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WORKING PAPER

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From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (HTA) Working Party on Pharmaceuticals and Medical Devices (Attachés)
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Subject:	Report on Competition enforcement in the pharmaceutical sector

Delegations will find attached the presentation given by the Commission on the above mentioned topic at the Working Party on 25 March 2019.



Council Pharmaceuticals/Medical Devices Working Party, Brussels,
25 March 2019

Report on Competition enforcement in the pharmaceutical sector



██████████, Head of Unit
DG Competition, European Commission



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 (meetings twice a year)



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

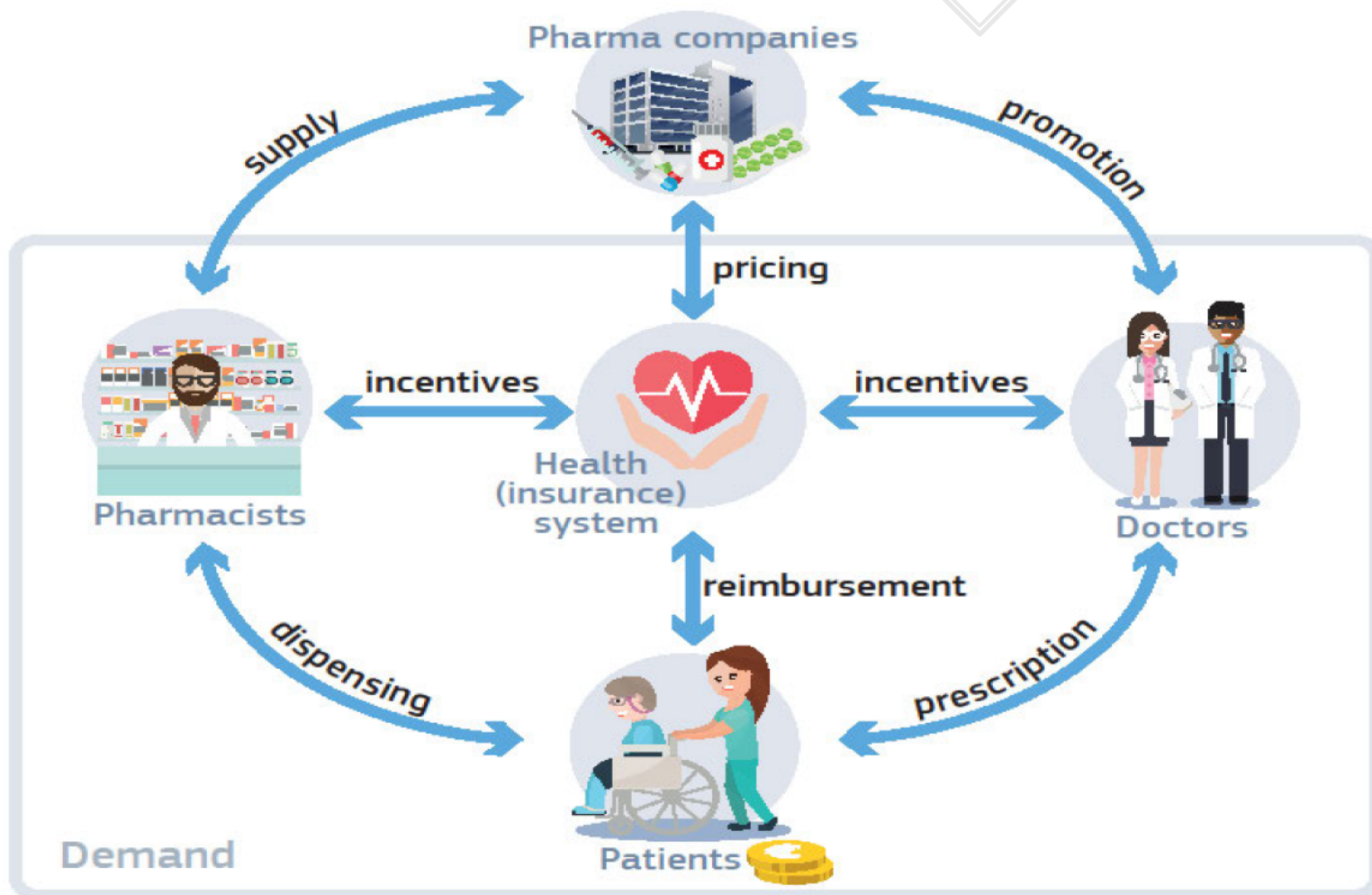
Focus: pharmaceuticals for human use

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

Available in all languages:

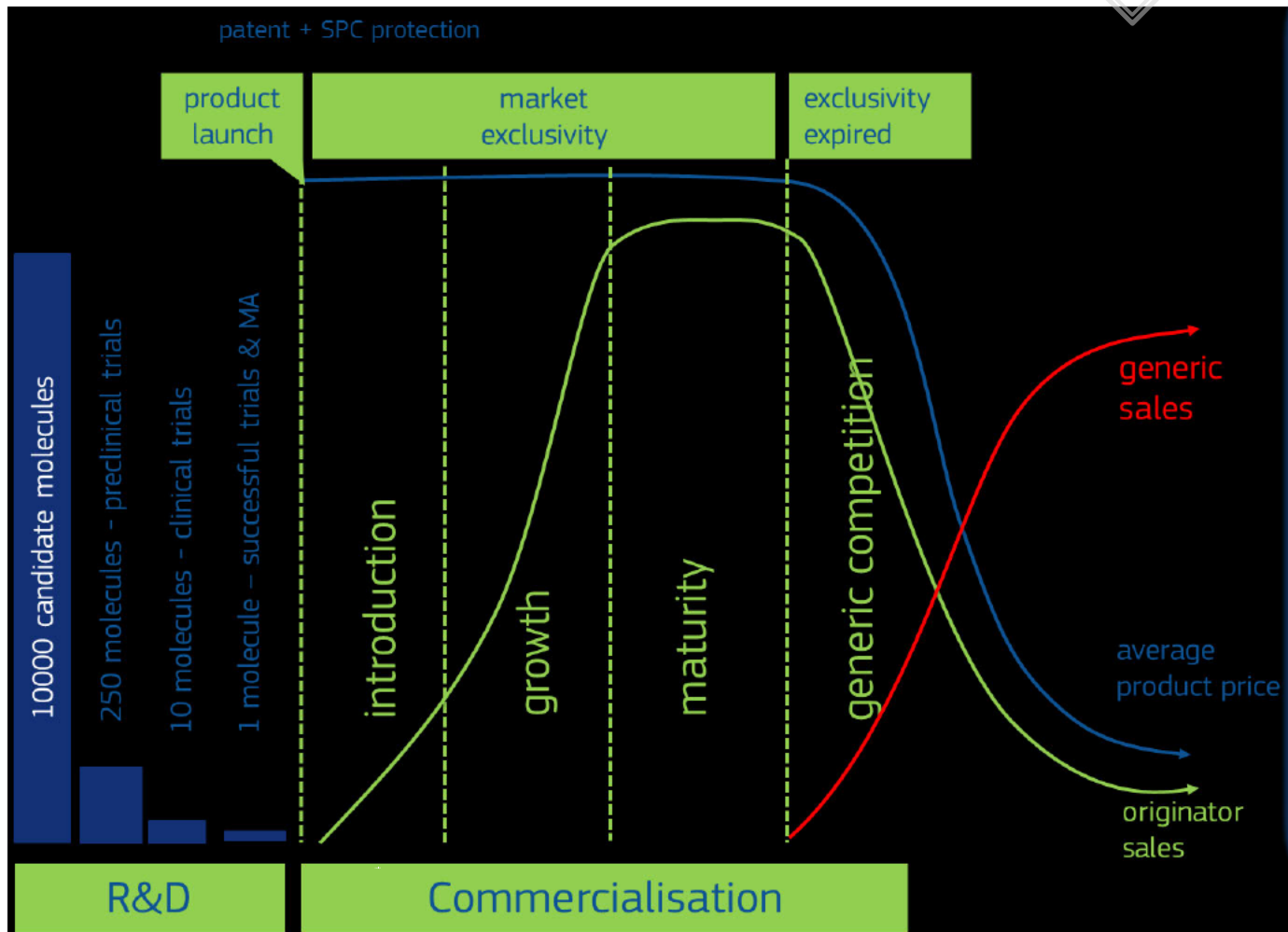
<http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html>

Particularities of competition in the pharmaceutical sector (i) Demand structure



Particularities of competition in the pharmaceutical sector (ii)

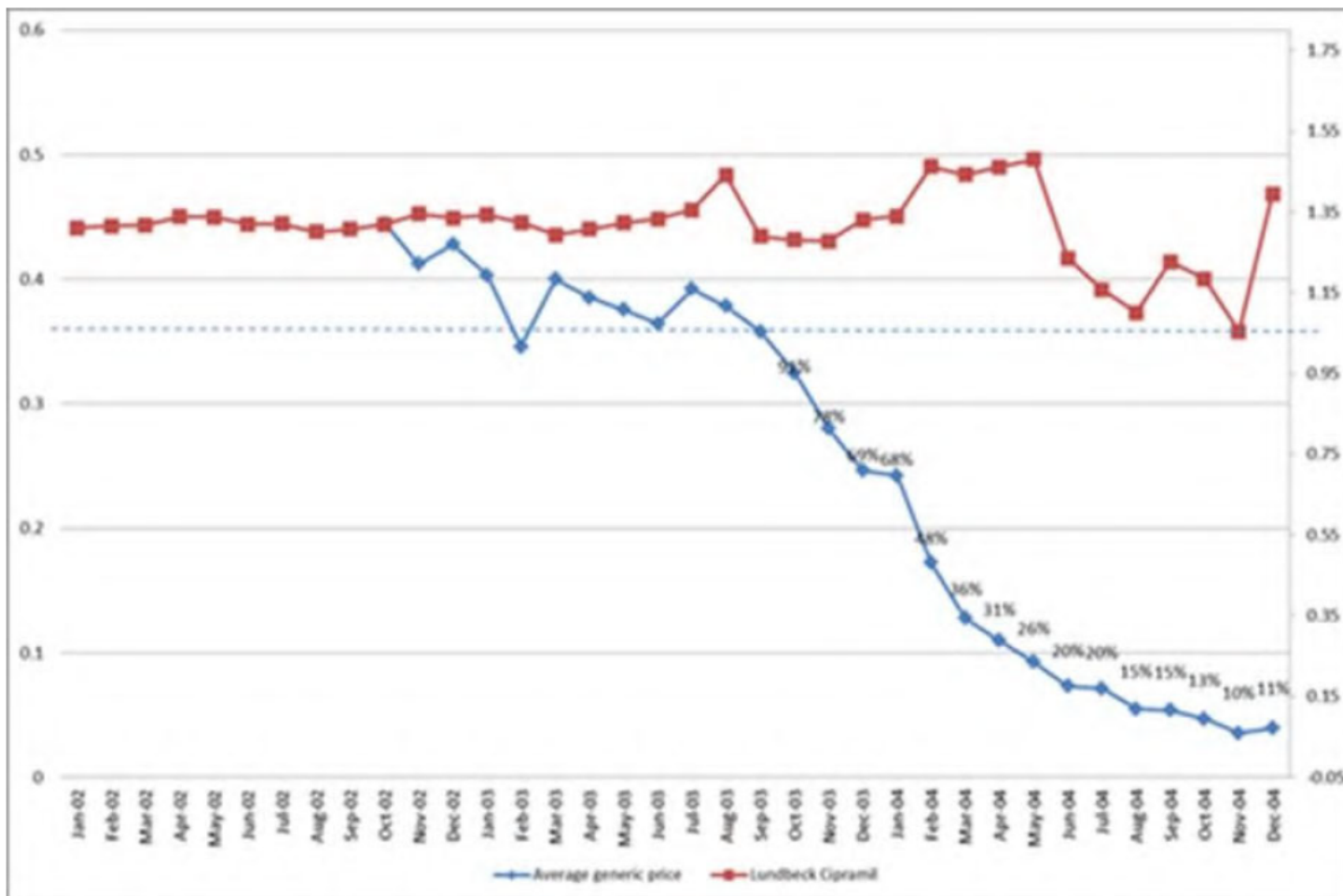
Life cycle of medicines



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

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

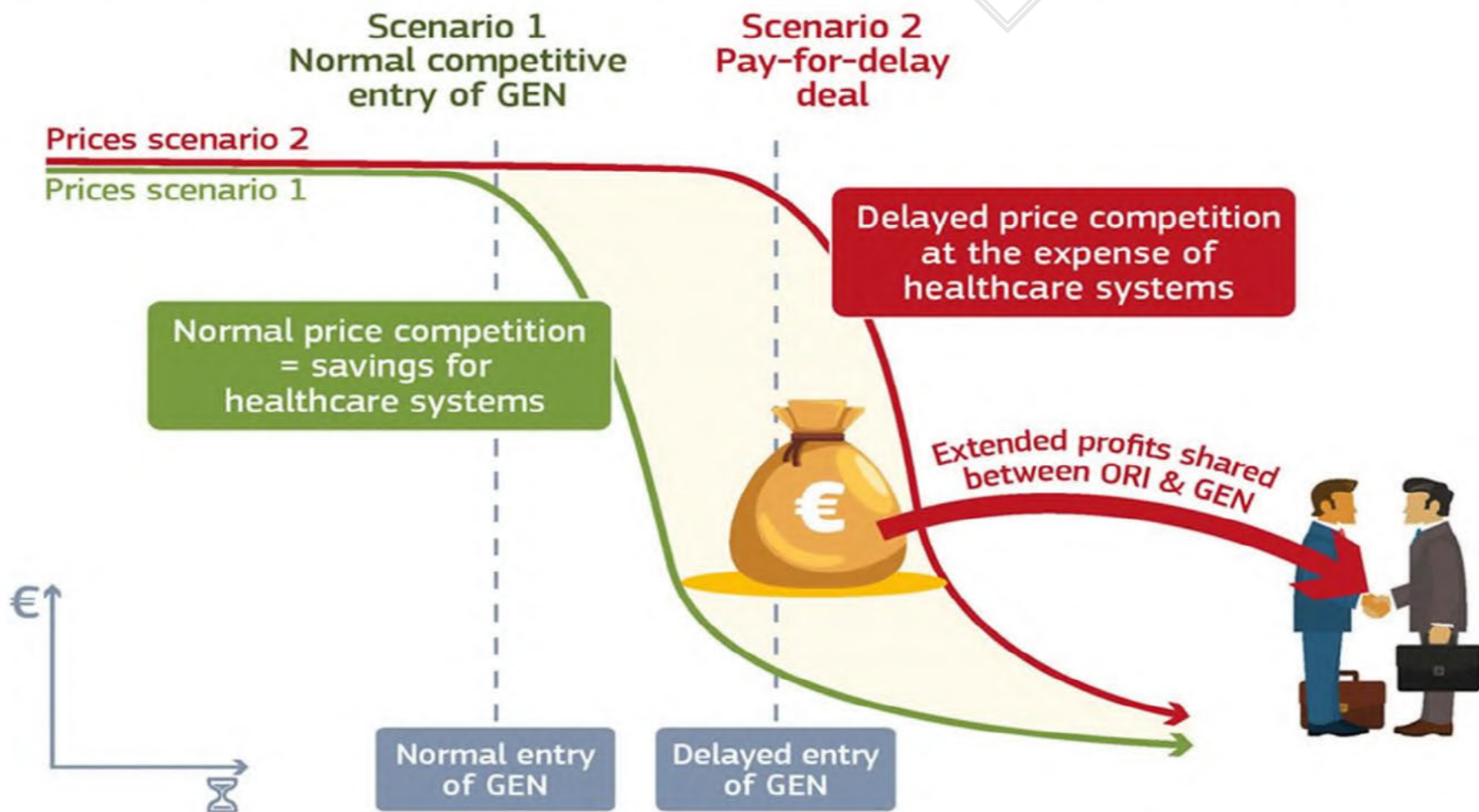


Red line: Lundbeck

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

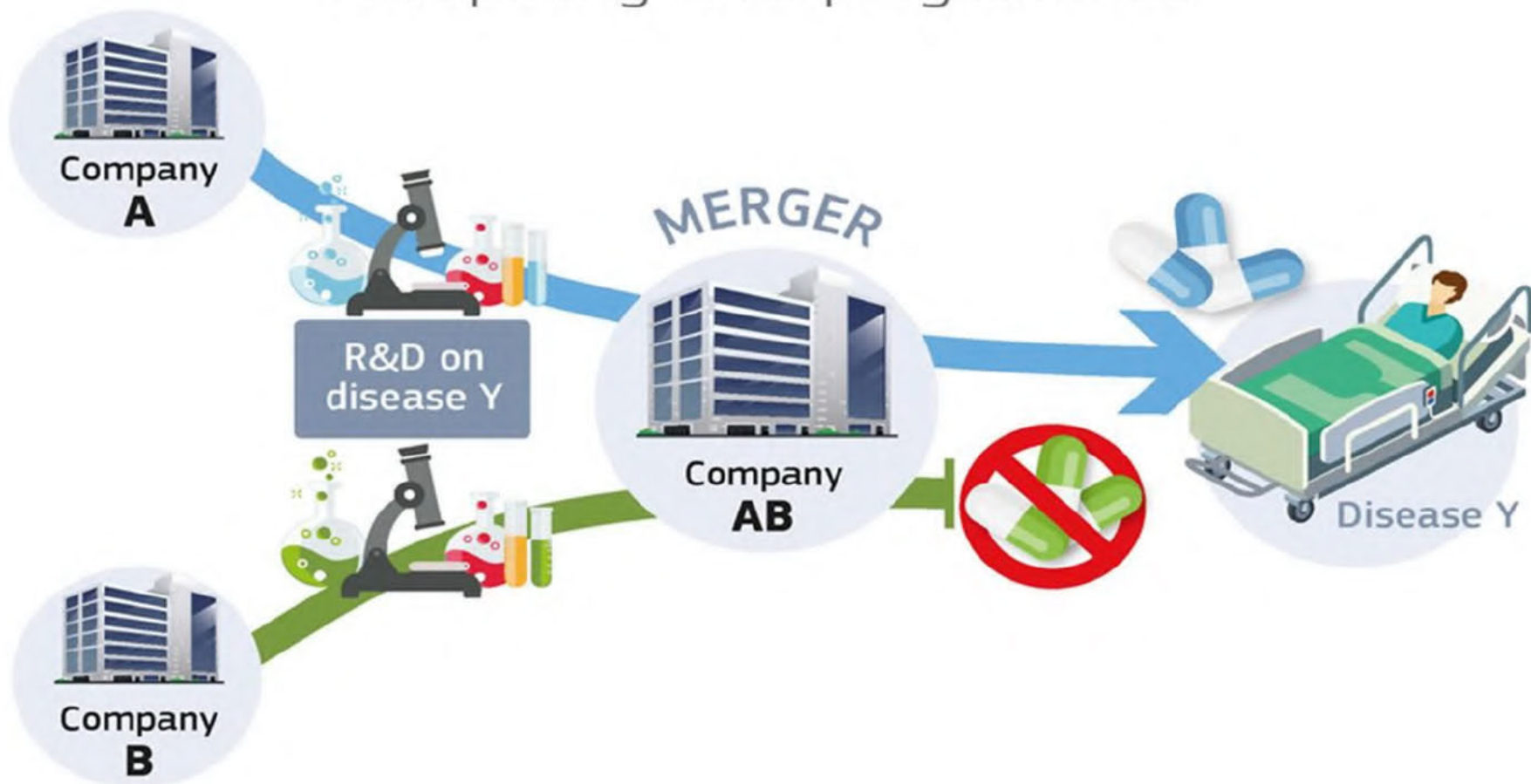
Ensuring that changes in the market structure do not lead to higher prices

- 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



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



ANTITRUST

MERGERS



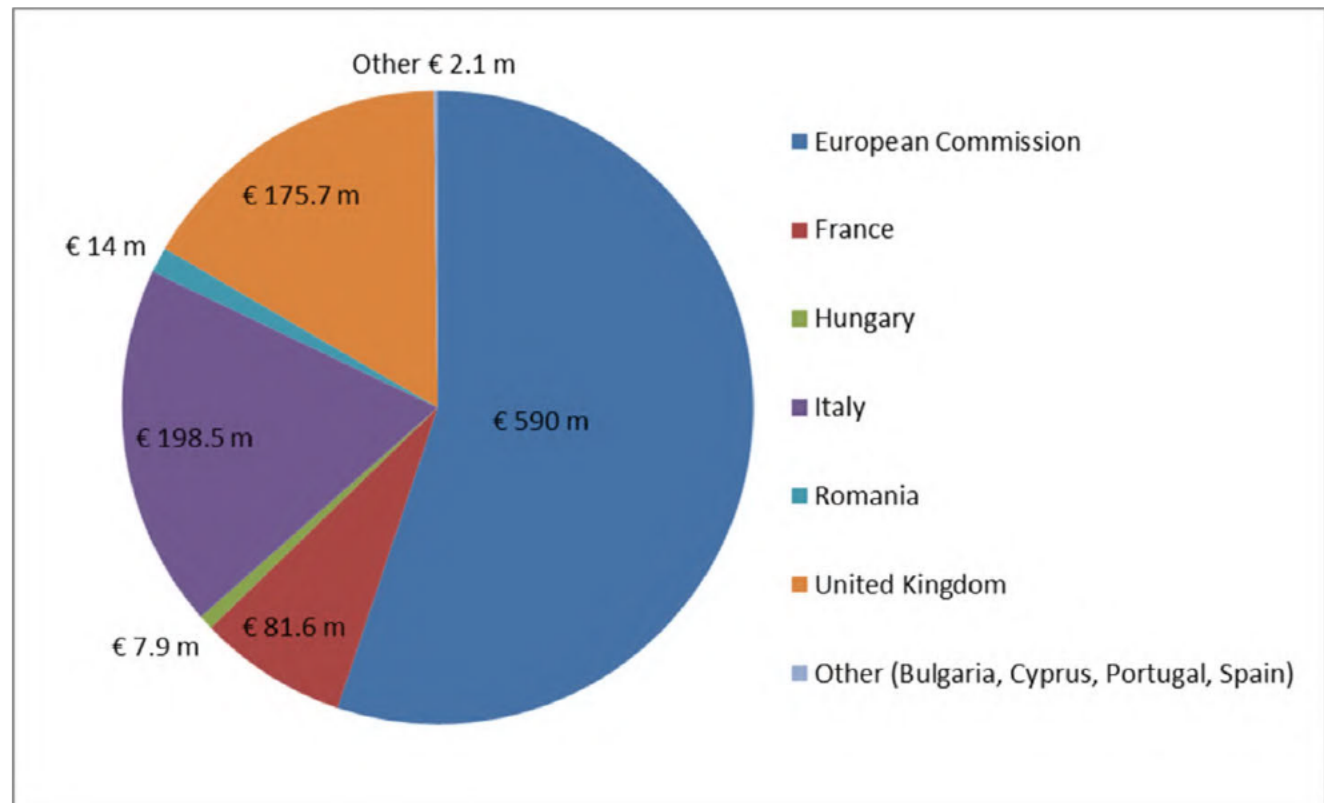
AFFORDABILITY

INNOVATION / CHOICE

Competition

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/contacts/electronic_documents_en.html

European Competition Network:



http://ec.europa.eu/competition/ecn/competition_authorities.html