



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Proposals for strengthening the interaction between PDCO and PRAC

Pharmacovigilance in the Paediatric Population Workshop,
28.04.14

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Paediatric Office





Agenda

- 1. Existing Interactions PDCO-PRAC**
- 2. Newly proposed interactions PDCO-PRAC**
- 3. Wider initiatives in paediatric safety**



1. EXISTING INTERACTIONS PDCA-PRAC

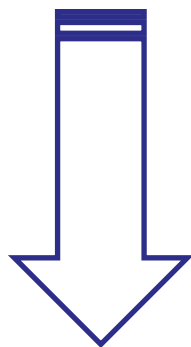
- **Routine Coordination**
- **Information sharing issues to build knowledge of product benefit/risk in paediatrics during evaluation of:**
 - **RMP**
 - **Safety signals**
 - **PSUR**
 - **PASS**
 - **Art.31 Referral to PRAC**



Monthly screening of PRAC agenda

Identification of paediatric safety issues

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PDCO**



PRAC

Identification of product paediatric safety issues at PRAC
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Identified potential safety concerns for **long term safety and/or efficacy in PIP agreed Decision**



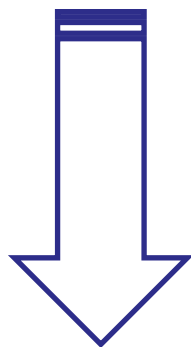
PDCO concerns related to long term safety and/or efficacy to be reflected in **current RMP** or to **initiate RMP update**



Monthly screening of PRAC agenda

Identification of paediatric safety issues

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PDCO**



PRAC

Identification of product paediatric safety issues
at PRAC

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No specified potential safety concerns for long
term safety and/or efficacy by PDCO

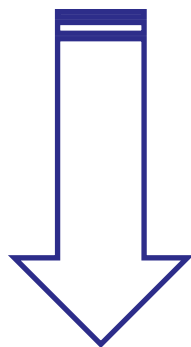


Paediatric safety/efficacy concerns raised by
PDCO during PIP assessment to be reflected in
current RMP or to **initiate RMP update**



Standard EudraVigilance Paediatric (SEVP) Queries

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PRAC**



PDCO

- **Potential** safety signal in children raised by PDCO during PIP assessment (Art.8 or 30)
- Based on off-label use or known product safety in adults or paediatrics for another indication/condition



- **SEVP Query Report** (safety profile of EudraVigilance reported ADRs)
- **Conclusion** on the potential safety signal in children



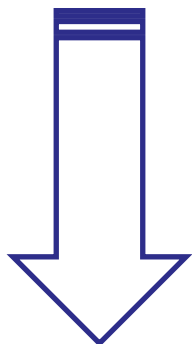
2. NEWLY PROPOSED INTERACTIONS PDCO-PRAC

- To make best use of expertise with PDCO and PRAC
- Access to Committee Expertise in evaluating product benefit/risk issues:
 - Safety signals
 - Safety reviews (Art.31 referral to PRAC)
 - PIP assessment



Evaluation of safety signals and safety reviews (Art.31 Referrals to PRAC)

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PDCO



PRAC

Discussions at PRAC on:

- Identified **safety signals** in children
- Ongoing safety reviews (**Art.31 referral**)

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Input from PDCO members is needed

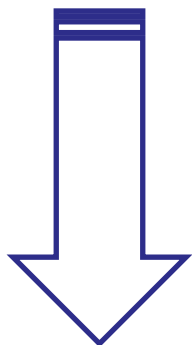


- PRAC to send list of safety questions to nominated PDCO Rapporteur
- PDCO to adopt **opinion/clinical or scientific report** from PDCO Rapporteur to PRAC, on the safety issues



Safety evaluation during PIP assessment

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PRAC**



PDCO

- Ongoing PIP assessment of **open-label safety extension study** (rare frequency)
- PIP assessment with **safety** component

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Input from PRAC members is needed



- PIP Summary Report with comments from evaluation team (EMA Paed Co, PDCO Rapp and Peer Reviewer) to nominated PRAC Rapp
- PRAC Rapp to **comment on PIP Summary Report** (on safety matters)



3. Wider Initiatives in paediatric safety

- **Revised guideline** on the conduct of pharmacovigilance for medicines used by the paediatric population
- **Best practice guide** on Risk Minimisation and Prevention of Paediatric Medication Errors
- **Utilisation of paediatric clinical research infrastructure: Enpr-EMA, EnCePP and Enpr-EMA Working Group 8 on Pharmacovigilance**



Questions and Discussion