Pharmaceuticals and antitrust: an overview of enforcement in the EU

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Competition in the pharma sector

- A sector of major societal importance (public health, competitiveness, R&D, public budgets…)
- How competition law enforcement (antitrust and mergers) has helped to safeguard EU patients' access to affordable and innovative medicines?
- Significant increase of competition law enforcement activities over the past 20 years:
  - AstraZeneca in 2005, Sector Inquiry 2008-2009 etc.
  - Period 2009-2017 first pharma report
  - Recently: updated report from 2018-2022

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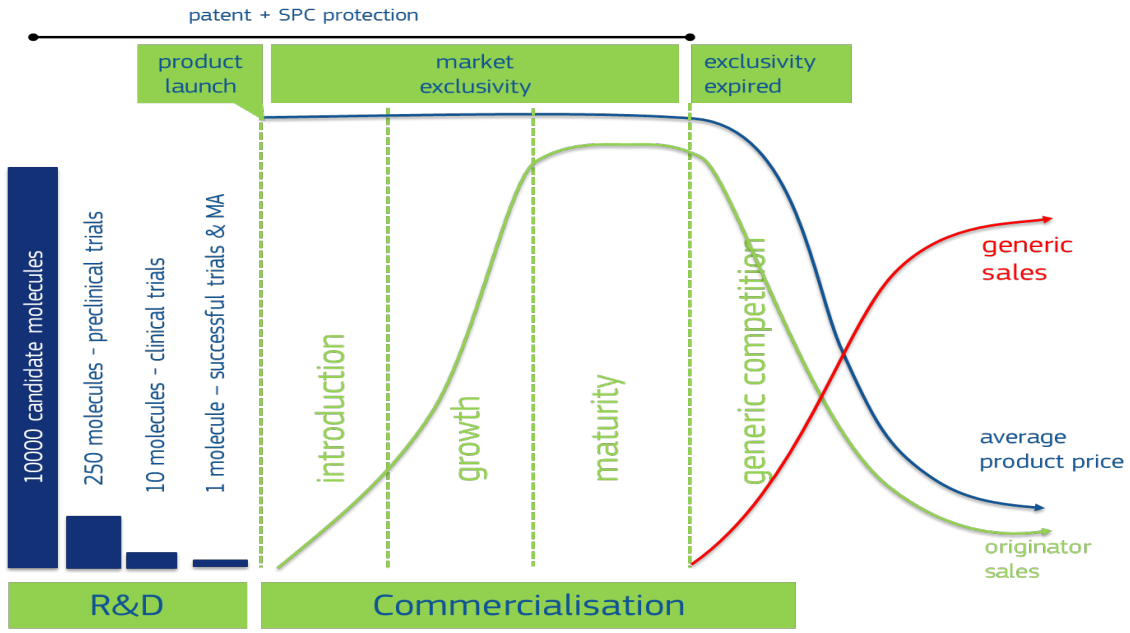
What makes pharma so special?

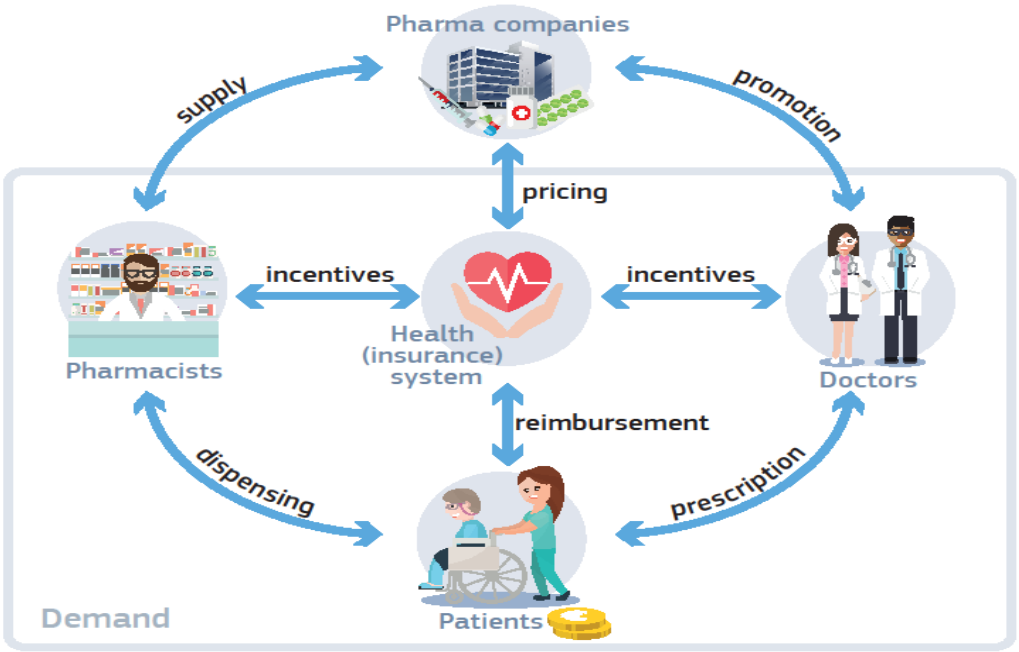
1) Life cycle of medicines



Evolving nature of competition:

- ✓ Developing new medicines – competition on innovation
- ✓ Market exclusivity for new medicines is limited in time
- ✓ Loss of protection and generic competition

2) Demand structure



1) high investment and high return over a relatively long time - strong incentives to protect market exclusivity throughout the cycle, and beyond;
2) multitude of mechanisms to exclude competition – sometimes blurred lines between legitimate and anticompetitive conduct (eg misuse of patent system)

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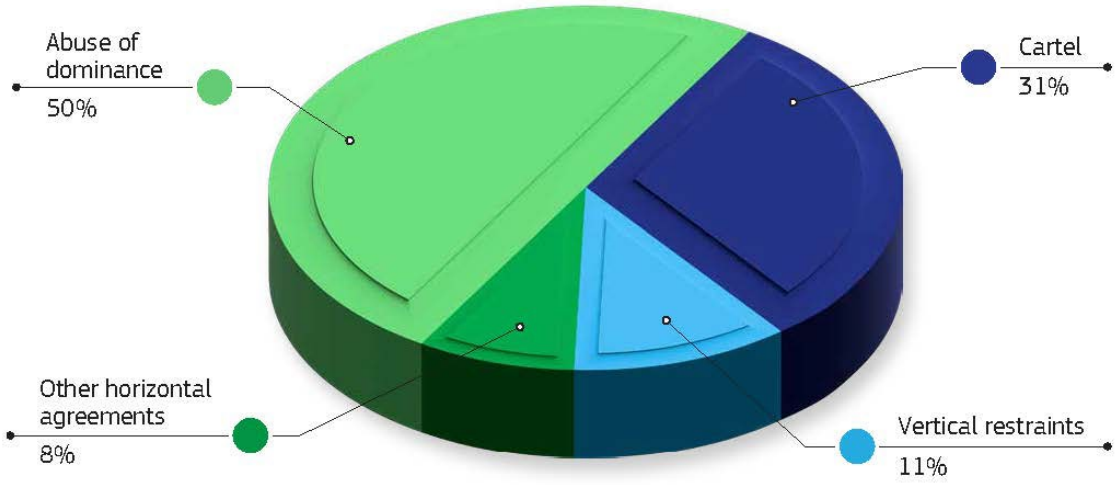
Focus on recent antitrust enforcement in pharma 2018-22

Around 100 investigations by COM and NCAs (Belgium, Romania and Spain more active ones):

- 26 intervention decisions (17 infringement decisions, 9 commitment decisions)
- More than 30 ongoing investigations
- More than 40 investigations closed without intervention

Type of competition issues in intervention cases



Fines total close to EUR 780 m (though FR record 444m fine annulled, with appeal pending)

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EU merger enforcement

EU merger enforcement in the pharmaceutical sector:

- >30 mergers in the pharmaceutical sector
- 4 problematic mergers cleared with remedies,
  1 abandoned due to concerns
- intervention rate of 17% in pharma sector

Typology of enforcement actions

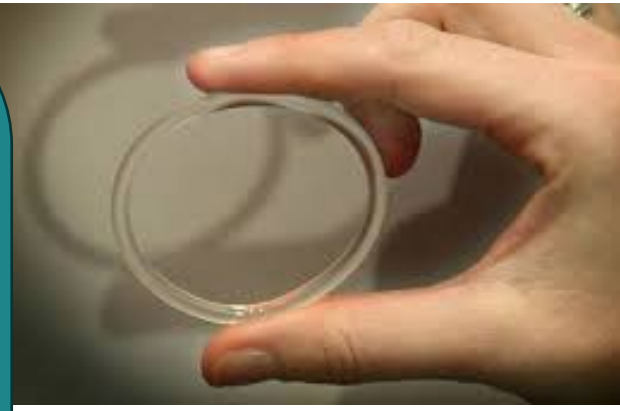
1) Competition promotes access to **affordable medicines**

- Enforcement against dominant firms charging unfairly high prices (excessive prices)
- Other anti-competitive practices capable of inflating prices
- Merger control and affordable medicines

Example:
patent misuse and vexatious litigation

The *MSD rings* case

- Spanish NCA
- Contraceptive product (vaginal ring)
- Investigation of strategy to mislead court to hinder market entry of generic-like competitor (withholding relevant information and providing misleading information to obtain injunctions)



Example:
abusive rebates and predatory pricing

The ***temozolomide*** **case**
(brain tumor drug, also by MSD)

- Austrian NCA (after Commission inspections)
- Investigation into foreclosure of generic manufacturers' access to hospitals (originator setting hospital prices below cost to ensure patients continue using branded product when out of hospital)

Example: excessive pricing

Enforcement against dominant firms charging unfairly high prices

The *Leadiant* cases

- Dutch, Italian, and Spanish NCAs
- Investigation into excessive pricing of drug for rare genetic disease (excessive price increases, relaunch as orphan drug, no therapeutic added value)

2) Innovation and choice of medicines

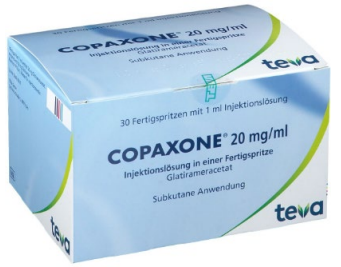
Competition drives **innovation**
and increases the **choice** of medicines

- Antitrust enforcement contributes to patients' choice and access to innovative medicines
- Intervention to ensure companies do not abstain from innovation practices or prevent others from innovating
- Merger control to ensure R&D efforts and existing medicines are not affected because of mergers

Overview of current Commission‘s enforcement priorities in antitrust

- Decade of pay-for-delay decisions (Lundbeck, fentanyl, Servier) coming to a close with decision in Cephalon in November 2020 (confirmed by GC in October 2023)
- However, appeals before Court of Justice still pending in Cephalon and Servier (also on broader policy issues such as how to define the relevant market for end-of-lifecycle pharmaceuticals)
- Commission currently investigating a number of cases, including the following ones

Teva Copaxone - misuse of the patent system and exclusionary disparagment



- Teva‘s main patent protecting its blockbuster multiple sclerosis medicine Copaxone expired in 2015

- the Commission is investigating whether Teva may have abused its dominant position by hindering the entry and/or expansion of its generic competitors, in particular whether it:
  - *„artificially extended the market exclusivity of Copaxone by strategically filing and withdrawing divisional patents, repeatedly delaying entry of its generic competitor who was obliged to file a new legal challenge each time“*
  - *„pursued a communication campaign to unduly hinder the use of competing glatiramer acetate products… Teva's campaign, primarily directed at healthcare institutions and professionals, may have targeted competing products to create a false perception of health risks associated with their use, even following the approval of these medicines by competent public health authorities“*

- Statement of Objections issued to Teva in October 2022, Oral Hearing in March 2023

Vifor – disparagement

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Update – commitments procedure underway

Preliminary Assessment sent on 16 April 2024, preliminary findings:

- Vifor‘s Ferinject dominant on several national markets for IV iron medicines
- Concerns regarding communication campaign with the purpose of leading doctors and payers into believing that using a competing innovator product, Pharmacosmos‘s Monofer, could entail serious health risks and that it had a worse risk profile compared to Ferinject
- Possible abuse of dominance: messages may be misleading if based on inaccurate and/or incomplete information that is capable of confusing / inducing into error its addressees and of discrediting a competing product, foreclosing competition without an objective justification

Vifor – commitments procedure

Proposed commitments :

- Required Conduct: a comprehensive communication campaign in relevant countries to rectify and undo the effects of the potentially misleading messages previously disseminated by Vifor regarding the safety of Monofer => pre-approved clarificatory communication for multichannel dissemination (handouts to doctors, medical journals, website etc);
- Prohibited Conduct: Vifor commits not to engage in promotional and medical communications about Monofer's safety profile containing information that is neither based in Monofer's Summary of Product Characteristics ('SmPC') nor derived from randomised, controlled clinical head-to-head trials, 10 years, entire EEA

Market test concluded on 22 May 2024

Zoetis – exclusion of pipeline competition

- Initiation of proceedings on 26 March 2024:
  - Zoetis – a leading animal health company - developed and marketed Librela, the first and only mAb to treat osteoartritic pain in dogs - but
  - also acquired another late-stage pipeline product for the same indication, to be commercialised in the EEA by Virbac, a competitor;
  - following acquisition, terminating the development of the acquired pipeline and refusing to transfer it to the competitor with commercialisation rights;
- In-depth investigation ongoing into post-acquisition conduct as a possible abuse of dominance

Commission‘s own pipeline – beyond pharmaceuticals

PRESS RELEASE | 19 September 2023 | Brussels | 1 min read

Antitrust: Commission carries out unannounced inspections in the medical devices sector

The European Commission is carrying out unannounced inspections at the premises of a company active in medical devices for cardiovascular applications.

The Commission has concerns that the inspected company may have violated EU antitrust rules that prohibit abuses of a dominant market position (Article 102 of the Treaty on the Functioning of the European Union).

The Commission officials were accompanied by their counterparts from the national competition authority of the Member State

Conclusion

- competition authorities across the EU actively investigating exclusionary and exploitative conduct in the pharma sector and beyond
- Commission‘s recent investigations focussed on unilateral exclusionary conduct
- drawing a line between abuses and competition on the merits and the legitimate exercise of rights can be difficult
- distortion of competition through delaying strategies has major impact for patients and health systems (price, innovation)
- investigations beyond end-of-lifecycle cases, including into conduct impacting competition between innovators

Thank you

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