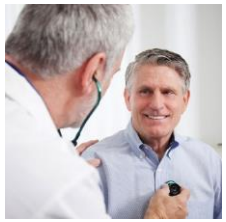
European Federation of Pharmaceutical Industries and Associations

EU IP Incentives Analysis – Threat or opportunity for Innovation?

Kristine Peers, General Counsel EFPIA

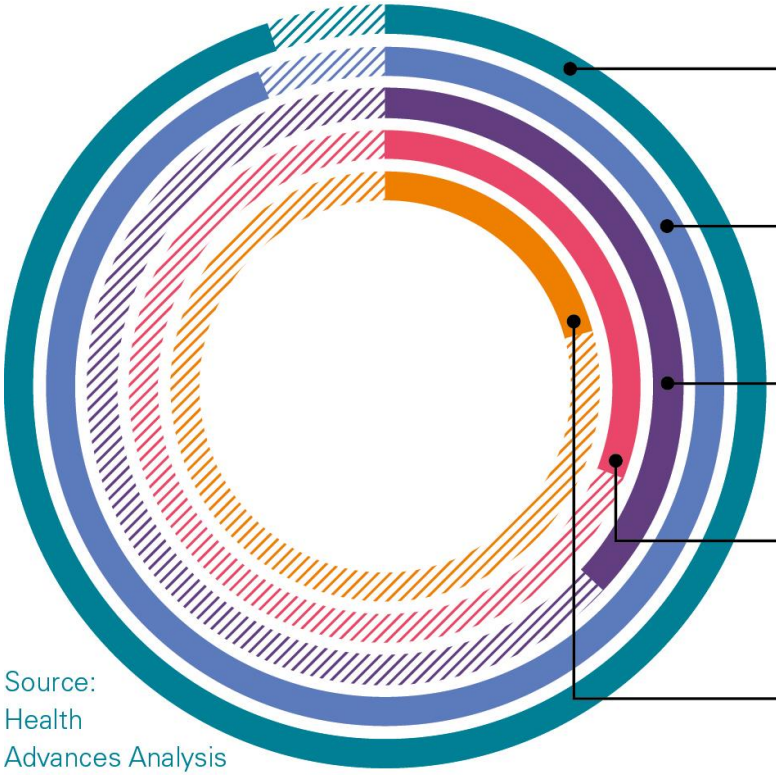





Athens, March 2018

OVER RECENT YEARS, THERE HAS BEEN DRAMATIC PROGRESS IN TACKLING MAJOR DISEASES

Medicines & vaccines are some of the most powerful tools that help patients in Europe to live longer, healthier, and more productive lives



95% of the 15 million patients in Europe living with **HEPATITIS C** can be cured through an 8-12 week course of treatment

94% Since 1991 there has been a 94% reduction in age-standardised death rates for patients living with **HIV** in France

37% Between 2000 and 2012, the death rate from **CARDIOVASCULAR DISEASE** fell 37% in the EU5

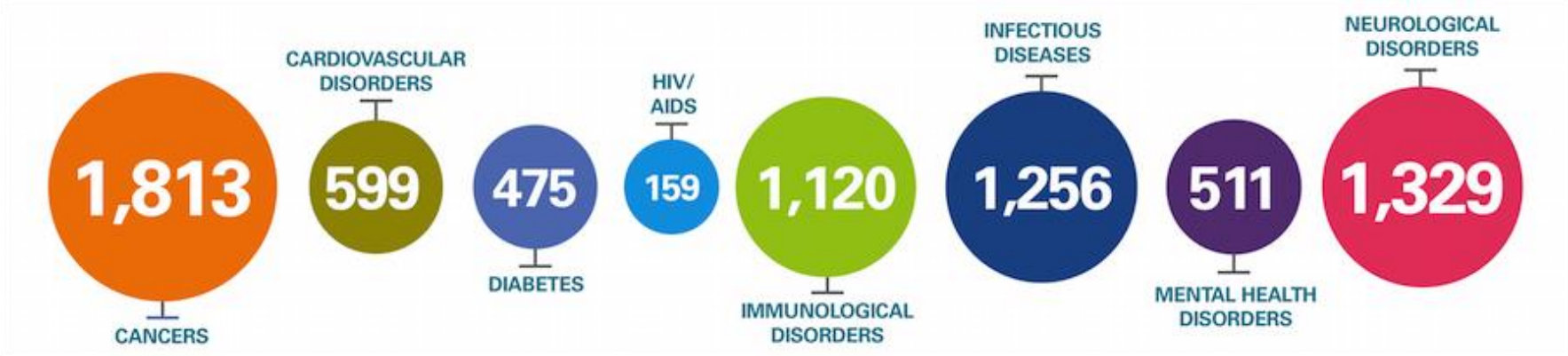
31% Between 2000 and 2012, new therapies contributed to a 48% and 31% decline in the **DIABETES** death rate in Korea and Canada respectively

21% Since 1991 there has been a 21% reduction in mortality rates from all **CANCERS**

Source: Health Advances Analysis

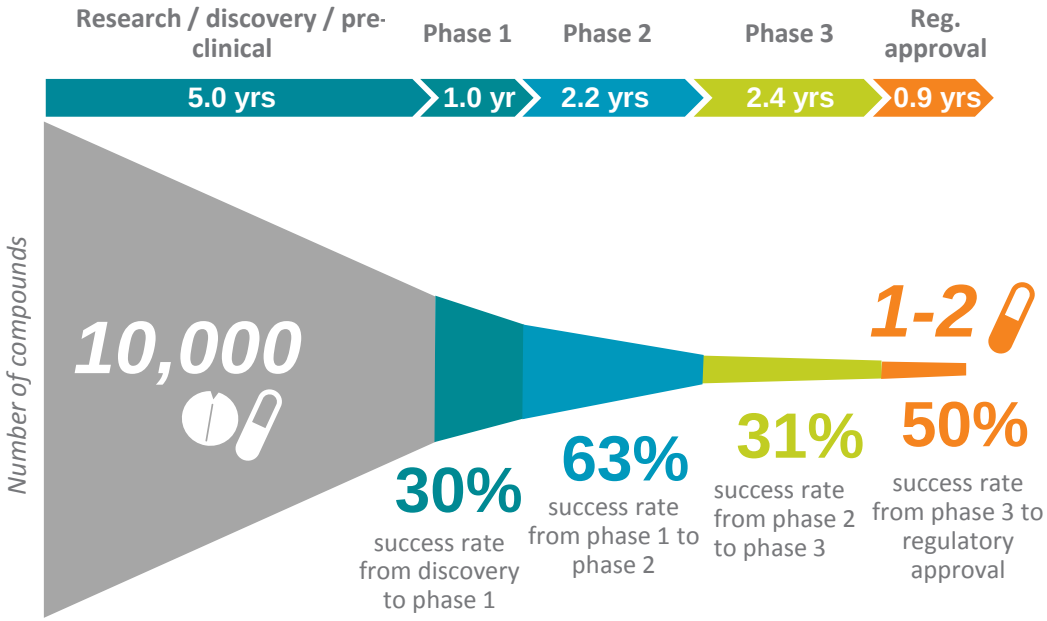
TODAY'S PIPELINE REFLECTS THE UNMET NEEDS OF TOMORROW

With over 7000 medicines in development, the exciting new wave of medical innovation will play a key role in addressing challenges faced by patients & healthcare systems

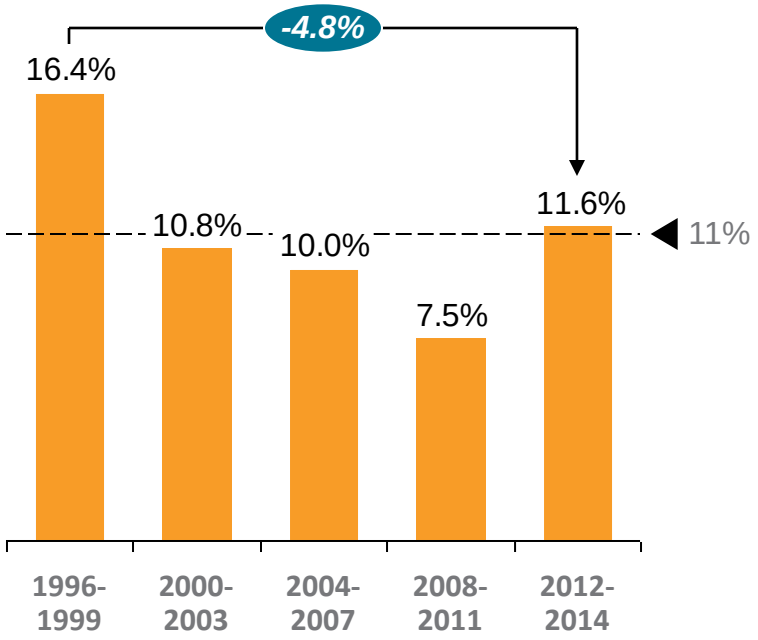


On average, it takes 12 years to develop a promising molecule into a medicine – overall failure rates remain high

Time & success rates from drug discovery to launch[1-3]



Cumulative success rates from phase 1 to launch over time[5]



* On average, only 1 to 2 of every 10,000 substances synthesized in laboratories will become a marketable medicine[4]

POS=PROBABILITY OF SUCCESS; SOURCE: 1. BIOTECHNOLOGY INNOVATION ORGANISATION. 'CLINICAL DEVELOPMENT SUCCESS RATES 2006-2015' (2016); 2. FDA REVIEW. 'THE DRUG DEVELOPMENT AND APPROVAL PROCESS' (2016); 3. MESTRE-FERRANDIZ ET AL. 'THE R&D COST OF A NEW MEDICINE' (2012); 4. EFPIA. THE PHARMACEUTICAL INDUSTRY IN FIGURES (2017); 5. SMIETANA ET AL. 'TRENDS IN CLINICAL SUCCESS RATES', NATURE REVIEWS DRUG DISCOVERY (2016);

The EU has refined the IP incentives and rewards system to encourage research into areas of unmet need

Overview of European IP incentives[1]

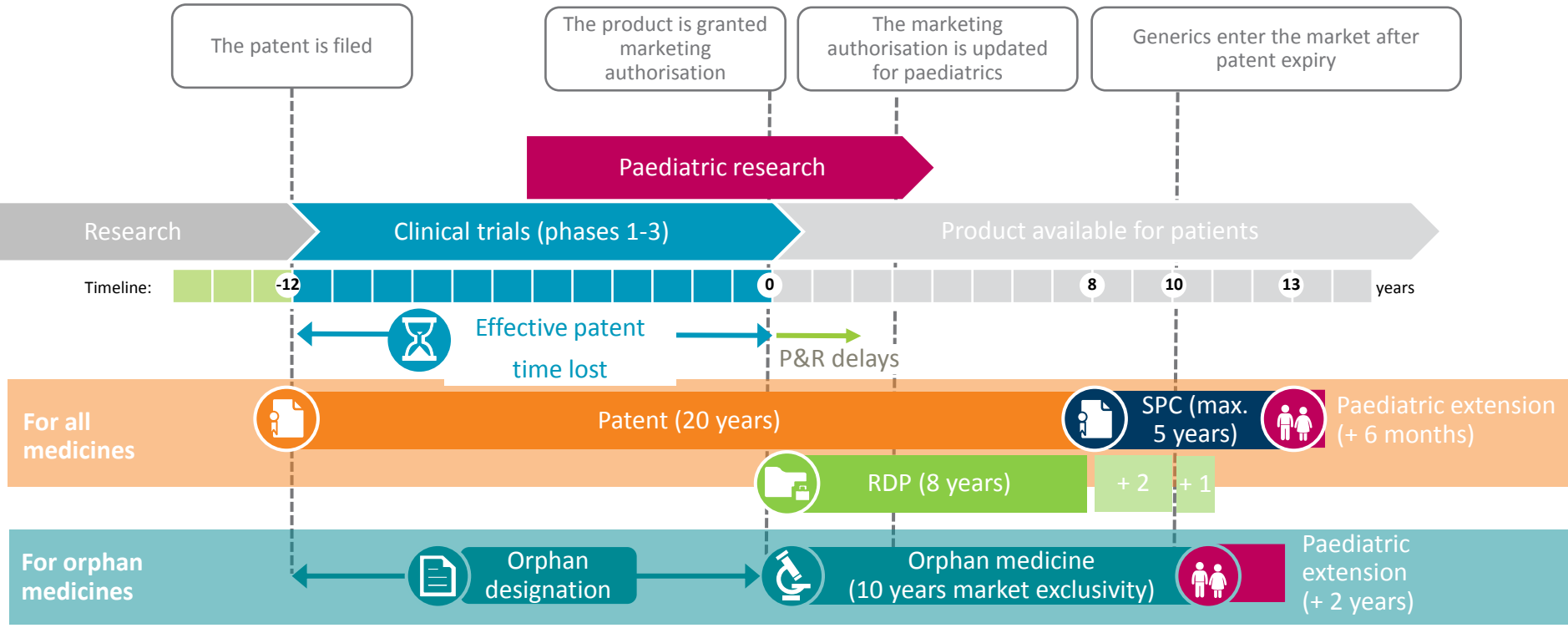
Patent (1450*)	Encourage companies to invest in R&D by protecting any invention from copies for a limited period of time during which the patent holder can ensure absence from unfair competition by manufacturers that did not have to undergo risky, expensive & complex R&D processes; in exchange for exclusivity, the investor makes the invention public so that more research can follow
Supplementary Protection Certificate (1992)	Extend exclusivity for a pharmaceutical product that is protected by a patent to compensate for part of the time lost during the lengthy development period before a medicine can be made available on the market and ensure sustainable funding for such research
Regulatory Data Protection	Protect product developers' investment to generate the pre-clinical and clinical data required to obtain a marketing authorisation from unfair commercial use
Orphan Designation (2000)	Incentivise companies to research and develop medicines for rare diseases by providing specific development support and protecting them once marketing authorisation is obtained from market competition with similar medicines for the same rare ('orphan') indications
Paediatric Extension (2007)	Reward companies for undertaking the significant additional testing needed to ensure the safety and efficacy of the medicine for children, as required under Paediatric Regulation

"[SPC] aims to guarantee laboratories working to develop new medicinal products a level of protection equal to that enjoyed by R&D in other sectors."[2]

EU=EUROPEAN UNION; IP=INTELLECTUAL PROPERTY; SOURCE: 1. MANUFACTURER STATEMENT (2017); 2. EUROPEAN COMMISSION. PROPOSAL FOR A COUNCIL REGULATION CONCERNING THE CREATION OF A SUPPLEMENTARY PROTECTION CERTIFICATION FOR MEDICINAL PRODUCTS (1990)

IP provisions work side-by-side to enable pharmaceutical companies to continue innovating despite obstacles

Application of IP incentives[1]

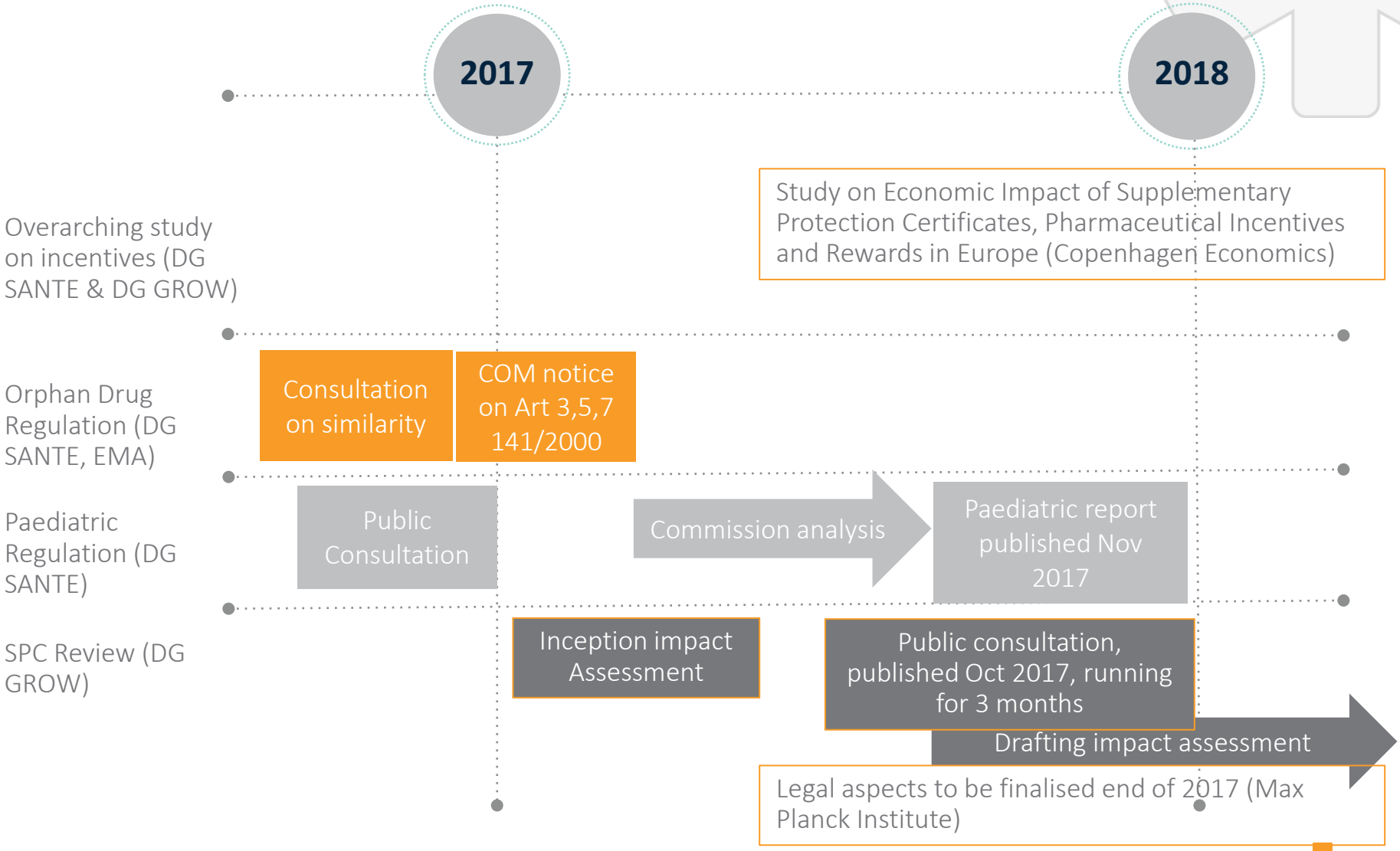


IP systems have been designed to foster and ensure the competitiveness of European countries for innovation

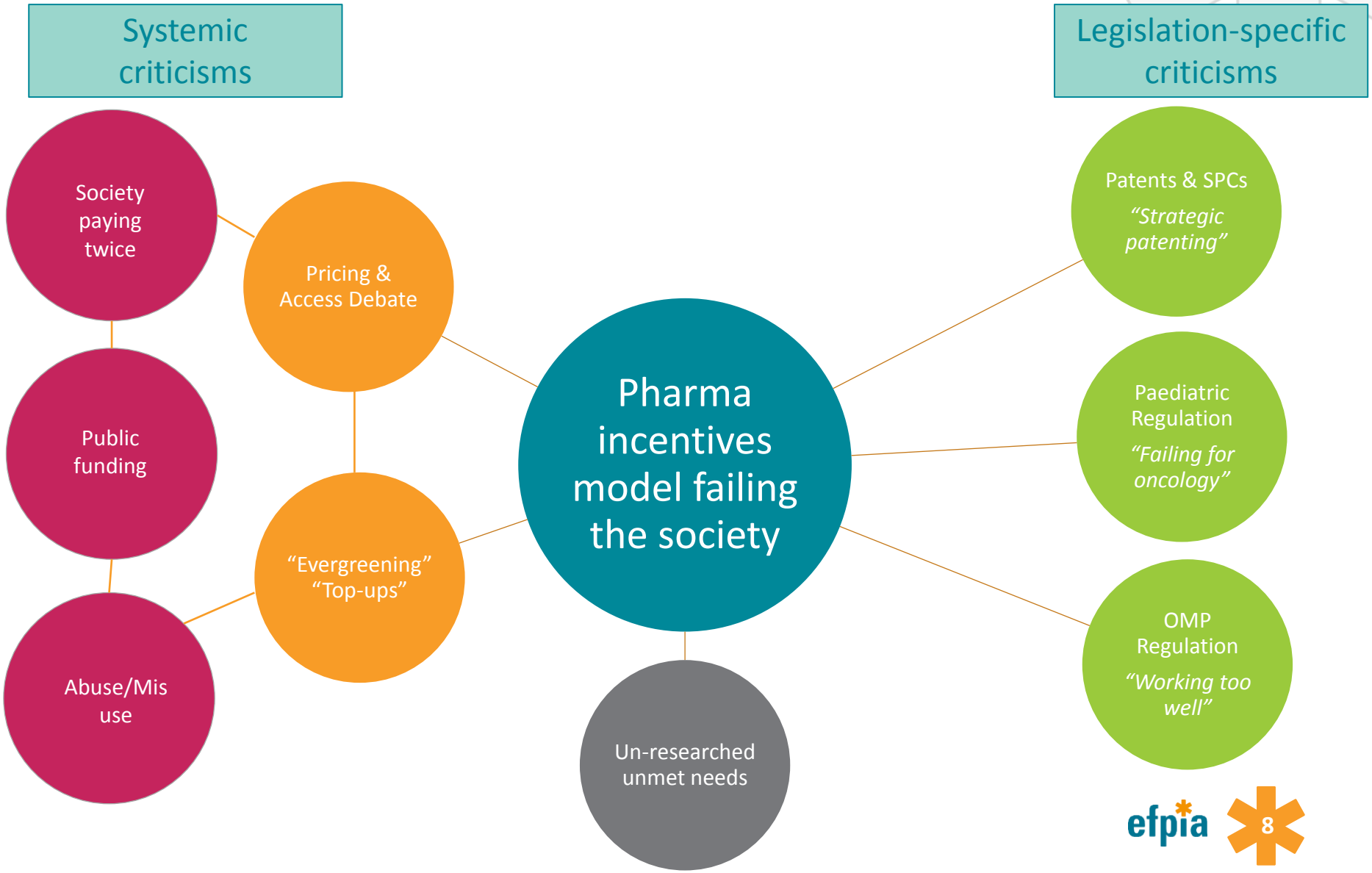
EU=EUROPEAN UNION; IP=INTELLECTUAL PROPERTY; RDP=REGULATORY DATA PROTECTION; SPC=SUPPLEMENTARY PROTECTION CERTIFICATE

SOURCE: 1. EFPIA, ABOUT IP INCENTIVES (2017)

EU IP Incentives Review



Mapping the public debate



COUNCIL CONCLUSIONS

ON STRENGTHENING THE BALANCE IN THE PHARMACEUTICAL SYSTEMS IN THE EU AND ITS MEMBER STATES

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(…) further **analysis** to examine the current functioning of the pharmaceutical system in the EU and its Member States, in particular in relation to the **impact** of certain **incentives** in EU pharmaceutical legislation**, the use thereof by economic operators and the consequences for the innovation, availability, accessibility and affordability** of medicinal products for the benefit of patients (…)

Where relevant, the analysis of impacts should also address - *inter alia* - the development of medicinal products and the **effects of the pricing strategies** of industry in relation to these incentives.

The Commission will conduct the analysis on the basis of the information that is made available or gathered, including from the Member States and other relevant sources.

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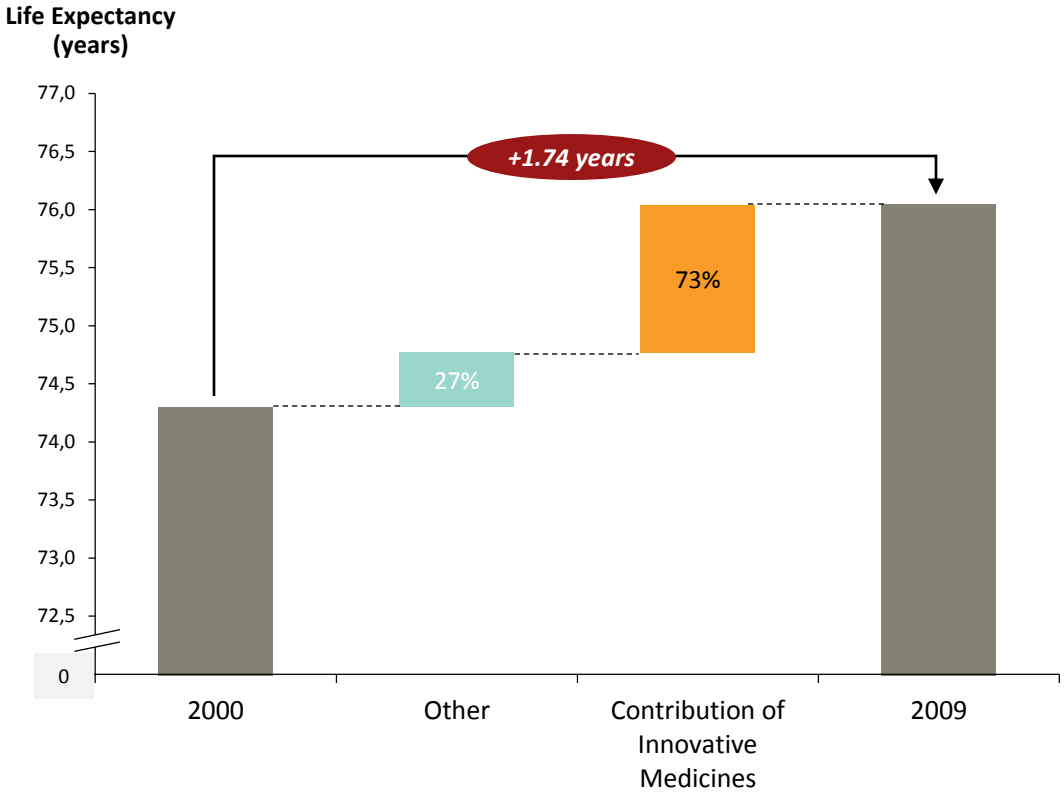
17 June 2016

Challenges are real : Life expectancy continues to improve today – and medicines usage has made major contribution to recent advances

Contribution of innovative medicines to increase in life expectancy (2004-2009)



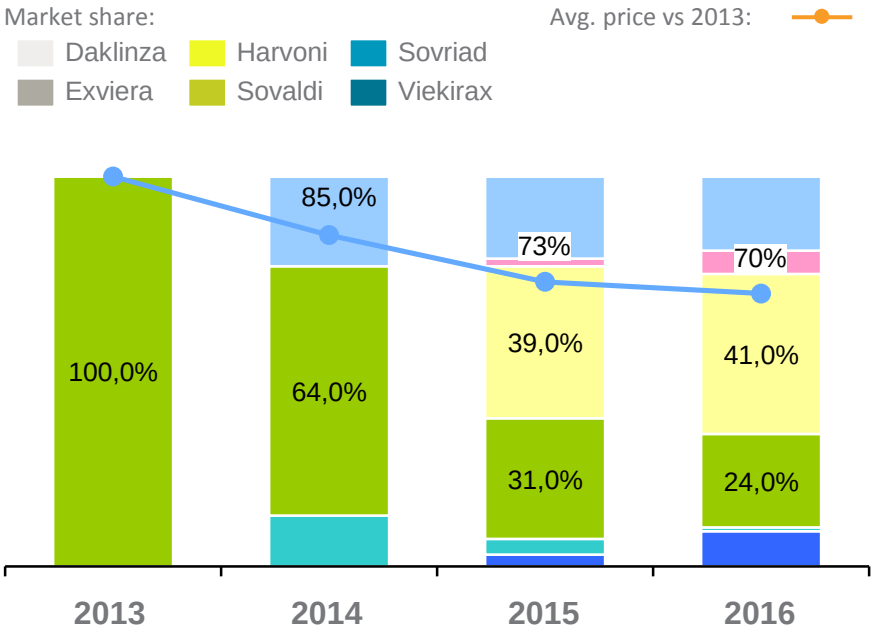
- From 2000 – 2009, an improvement in population weighted mean life expectancy at birth of 1.74 years was seen across 30 OECD countries.
- Innovative medicines are estimated to have contributed to 73% of this improvement once other factors are taken into account (e.g. income, education, immunization, reduction in risk factors, health system access).

SOURCE: LICHTENBERG, F: PHARMACEUTICAL INNOVATION AND LONGEVITY GROWTH IN 30 DEVELOPING OECD AND HIGH-INCOME COUNTRIES, 2000 - 2009 (2012)

Reducing IP incentives is not a solution

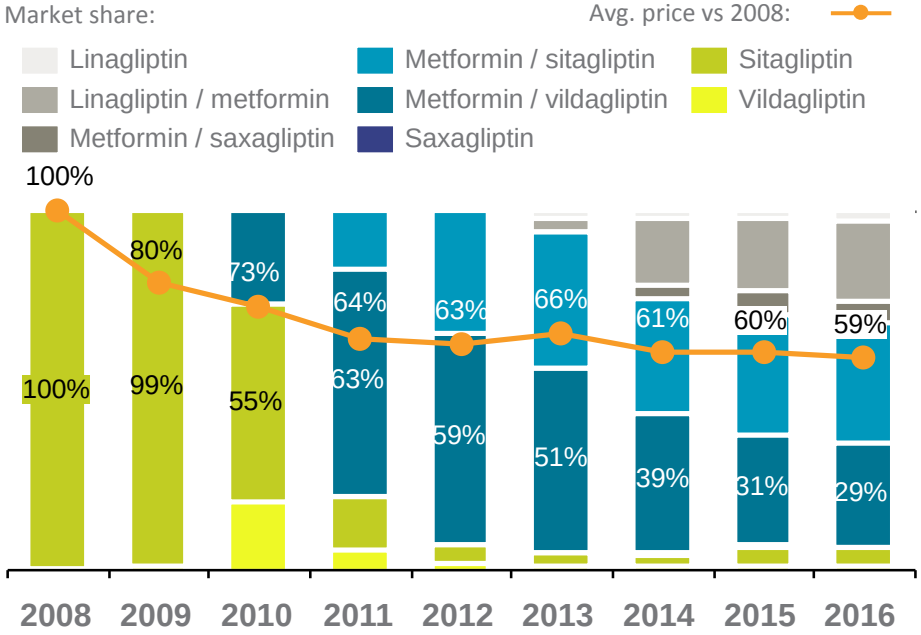
IP protection enables the innovation necessary to foster competitive conditions, in turn driving down medicines prices

Product volume market share & price for hepatitis C treatment in France*,[1]



* Over four years, the entry of five new competitors led to a 30% decrease in the average price of treatment

Product volume market share & price for anti-diabetics (DPP-4's) in Bulgaria*,[1]



* Over eight years, the entry of seven new competitors led to a 41% decrease in the average price of treatment

IP and pricing are not linked: IP does not create a economic monopoly

*EX-MANUFACTURER PRICES; EXCLUDE REBATES, DISCOUNTS & OTHER AGREEMENTS
IP=INTELLECTUAL PROPERTY; NOAC=NOVEL ORAL ANTICOAGULANT; CF=CYSTIC FIBROSIS; CL=CHRONIC LYMPHOCYTIC LEUKAEMIA, PAH=PULMONARY ARTERIAL HYPERTENSION
SOURCE: 1. IMS. 'THEORIES OF HARM & KEY ELEMENTS OF RESPONSE' (2017)

IP incentives are key for innovation

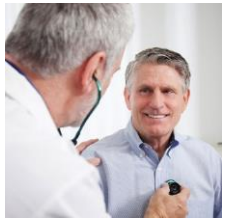
- Incentives are the foundation for innovation
- Still unmet medical need in many disease areas + new challenges emerge such as AMR
- Analysis of the existing incentives should be evidence-based and comprehensive
- Any dilution of IP protection in Europe would be detrimental to
  - Europe's ability to compete effectively for global R&D investments
  - competition in the market
  - Patient access to innovative medicines

Europe should continue to build on successes from IP incentives and consider opportunities to address new challenges

European Federation of Pharmaceutical Industries and Associations

Thank you for your attention
Any questions?



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