

2 August 2013 EMA/CHMP/241120/2013 Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 22-25 July 2013

The guidelines and concept papers which have been adopted during this meeting of the Committee for Medicinal Products for Human Use (CHMP) will be published shortly on the European Medicines Agency's website under Regulatory/Human/Scientific guidelines. Documents for public consultation will also be available under Document search/Public consultations.

Central Nervous System Working Party (CNSWP)

| Reference number | Document | Status |
|---------------------|--|-----------------------------|
| EMA/CHMP/40105/2013 | Guideline on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis (ALS) | 6-month public consultation |

Pharmacokinetics Working Party (PKWP)

| Reference number | Document | Status |
|-----------------------|--|-----------------------------|
| CHMP/PKWP/423137/2013 | Concept paper on the development of product-specific guidance on demonstration of bioequivalence | 2-month public consultation |

Quality Working Party (QWP)

| Reference number | Document | Status |
|------------------|---|---------|
| EMA/414248/2013 | Guideline on Pharmaceutical Development of Medicines for Paediatric Use • Overview of comments | adopted |
| | (EMA/414249/2013) | |



Safety Working Party (SWP)

| Reference number | Document | Status |
|---------------------------------------|--|-----------------------------|
| EMA/704345/2012 | Work plan for the Safety Working Party 2013 | adopted |
| EMA/CHMP/CVMP/JEG- 3Rs/443879/2012 | Work plan for the joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (JEG 3Rs) 2013 | adopted |
| EMA/CHMP/241120/2013 | Reflection Paper on the data requirements for IV iron-based nano-colloidal products developed with reference to an innovator product | 6-month public consultation |