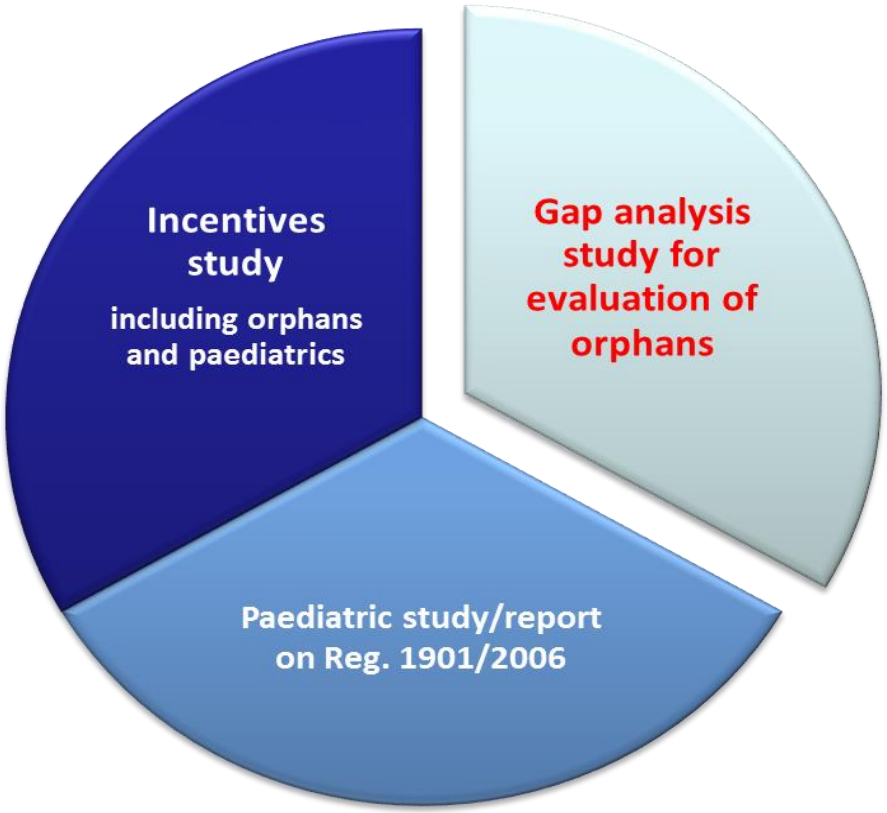
Evaluation of EU Orphan and Paediatric Regulations

- Legislation on medicines for 'special purposes':
  - **medicines for children (Regulation (EC) No 1901/2006)**
  - **medicines to treat rare diseases (Regulation (EC) No 141/2000)**
- Evaluation will:
  - assess efficiency and effectiveness EU legislation
  - consider whether 'fit for purpose' also in light of pharmaceutical developments
  - look into impact of the incentives introduced (research, development and marketing purposes).

Underlying studies for evaluation



Timeline of the evaluation

December 2017

Roadmap

4-week public consultation

April 2018 – March 2019

Study on orphans (gap analysis)

Public consultation: 12 October – 4 January 2018
Targeted consultations (incl. MS): October – November 2018

2019

Evaluation of orphans and paediatrics

Staff Working Document

Stakeholders' consultations

- **Targeted consultations**: national public authorities, companies, developers of generics/biosimilars, academic experts and patients
  - **COMP, PDCO and CAT**
  - **Members of the Pharmaceutical Committee also received an invitation**
- **Timing**: October – November 2018
- **Open Public consultation**: citizens and healthcare professionals
- **Timing**: mid-October 2018 - 4 January 2019