Pharmaceutical systems and current developments

Olga Solomon, Head of DG SANTE Unit B5

"Health as the Real Winner : Presidency Conference on Options to Provide Better Medicines for All" - Sofia, 6 March 2018

Health and Food Safety

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OUTLINE

- Challenges and political context
- Optimisation of existing legal framework
- Review of the system

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Challenges (I)

Does the pharmaceutical framework ensure **balance** between

- Innovation

- Availability & patient access?

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Challenges (II)

Council Conclusions June 2016

- The functioning of the pharmaceutical systems depends on **a delicate and complex set of interactions** between **marketing autorisation and measures to promote innovation**, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicinal products

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

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Political context

- **1 December 2014**: Council Conclusions on innovation for the benefits of patients

- **17 June 2016**: Council Conclusions on strenghtening the balance in the pharmaceutical systems

- **2 March 2017**: European Parliament Resolution on EU options for improving access to medicines

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Council Conclusions of June 2016

23.7.2016 EN Official Journal of the European Union C 269/31

Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States

(2016/C 269/06)

http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/

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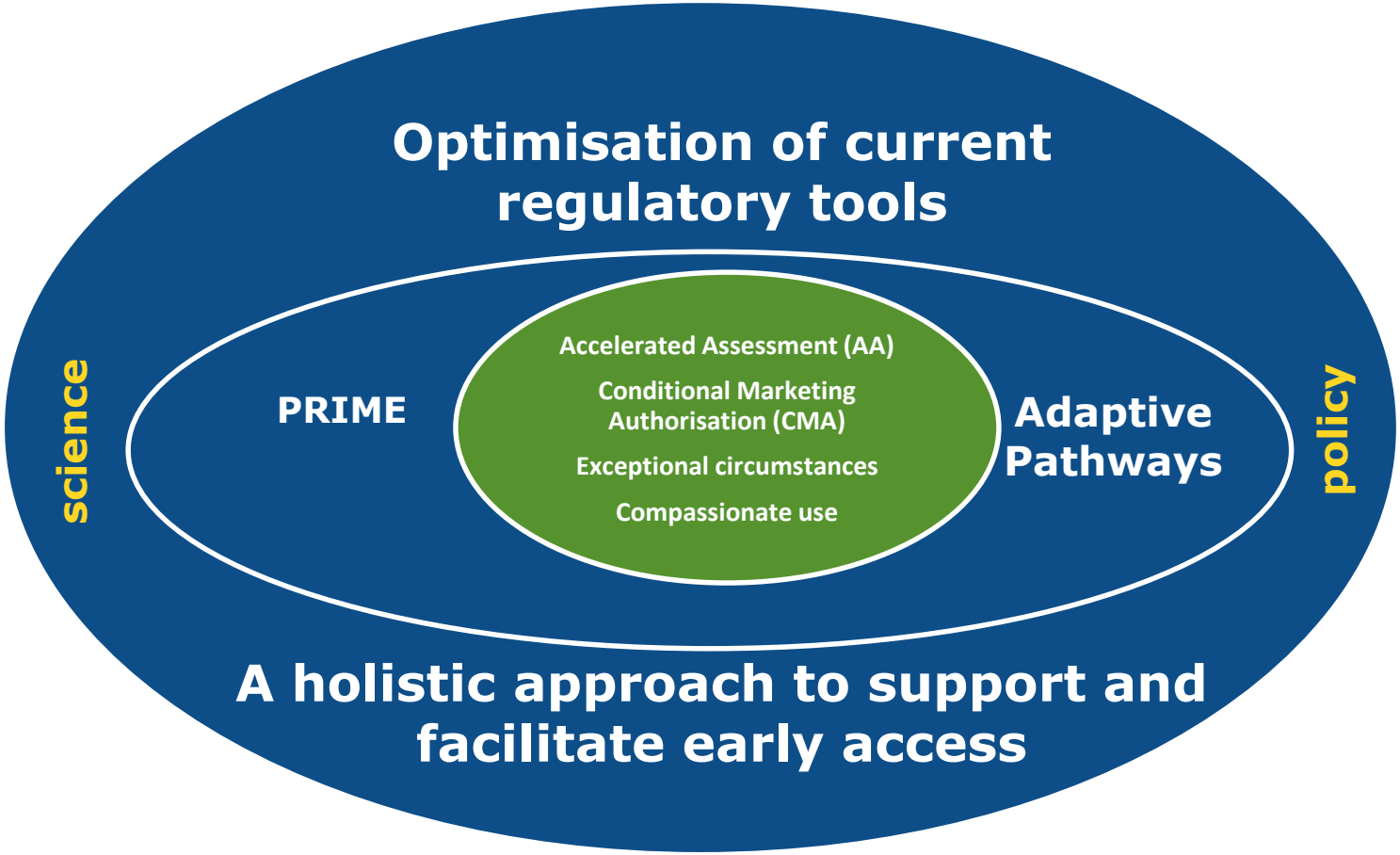
Access to medicines - STAMP



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Optimisation of existing tools

Main initiatives within STAMP – 2015-2017

Repurposing

Early access initiatives

Compassionate use

Synergy with HTA Network

Off-label use

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Repurposing - Main challenges

- Regulatory framework
- Incentives
- Off-label use
- Data quality
- Cooperation between stakeholders
- Pricing

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Repurposing - opportunities

- Underlying reasons for industry's reluctance to include new indications
- Improve knowledge of non-industry organisations and academics about the regulatory framework for the authorisation of medicines
- Mechanisms to provide advice or support on data quality
- Bring stakeholders together within a platform

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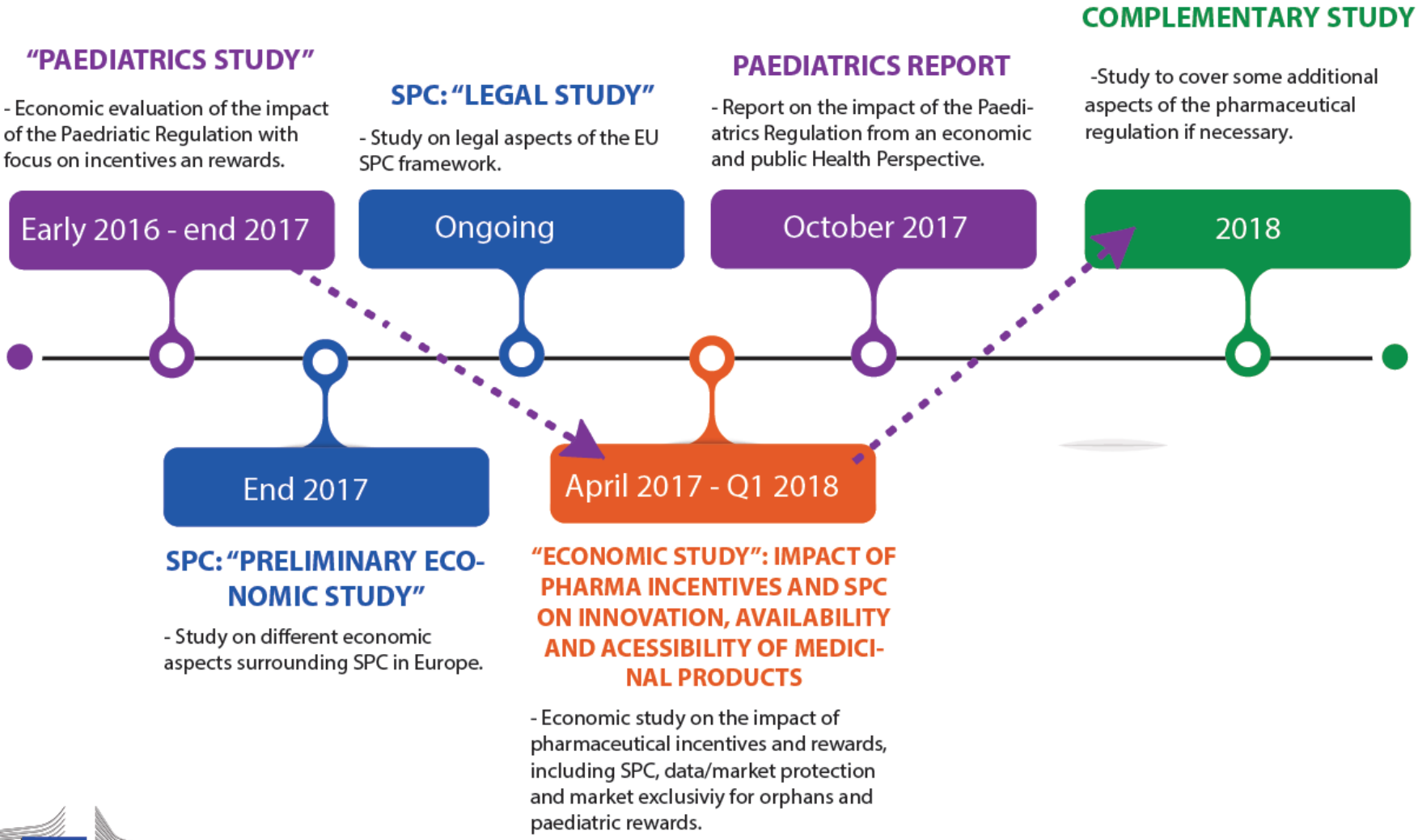
Analysing the impact of pharmaceutical incentives



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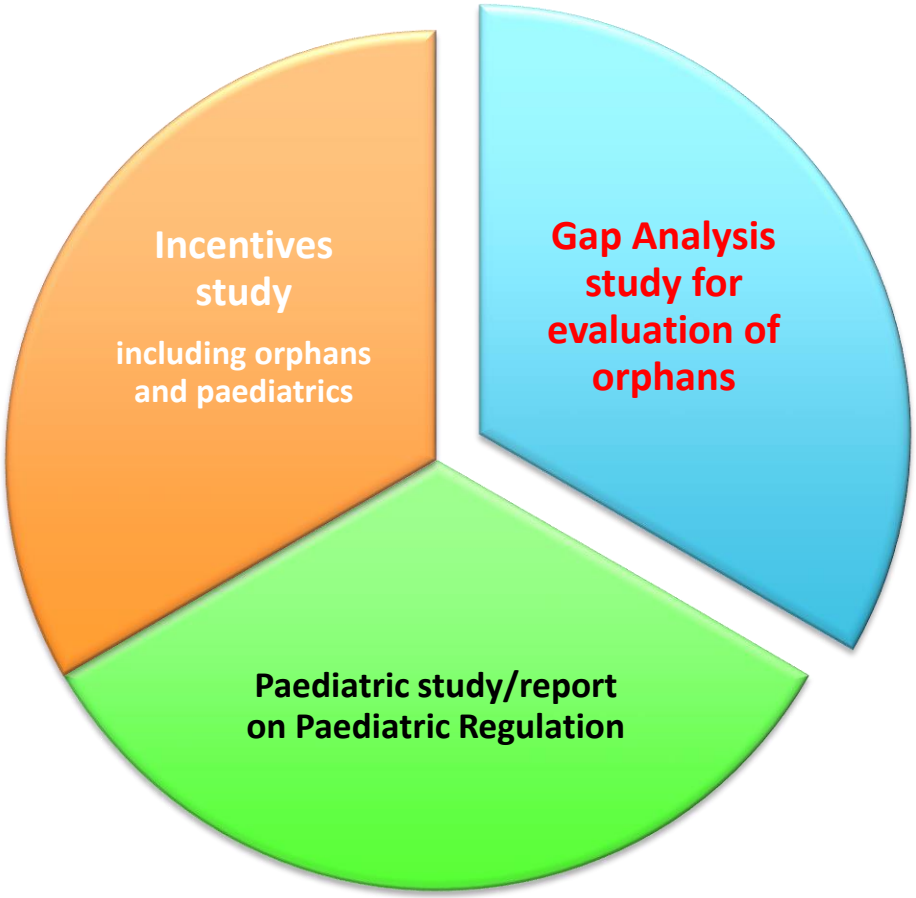
Evaluation



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TIMELINE

November 2017 - Roadmap

4-week public consultation

2018/2019 Study on orphans

Various stakeholders' consultations

2019 Evaluation

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Supplementary Protection Certificates

- DG GROW is assessing **three aspects**:

  - the possibility of creating a "unitary" SPC title
  - an update of the scope of the EU patent Bolar and research exemptions
  - the introduction of an SPC manufacturing waiver.

- **Oct. 2017 - Jan. 2018**: 12-week on-line public consultation on SPC and patent research exemptions

Possible SPC manufacturing waiver

- **May 2016:** European Parliament Resolution:

  'Urges the Commission to introduce and implement before 2019 an SPC manufacturing waiver'

- **Stakeholder consultation**: suggested that the SPC regime does not optimise the competitiveness of EU generic and biosimilar firms versus non-EU firms

- Various studies published and others nearing completion

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Possible SPC waiver (II)

- Impact assessment work in view of a possible targeted initiative is currently ongoing

- No decision on a legislative proposal taken

- EU remains committed to pharmaceutical innovation via SPC protection (both at home and abroad)

Thank you !

More information:

http://ec.europa.eu/health/documents/pharmaceutical-committee/stamp/index_en.htm