



Intellectual Property and regulatory protection of pharmaceuticals in the EU

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IP protection

- **Patents** (max. 20 yrs) (for all products, e.g. masks & medicines)
- **Supplementary Protection Certificates** ("SPCs"):
 - (USA: "Patent term restoration" – PTR)
 - for medicinal products: Reg. 469/2009
(for plant protection products: Reg. 1610/96)
 - up to 5 additional years of patent protection
 - if the relevant delay (pat. applic. > MA) exceeds 5 years
 - + possibly 6 months for paediatric uses (Reg. 1901/2006)
 - *within the limits of the marketing authorisation*
- **Data/market exclusivity** (not IP): see next slide

Regulatory protection

Data & Market Exclusivity (not IP):

- Intended to protect investments in approval procedures
- “**Data exclusivity**” period of **8** years (after an initial marketing authorisation in the EU) during which the “abridged procedure” cannot be used to seek authorisation for a generic medicine
- “**Market exclusivity**” period of **10** years, during which a generic medicine cannot be placed on the market (+ possibly **1 more** year for new therapeutic indications)
- Market exclusivity for orphan medicines: also **10** years but broader scope; + possibly **2** additional years for paediatric use

Patent
(20 yrs)

SPC
(max. 5 yrs)
(Reg. 469/2009)

**Paediatric
extension**
(6 months)
(Reg. 1901/2006)

Data protection

(8 yrs) (Dir. 2001/83, Art. 10.1
& Reg. 726/2004, Art. 14.11)

Market exclusivity

(10 yrs) (Dir. 2001/83, Art. 10.1
& Reg. 726/2004, Art. 14.11)

**Extension for new
therapeutic indications**

(1 yr) (Dir. 2001/83, Art. 10.1 &
Reg. 726/2004, Art. 14.11)

**Market exclusivity
for orphan medicines**

(10 yrs) (Reg. 141/2000, Art. 8.1)

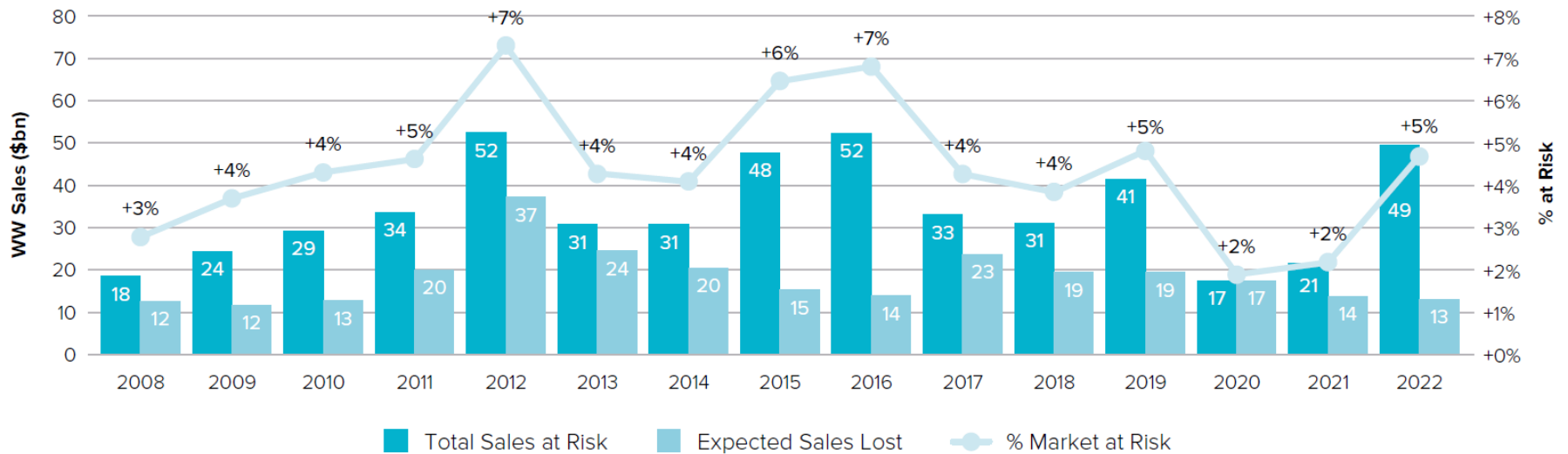
Extension for paediatric use
(2 yrs) (Reg. 1901/2006, Art. 37)

Exclusions (Reg.
1901/2006, Art. 36.4 & 5)

Economic impact of pharma patents

Worldwide Sales At Risk from Patent Expiration (2008-2022)

Source: Evaluate, May 2017



Upcoming Communications

- **IP Action Plan** (DG GROW & al.):
 - Specific initiatives will follow (e.g. unitary SPC)
 - See Roadmap; adoption planned in November
- **Pharma Strategy** (DG SANTE):
 - Promoting both innovation and access to medicines
 - Specific initiatives will follow
 - See Roadmap; adoption planned in November
- **'Covid-19 – Lessons learnt'** (DG SANTE):
 - About health crises preparedness, shortages, etc.