EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GVP Paediatrics highlights Product- or Population-Specific Considerations IV: Paediatric population

Update on status

13th industry stakeholder platform – operation of EU pharmacovigilance

Presented by Roberto De Lisa on 20 March 2018
Scientific Administrator – Paeditaric Medicines Office EMA

Timelines

- Public consultation concluded on 13 October 2017, main contributors: Association of the European Self-Medication Industry (AESGP); Astra Zeneca Pharmaceuticals; European Association of Hospital Pharmacists (EAHP); EFPIA; ENCePP-EnprEMA; European CRO Federation (EUCROF) Paediatric Working Group (PWG); Medicines For Europe; Pierre Fabre; Royal College of Physicians; European Society for Paediatric Oncology SIOPE; UCB BioPharma
- Comments discussed with PDCO and PRAC
- Further discussion with PRAC expected April 2018
- Finalisation after PRAC April 2018 meeting

Main feed-back received

- Objective of the document to be stated
- Intended applicability and integration with other GVP modules to be clarified
- What is new guidance – in comparison to other modules - to be clarified
- Processes: e.g. YPAG (Young Persons' Advisory Groups): criteria, specific situations, process and timelines when YPAG can be consulted missing
- Recommendations vs requirements: e.g. specific criteria on the lowering of signal threshold and when to increase the frequency of submission of PSURs need to be provided

What is the objective of the GVP Chapter?

Aspects relating to paediatric pharmacovigilance and risk management are contained in:

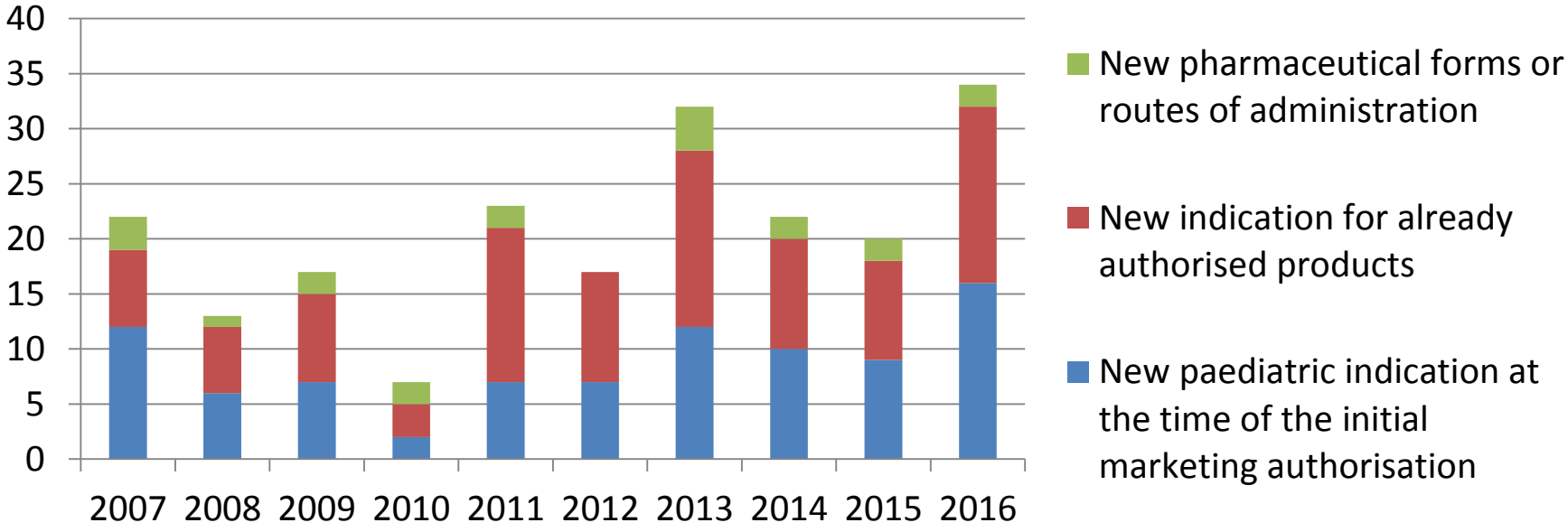
- Guidance on paediatric subjects provided in GVP Modules V and Guidance on the format of the RMP, VI, VII, IX, Product- or Population-Specific Considerations I: Vaccines
- ENCePP Guide on Methodological Standards in Pharmacoepidemiology
- Good practice guide on risk minimisation and prevention of medication errors
- Good practice guide on recording, coding, reporting and assessment of medication errors

All GVPs are under regular update and revision: not all aspects relating to specific population(s) can be covered in detail. An integrated view is necessary to address all stakeholders' information needs and this what the Chapter aims to provide

What has been revised after public consultation?

- Scope and applicability of the Chapter clarified; roles and responsibilities simplified
- *Pharmacovigilance aspects specific to the paediatric population: general considerations,* widened and clarified
- RMP: characterisations of risks important for paediatric patients explained; Consideration on risk minimisation approaches, interface with PIP and cross link to 'Guidance on the format of the RMP' introduced
- PSUR: clarification on how to reflect off-label paediatric use when there are signals or identified safety issues as well as periodicity in relation to new paediatric indication under discussion
- Signal management: clarification on recommendations vs requirements
- PASS: paediatric aspects cross linked to ENCePP Guide on Methodological Standards in Pharmacoepidemiology; info on possibility to request Scientific Advice

New paediatric medicines: centralised products 2006 - 2016



Annex 10-year Report to the European Commission
General report on the experience acquired as a result of the application of the Paediatric Regulation

Conclusions

- EMA thanks all the contributors for the input received
- Vast majority of comments on text have been implemented
- Experience of use of pharmacovigilance tools in paediatric patients is wide but some approaches need further validation: practice cannot yet be consolidated into prescriptive guidance or requirement
  - E.g. Consultation of YPAG relatively new concept, organisation(s) moving their first steps
  - E.g. How to adapt risk minimisation strategies used in adults to children
- Comments triggered the need to perform and make available data on positive examples of risk minimisation and signal detection
- New aspects introduced by the Chapter to be highlighted in communications accompanying publication of the new Chapter

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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