



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GVP paediatric population and “direction of travel”

12th industry stakeholder platform – operation of EU pharmacovigilance
24 November 2017





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GVP Product- or Population-Specific Considerations IV: Paediatric population I/II

- End of consultation 13 of October 2017

Comments received from:

1. Association of the European Self-Medication Industry (AESGP)
2. Astra Zeneca Pharmaceutical
3. European Association of Hospital Pharmacists (EAHP)
4. European Federation of Pharmaceutical Industries and Associations (EFPIA)
5. ENCePP-EnprEMA joint working group
6. European CRO Federation (EUCROF) Paediatric Working Group (PWG)
7. Medicines For Europe
8. Pierre Fabre
9. Royal College of Physicians
10. European Society for Paediatric Oncology (SIOPE)
11. UCB BioPharma

GVP Product- or Population-Specific Considerations IV: Paediatric population II/II

- EMA deeply appreciates the constructive and supportive contributions received so far
- Further clarity needed on:
 - Scope, intended applicability, interface with other GVP modules
 - Additional granularity and examples needed in some areas
- Discussion will be taken forward at PRAC and PDCO next months
- Expected finalisation 1Q 2018