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

- **Incentives study**
  - including orphans and paediatrics

- **Paediatric study/report on Reg. 1901/2006**

- **Gap analysis study for evaluation of orphans**
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