

# Rebates and tying in the pharmaceutical industry : An EU perspective

GMU's Global Antitrust Institute conference

23 September 2014

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# Structure of the pharmaceutical market

Price competition is the main form of competition on many markets. The pharmaceutical market is, however, rather unique in that it involves many actors in addition to producers and patients:

- **Third-party payers** (governments, statutory health insurance funds, private insurers): they act on behalf of consumers or patients and take part in reimbursement decisions;
- **Wholesalers** are responsible for distributing pharmaceuticals from source to pharmacies, and in doing so they are interested in acquiring pharmaceuticals from the cheapest source;
- **Prescribing physicians** make decisions on behalf of their patients; and
- **Dispensing pharmacists** usually follow physicians' instructions on what to dispense, but their dispensing behaviour can be influenced by the incentive structure of their payment method.

In addition, prescribed drugs are generally subject to price regulation.

# Drug distribution flows in Europe

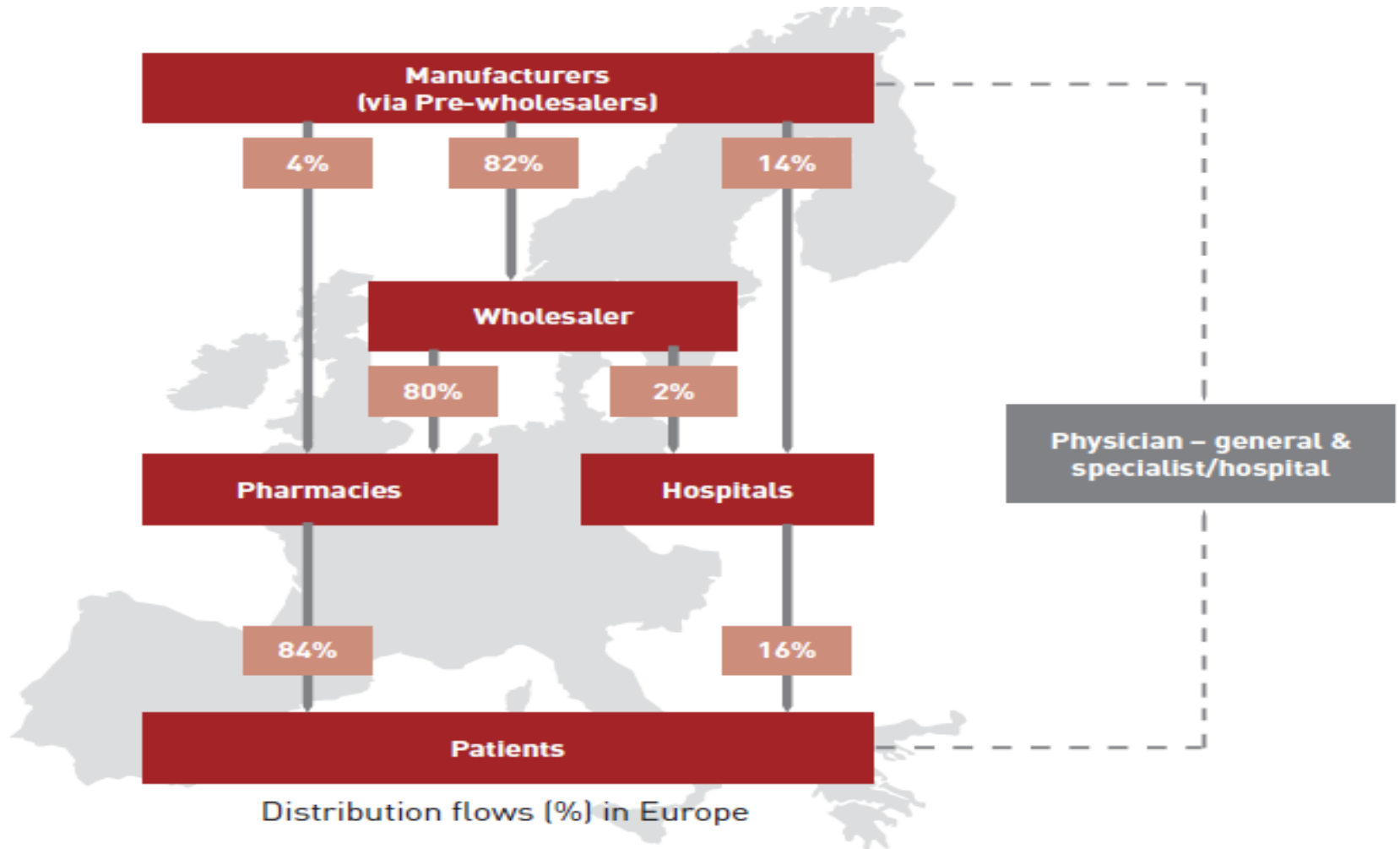


Figure 2.3: Drug distribution flows in Europe

# Price incentives

- Price incentives can take different forms:
  - **Discount** is a price reduction granted to specified purchasers under specific conditions prior to purchase.
  - **Rebate** is a payment to the purchaser after the transaction has occurred.
  - **Bundling** is a marketing strategy that involves offering several products for sale at a lower price than if the products were purchased separately.
- From a competition law standpoint, the problem is not the price reduction in itself, but the conditions attached to the price reduction (purchasing of certain quantities, exclusive purchasing, etc.).

# Article 102 TFEU

- Article 102 TFEU prohibits abuses of a dominant position.
- Two conditions must be met for Article 102 TFEU to apply:
  - You need a firm in a dominant position (may require complex assessment for pharmaceutical products)
  - That firm must have engaged in an abusive conduct. Abusive pricing strategies can take a variety of forms: predatory pricing, margin squeeze, price-discrimination, etc.
- Non-dominant firm are free to prices their products as they like (although they cannot collude with competitors).

# Rebates

- Rebates are usually pro-competitive and beneficial to customers, but may be anticompetitive when they exclude “equally efficient” rivals, i.e. rivals that should normally be able to compete on the merits.
- The EU Courts have generally taken a strict view on rebates, which is detached from the economic reality.
- A distinction should be made between:
  - single-product rebates; and
  - multi-product rebates (also referred to as bundling).

# Conditional rebates

- Conditional rebates can be classified into different categories.
  - The *type of thresholds* can be defined in terms of:
    - volume targets (quantity rebates);
    - percentage of total requirements (loyalty or market-share rebates); and
    - increase in purchases (target rebates).
  - The *scope of application*, i.e. whether they are:
    - forward-looking, i.e. they apply to incremental units above the threshold (incremental rebates); or
    - backward looking, i.e. applying to both units below and above the threshold (retroactive rebates or roll-back rebates).

# The case-law of the EU courts

- *Hoffmann-La Roche* (1979) – Fidelity rebates
  - Discounts conditional on the customer's obtaining all or most of its requirements from one supplier, irrespective of whether the quantity of the purchases is large or small.
  - Distinct from quantity rebates linked with the volume of purchases.
- *Michelin I* (1981) – Annual variable discount based on an annual sales target set by Michelin
  - CJEU considered all circumstances and concluded that the system increased pressure on buyer to reach purchase figure at the end of the period concerned (one year).
  - CJEU considered the retroactive nature of discounts – slight variations can increase pressure on dealers, especially as target or scale of discounts were not written.
- *Michelin II* (2003) – GC confirmed the absence of foreclosure effect of quantity rebates, but:
  - Only if the amount of the rebate is directly linked to the cost savings achieved through the greater volume of supply
  - GC rejected the argument that a detailed analysis of the effects should have been carried out – it is sufficient that the conduct “tends” to restrict competition



# The approach of the Commission Guidance Paper

- In its Guidance Paper on Article 102 TFEU adopted in 2010, the Commission adopted an economic approach to the analysis of exclusionary conduct, including anticompetitive rebates.
- Economic analysis taking the form of “price/costs” test is used to determine whether a rebate granted by a dominant firm to a customer could exclude an “as efficient” competitor.
- The proposed tests relied on certain measures of costs, including:
  - Average avoidable costs (“AAC”)
  - Long-Run Average Incremental Costs (“LRAIC”)

# Single product rebates:

## Incremental rebates

- An incremental rebate is a conditional rebate that is available only to incremental purchases above the threshold set by the dominant seller.
- Incremental rebates are subject to the following test:
  - If **effective price > LRAIC** of the dominant undertaking, an equally efficient competitor would normally be able to compete profitably notwithstanding the rebate. In those circumstances the rebate is usually not capable of foreclosing rivals in an anti-competitive way.
  - If **effective price < AAC**, as a general rule the rebate scheme is capable of foreclosing even equally efficient competitors.
  - Where **AAC < effective price < LRAIC**, the Commission will investigate whether other factors point to the conclusion that entry or expansion even by equally efficient competitors is likely to be affected.

# Retroactive rebates

- A retroactive rebate applies to all purchases below and above the threshold once the latter is exceeded. Retroactive rebates are subject to an “attribution test”, which seeks to determine whether an as efficient rival could compete with the effective price of the product sold by the dominant firm.
- The test consists in applying the entire rebate on the contestable share of a given customer’s demand:
  - If **effective price > LRAIC** : no exclusionary effect.
  - If **effective price < AAC**: possible exclusionary effect.
  - Where **AAC < effective price < LRAIC**: one has to look at all the circumstances.
- Now, this test is extremely difficult to apply because it is hard to determine what share of a customer’s demand is contestable.

# Multi-product rebates: The EU courts' case-law

- In *Hoffmann-La Roche*, the CJEU held that “across-the-board” rebates granted to its customers by a dominant firm upon the purchase of a bundle of products constituted an illegal tie-in in breach of Article 102 TFEU.
- The CJEU, as well as the Commission in its early decisions, seem to have taken the strict view that mixed bundling is *per se* contrary to Article 102 TFEU, absent cost-savings attributable to the bundle.
- National competition authorities seem to have taken a similar approach, e.g. *Lilly* (1996, France), *Sandoz* (2003, France), *Wyeth Hellas and Phadisco Ltd* (2009, Cyprus).

# Multi-product rebates: The Guidance Paper

- Multi-product rebates may be anti-competitive on the market for any of the bundled products if it is so large that equally efficient competitors offering only some of the components cannot compete against the discounted bundle.
- The test used by the Commission is as follows:
  - If incremental price that customers pay for each of the dominant undertaking's products in the bundle is above the dominant firm's LRAIC of including that product in the bundle, an equally efficient competitor with only one product should be able to compete profitably against the bundle. No intervention needed.
  - Enforcement action may, however, be warranted if the incremental price is below the LRAIC of including the product, because in such a case even an equally efficient competitor may be prevented from expanding or entering.

# The Intel judgment (June 2014): Loyalty rebates

- The court confirms that rebates contingent on exclusivity or quasi-exclusivity are effectively *per se* unlawful. No other evidence is required.
- This arises because “exclusivity rebates granted by an undertaking in a dominant position are by their very nature capable of restricting competition” as they foreclose competitors and even if they merely make access more difficult.
- No further analysis is required because of the special responsibility of the dominant firm not to impair genuine undistorted competition.

# Other types of rebates

- Quantity rebates are fine, but they must reflect gains in efficiencies and economies of scale made by the dominant firm.
- Other rebates (not conditioned on exclusivity or quasi-exclusivity, such as, for instance, “target rebates”): necessary to look at all the circumstances, including whether:
  - the rebates tend to remove or restrict the buyer’s freedom to choose its sources of supply
  - it bars competitors from access to the market, or
  - it strengthens the dominant position by distorting competition.

# Naked restrictions

- Naked restrictions constituted payments made by Intel to customers inducing them to either delay or cancel the launch of competing products.
- The Commission considered that these restrictions breached Article 102 TFEU unless they could be objectively justified.
- The Court went one step further and declared them *per se* illegal
  - “The only interest that an undertaking in a dominant position may have in preventing in a targeted manner the marketing of products equipped with a product of a specific competitor is to harm that competitor. Consequently, by applying naked restrictions ... the applicant pursued an anti-competitive object.”



# Tying of pharmaceutical products

- Anti-competitive tying arises if:
  - the tying and the tied goods are two separate products;
  - the undertaking concerned is dominant in the tying product market;
  - the undertaking concerned does not give customers a choice to obtain the tying product without the tied product; and
  - the tying in question forecloses competition.
- Even when these conditions are met, the dominant firm can justify the tie if it has an objective justification.

# Conclusions

- There is a clear disconnect between economic theory and the position taken by the courts and competition authorities in the field of rebates.
- The current state of the law can be summarized as follows:
  - Single product rebates :
    - Loyalty (percentage-based) rebates are *per se* illegal;
    - Quantity rebates are legal when they are related to cost-savings;
    - Target rebates: One needs to look at all the circumstances
  - Multi-product rebates: Problematic for most competition authorities and courts.
  - Naked restrictions: *Per se* illegal.
- Tying by dominant firm is generally seen unfavourably by the EU courts unless there is an objective justification.