Overview

• EU competition law – elements and actors

• Origin and focus of the Report

• Particularities of competition in the pharmaceutical sector

• Promoting access to affordable medicines

• Driving innovation and increasing the choice of medicines

• Summary facts and figures

• Conclusions
EU competition law – elements and actors (i)

• Anticompetitive **agreements** (Article 101 TFEU)
  o Parallel competences – the Commission and the NCAs

• **Abuse** of dominant position (Article 102 TFEU)
  o Parallel competences – the Commission and the NCAs

• **Merger control**
  o Commission’s exclusive competence to assess concentrations with “European dimension”

• Commission enforces **State aid** rules in the internal market
EU competition law – elements and actors (ii)

- **ECN**: the Commission and the NCAs
  - Cooperation: exchange of information, coordination of and assistance in investigations & policy
  - NCAs inform the Commission about their envisaged decisions → coherent application of EU competition rules

- **Enforcement**: leads/complaints/*ex officio*, inspections, sector inquiries, decisions with fines, rights of defence, etc.

- **Pharma & health** are a specific focus:
  - Specific units in DG COMP dedicated to antitrust and mergers
  - Dedicated ECN subgroup
Origin: Council conclusions on strengthening the balance in the pharmaceutical systems (June 2016); European Parliament resolution on EU options for improving access to medicines (March 2017)

- Report is only one of the initiatives

Focus: pharmaceuticals for human use

- Enforcement by ECN – COM and national authorities (NCAs)
- Antitrust (COM + NCAs)
- Mergers (COM)
- Market surveys & advocacy (COM + NCAs)

Available in all languages:
Particularities of competition in the pharmaceutical sector (i)

Demand structure

- Pharma companies
- Pharmacists
- Doctors
- Patients

Supply, promotion, pricing, incentives, dispensing, prescription, reimbursement
Particularities of competition in the pharmaceutical sector (ii)

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
Real life example: impact of generic citalopram entry in the UK (from Lundbeck decision)

Red line: Lundbeck

Blue line: generic citalopram prices (per DDD weighted average, in GBP).

Generic price from Sept. 2003 to Nov. 2004 in UK: 90% price decline
Contributing to access to affordable medicines

1. Supporting swift market entry of cheaper generic medicines
   - Pay for delay cases
     - EU (Fentanyl, Lundbeck, Servier), UK (Paroxetine)
   - Misuse of regulatory framework (AstraZeneca)
     - Withdrawal of the reference medicine – UK (Gaviscon)
     - Strategy of filing for and obtaining divisional patents, SPCs and paediatric extensions – IT (Pfizer)

2. Other practices curbing demand for generics
   - Disparagement – FR (Durogesic, Subutex, Plavix)
   - Pharmacists boycotting generic products – ES (Laboratorios Davur)

Impact of pay-for-delay deals on healthcare systems

- Scenario 1: Normal competitive entry of GEN
  - Prices scenario 1
  - Normal price competition = savings for healthcare systems
- Scenario 2: Pay-for-delay deal
  - Prices scenario 2
  - Delayed price competition at the expense of healthcare systems
  - Extended profits shared between ORI & GEN

Normal entry of GEN

Delayed entry of GEN

Euros
Contributing to **affordable** medicines (ii) – antitrust

2. **Enforcement against dominant firms** charging **unfairly high prices** (excessive pricing)
   - IT (*Aspen*), UK (*Pfizer/Flynn*), DK (*CD Pharma*)
   - Pending Commission’s investigation in *Aspen*

3. **Other practices** capable of inflating prices
   - **Coordination between competitors**: market sharing by pharmacists (ES), bid-rigging in hospital tenders (HU, SI), exchange of sensitive information, coordination of trading conditions (DK, DE, IT), etc.
   - **Excluding rivals**: offering loyalty discounts to doctors & pharmacies (CY), restricting rivals’ access to a key input for production (IT), restricting parallel trade (RO), etc.
Contributing to affordable medicines (iii) – mergers

Ensuring that changes in the market structure do not lead to higher prices

- Preventing acquisitions of close competitors:
  - GEN-GEN (e.g. Teva/Allergan)
  - ORI-GEN (e.g. Sanofi/Zentiva)
  - ORI-ORI (e.g. GSK/Novartis – human vaccines)

- Preserving price pressure from biosimilars (e.g. Pfizer/Hospira)

- Concerns addressed through divestments
Contributing to **innovation** and **choice** (i) – antitrust

- Actions against practices preventing innovation or limiting choice
  - Incentivizing innovation by enforcing the end of the market exclusivity – e.g. EU (Servier)
  - Protecting biosimilar against exclusionary rebate scheme – PT (Roche Farmacêutica)
  - Protecting off-label use of an oncologic product – IT (Avastin/Lucentis)

- Competition rules support procompetitive co-operation on innovation
  - e.g. EU Block Exemption Regulation on R&D agreements
Mergers may reduce competition on innovation, affecting the incentives to engage in parallel R&D efforts. Merger control may intervene where the merger would negatively impact the incentives to continue R&D of life-saving cancer drugs; e.g., Novartis/GSK Oncology. Merger control may also remove competition concerns related to pharmaceutical pipeline products, protecting innovation already in early stages of development; e.g., Johnson & Johnson/Actelion.
Antitrust

29 decisions by 13 NCAs and the Commission:
- 24 prohibition decisions + 5 commitment decisions
- substantial investigative work in more than 100 other cases
- over 20 currently pending cases

Mergers

More than 80 merger control proceedings by the Commission:
- 19 problematic mergers with remedies
- intervention rate: 22% (vs. 6% overall)

More than 100 market monitoring & advocacy actions by 17 NCAs and the Commission
Fines totaling over EUR 1 billion imposed in 21 cases
Conclusions

Enforcement of the competition law:

• Within its remit contributes to access to affordable and innovative medicines and treatments

• Complementary to legislative and regulatory action

• Remains a matter of high priority for competition authorities:
  • European Commission
    – Pending investigation in *Teva/Cephalon* (pay for delay)
    – Pending investigation in *Aspen* (unfair pricing)
  • More than 20 pending NCA cases
Contacts

European Commission:
http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html


European Competition Network:
http://ec.europa.eu/competition/ecn/competition_authorities.html