European Commission

Copenhagen Economics report on the impact of pharmaceutical incentives on innovation, availability and accessibility of medicinal products

STAMP Expert Group meeting, 8 June 2018

Health and Food Safety

Study on incentives for pharmaceuticals

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OUTLINE

- **Rationale & objectives**
- **Methodology**
- **Findings**
- **Next steps**

Rationale & objectives

EC Single Market Strategy (2015)

- '..consolidate and **modernize IP rights** as a way to stimulate innovation and growth…, and to engage in a **reflection** on ways to **improve the patent system** in Europe for pharmaceuticals'

Council Conclusions (2016) - COM invited to prepare:

- an **overview** of various pharmaceutical incentives and rewards
- **an evidence based analysis** of impact on innovation, availability and accessibility

"Pharmaceutical incentives"

The study looks at the following five incentives:

- The supplementary protection certificate (SPC)
- Data protection
- Market protection
- Market exclusivity for orphan medicinal products
- Rewards for paediatric medicinal products

Methodology

- **Quantitative information**: economic and econometric analysis
  - newly created dataset of 558 medicinal products (sample)
- **Qualitative information:** literature review + case studies + interviews with stakeholders
- Member States involvement: meeting with contractor in September 2017

Key findings (general)

- Effective protection period has declined (15 → 13 years)
- Average development time increased (10 → 15 years)
- 10% of products enjoy > 20 years of protection (secondary patents?)
- 51% of sample patent last to expire
- EU has very/most attractive pharma incentives regime in comparison to other jurisdictions

Key findings SPC

- 45% of medicinal products in dataset have obtained an SPC in at least one of the MS
- Average duration of protection for all granted SPCs: 3.5 years (max. 5 years)
- Where the SPC expires last, it adds on average 2.6 years beyond the patent, market or data protection

Main findings (innovation)

- Positive relationship between effective protection period and level of pharma R&D
- Other factors also influence R&D investments (e.g. tax, education, work force)
- Countries with high GDP per capita ('wealth') constitute most important medicinal markets

Main findings (availability)

- Products are not launched in all countries in EU (market size and willingness to pay)
- Great variety in launch of product between ATC codes:

→ Medicinal products with highest estimated launch are ATC 1 "Antineoplastic and immuno-modulating agents" (incl. many **cancer** medicines)

→ Medicinal products with lowest estimated launch are ATC1 category of "**Dermatologicals**"

Main findings (accessibility)

- Generic introduction leads to ~ 50% decrease in price (on average)
  - a hypothetical 10% change in spending from originators to corresponding generics would entail a possible saving of > 10 billion euros in EU.
- Generic policies vary greatly within EU

Next steps

- External input in ongoing analysis requested by Member States in the Council Conclusions of June 2016
- Evaluation of Orphan and Paediatric Regulations in 2019
- Commission will continue to engage with MS and stakeholders

Thank you for your attention !