Submission of applications containing paediatric data and their assessment by MHRA teams

- Older paediatric studies Article 45
- New paediatric studies Article 46
- Variations to update SmPC after Worksharing

European Paediatric Worksharing

- CMDh/EMA Paediatric Subgroup (UK Delegate as Rapporteur)
- CHMP (UK Delegate as Rapporteur or Co-Rapporteur)
- Centralised procedures
- National/MR/DC Procedures

Marketing Authorisation applications
  - New medicinal products
  - Extensions
  - Variations * (including for paediatric use)

- CHM/Paediatric Medicines Expert Advisory Group
- MHRA Special Populations Group (VRMM Division)
- MHRA Product Lifecycle Assessment Teams (Licensing Division)

SAWP (UK Delegate as Rapporteur)

- European
- Requests for scientific advice

- Clinical Trials Unit (Licensing Division)
- Clinical Trial applications
- Paediatric Investigation Plan applications

- PDCO (UK Delegate as Rapporteur or Peer Reviewer)

- National

*Safety variations will be routed to VRMM Division