Competition Issues in the Life Science Sector

Brussels, 3 July 2018
DG Competition, European Commission

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- ***Today when I speak about a particular conduct, type of agreement or arrangement between firms, or a particular fact pattern or hypothetical situation, I do not intend to convey an express or implied message that the described conduct, etc violates EU competition law. Instead, I would like to raise awareness of such arrangements, conducts and fact patterns as they may raise competition law issues that should be carefully analyzed and considered***

- ***Nothing that is presented today should be construed as an official or unofficial position or policy of DG Comp or the Commission, or a personal opinion on my part, that modern antitrust policy should focus more on exploitative abuses than on exclusionary abuses.***

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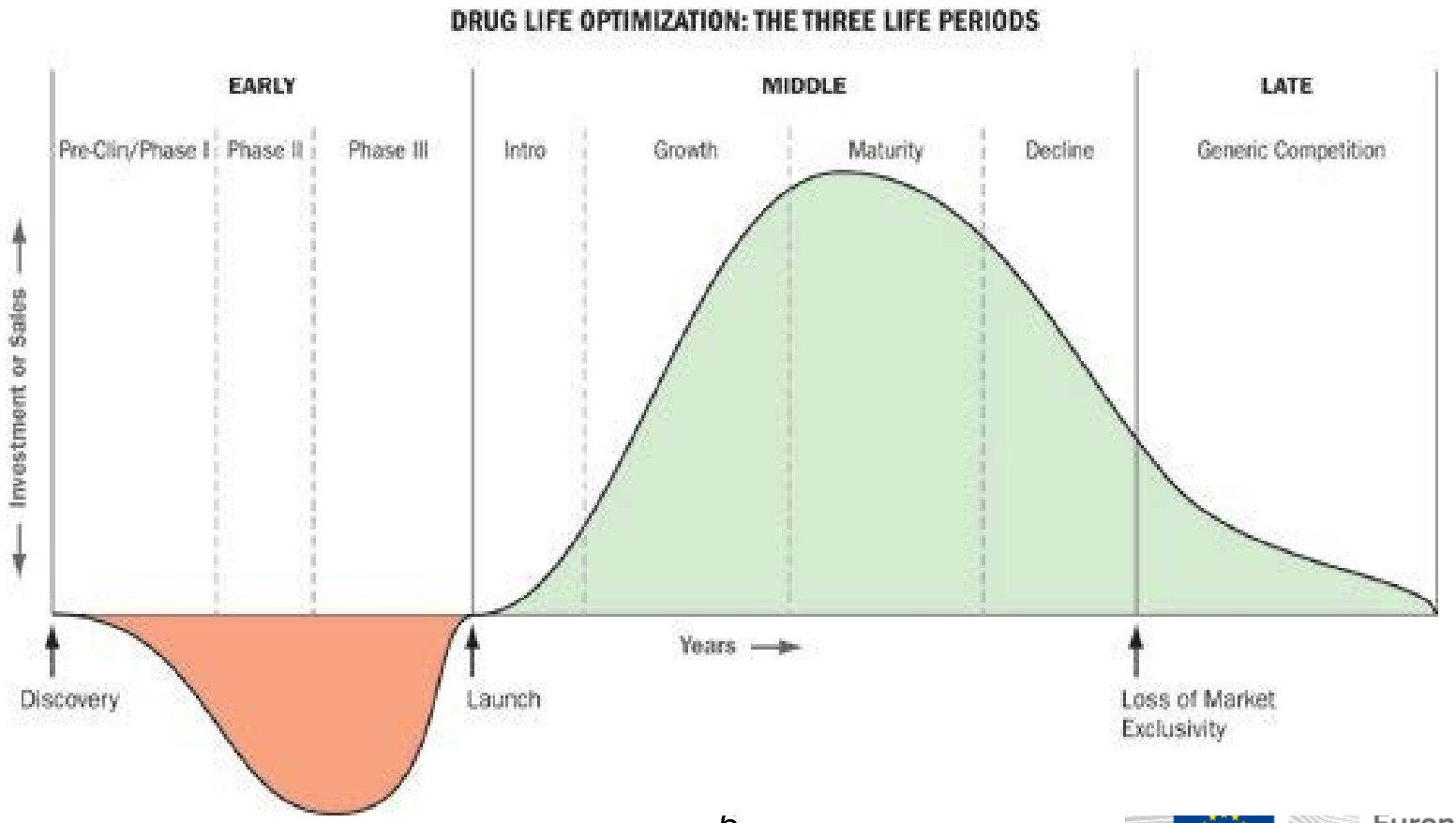
Overview

1. *Overview*
2. *Biologicals & Biosimilars: Policy/Regulatory Elements*
3. *Delay / Hinder Generic Entry*
4. *Pharma Market Definition*
5. *Merger Control*

Overview
Outline

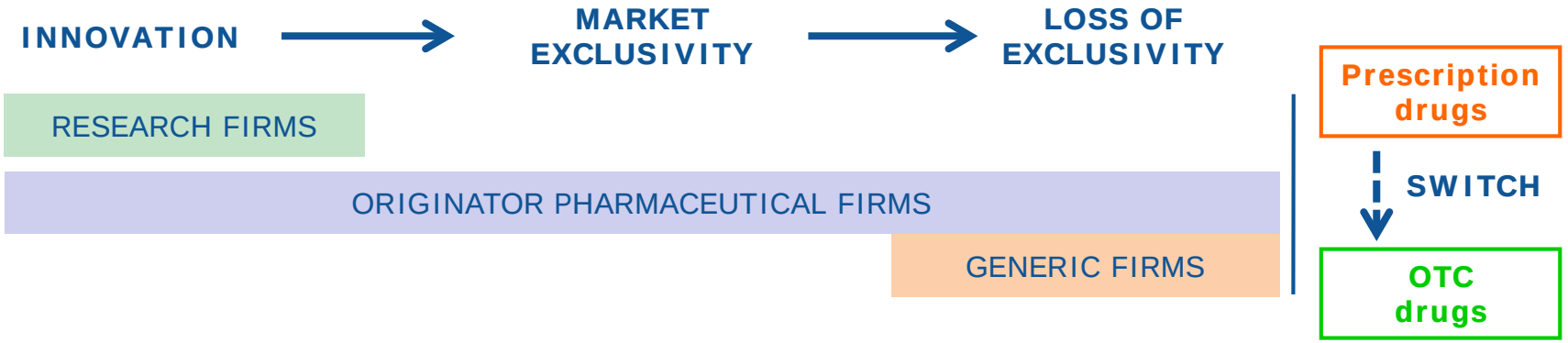
- The broader context, life cycle management
- Conducts that may run foul of Articles 101 and 102 TFEU
- Interaction between competition law, regulation and IPR
- EU merger review – innovation and procedural compliance issues

Life Cycle Management



How Competition Takes Place

- Three stages in the life cycle of a pharmaceutical product:



- Competition stemming from different players at each stage (case-by-case):
  - Innovation: pipeline products
  - Exclusivity: pipeline & marketed products
  - Loss of exclusivity: generic versions of the molecule
  - Over-the-counter: “consumer goods” (non-originator brands, private-label…)

Conducts that may run foul of Articles 101 and 102

- **There are three basic types of competition law violations:**

  Cartels (Art 101, but can also be a criminal offence in some jurisdictions)
  Other potentially anticompetitive agreements (Art 101)
  Abuse of dominant position (Art 102)

- **Violations of competition law are seldom self-evident; some of them are conducted in secret; often there are factual and perhaps legal uncertainties surrounding the case that make the legal analysis difficult**

Is excessive pricing an abuse?

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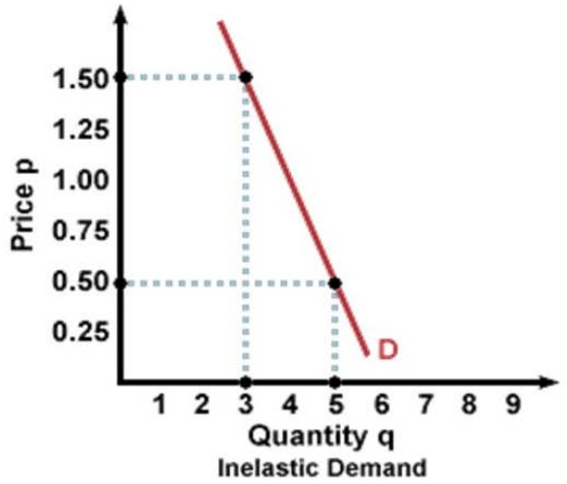
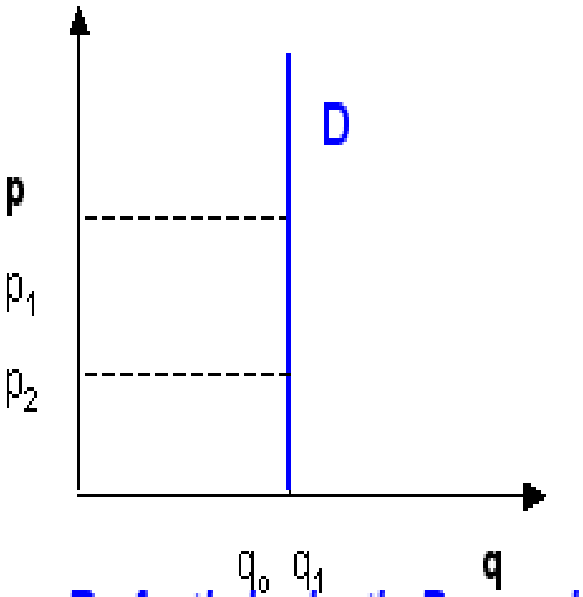
Excessive Pricing in Pharma *(cont'd)*

Graph of Inelastic Demand



Inelastic Demand is shown by drawing a very vertical demand curve.



Perfectly Inelastic Demand

Excessive Pricing in Pharma

- **Views are split on excessive pricing as an antitrust violation**
  - trust in the self-correcting mechanism of markets; opportunity to charge monopoly prices leads to more risky R&D; only transfer of wealth from consumer to monopolist involved, not loss of wealth to society generally; price regulation never works
  - *cf*. markets may fail; when output is restricted there is welfare loss; additional social costs of monopoly; ***legislative mandate to address***

- **Additionally, commentators point to practical difficulties with the doctrine and its enforcement**
  - "formidable difficulties" in telling when a price is excessive; difficulty in translating policy into administrable legal test

Excessive Pricing in Pharma *(cont'd)*

- **In the EU, Art 102 TFEU expressly provides that imposing unfair prices may constitute an abuse by a dominant undertaking**
  - "… abuse [of a dominant position] may, in particular, consist in: (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;…"
  - EU jurisprudence (*United Brands, AKKA*)

- **Other jurisdictions also aim at controlling high drug prices**
  - *Eg, US State of Maryland law enabling the State Attorney General to sue makers of generic or off-patent drugs for an "unconscionable" price increase (US Court of Appeal struck it down in April 2018)*

Access to medicines

- ## Access to medicines - a concern

Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (17 June 2016)

- *Recognises that a balanced and strong, functioning and* ***effective intellectual property environment*** [...] *is* ***important for*** *supporting and promoting access to* ***innovative, safe, effective and quality medicinal products*** *in the European Union* (§7)
- Invite… *"…to* ***safeguard*** *common interests, ensuring access of patients to safe,* ***effective and affordable medicinal products*** *as well as the sustainability of national health systems"* (§29).

[Specifically concerning COMP:]

- *"****Continue and where possible intensify****, including through a* ***report*** *on recent competition cases following the pharma sector inquiry of 2008/ 2009, the merger enforcement pursuant to the EC Merger Regulation (Regulation 139/2004) and* ***the monitoring, methods development and investigation*** *- in cooperation with national competition authorities in the European Competition Network (ECN) -* ***of potential cases of market abuse, excessive pricing as well as other market restrictions*** *specifically relevant to the pharmaceutical companies operating within the EU, such in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union"* (§48).

European Parliament "***Resolution on EU Options for Improving Access to Medicines***" (2 March 2017)

- ## *Industry – regulation/competition law*

Best way sometimes: to change the regulations

Under conditions (cf. United Brands), EC and NCAs could act under Art. 102 TFEU on a case-by-case basis considering the relevant facts and circumstances

Antitrust and Competition Issues in the Life Science Sector:

- *Biologicals/Biosimilars:*
- *Policy/Regulatory elements*

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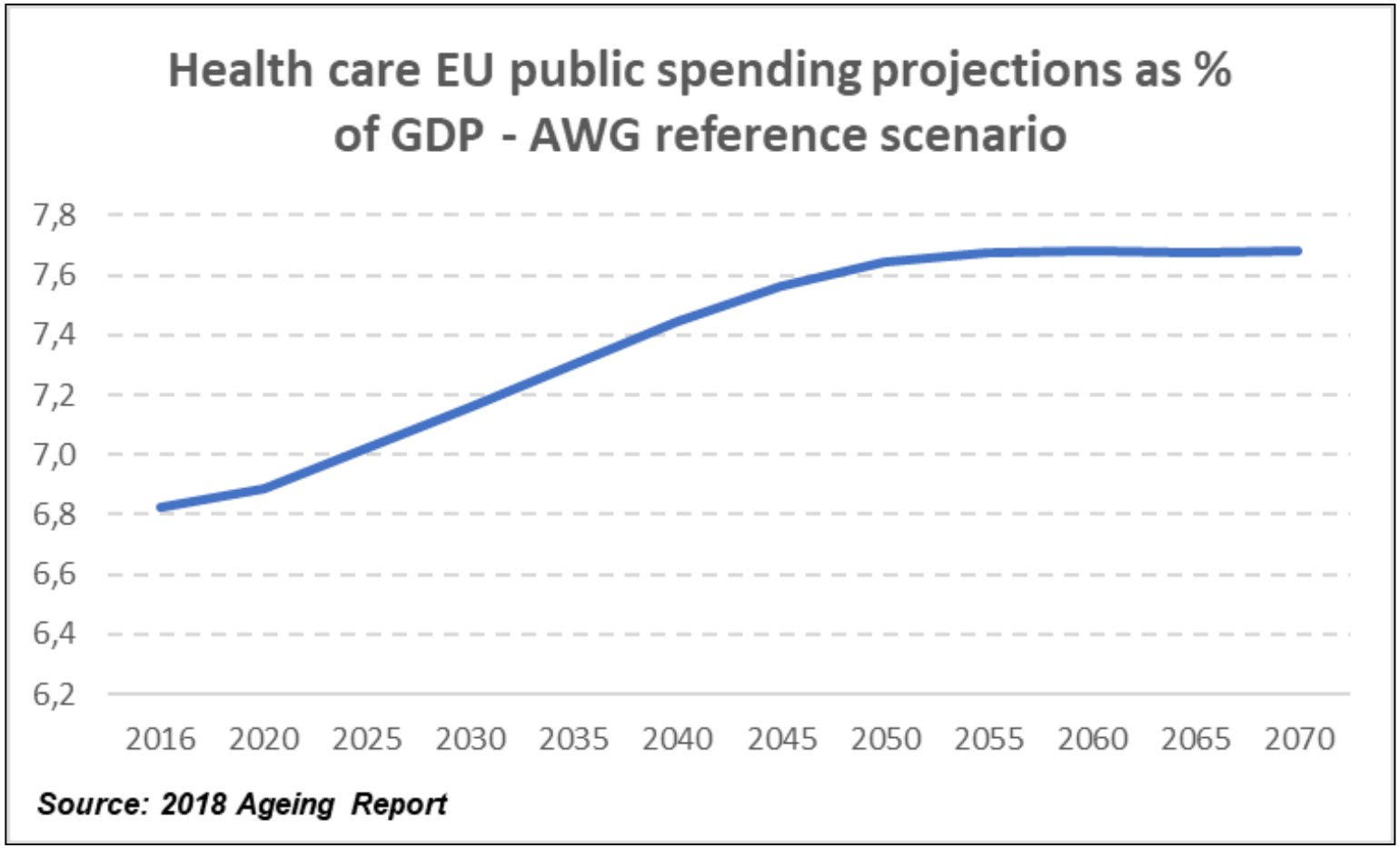
Health care and EU health systems: Fiscal Sustainability



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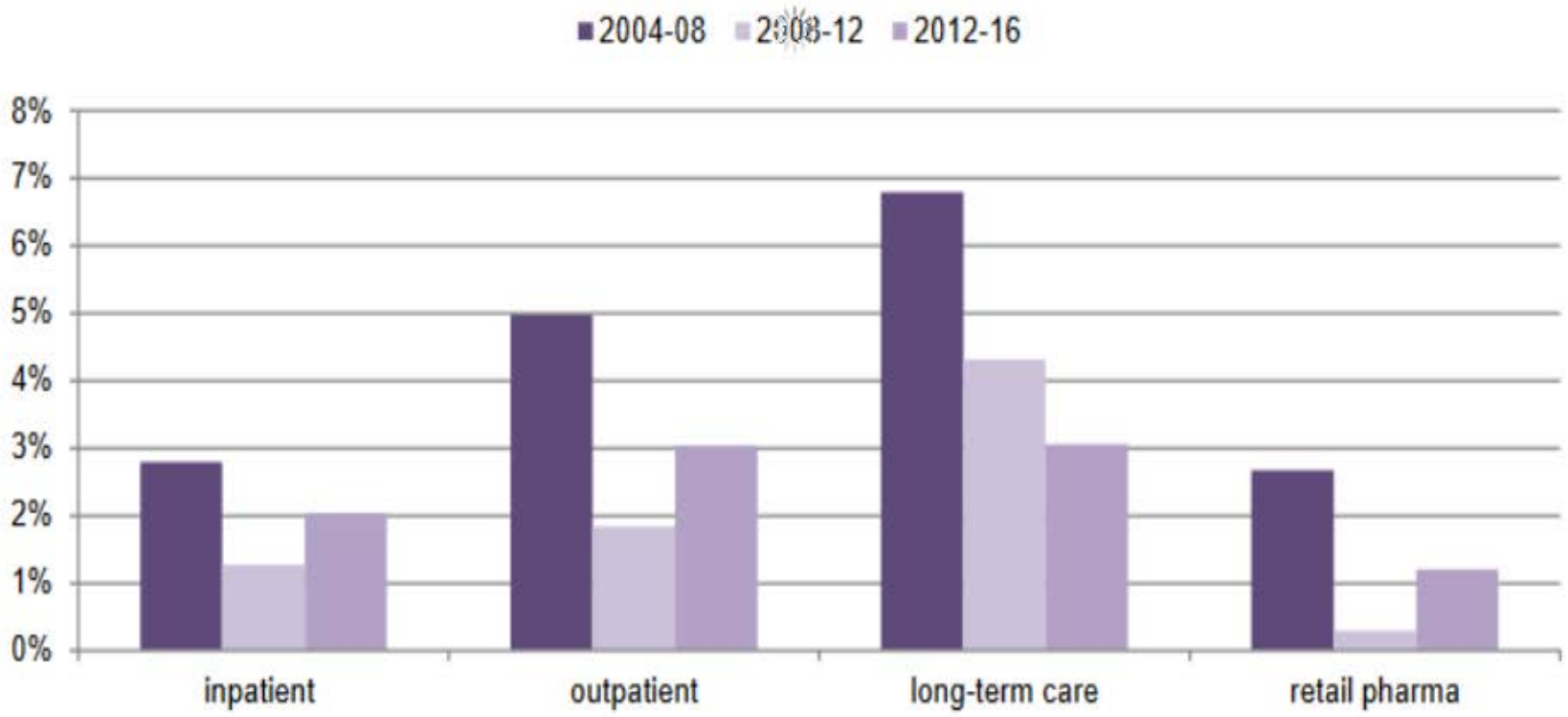
Pharma and EU health systems: Fiscal

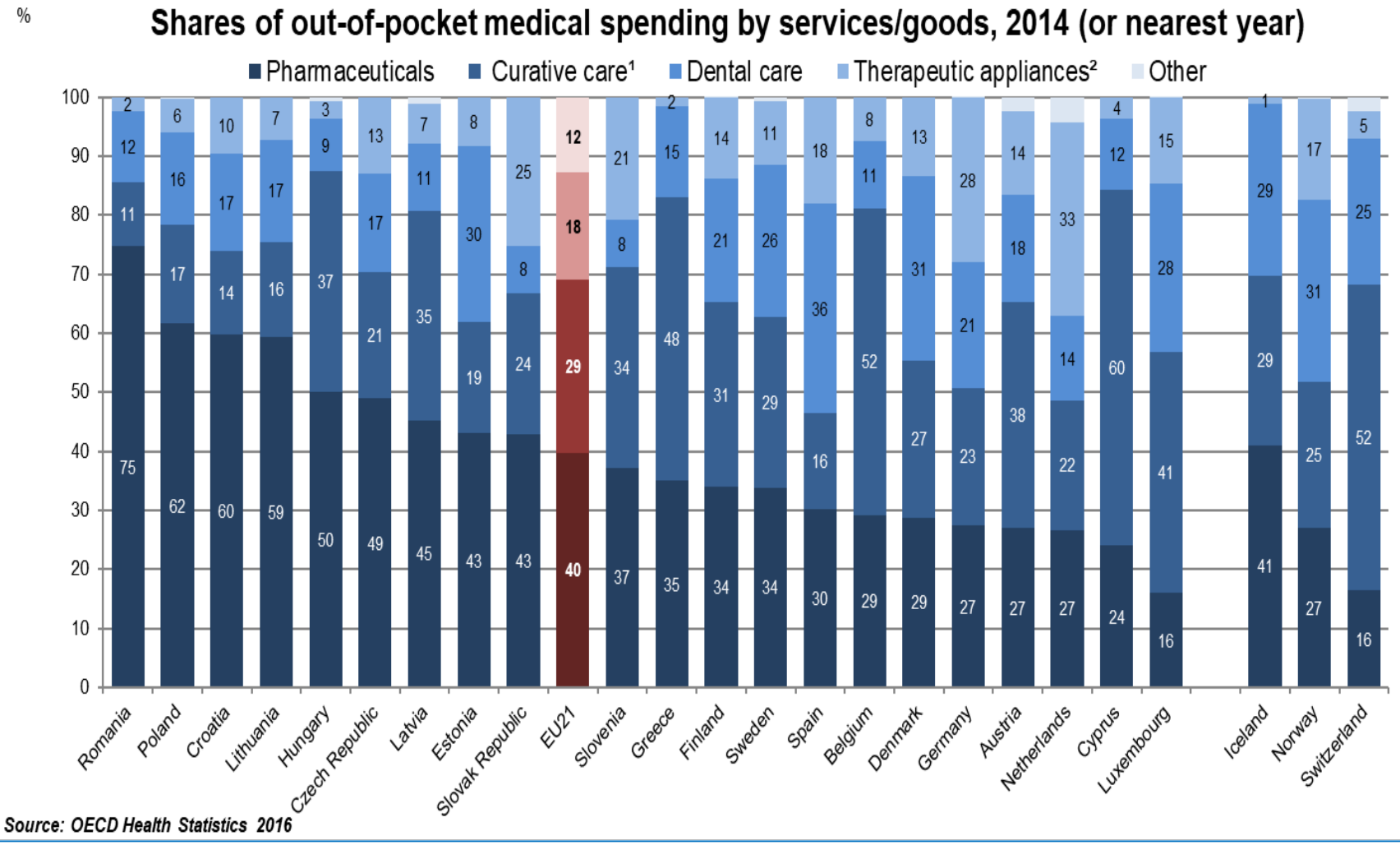
Figure 4. Average annual growth of selected health care services, OECD average, 2004-16



Note: Retail pharmaceuticals exclude the costs of pharmaceuticals used as part of an inpatient treatment episode.

Source: OECD Health Statistics 2018.

Pharma and EU health systems: Access



Source: OECD Health Statistics 2016

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Biosimilars and EU health systems: Sustainability

"Encouraging the use of generics and biosimilar medicines. With the availability of generics and biosimilars, the original patented drug has competition. This can lead to significant savings, while not compromising on quality."

Biosimilars and EU health systems: Sustainability

"For biologics, it seems more difficult to achieve cost-savings via traditional competition mechanisms, as biosimilars are expected to reduce prices to a lesser degree than small-molecule generics (Mulcahy et al., 2014) and substitution of originator biopharmaceuticals by biosimilars is not as straightforward as that between originators and generics for small molecule medicines."

Biosimilars and EU health systems: Sustainability/Competition

"[… However, unlike generics, biosimilars are not exact copies. Consequently, there is room for differentiation strategies and non-price competition between distinct biosimilars of the same molecule. Biological drugs are among the most expensive therapies, and biosimilars are expected to lower prices for healthcare systems and widen patients' access to biological drugs."

Biosimilars and EU health systems: Access/Competition

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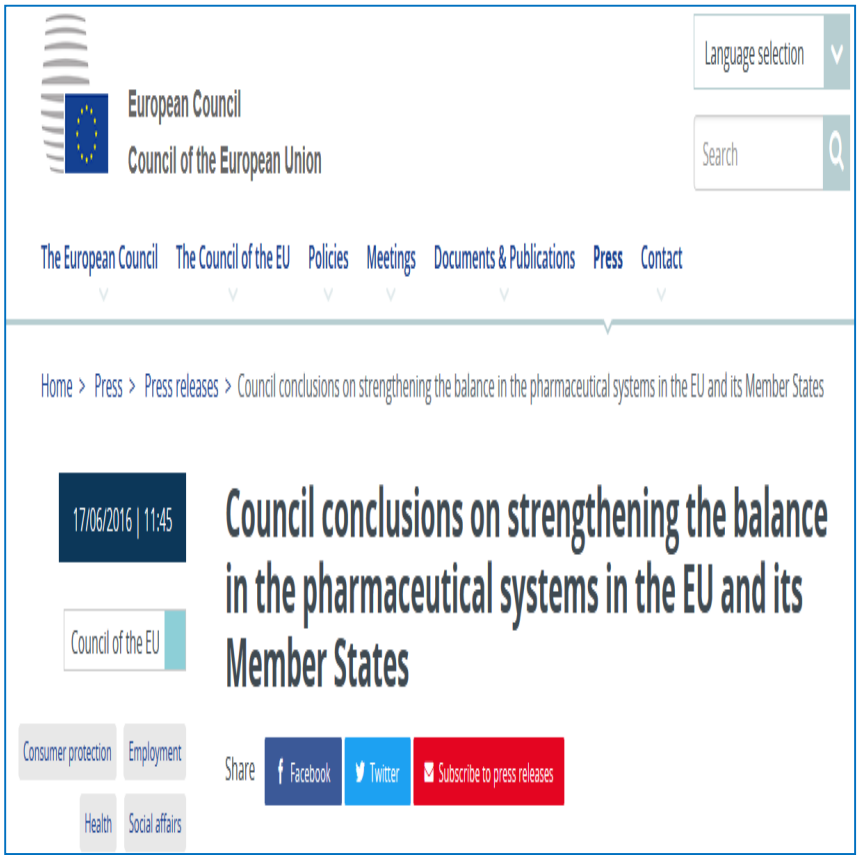
Growing understanding of role biosimilars



"UNDERLINES the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems"
"UNDERLINES the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems"

Growing understanding of role biosimilars

Procedure : 2016/2057(INI)

Document selected : A8-0040/2017

Texts tabled :

A8-0040/2017

Debates :

PV 01/03/2017 - 24

CRE 01/03/2017 - 24

REPORT

14 February 2017

on EU options for improving access to medicines
(2016/2057(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Soledad Cabezón Ruiz

"Points out that biosimilar medicines enable increased competition, reduced prices and savings for healthcare systems, thus helping to improve access to medicines for patients; stresses that the added value and economic impact of biosimilar medicines on the sustainability of healthcare systems should be analysed, their market entry should not be delayed, and, where necessary, measures to support their introduction to the market should be examined;"

Biosimilars and EU health systems:

- *Key Questions for health systems (1):*
  - Will barriers to entry for biosimilars grow (e.g. need for switch trials?)
  - Can price linkage be applied as done for generics and originators?
  - How would internal reference pricing schemes and patient cost sharing impact on access?

Biosimilars and EU health systems:

- *Key Questions for health systems (2):*
  - Prescriber incentives: awareness building, guidelines, minimum prescription quota, gain-sharing, … ?
  - Procurement:
    - Treatment-naïve vs established pat's?
    - Price linkage retail – hospital?

- **THANK YOU!**

- *Dirk.van-den-steen@ec.europa.eu*

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- *Public Health information:*
- *http://ec.europa.eu/health/index_en.htm*
- *Health Systems*
- *http://ec.europa.eu/health/systems_performance_assessment/policy_en*
- *Expert Panel*
- *http://ec.europa.eu/health/expert_panel/home_en*
- *The State of Health in the EU:*
- *https://ec.europa.eu/health/state/summary_en*
- *Health Technology Assessment:*
- *https://ec.europa.eu/health/technology_assessment/policy_en*
- *State of children's medicines in the EU:*
- *http://europa.eu/rapid/press-release_IP-17-4121_en.htm*

Delay / hinder the entry of generics and biosimilars

Brussels, 3 July 2018

Rainer Becker
DG Competition
European Commission

What happens at generic entry?

Generic entry from a competition perspective:

- Price competition
- Pressure on originators to innovate

Lundbeck

Weighted average generic citalopram prices
(per DDD in the UK (GBP) 2002-2005, Decision, ¶212)

Overall impact of delays in generic entry can be immense.

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Findings in the Sector Inquiry

- *Factually observed: practices for delaying or blocking the entry of generics, e.g.:*
  - (Settlement) agreements
  - Patent filing strategies (e.g. clusters of secondary patents)
  - Patent-related litigation
  - Strategies before marketing, pricing & reimbursement authorities
  - Life cycle strategies such as product hopping
  - Others
- *In-depth investigations of some practices by competition authorities; often confirmed in court*

First follow up to SI: pay-for-delay cases

- *Commission's focus on most harmful practices: pay for delay arrangements*
  - *Lundbeck*, 2013 (General Court 2016): six agreements with four parties (Article 101)
  - *Fentanyl*, 2013*:* co-promotion agreement (Article 101)
  - *Servier*, 2014: five reverse payment agreements (Article 102 and Article 101)
  - *Cephalon*, ongoing (Article 101)
- *NCA enforcement: Paroxetine (UK), reference to CJEU*

Exclusionary abuses decided so far:

- **Withdrawal & delisting of a product (product hopping):**
  2011 (UK): *Reckitt Benckiser*
- **Misuse of rights / abuse related to procedures:**
  2012 (IT): *Pfizer*
- **Misleading information to obtain SPC / withdrawal of MA:**
  2005 (EU): *Astra Zeneca*, ECJ in 2012
- **Acquisition of technology foreclosing generics:**
  2014 (EU): *Servier*, on appeal
- **Disparagement:**
  2013 and 2017 (FR): *Schering-Plough, Sanofi-Aventis, Janssen-Cilag* and *Johnson & Johnson*
- **Exclusionary discounts:**
  2001 (UK): *NAPP* (and excessive pricing)
  2017 (UK): *Merck Sharp & Dohme* (SO)

Outlook

- *Subtle practices more likely than blatant payments*
- *Drawing a line between abuses and competition on the merits and the legitimate exercise of rights can be difficult*
- *Thorough investigation into facts of each specific case*
- *In all cases so far: exclusionary strategy observed, although not necessary for finding abuse*
- *Distortion of competition through delaying strategies has major impact for patients and health systems (price, innovation)*
- *Investments by CAs in investigating new cases necessary*
- *Administrative, and ideally judicial, precedents important to guide companies and to deter infringements*
- *Such precedents also relevant for biosimilars*

Pharma Market Definition

Outline

1. **Overview enforcement practice**

2. **Complex demand side (and regulation)**

3. **Approach to market definition for pharmaceuticals in EU merger and antitrust decisions**

EU Enforcement practice

I. EU merger experience

- Mergers raising serious doubts (i.e. with remedies):
  - 2009-June 2017: In total 300+ product markets investigated in view of serious doubts (majority ORI-GEN and GEN-GEN)

II. EU antitrust experience

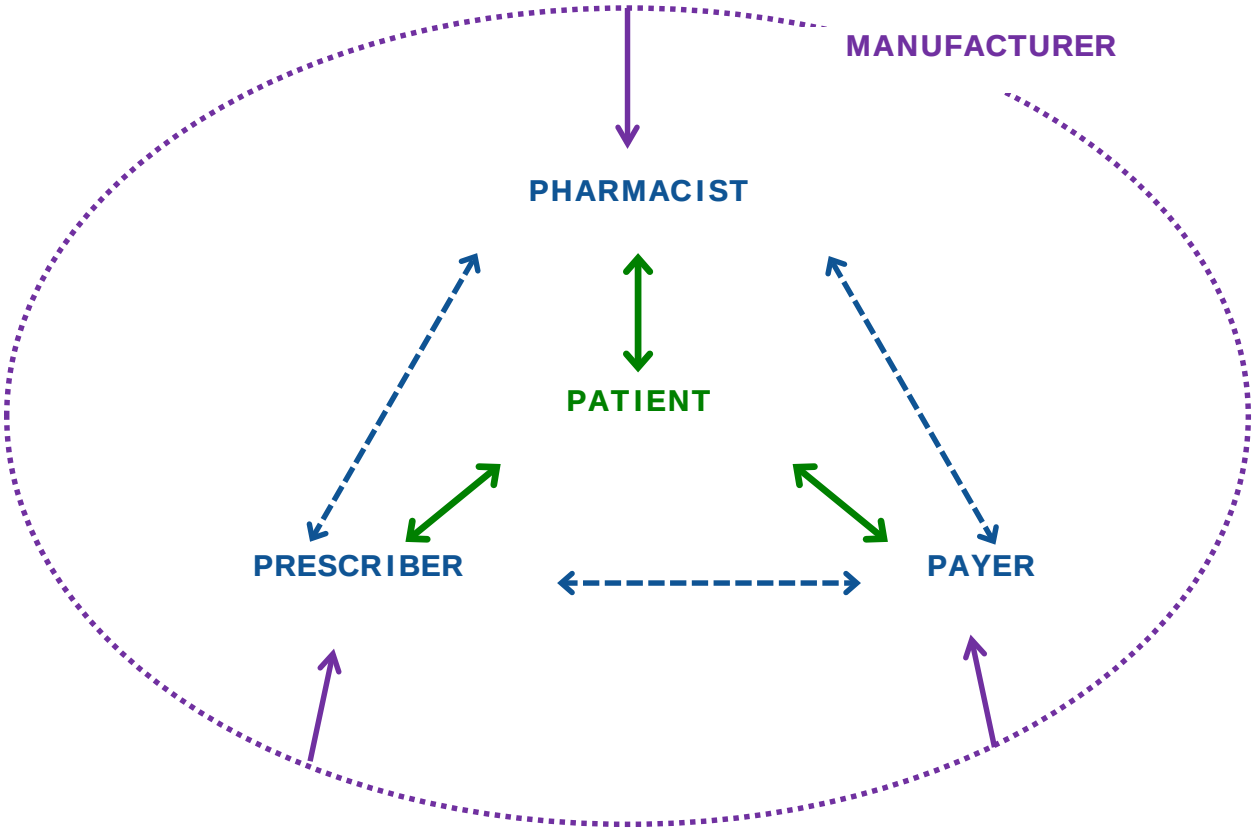
- *AstraZeneca* (2005) and *Servier* (2014) Decisions
- Investigations, including a Statement of Objections in *Cephalon*

III. EU court cases (only antitrust) (including pending ones)

- *AstraZeneca* (GC and ECJ); *Servier* pending (GC); *PR Hoffmann-La Roche* (ECJ); *Paroxetine* pending (ECJ)

Complex demand structure of pharmaceuticals

Prescription drugs



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Legal framework: Commission MD Notice

- **Given regulation, is the Commission's Market Definition Notice applicable at all? Yes (T-321/05 *AstraZeneca*)**

- **MD is facts specific and may have to consider the '*nature of the competition issue being examined*' (MDN, ¶12).**
  - How does the demand respond to changes in relative quality, advertisement effort, and prices?
  - Constraints throughout product life-cycle

- **Functional / economic substitutability (that is constraining independent behaviour):**

Legal framework ct'd (2)

But what about the absence of price constraints, are those relevant?

- *Paroxetine,* CAT (8 March 2018), request for preliminary ruling:

"[W]e do not accept the CMA's approach of using the price levels… as the basis [… for] a SSNIP test." (¶401)

Where conduct effectively excludes generic[s] from the market, are those generic products to be taken into account for the relevant product market even if entry could be unlawful if patent infringed? (on a similar question relating to MA see C-179/16 *Hoffmann-La Roche*, ¶¶52,60,61,64,67)

- *AstraZeneca*:

'Where […] a [product or a] group of products is not subject to a significant extent to competitive [price] constraints […] the type or nature of the factors that shield that group of products from any significant competitive [price] constraint is of only limited relevance…' (in this case: the regulatory framework) (¶175, T-321/05 *AstraZeneca)*

- **When '*evidence of substitution in the recent past*' is available '*it will normally be fundamental for market definition*' (¶38)**

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MD in practice 1

- **ORI / ORI: Starting point analysis: Medical Guidelines and other relevant information (ATC classes…)**
  - Analysis of chemical, pharmacological, and therapeutic properties. (Important elements, e.g., similar mode of action etc.)
  - Group of molecules or molecule level
- **ORI / GEN and GEN / GEN: Starting point molecule level**
  - Generic companies compete principally "*for sales of products based on the originator molecule . . . and only to a limited extent against products based on other molecules".* ('closest substitutes')

MD in practice 2

- **Relevant product characteristics to be assessed:**

  indications, efficacy, contra-indications, side effects;

  first-line, second-line treatment; complementarity; stages of a disease;

  short-acting, long-acting (frequency of administration);

  formulation/routes of administration (e.g. injection or tablets)

- **Other factors:** e.g. lock-in effect; doctors' inertia

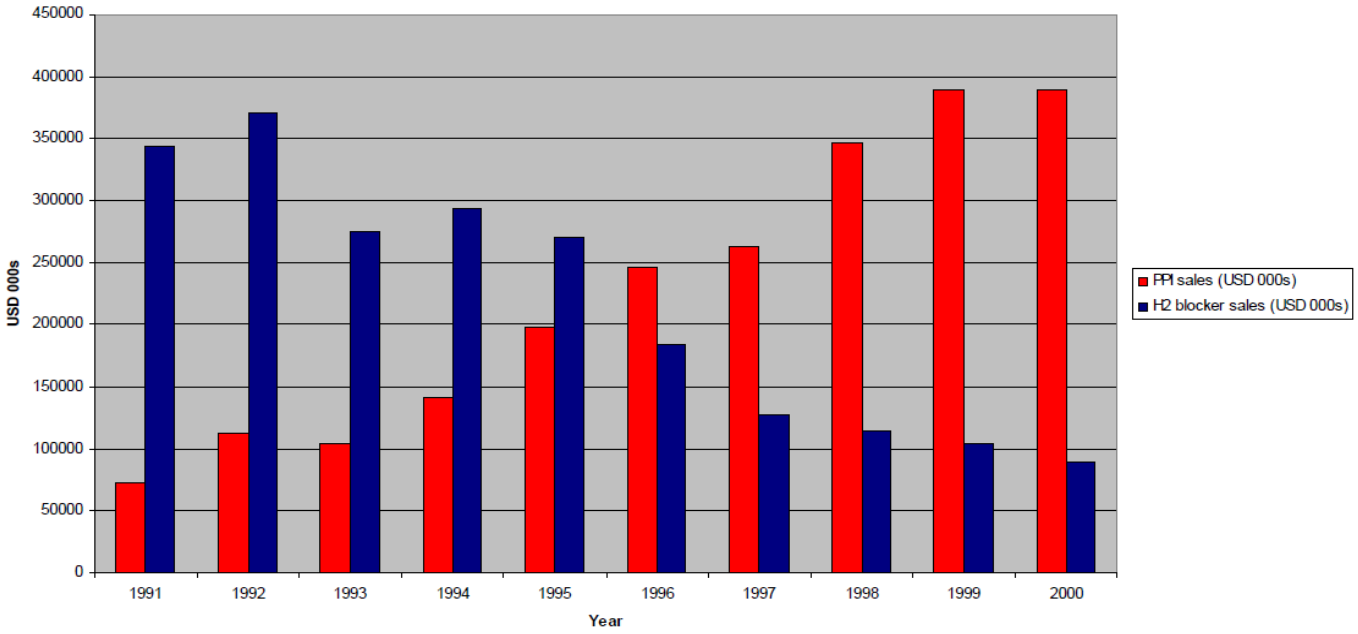
- **Other pharma markets**: Pipeline to pipeline/market competition; over the counter ("OTC") medicines; intermediates; API; API technology market; medical devices (including for administering a drug); retail/hospital; distribution

EU: Antitrust experience

1. 37.507 *Astra Zeneca* Decision of 15 June 2005, confirmed by the GC (2010) and ECJ (2012) (abuse)
   - ATC 4 level: Market defined as proton-pump inhibitors ('PPIs'), excluding H2 blockers. PPIs were a revolutionary product for treatment of gastro-intestinal acid-related disease with new mode of action; dominance with omeprazole (Losec).
2. 39.612 *Servier* Decision of 9 July 2014 (under appeal)
   - Molecule level: Market for the perindopril molecule: other me-too "prils" (also antihypertensive medicines) were unable to meaningfully constrain Servier's sales and prices; only generic versions of perindopril constrained Servier. (Also: technology market.)

Quantitative analysis: launch of innovative drug (AZ)

GERMANY
PPI and H2 blocker sales 1991-2000 (USD 000s)



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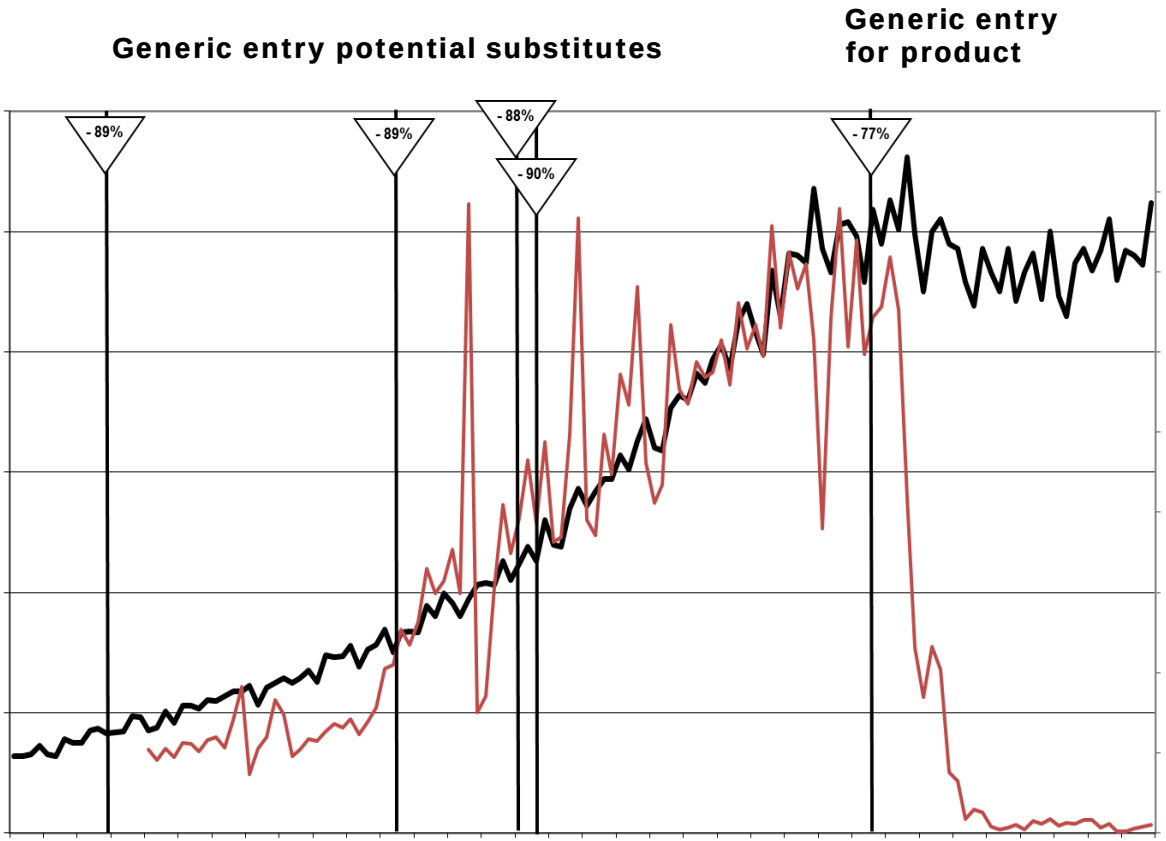
Quantitative analysis: generic entries in ATC3 universe

Product A sales

Company sales of product A



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Can dominance be assessed directly?

- The objective of market definition: to define the market by reference to a company's ability to behave independently.

- Dominance: *'power to behave to an appreciable extent independently…'*

- *Servier* decision:
  - '*The **direct assessment of market power becomes possible**' when high economic rents can be compared to rents under conditions of effective competition*'. (¶2596)

Antitrust and competition issues in the life science sector

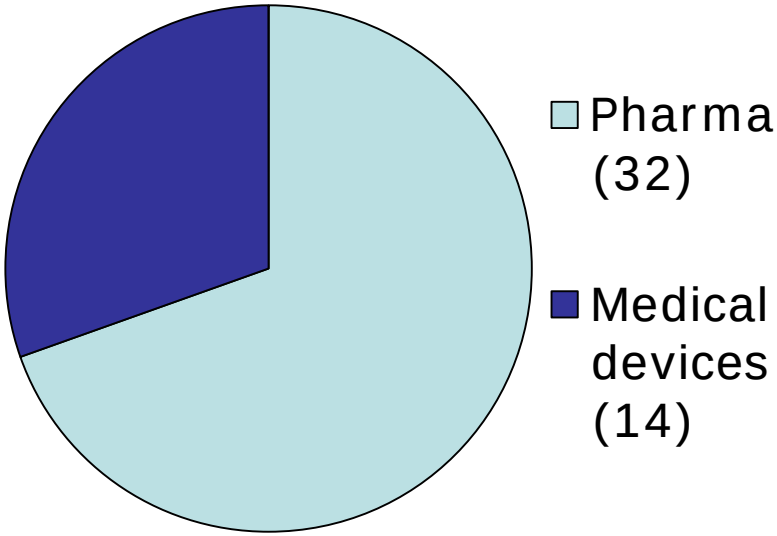
Merger control

3 July 2018

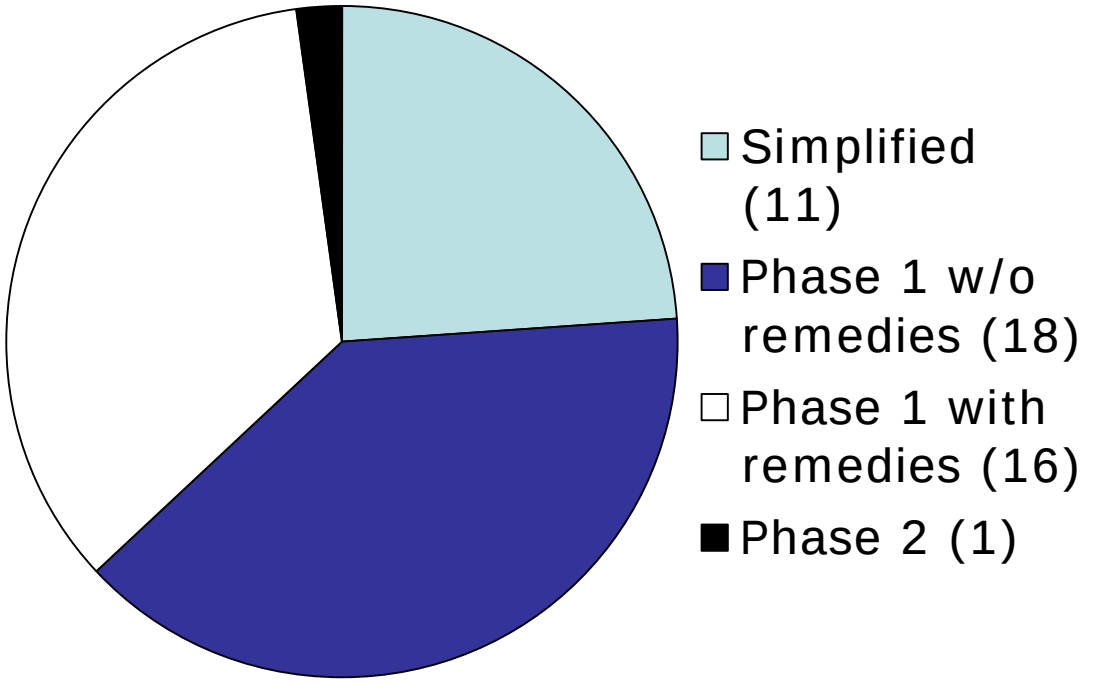
European Commission

1. OVERVIEW OF LIFE SCIENCE MERGER CASES
2015-2017

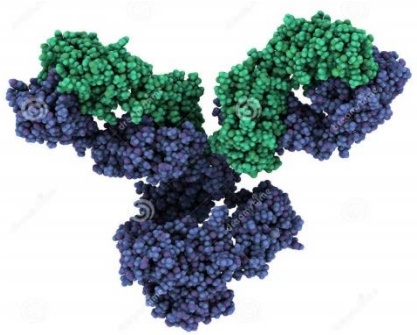
By sector



By procedure



→ Two procedural infringement investigations ongoing: possible gun jumping (Art. 14(2) EUMR) and Provision of incorrect and misleading information (Art. 14(1) EUMR)



2. MARKET DEFINITION

- **General principles**: Substitutable drugs from demand side, using different tools (clinical guidelines, ATC class…)

- **Established practise**:
  - ✓ **M.7746 Teva/Allergan Generics**: small molecule generics, likely at molecule level
  - ✓ **M.7919 Sanofi/BI Consumer Healthcare**: Over-the-Counter products, importance of targeted patients population

- **New types of medicines:**
  - ✓ **M.7559 Pfizer/Hospira**: monoclonal anti-bodies biosimilar *infliximab*, at molecule level including originator and biosimilars

3. COMPETITIVE ASSESSMENT

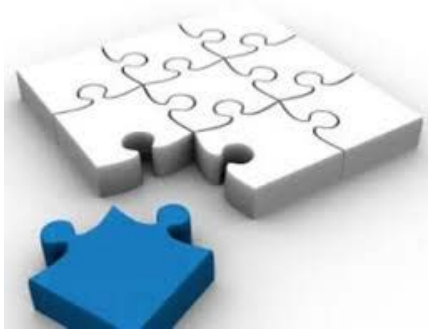
➢Market shares but not only….Closeness of competition:

- ✓ **M.7746 Teva/Allergan Generics**: Only generics direct-to-market players in the UK
- ✓ **M.7982 Abbott/Alere**: Only handheld Point-of-Care blood testing devices
- ✓ **M.7435 Merck/Sigma Aldrich**: Strongest brands and highest quality laboratory chemicals

➢On-market products but not only…. Pipelines:

- ✓ **M.7275 Novartis/GSK oncology**: 3 to 2 in the development of innovative skin cancer therapies (*B-Raf and MEK inhibitors*)
- ✓ **M.8401 J&J/Actelion**: 3 to 2 in the development of innovative insomnia treatments (*orexin-antagonists*)

4. REMEDIES



- **From individual products divestiture and manufacturing transfer…**
  - ✓ **M.7919 Sanofi/BI Consumer Healthcare**: Individual Over-the-Counter products
  - ✓ **M.7275 Novartis/GSK oncology**: All clinical trials of two compounds
  - ✓ **M.7917 BI/Sanofi Animal Health**: Swine vaccines (fix-it-first)

- **…To full supply chain divestment: Manufacturing plant up to sales organisation**
  - ✓ **M.7746 Teva/Allergan Generics**: Generics business in the UK and Ireland
  - ✓ **M.7982 Abbott/Alere**: Global point of care devices business
  - ✓ **M.7435 Merck/Sigma-Aldrich**: EEA laboratory chemicals business