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Pharmaceutical Committee

Council Conclusions on stregthening the balance in the pharmaceutical systems in the European Union and its Member States

18 October 2016

Health and Food Safety

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Actions for Member States

- Consider further voluntary and Member State driven cooperation on pricing and reimbursement
- Strategic policy reflection and exchange between Member States
- Develop agenda 2017-2020, setting mutual experienced concerns and challenges
- Collaboration across the system to ensure follow up actions

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Actions for Member States & COM

- **Cooperate together and set clear and enforceable (pre-) conditions regarding the use of early access tools**
- Further develop cooperation on Health Technology Assessment at EU level
- **Improve and strengthen dialogue and cooperation (**between regulators, HTA bodies*)* **in existing fora in the field of pharmaceuticals, while also assessing their relevance, functioning and added value**
- Invest in essential R&D to address unmet medical needs and registries
- Also promote open access to data and ensure fair return on investment of successful publicly funded research

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Actions for the Commission

- **Streamline implementation orphan regulation; ascertain proper application rules, incentives and rewards; revise if necessary**
- Create overview of EU pharma legislation in relation to IP related incentives and their intended purpose
- **Analyse effects of these incentives on the accessibility, availability and affordability of medicines, as well as the price strategies of industry**
- **Analyse functioning of the EU pharma market in terms of transparency, market behaviour and competition and strengthen market oversight**
- **Recommend possible remedies in context of agenda 2017-2020**

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What will/could be the follow up?

- Ongoing/ foreseen EC studies:
  - Study on the pediatric regulation, to be delivered by end 2016, followed by an EC report in 2017
  - SANTE/GROW study on the impact of SPC, data and market exclusivity on innovation, availability and accessibility
    - ToRs to be published before the end of 2016
    - Study to be carried out and finalised by end 2017
    - Time-frame and methodology to be presented to Council end 2016
- Cooperation- *Consider ways to:*
  - to Improve and strengthen dialogue and cooperation between regulators, HTA bodies
  - discuss clear and enforceable (pre-) conditions regarding the use of early access tools

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Thank you

More information:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XG0723(03)

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