Network: **AmCham EU Guest** Password: **Welcome@AEU**

**#Transatlantic2018**

# POLICY BRIEFING

## TRANSATLANTIC WEEK 2018

WEDNESDAY, 7 - FRIDAY, 9 MARCH

**amchameu.eu/transatlanticweek**

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SPEAKING FOR AMERICAN BUSINESS IN EUROPE

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Briefing session:

# Healthcare

## The role of Member States in adapting sustainable and affordable healthcare systems

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# Overview

## Introduction

AmCham EU Healthcare Committee

2018 priorities

Life sciences in Europe: challenges and opportunities

## Key policy issues

1. IP incentives review for pharmaceuticals
2. Health Technology Assessment (HTA): Strengthening Member State cooperation

## Working together

Q&A

# AmCham EU's Healthcare Committee

## Representing various sectors of the healthcare industry

**Represented sectors**

- Pharmaceuticals
- eHealth and mHealth
- Medical Devices
- Consumer Goods
- Food
- Transport
- Consultancies & Lawyers

**63 members**
**219 individuals**

**Topics**

- **Competitiveness**: how smart regulations reduce red tape, stimulate innovation and contribute to growth and job creation
- **Society**: how healthier people impact the society and the economy
- **Health systems**: How innovation contributes to more efficient and sustainable health systems

**Tools**

- **Position papers**: Working together to fight AMR; EU IP rules and incentives; Transformation of health and care in the DSM; Improving access to medicines; Regulation on medical devices and IVD; Strategic use of procurement to stimulate healthcare innovation uptake; EU-US cooperation on eHealth; Effective, accessible and resilient health systems; Access to healthcare services; Mobile health opportunities for future health systems; Future of Investment in Healthcare; Balancing environmental and public health concerns
- **Publications**: *Challenges and opportunities for life sciences in Europe* (2018); *Forever Healthy* (2014); *The EU Single Market* (2013); *Investment in Healthcare* (2011)

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# AmCham EU's Healthcare Committee
## 2018 priorities and projects

### 2018 priorities

1. Strengthening Europe's competitiveness through life sciences
2. Safeguarding intellectual property (IP) incentives to drive innovation
3. Value-based healthcare to foster safe and sustainable health systems
4. Unleashing the potential of health technologies
5. Fight against Antimicrobial Resistance (AMR)

**Ongoing projects**

- Report on Life Sciences
- Position on IP incentives review and participation in consultation
- Position on AMR
- Position on HTA (ongoing)

# 2018 AmCham EU report on life sciences in Europe

## What?

Report for the public domain that reviews the challenges and opportunities facing the life sciences sector in Europe, covering:

- Medicines
- Medical devices
- Digital health (eHealth and mHealth)
- Diagnostics

## How?

- Analyse the broader policy framework for the life sciences sector and the role it has in Europe's economy and society
- Set out recommendations for policies to improve the policy environment by promoting more favourable conditions for innovation and its uptake as part of an integrated life sciences strategy

## When? **Final report expected May 2018**

| Issue | Need for novel policy solutions |
|---|---|
| Limited funding & budget silos (separate reimbursement systems) | High |
| Pressure to reduce cost and bring prices down | Medium |
| Inconsistent regulatory regime across technologies | Medium |
| Inconsistent HTA / Value assessment frameworks | High |
| Need for framework for Real World Evidence (RWE) collection | Medium |
| Cross border collaboration on pricing & joint procurement | Low |
| Interoperability of technologies | Low |
| Immature data & health infrastructure / education of HCPs | Medium |
| Review of incentives & IP framework | Medium |
| Limitations in utilising "Big Data" (privacy / ownership) | High |
| Impact of market consolidation | High |
| Environmental issues | Medium |

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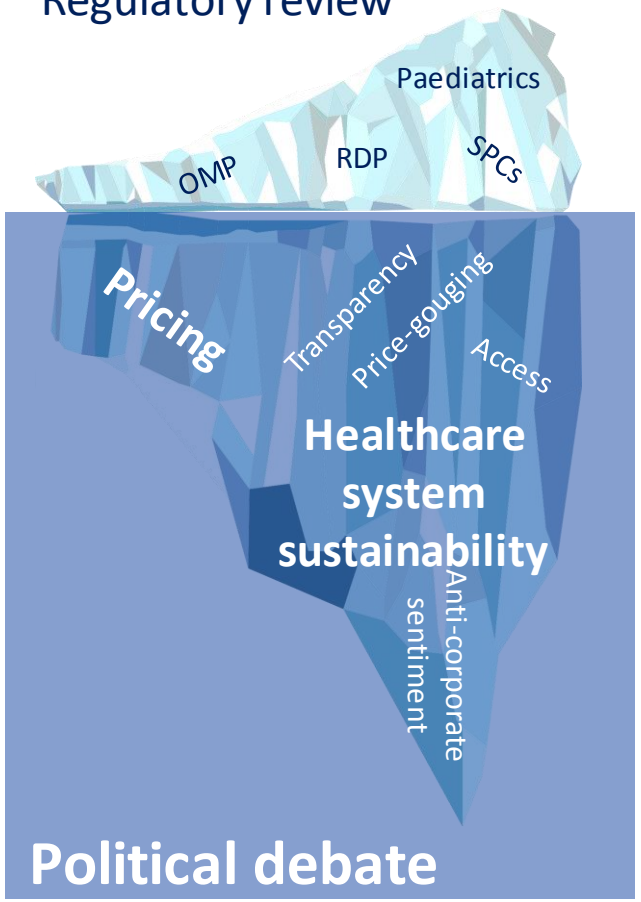
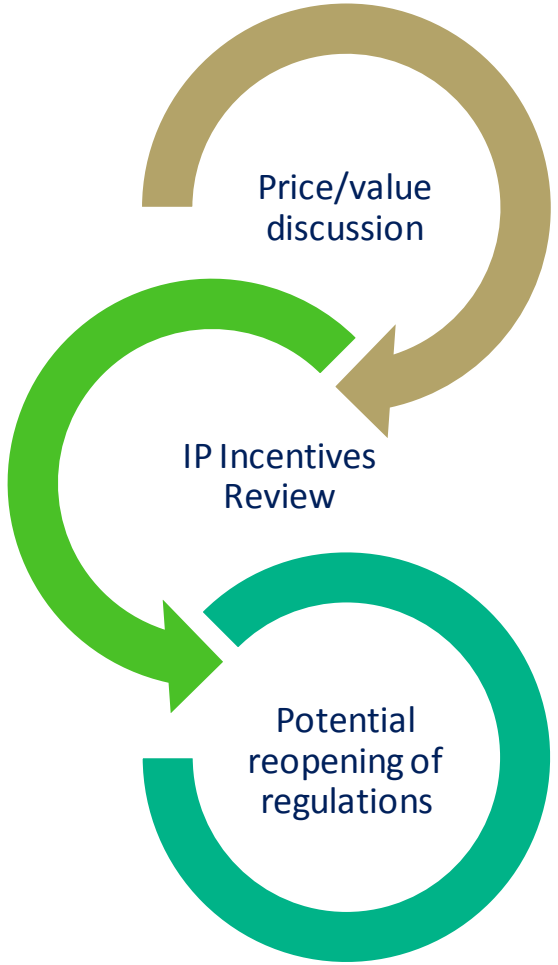
# The EU Intellectual Property incentives review
## The pricing debate driving the analysis

### Regulatory review




Since pricing and reimbursement remain a competence of Member States, policymakers in Brussels see the IP incentives framework as an alternative to addressing the issue of pricing

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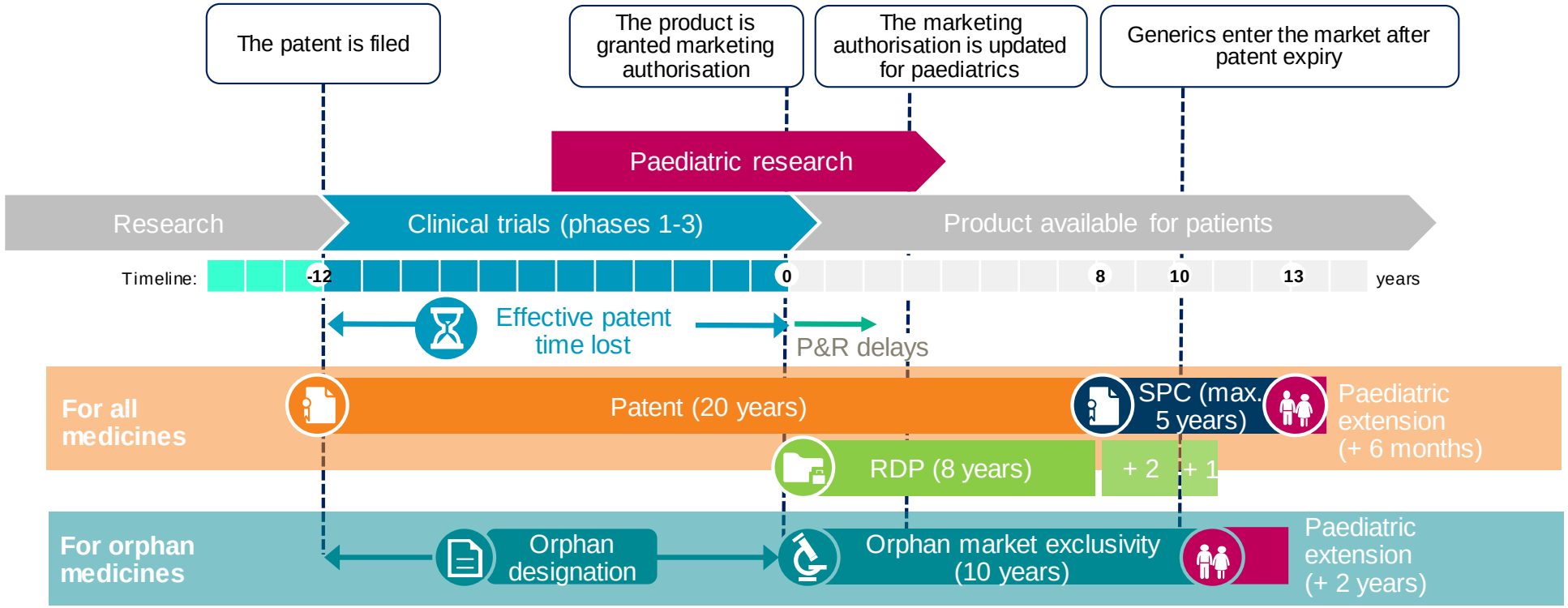
# Pharmaceutical incentives play different and complementary roles in support of innovation, meeting societal needs




EU=European Union; IP=intellectual property; RDP=regulatory data protection; SPC=supplementary protection certificate
Source: 1. EFPIA, About IP incentives (2017)

# IP incentives review: what does it mean?

## What is it?

The European Commission is undertaking an analysis of existing intellectual property (IP) incentives framework for pharmaceutical and plant protection products.

2018 focus on:

- Supplementary Protection Certificate (SPC) manufacturing waiver
- Patent research (bolar) exemptions
- Joint evaluation of Orphan Medicinal Product (OMP) and Paediatric regulations

# IP incentives review: why does it matter to you?

## What is the impact?

Addressing **unmet health challenges** that cover a complex range of medical needs (e.g. OMP)

The pharmaceutical and biotechnology sector is one of the **largest investors** in R&D in Europe.

Weakening protection will send a **negative signal to investors** about attractiveness of Europe as investment location

SPC waiver could cost **Europe 4,500-7,500 direct jobs and between 19,000-32,000 indirect jobs**

Countries such as China considering increased SPC-like patent mechanisms while Europe going in other direction?

# Our position

- Incentives review would undermine medical innovation
- Weakening the framework will undercut R&D investment by large and small innovators
- Europe will be placed at a disadvantage with competitors, jeopardising future growth
- More robust impact assessment needed

→ EU incentives framework as a whole must be **preserved**

# Innovative industry position
## Key elements opposing the SPC waiver

| | |
|---|---|
| Threat to the IP system | With the SPC waiver, the SPC would no longer confer the same level of protection as the patent |
| Negative spillover effect on IP internationally | Third countries would be encouraged to implement similar measures and send a signal of weakening IP to countries like China etc.<br>In contradiction with EU's effort to promote IP through trade agreements. |
| Difficulty of enforcement | It would be complex to make sure that generics manufactured in the EU are only supplied to non-protected markets (Note: this is a risk even within current rules) |
| Loss of export value | EU generic exports to non-SPC third countries take place to the detriment of originator exports due to higher competition |
| Overestimated benefits | • Limited opportunity in key export markets due to small differences in patent expiry dates between EU and key target markets; the latter generally have localisation policies in place<br>• EU manufacturers generally among first entrants;<br>• Lack of meaningful data proving the competitiveness of EU as a generic manufacturing location |

# The EU IP incentives analysis

## Current status

| | TODAY | LATEST DEVELOPMENTS |
|---|---|---|
| **Paediatric Regulation** (1901/2006) | • 6-month SPC extension<br>• 2-year Orphan Market exclusivity extension<br>• 10-year Regulatory Data Protection for Paediatric Use Marketing Authorisations | **Commission roadmap on joint evaluation of OMP and Paediatric regulations (12 Dec 2017)**<br>→ European Commission study on orphan drugs<br>Report due in 2019<br>→ Joint evaluation of the Paediatric and OMP Regulations (2018/2019) |
| **Orphan Drug Regulation** (141/2000) | • 10-year Market exclusivity linked to a single orphan designation<br>• 1 market exclusivity per medicine per « designated » orphan condition (possibility for several MEs for a single orphan medicine) | |
| **SPC Regulation** | • Supplementary Protection Certificate (max. 5 years, max. total exclusivity period of 15 years from MA) | **Potential Commission proposal before May 2018 for a SPC manufacturing export and stock piling waiver →**<br>Adoption before end 2019 (worst case scenario) |
| **Pharmaceutical Directive** (2001/83) | • 10-year Regulatory Data Protection | |

High Probability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# IP incentives review: how AmCham EU has engaged

## Developed positioning

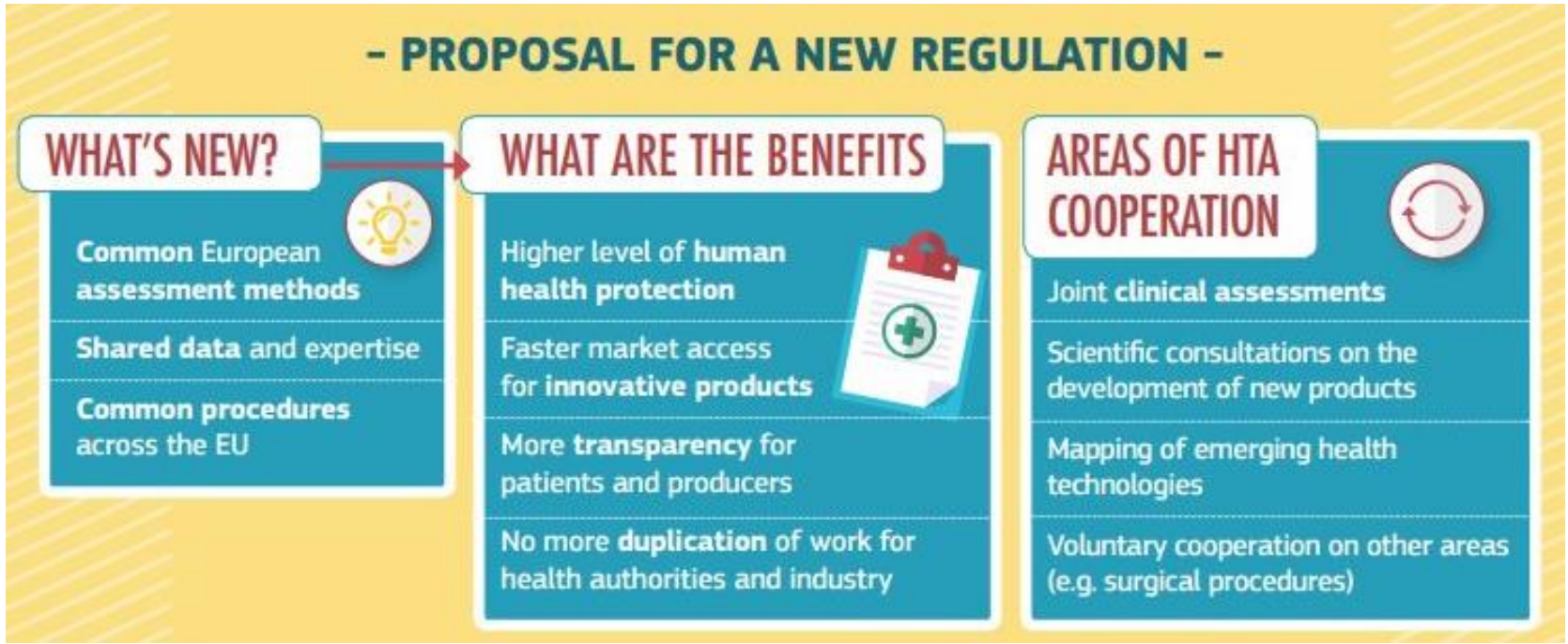
- AmCham EU position on *EU IP rules and Incentives: Why good policy is as important as good science*
- Joint letter to VP Katainen with US Chamber and national AmChams

## Advocacy

- Meetings with European Commission and response to SPC Consultation
- Meetings with Member State Permanent Representations to the EU
- European Parliament: meetings with MEPs and assistants briefing *upcoming* (Q2 2018)
- Member State outreach to capitals (Ministries of Economy/Industry and Health) *upcoming (Q2-Q3 2018)*
- Cooperation with US Mission to the EU and local embassies
- Cooperating with US and sectoral associations

# Member State cooperation on Health Technology Assessment (HTA)

## January 2018: EU proposal to strengthen HTA cooperation



# How can we work together?

AmCham EU invites AmChams to engage with national businesses and governments to inform and shape the outcome of these discussions:

- Develop position and assess national impact
  → Joint call between Healthcare Committees/leadership
- Identify key decision-makers
- Engagement with national governments
- Engagement with/letter to your European Commissioner
- Host event to raise awareness
- Toolkit
- Joint letters and statements

# Thanks!

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