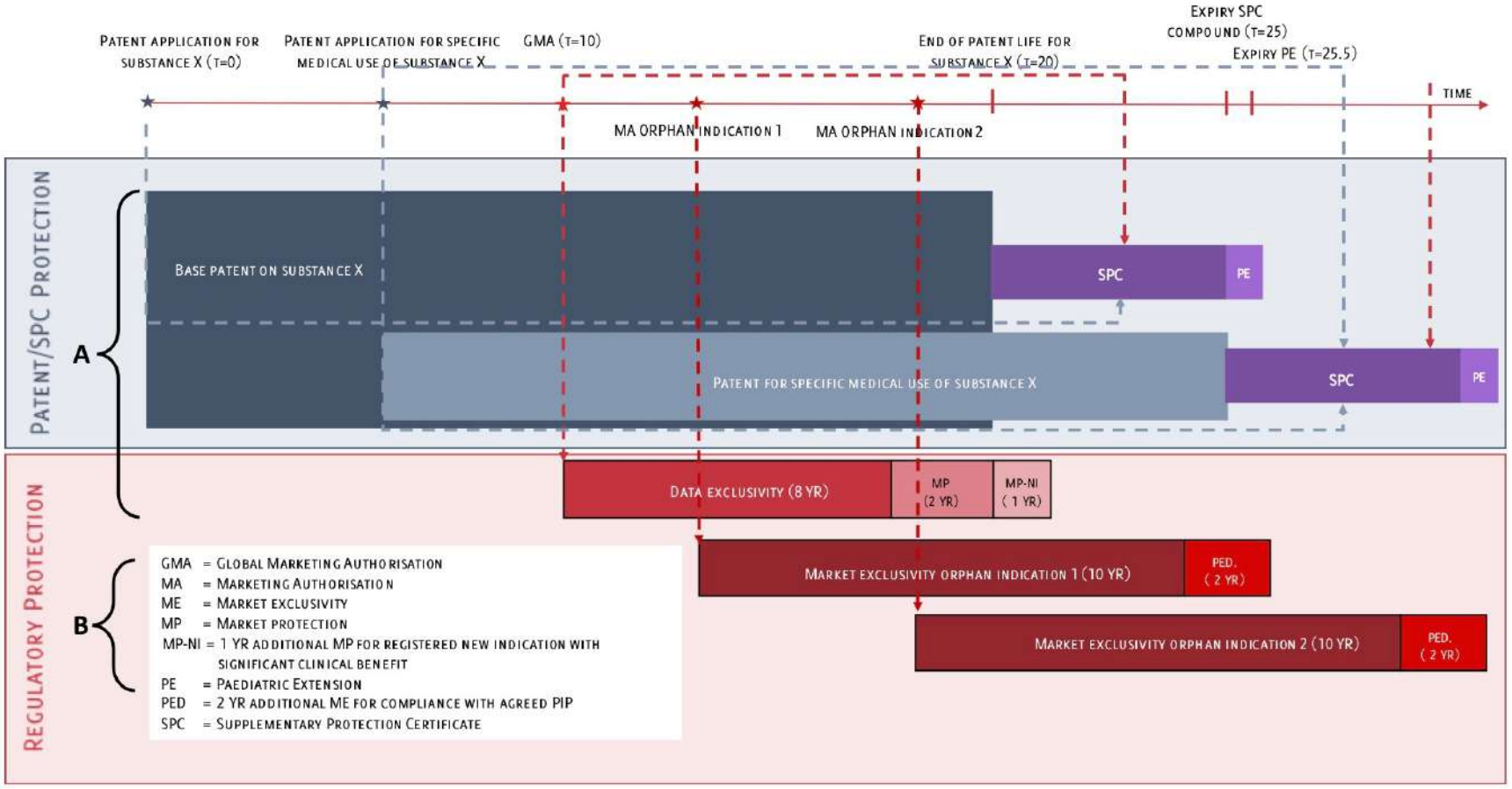
Review of European Pharmaceutical Incentives

Ellen ‘t Hoen, LLM, PhD

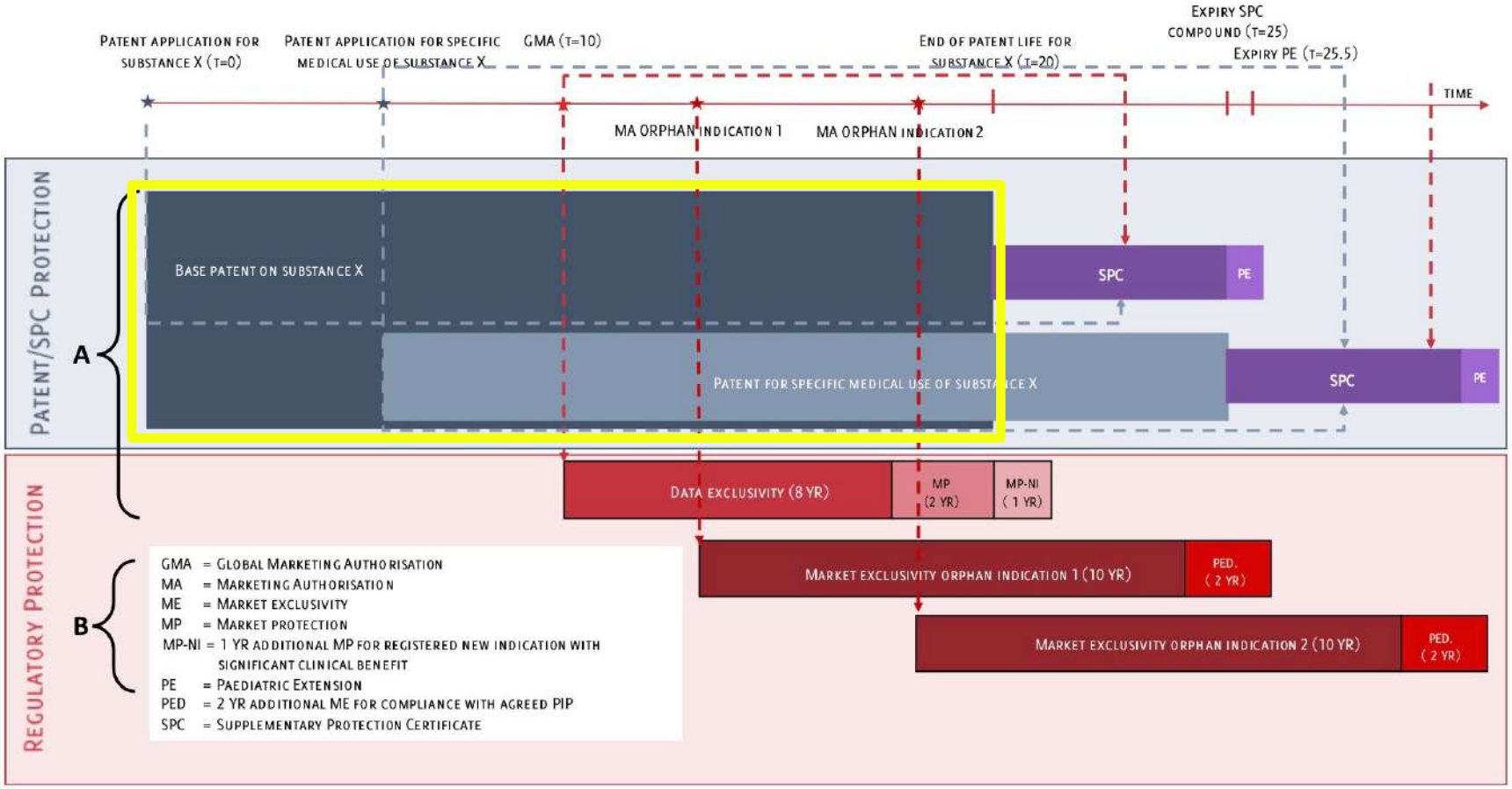
Seminar on extending Monopolies, Graduate Institute Geneva, Global Health Centre, 25 June 2020.

Patent and regulatory market exclusivity



Source: http://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/

Patents

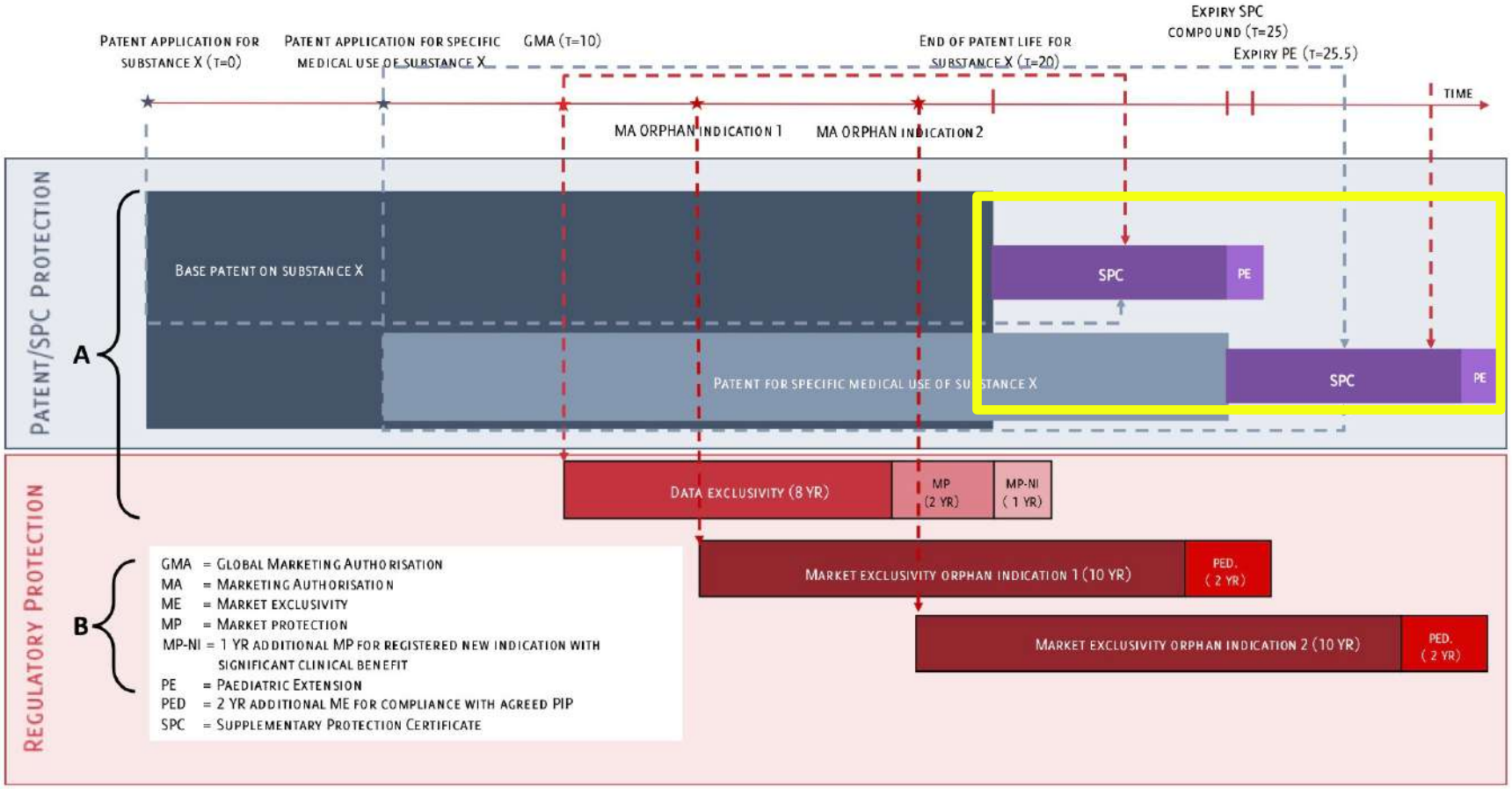


Source: http://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/

Patents

- Right to exclude others from making, using, offering for sale, selling, and importing the patented product (or a product made with a patented process)
- To encourage innovation
- Right granted by a national or regional authority for a minimum 20 years upon application
- Patents are national – global patent application procedures exist (WIPO PCT) but a global patents do not.
- Patent law has public interest safeguards: e.g. compulsory license

Supplementary Protection Certificates



Source: http://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/

Supplementary Protection Certificates

- Up to **5 years of additional patent-like protection** to a registered medicine

- To compensate for lack of commercial exploitation before the medicine's regulatory approval & increase pharma R&D in EU
  - Ensure **15 years of effective patent protection**
  - Deemed necessary **"to cover the investment put into the research"**

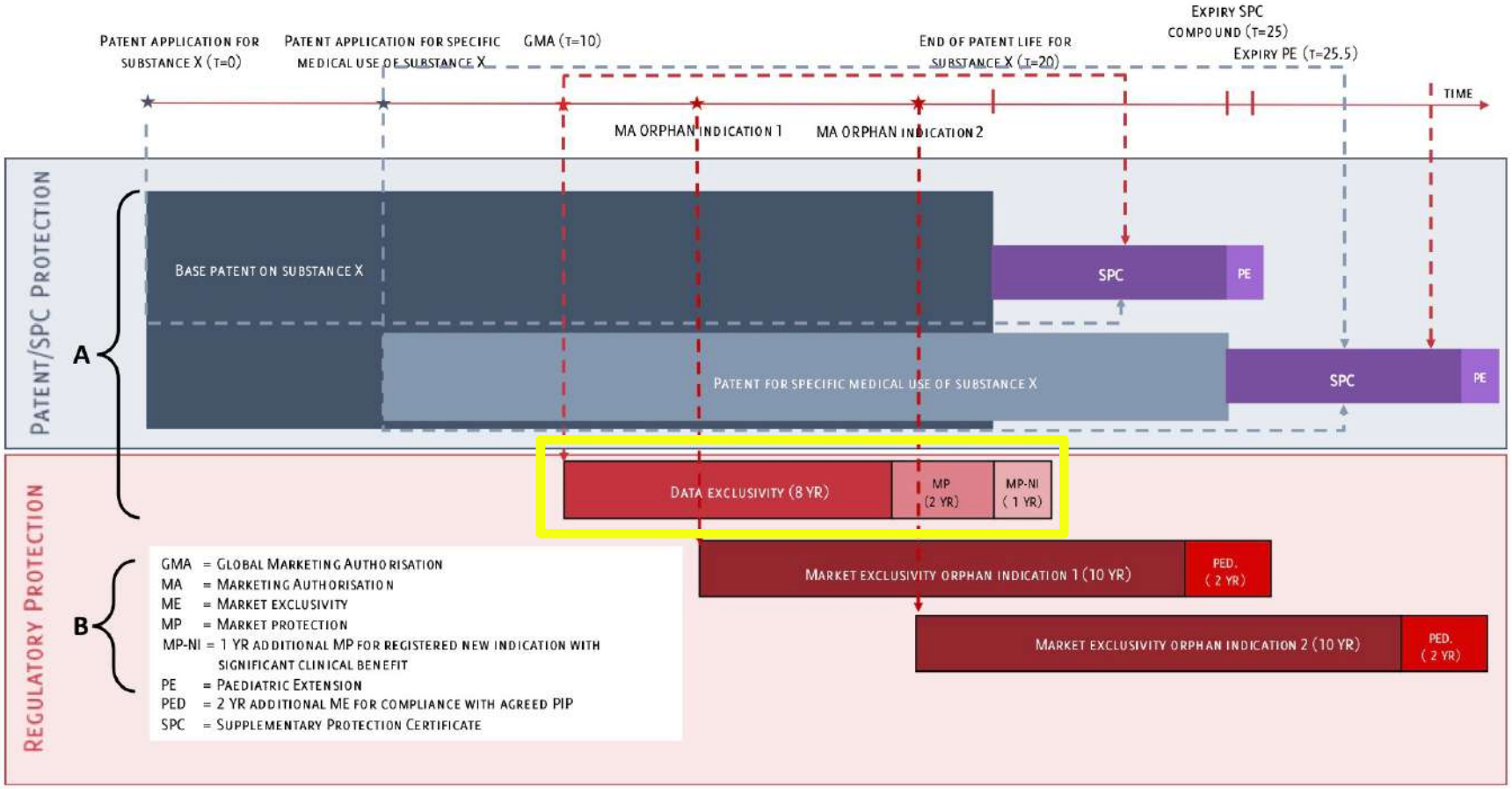
Regulation (EEC) No 1768/92, Regulation (EC) No 469/2009

Higher prices of medicines with SPCs

Example of the HIV medicine TDF/FTC (Truvada)

Country	SPC status	Price (30 tablets) in €
The Netherlands	Never granted	30,65
France	Revoked	170
Switzerland	In force	800

Data Exclusivity



Source: http://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/

Data Exclusivity 1/2

- Data exclusivity was first introduced in the EU in 1987
  - 6 years / 10 years biologics
  - 2004 EU exclusivity regime expanded: '8+2+1 rule'

- To protect the investment in the production of test data needed to obtain marketing authorisation by **preventing use by generic companies** for a certain period of time

- During the period of data exclusivity, a generic **competitor product cannot be considered for registration**

Data Exclusivity 2/2

- Data exclusivity is automatic:
  - **does not require an application** nor evidence of its need
  - data exclusivity is granted **regardless of the level of investment** in generating the test data
  - **quietly enforced through medicines regulation**

- **No international obligation** to provide data exclusivity
  - WTO TRIPS 39.3: protect certain kind of data related to new chemical entities (NCEs) against unfair commercial use
  - A majority of WTO members do not provide data exclusivity

- EU generally requires data exclusivity **commitments in Free Trade Agreements** (FTAs)

Data Exclusivity and compulsory licensing

- **Data Exclusivity** can hamper effective use of compulsory licensing by EU member states

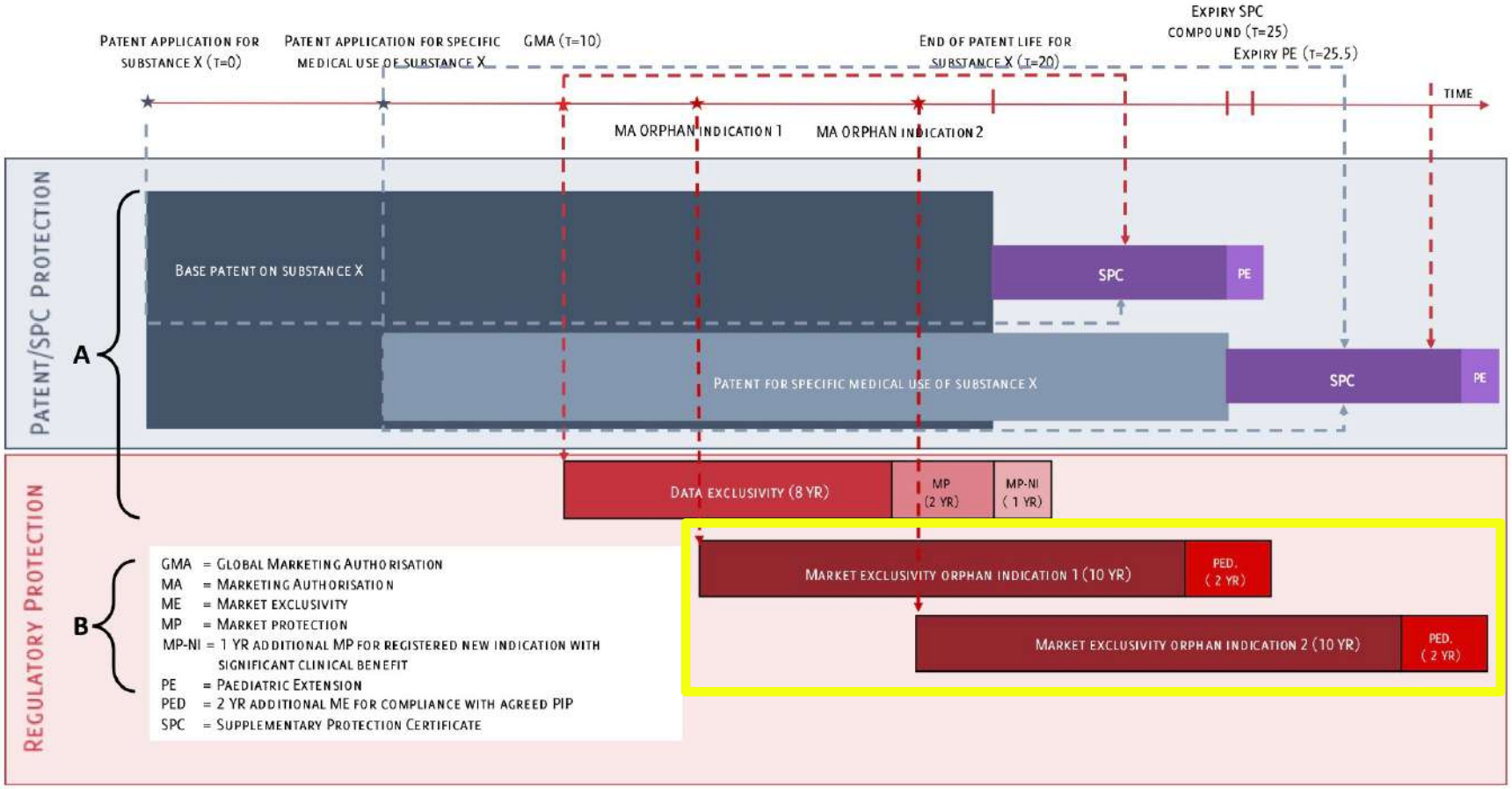
- **EU law** has no waiver for DE to facilitate the use of compulsory licensing for domestic use by EU member states

- **EU regulation on compulsory licensing of patents for the manufacture of pharmaceutical products for export outside the EU** does include waivers to enable EMA opinions.

Data Exclusivity - the case of Ukraine

- EU-Ukraine DCFTA ->5-year data exclusivity
- SOF not patented in the Ukraine
- Generic company Pharco 1st to apply for marketing authorisation (MA) (granted 18.11.15)
- Originator Gilead granted MA on 9.10.15 claiming DE until 2020
- Under legal pressure (inc. ISD threat) Ukraine revoked Pharco's MA

Orphan Medicinal Products



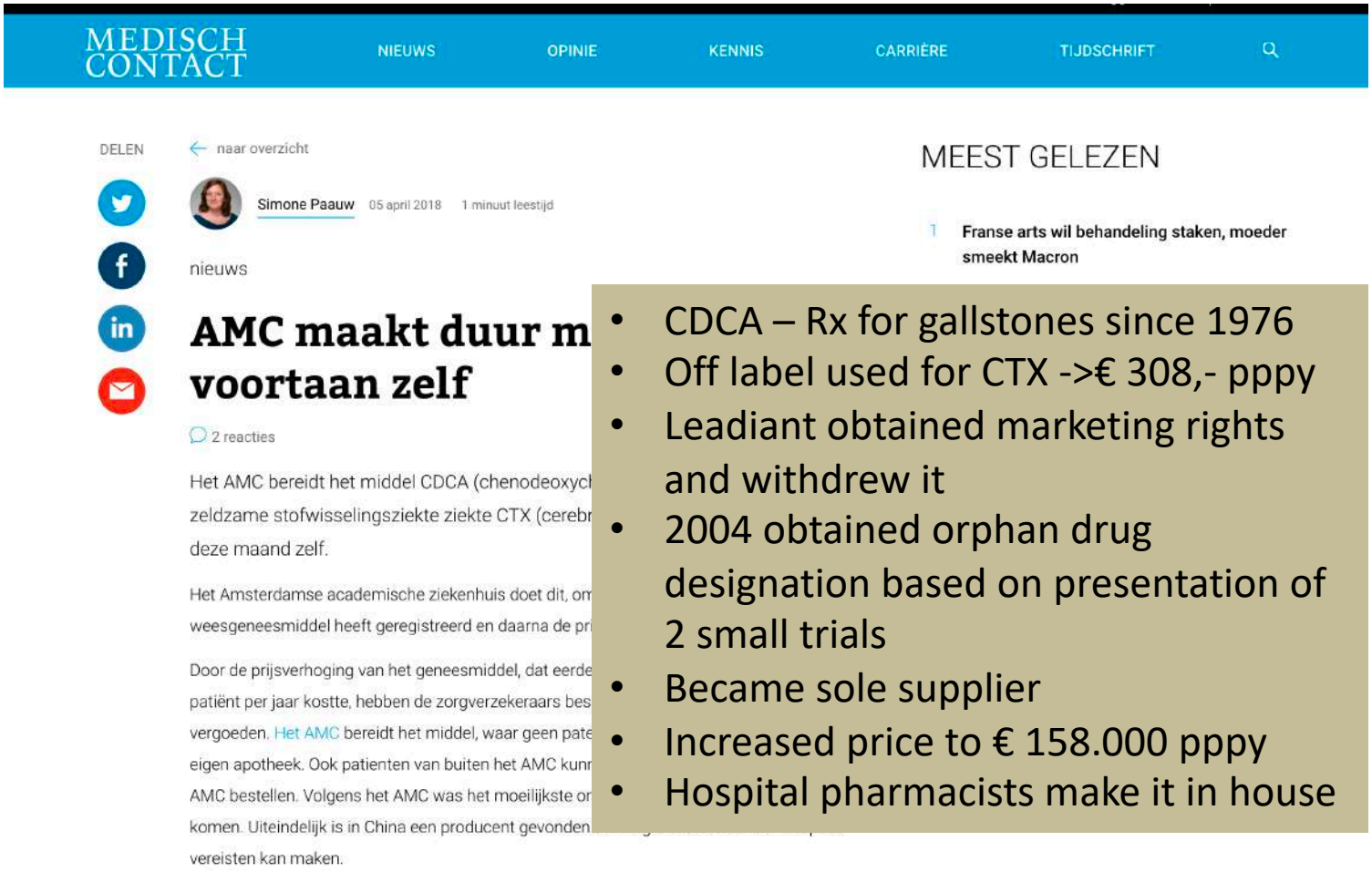
Source: http://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/

Orphan Medicinal Products

- Targets rare diseases **≤ 5 patients/10,000 of population**
- Estimated to be at least **8,000 such rare diseases** and c. 30 million EU citizens affected
- A mix of **push and pull incentives**
  - Protocol assistance
  - Fee waiver
  - Framework for EU and Member State R&D funding
  - 10 year market exclusivity

Regulation EC 141/2000

Gaming the Orphan Drug Act: CDCA in the Netherlands



- CDCA – Rx for gallstones since 1976
- Off label used for CTX ->€ 308,- pppy
- Leadiant obtained marketing rights and withdrew it
- 2004 obtained orphan drug designation based on presentation of 2 small trials
- Became sole supplier
- Increased price to € 158.000 pppy
- Hospital pharmacists make it in house

Orphan Medicinal Products

- Targets rare diseases **≤ 5 patients/10,000 of population**
- **Or demonstrate insufficient return on investment (ROI) – requires transparency on cost and turn over.**

- Estimated to be at least **8,000 such rare diseases** and c. 30 million EU citizens affected

- A mix of **push and pull incentives**
  - Protocol assistance
  - Fee waiver
  - Framework for EU and Member State R&D funding
  - 10 year market exclusivity

Regulation EC 141/2000

EU Review of Pharmaceutical Incentives Systems

- **2006 EU council decided to review pharmaceutical incentive systems" to strengthen the balance in the pharmaceutical systems in de EU and its Member States" This review is ongoing and is not going very well.**
- **Studies commissioned that assess the EU pharma incentives (MPI, Copenhagen Economics an Technopolis)**
- **Not all reports are published yet by the Commission**
- **Commission seems to have narrowed the review to orphan medicines regulation and paediatric incentives.**

https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/

EU Review of Pharmaceutical Incentives Systems

- **Preliminary findings point out that the generous incentive system in the EU fails to meet objectives:**
  - Stimulate European industry and attract industry (majority of SPCs in the EU derive from the US 44% vs 30% EU)
  - Achieve lower prices by offering longer period to recoup investment (SPC) :
    - E.g. the Technopolis Group concludes that "[t]he implicit objective of encouraging lower prices for still-protected products, by offering pharmaceutical innovators increased time to recoup their investments, appears not to have been realised at all."
  - Stimulate R&D
    - "The SPC Regulation offers innovator companies an adequate compensation for their effective loss of patent term." However, as an incentivising measure, the report says, "the effect is much less clear.

High Medicines Pricing a Global Issue

Campaigners protest outside the National Institute for Health and Care Excellence over

s no longer an option

Why Access

JUNE 2016

EDITORIAL

Jonathan D. Alp

bold enough. Im
an international
financing for R&D.
transparency, good g
all emphasised, includi
that pressure countries

The report was oppos by the US
the pharmaceutical industry whose attempts to dilute health and development agenda. ■ *The Lancet*

For the **High-Level Panel report** see http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf

For **Essential Medicines are still essential** see Comment *Lancet* 2016; **386**: 1061–63

Thank you!

@ellenthoen

Download our reports:
https://medicineslawandpolicy.org/useful-resources/briefs/