



Pharmaceutical Committee, Brussels, 1 April 2019

# Report on Competition enforcement in the pharmaceutical sector



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## 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)
  - Parallel competences – the Commission and the NCAs
- **Abuse** of dominant position (Article 102 TFEU)
  - Parallel competences – the Commission and the NCAs
- **Merger control**
  - 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:

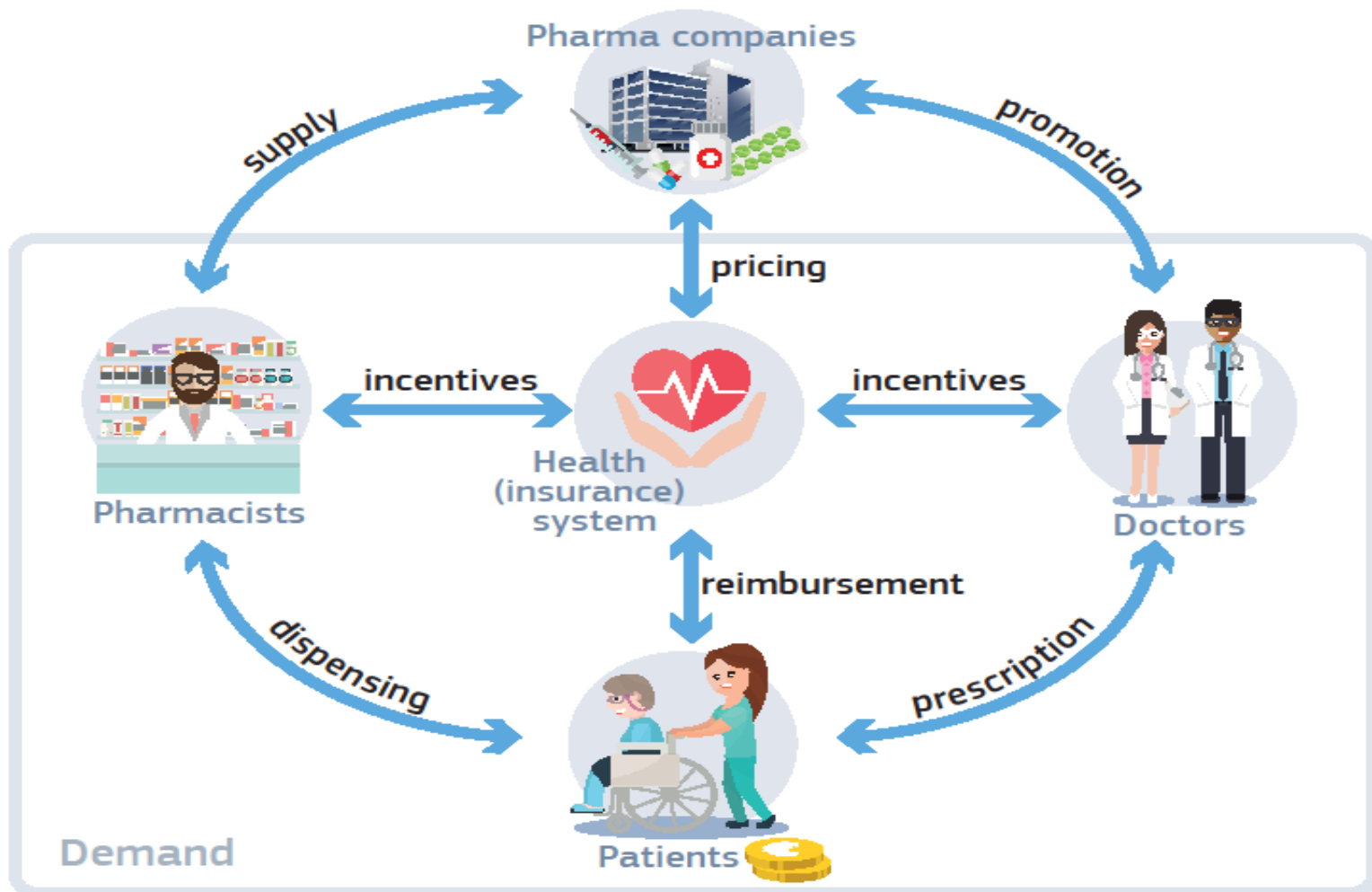
<http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html>



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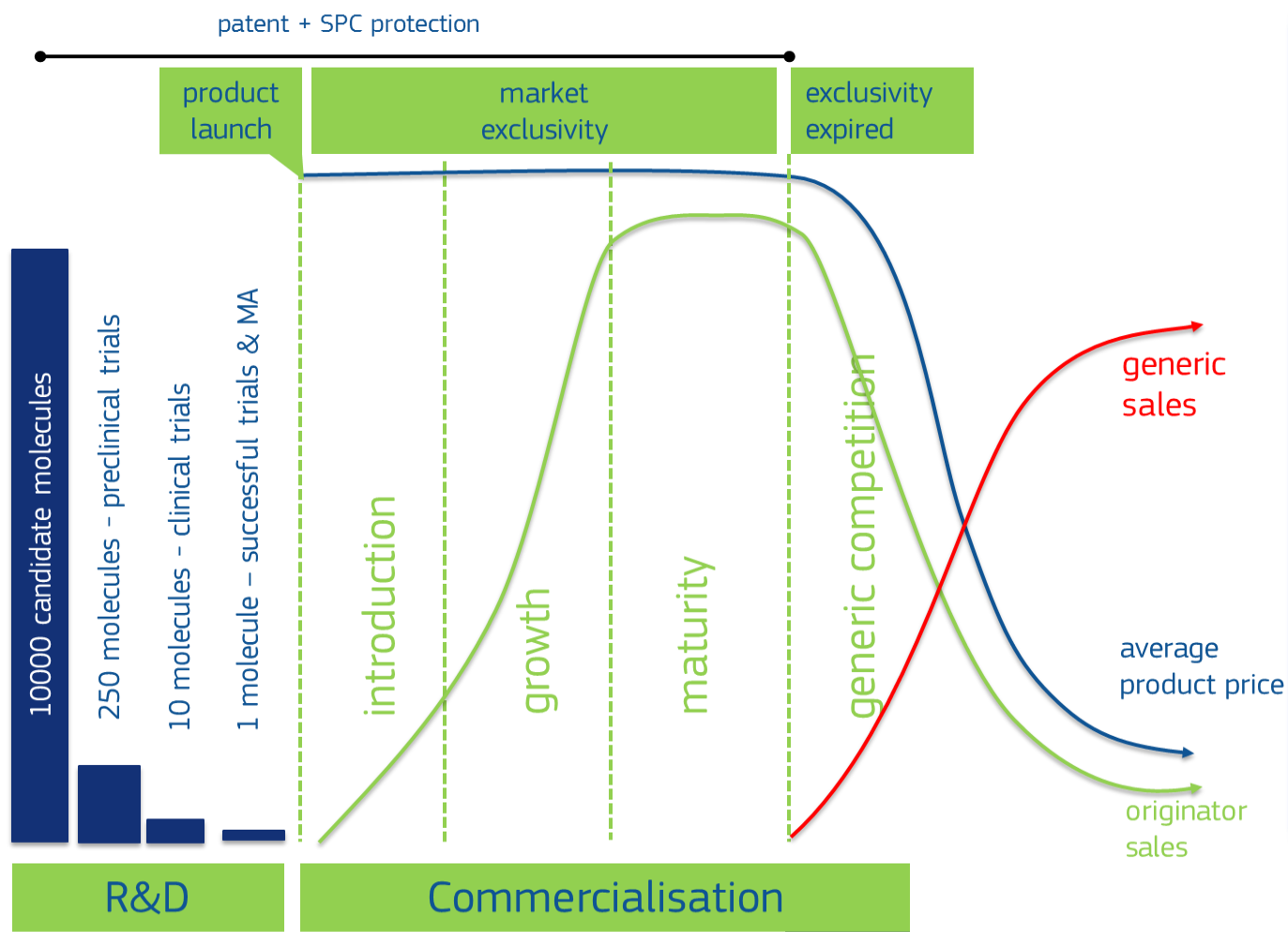
# Particularities of competition in the pharmaceutical sector (i)

## Demand structure



# Particularities of competition in the pharmaceutical sector (ii)

## Life cycle of medicines



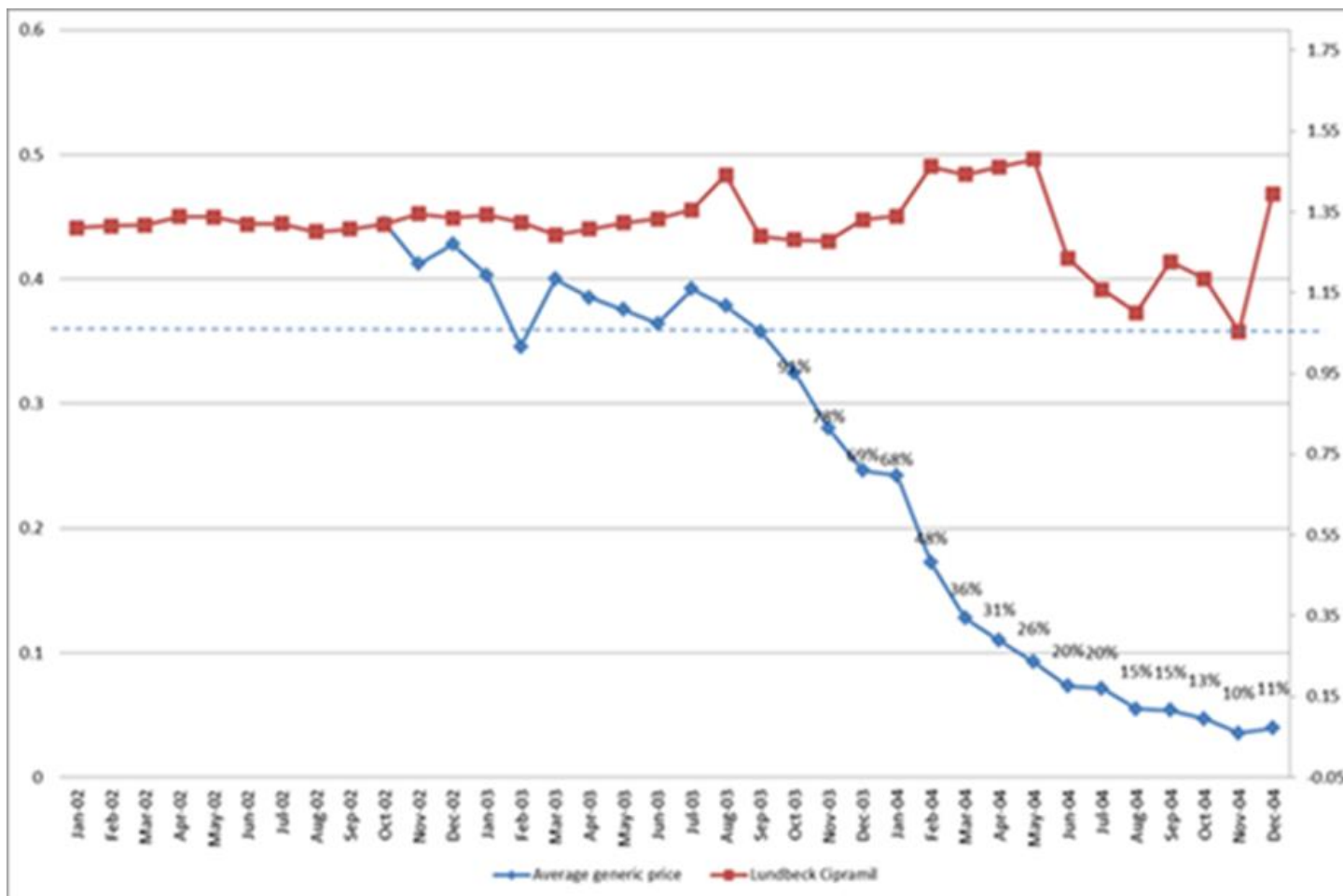
Evolving nature of competition:

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



European Commission

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



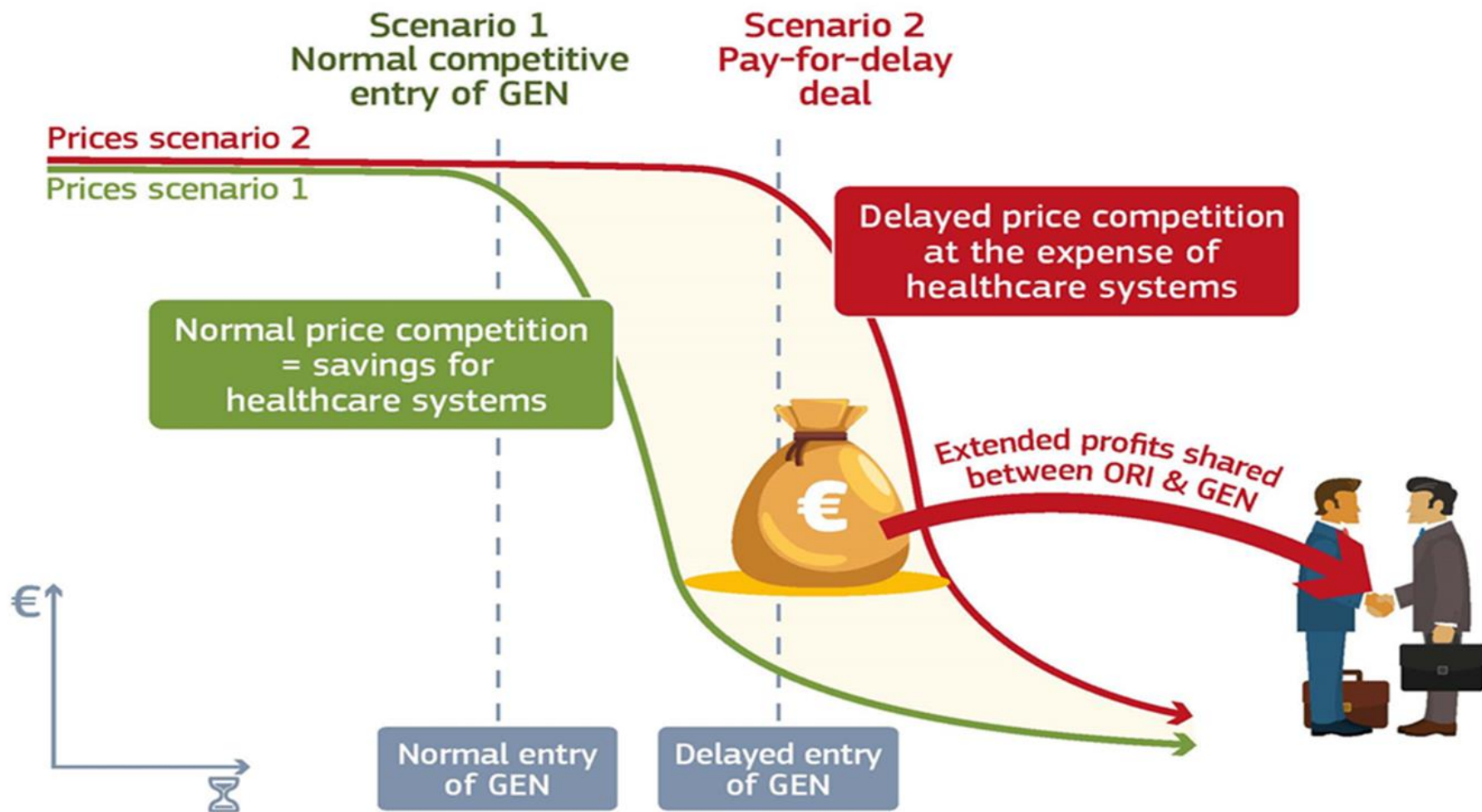
Red line: Lundbeck

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

Generic price from Sept. 2003 to Nov. 2004 in UK: **90% price decline**



# Impact of pay-for-delay deals on healthcare systems



## 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

## Merger threatening to eliminate competing R&D programmes



## Report: summary facts and figures (i)

### 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

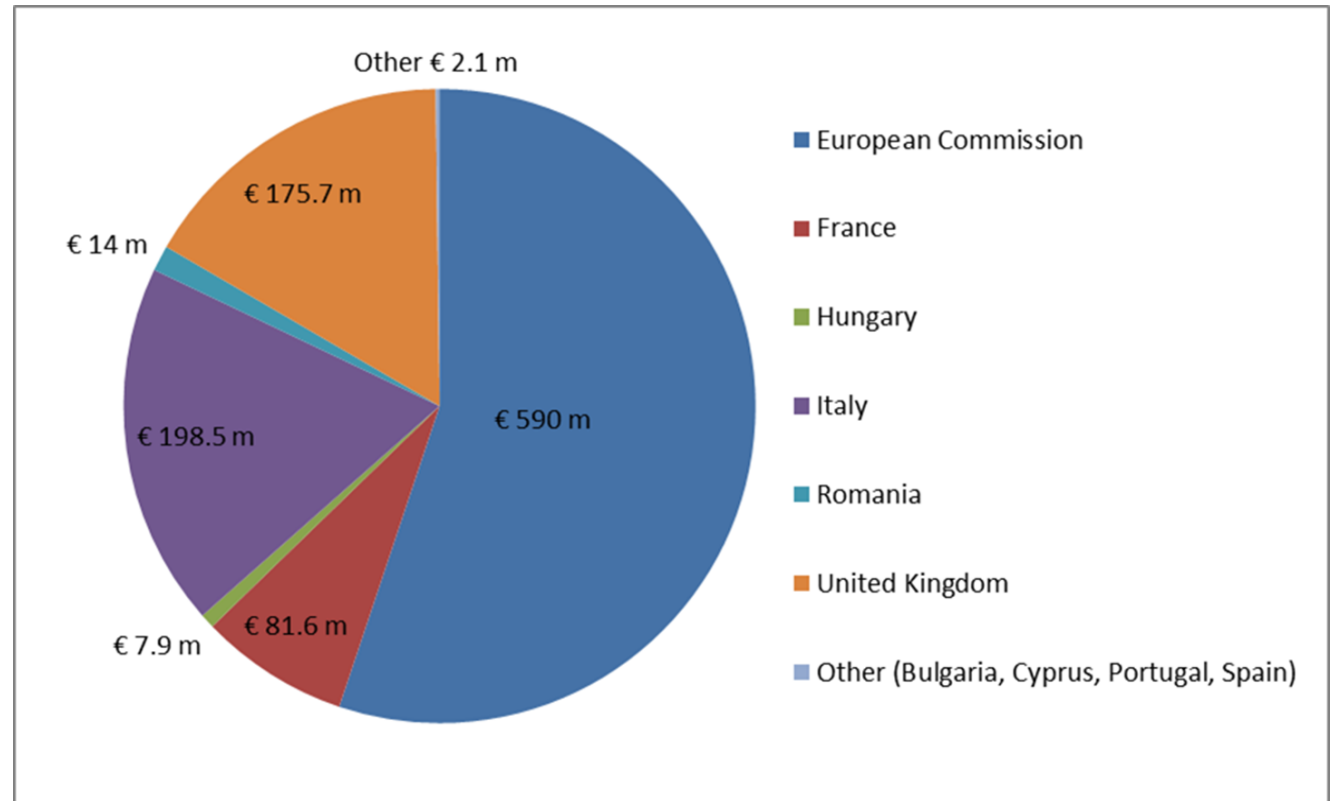
More than 80 merger control proceedings by the Commission:

- 19 problematic mergers with remedies
- intervention rate: 22% (vs. 6% overall)

More than 100 market **monitoring & advocacy** actions by 17 NCAs and the Commission

## Summary facts and figures (ii)

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](http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html)

[http://ec.europa.eu/competition/contacts/electronic\\_documents\\_en.html](http://ec.europa.eu/competition/contacts/electronic_documents_en.html)

## European Competition Network:



[http://ec.europa.eu/competition/ecn/competition\\_authorities.html](http://ec.europa.eu/competition/ecn/competition_authorities.html)