



# DG SANTE update

Revision of the EU Orphan and Paediatric  
Regulations

**Pharmaceutical Committee**

**17 September 2021**

European Commission  
Directorate-General for  
Health and Food Safety

## 8. Update impact assessment/revision EU orphan and paediatric legislation

- The Evaluation of the EU orphan and paediatric legislation was published in August 2020
- Impact assessment of revision of EU legislation on medicines for children and rare diseases is ongoing:
  - **Open Public Consultation (ended on 30 July)**
  - **Targeted surveys (options for revision/questionnaires costs of development; interviews with stakeholders)**
- Proposal for revision of legislation: 4th quarter 2022
- Coordination and consultation with public authorities/Member States:
  - (Extended) Pharmaceutical Committee