

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 (EMA/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

