parallel trade. This benefits neither social security nor patients and deprives the industry of additional resources to fund R&D. Parallel trade was estimated to amount to € 5,589 million (value at ex-factory prices) in 2014.

POSITIONS

- **EU Commission's View on Parallel Trade**
  Overarching Principle of the EEA: Free Movement of Goods

  Parallel trade increases price competition and this increases consumer welfare as this forces sellers in country of destination to reduce prices (Competition Policy Newsletter 1, 2007):

EC Treaty. The Commission's approach is predicated by two principles ([5]):

- The Single Market in pharmaceuticals requires the unhindered free movement of products — private companies cannot erect barriers to undermine this without distorting intra-brand competition.
- The efficiency claims advanced by the research based pharmaceutical industry is unsubstantiated — i.e. there is no evidence that partitioning the common market would spur on global investment in inter-brand innovation.

POSITIONS

- **View of the General Court and the ECJ on Parallel Trade:**
  - Somewhat more balanced trend to listen to company‘s rationals
  - But guiding principle: **Maintenance of Single Market**

HOW COMPANIES ARE DEALING WITH PARALLEL TRADE

- **Pricing and Product Differentiation Strategies:**
  - Dual Pricing
  - Sell different products/different prices in different territories

- **Setting of Country Quotas:**
  - Limit quantities of products delivered to each countries

- **Repackaging/Re-Labelling issues with Importers:** Exhaustion of Rights («5 BMS Conditions»)

LEGAL FRAMEWORK EU

- **Art. 101 TFEU:**
  Agreements/concerted practices affecting trade between Member States which have as their object or effect the prevention/restriction/distortion of competition are prohibited, unless efficiencies outweigh anticompetitive effects

- **Art. 102 TFEU:**
  Prohibition of the abuse of a Dominant Position

LEGAL FRAMEWORK EU

Article 101 TFEU

1. The following shall be prohibited as incompatible with the internal market: all **agreements** between undertakings, **decisions** by associations of undertakings and **concerted practices** which **may affect** trade between Member States and which have as **their object** or **effect** the prevention, restriction or distortion of competition within the internal market, and in particular those which: [..]
2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.
3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of: any agreement [..] which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:
   (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
   (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

LEGAL FRAMEWORK EU

Article 102 TFEU

Any **abuse** by one or more undertakings of a **dominant position** within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
(b) limiting production, markets or technical development to the prejudice of consumers;
(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

RELEVANT MARKET

- **Relevant Product Market:**
  Intra-brand competition (not inter-brand competition): All medicines which are capable of being subject to parallel trade in a member state constitute a relevant product market

- **Relevant Geographic Market:**
  National – different price and reimbursement regulations, prescription habits

PRICING/PRODUCT DIFFERENTIATION

- **Assessment under Art. 101 TFEU: Agreements with wholesalers or other market participants vs. unilateral behavior**
  - **Purely Unilateral Conduct** – Action undertaken by an undertaking without coordination with another undertaking does not infringe Art 101(1) TFEU – **Leading Case Bayer Adalat** (Joined Cases C-2/01P and C-3/01 P)
  - **Agreement – Concurrence of Wills**
    Acquiescense to Unilateral Policy, tacitly or by powers set out in a contract – **Example: Dual Pricing – GSK Case** (Case T-168/01 and Joined Cases C-501/06, C-513/06 P, C-515/06 P and C-519/06 P)

PRICING/PRODUCT DIFFERENTIATION

- **Assessment under Art. 101 TFEU: Agreements with wholesalers or other market participants vs. unilateral behavior**

- **Bayer Adalat Case:** Bayer's measures to restrict quantities to wholesalers was confirmed to be unilateral by ECJ, no tacit incorporation into Bayer's distribution agreements (Joined Cases C-2/01P and C-3/01P):

  "The mere **concomitant existence of an agreement which is in itself neutral** and a measure restricting competition that has been imposed unilaterally does not amount to an agreement prohibited by that provision. Thus, the mere fact that a measure adopted by a manufacturer, which has the object or effect of restricting competition, falls within the context of continuous business relations between the manufacturer and its wholesalers is not sufficient for a finding that such an agreement exists. "

  "For an agreement within the meaning of Article 85(1) of the Treaty to be capable of being regarded as having **been concluded by tacit acceptance**, it is necessary that the **manifestation of the wish of one of the contracting parties to achieve an anti-competitive goal constitute an invitation to the other party**, whether express or implied, to fulfil that goal jointly, and that applies all the more where, as in this case, such an agreement is not at first sight in the interests of the other party, namely the wholesalers"

PRICING/PRODUCT DIFFERENTIATION

- **Assessment under Art. 101 TFEU: Agreements with wholesalers or other market participants vs. unilateral behavior**

  - **GSK Case (Case T-168/01 and Joined Cases C-501/06, C-513/06 P, C-515/06 P and C-519/06 P)**
    Dual Pricing: Agreement between Healthcare Product Manufacturer and Distributor/Wholesaler, applying different prices if product are sold in our outside the territory.

    - GSK had sent terms and conditions to wholesalers requesting to sending back a signed copy = Agreement

    - **ECJ**:
      - Agreement to restrict parallel trade is a restriction of competition by object, without need to address effects

      - **But:** Exemption under Art. 101 (3) TFEU is possible, if efficiencies outweigh anticompetitive effects.

PRICING/PRODUCT DIFFERENTIATION

- **Assessment under Art. 102 TFEU – Abuse of Dominance**
  - GSK Case – Evaluation by GC (Case T-168/01):
    - Dominant Company may set different prices in different Member States
    - Where these prices are applied on separate geographic markets

"It follows from the case-law to which the Commission refers that Article 82(c) EC **does not preclude an undertaking in a dominant position from setting different prices in the various Member States**, in particular where the price differences are justified by variations in the conditions of marketing and the intensity of competition, but prohibits it from applying artificial price differences in the various Member States such as to place its customers at a disadvantage and to distort competition in the context of an artificial partitioning of national markets *(Tetra Pak* v *Commission*, paragraph 152 above, paragraph 160 and the case-law cited) [..] **It is common ground that each of those Member States constitutes a distinct market, in so far as the relevant geographic market is national owing**, in particular, to the differences in the national regulations on the prices and the reimbursement of the medicines in question."

SUPPLY QUOTA SYSTEM

- **Assessment under Art. 101 TFEU**
  - **See Bayer Adalat Case:**
    - **Unilateral Conduct vs. Agreement – Decision of the General Court (Case T-41/96):**

"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."

SUPPLY QUOTA SYSTEM

- **Assessment under Art. 102 TFEU**
  - **See Syfait II Case (Joined Cases C-468/06 to C-478/06):**
  - If a dominant company refuses to meet prior «**ordinary orders**» in order to prevent parallel trade => **Abuse of a dominant position**

  This means that:

  - Orders may be **legitimately refused** by a **dominant pharmaceutical company** if they are out of the ordinary in terms of:
    - Size of the orders and
    - Previous business relationship with wholesaler concerned
  -

WHAT IS HAPPENING ON A NATIONAL LEVEL?

- France: French Competition Commission - Sector Inquiry into the Distribution of Medicinal Products, Dec 19, 2013:
  - Importers of medicinal products which carry out parallel imports within the European Union can also contribute to the stimulation of competition, insofar as dispensing chemists can use the argument of lower prices that they obtain from importers in order to negotiate better commercial conditions from their usual suppliers. Importers of medicinal products must therefore continue to occupy their role as a driving force, while ensuring that such movements of medicinal products within Europe does not compromise the security of supply for the Member States, particularly France.
- Switzerland:
  - Gaba Judgment of the Swiss Federal Supreme Court
  - Restrictions on Parallel Trade Enforcement priority by ComCo

WHAT IS HAPPENING ON A NATIONAL LEVEL?

- Spain: March 21, 2017 Spanish Competition Authority

  Opens investigation into allegedly collusive behavior among a number of pharmaceutical companies, including Eli Lilly, Janssen-Cilag, Merck Sharp & Dohme, Novartis, Pfizer and Sanofi-Aventis. The parties are accused of having established a system of dual pricing for the distribution of pharmaceutical products in Spain.

  CNMC to determine whether a dual pricing clause contained in the general conditions of sale which a number of pharmaceutical suppliers apply in their dealings with distributors is compatible with competition law, in particular with Art. 101 TFEU and the equivalent provision under Spanish law. In addition, the separate question arises whether there is a concerted practice among the suppliers that apply the clause at issue.

- PARALLEL IMPORT IS STILL VERY HIGH ON THE AGENDA ALSO FOR NATIONAL COURT/COMPETITION COMMISSIONS

CONCLUSION

- **Commission and Courts**
  - Commission maintains its strict view that restrictions on parallel trade segregate the single market and are anti-competitive
  - Courts are more receptive than the Commission to the arguments of Healthcare Companies, recognizing that for an assessment of the exemption under Art. 101 (3) TFEU (if efficiencies outweigh anti-competitive effects) the nature and specific features of the sector to be taken into account as those specific features are decisive for the outcome of the assessment

CONCLUSION

- **Healthcare Companies**
  - A lot of factors are relevant to assess measures around parallel trade, like: Products concerned, markets shares, market situation, regulatory requirements, local legal requirements, contractual situation with wholesalers or other contracting parties
  - Case-by-case analysis for each product and market is required before implementing any measures that could have an impact on parallel trade