MIS À JOUR LE 25/05/2021

Recommandations concernant la recherche et le développement des médicaments pédiatriques

Guidelines qualité

- Guideline excipients in the labelling and package leaflet of medicinal products for human use
- Guideline excipients in the labelling and package leaflet of medicinal products for human use - annexe
- Guideline on pharmaceutical development of medicines for paediatric use
- Reflection paper on formulations of choice for the paediatric population
- Note of explanation to accompany publication of reflection paper on formulations of choice for the paediatric population (EMEA/CHMP/PEG/194810/2005)
- Quality of medicines questions and answers

Guidelines préclinique

- Guideline on the need for non-clinical testing in juvenile animals of pharmaceuticals for paediatric indications

Guidelines clinique (efficacité et sécurité d’utilisation)

- International Conference on Harmonisation E 11 (R1): Clinical investigation of medicinal products in the paediatric population - Step 5
- International Conference on Harmonisation E 11 (R1): Clinical investigation of medicinal products in the paediatric population - Step 5 - Addendum
- Ethical considerations for paediatric trials

Guideline on the investigation of medicinal products in the term and preterm neonate

Guideline on the role of pharmacokinetics in the development of medicinal products in the paediatric population

Joint DIA/EFGCP/EMA better medicines for children conference 2016 on optimisation of drug development for the benefit of children (10-11/10/2016)

Guideline on the qualification and reporting of PBPK modelling and simulation

Reflection paper on the use of extrapolation in the development of medicine for paediatrics

Guideline on clinical trials in small populations

Guideline on good pharmacovigilance practices (GVP) for the paediatric population

Guideline on the evaluation of anticancer medicinal products in man

Guideline on the evaluation of anticancer medicinal products in man - Addendum on paediatric oncology

Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements

Guideline on recombinant and plasma-derived FVIII products rev. 2

Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis

Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders (Rev 3)

Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy

Concept paper on the impact of brain immaturity when investigating medicinal products intended for neonatal use

Concept paper on the impact of lung and heart immaturity when investigating medicinal products intended for neonatal use

Concept paper on the impact of liver immaturity when investigating medicinal products intended for neonatal use

Discussion paper on the impact of renal immaturity when investigating medicinal products intended for paediatric use

CHMP Safety Working Party's response to the PDCO regarding the use of PEGylated drug products in the paediatric population

Concept paper on the involvement of children and young people at the Paediatric Committee (PDCO)

Guideline on the investigation of medicinal products in the term and preterm neonate

Reflection paper on formulations of choice for the paediatric population

Note of explanation to accompany publication of reflection paper on formulations of choice for the paediatric population

Draft paper on the impact of brain immaturity when investigating medicinal products intended for neonatal use

Draft concept paper on the impact of lung and heart immaturity when investigating medicinal products intended for neonatal use

Draft concept paper on the impact of liver immaturity when investigating medicinal products intended for neonatal use

Discussion paper on the impact of renal immaturity when investigating medicinal products intended for paediatric use

Ethical considerations for clinical trials on medicinal products conducted with the pediatric population

Guidelines multidisciplinaires

CHMP Safety Working Party's response to the PDCO regarding the use of PEGylated drug products in the paediatric population

Concept paper on the involvement of children and young people at the Paediatric Committee (PDCO)

Paediatric Gaucher disease : a strategic collaborative approach from EMA and FDA