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better access. better health.

International Health Forum 2017

Better Access, Better Health: Patient-Centered Solutions for Sustainability of Healthcare

Commission Review of Pharmaceutical Incentives

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Health Council Conclusions Process

- Dutch Presidency Health Council Conclusions (June 2016):
  - Stressed "*the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems*"
  - Issues identified :
    - High prices of new medicines
    - Re-assessment of pharmaceutical incentives (SPC, Data Exclusivity, Paediatric extension, Orphan exclusivity, etc.)
- Economic analysis (for 2018) by EC on impact of:
  - SPC
  - Orphan drugs exclusivity
  - Paediatric extension
  - Data exclusivity
- European Parliament Report of 2 March 2017
  - Encourages competition from generic & biosimilar medicines
  - Recognises the importance of value-added medicines innovation

Health Council Conclusions
Medicines for Europe actions

- Concrete actions to strengthen competition from generic, biosimilar and value added medicines

- Contribution to economic analysis on impact of SPC, pharmaceutical incentives and rewards

EU Study on pharmaceutical incentives

- Effects of Supplementary Protection Certificats (SPCs)
- Future impact of a possible Unitary SPC
- Economic impact of paediatric rewards
- Economic impact of data protection and market exclusivity

The Supplementary Protection Certificate (SPC)

- Patent protection lasts 20 years
- The **Supplementary Protection Certificate (SPC)*** extends exclusivity of patented products **by up to 5 years**
- To compensate originators for Marketing Authorisation delays in Europe

- Unintended effect? EU manufacturers forced to outsource to export to unprotected markets

Other issues on Brussels agenda

- SPC Manufacturing Waiver
  - Commission proposal to allow manufacturing for export under SPC
  - No impact on originator exclusivity.
  - Allows EU generic and biosimilar manufacturers to compete with Asia
  - Potential for 30-40 thousand new jobs in Europe
  - Timeline: Proposal expected in 2017 (+2 years for adoption)

- Harmonised implementation of Bolar clause
  - Different interpretation of bolar affects development
    - Generic and biosimilar contract manufacturing for development
    - Research for innovation development
  - Potential impact of Unified Patent Court
  - Commission to promote wide bolar to facilitate pharmaceutical development

How to stimulate competition in pharmaceuticals?

Efficient regulatory approvals

Competition from day 1 of the patent expiry

Pro-competition pricing and procurement policies

Objective, reliable and scientifcally up-to-date information to stakeholders about generic and biosimilar medicines

The Benefits

- High skill pharmaceutical R&D and manufacturing back into the EU
- Avoid relocation of production capacities
- Create high skill jobs
- Develop EU manufacturing science
- Boost European SMEs (reduce costs – spur growth)
- Support the European API industry
- Create economic growth in Europe
- Ensure high quality and continuity of supply in third countries (faster & increased access)
- Increase the EU trade balance (more export)
- Give opportunity to compete for global leadership

Negative impact on Originators?

- In <u>export markets</u>
  - No! - Originators cannot compete with Indian or Chinese generic industries anyway
- In <u>EU market</u>
  - No! - Originators would still benefit from market exclusivity on EU markets where they have sought approval
    - Competition in EU on day-1 comes anyway from abroad
- In no way SPC manufacturing waiver will undermine or change existing IPR equilibrium in the EU

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Thank you