EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

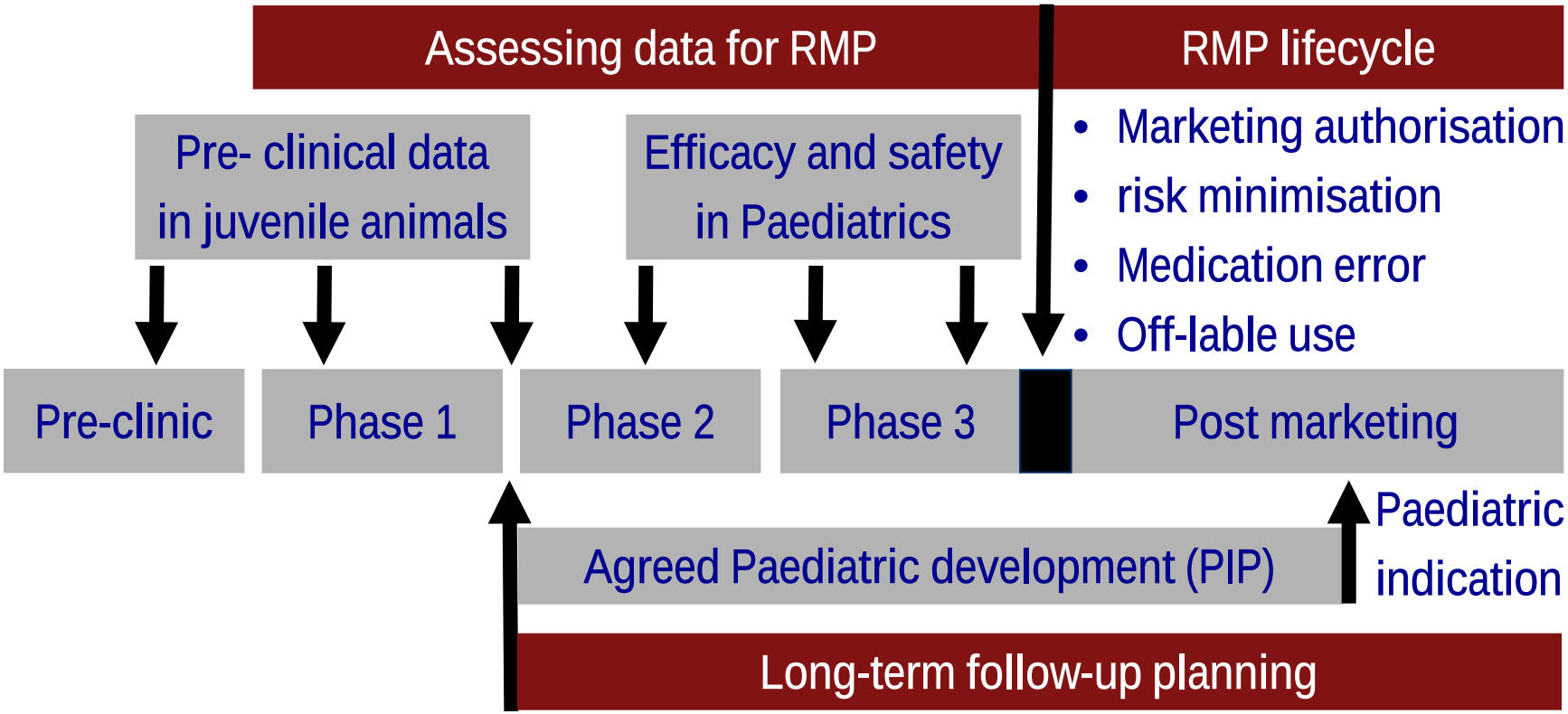
Final Draft Concept paper: Revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population

Dirk Mentzer
PDCO Chair, EMA

Background

- **Current guideline on conduct of pharmacovigilance for medicines used in the paediatric population:**
  - **26/01/2007**
- **EU Pharmacovigilance Regulation (EU 1235/2010):**
  - **new measures for proactive pharmacovigilance**
  - **irrespective of the authorised indication and population**
- **Adequate monitoring of paediatric medicines:**
  - **up-to-date and state-of-the-art pharmacovigilance guidance**
  - **ensure acceptable safety profile of products used in paediatrics**

Paediatric Pharmacovigilance and Risk Management Plan



- Staggered approach for inclusion of paediatric sub population
- Extrapolation of efficacy/ safety from adult development

Paediatric Pharmacovigilance and Risk Management Plan

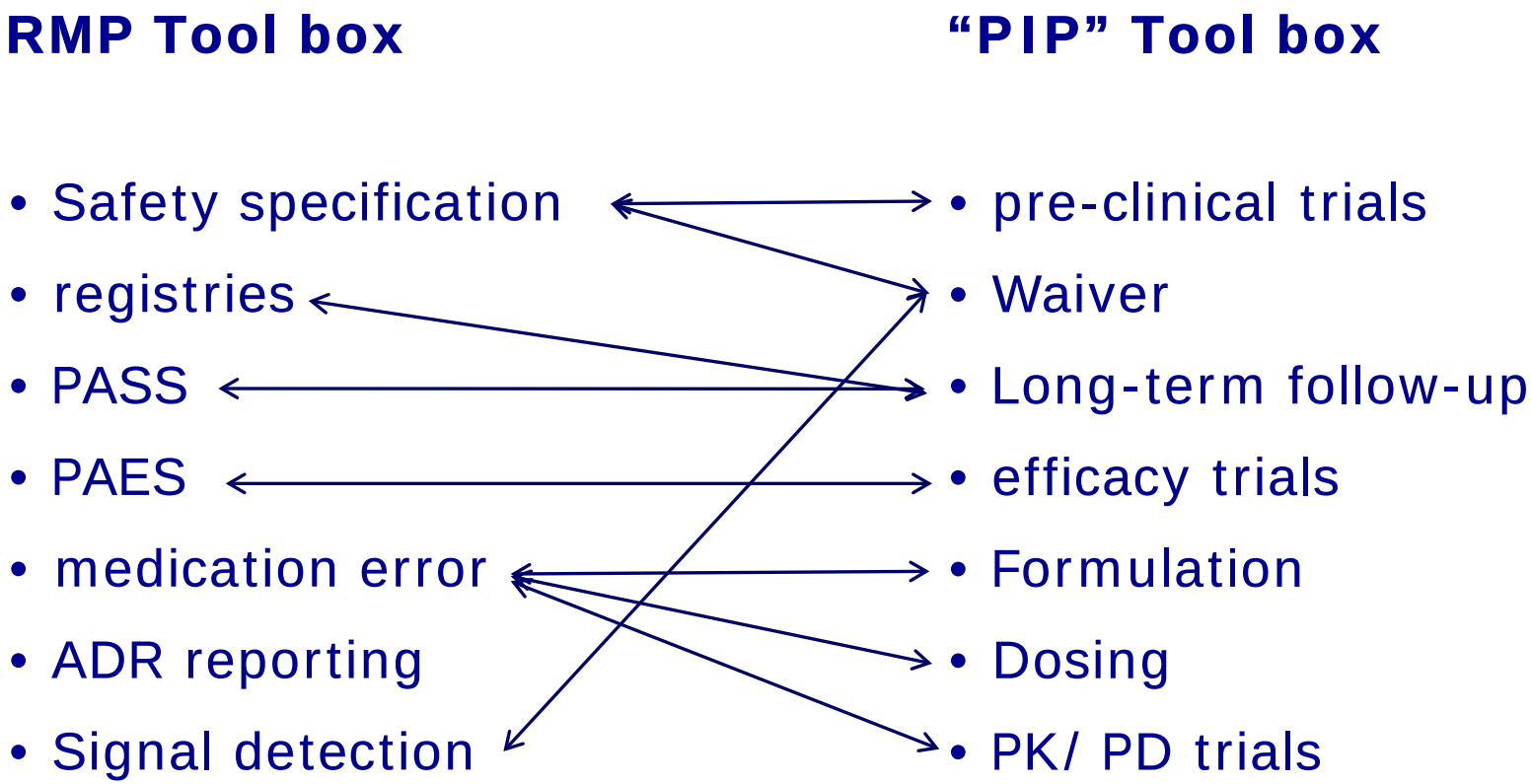
RMP Tool box

- Safety specification
- registries
- PASS
- PAES
- medication error
- ADR reporting
- Signal detection

“PIP” Tool box

- pre-clinical trials
- Waiver
- Long-term follow-up
- efficacy trials
- Formulation
- Dosing
- PK/ PD trials

Paediatric Pharmacovigilance and Risk Management Plan



Key elements in the revised guideline

Newly authorised medicinal products for the use in the paediatric population

Information from PIP assessment available for RMP

- recommendation for long term safety/efficacy follow-up from PIP assessment reflected in RMP
- Availability of age appropriate formulation
- Safety signals from paediatric development
- Relevance of inclusion/exclusion criteria in paediatric clinical trials for safety specification in the RMP
- Thorough assessment of ADR paediatric clinical trials for follow-up in PASS

Key elements in the revised guideline

Existing products used in the paediatric population

Information from spontaneous reporting

- inclusion of patient age or age group as mandatory field for spontaneous ADR reports
- Signal detection to be conducted in stratified to age/groups
- Paediatric specific ADRs should be flagged in the MedDRA coding data structures
- medicinal products with a potential for
  - off-label use
  - medication error
  - misuse
  - intentional or unintentional overdose

should be referred to intensified monitoring

Key elements in the revised guideline

Existing products used in the paediatric population

Risk minimisation measures

- Risk minimisation activities should include prevention of possible medication errors of medicinal products in the paediatric population

- Data used for modelling and simulations studies could have an impact proposal of risk minimisation measures (PASS/PAES)

- Reflection of special need for appropriate risk communication to HCP and patients/ parents

Timeframe

- **Adoption of draft Concept Paper:**
  - **PRAC ORGAM: April 2014**
  - **PDCO Plenary: April 2014**
- **Drafting of guideline and presentation to Committees:**
  - **Summer 2014**
- **Public consultation:**
  - **End of 2014**