



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Non-oncological MoA based PIP – Initial Deliberations from the PDCO working group discussions

Sabine Scherer





Issues identified by the PDCO working group

- Determination of the **PIP condition**
- **Class waiver list** needs to be revised to **allow for discussion** of potential alternative paed. developments
- **Available paed. data** is often limited -> **step-wise approach** might be useful -> **predictability** key issue
- **Potential to extrapolate** limited if there is no adult program -> PK, PD and safety data can still be taken into account, but **efficacy** will most likely need to be established **in the target population**



Potential fields for input from networks

- **Potential alternative developments**
- **Available data:** all data including non-clinical data should be taken into account. Data from off-label use, also from substances of the same class, might be especially useful.
- **Feasibility** of a paed. program or what a feasible paed. program could look like
- **Unmet paed. medical need** in clinical practice

Discussions with all stakeholders will be most useful during the implementation process



Thank you!