24 July 2012
EMA/CHMP/410522/2012
Press Office

# Guidelines and concept papers

## Adopted during the CHMP meeting 16-19 July 2012

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.

### Blood Products Working Party (BPWP)

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/BPWP/143744/2012 | Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration | **6-month public consultation** |

### Cardiovascular Working Party (CVWP)

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/450916/2012 | Guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with non-valvular atrial fibrillation | **6-month public consultation** |
| EMA/444348/2012 | Overview of comments received on the Guideline on clinical investigation of medicinal products in the treatment of diabetes mellitus (CPMP/EWP/1080/00 Rev. 1) | **adopted** |

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## ICH

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/ICH/435606/2012 | ICH guideline E3 - questions and answers Step 5 | **for information** |
| EMA/CHMP/ICH/820/2003 | ICH guideline M8 eCTD – questions and answers Step 5 | **for information** |
| EMA/CHMP/ICH/405290/2010 | ICH guideline Q4B Annex 13 to note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on bulk density and tapped density of powders – general chapter Step 4 | **adopted** |

## Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (JEG 3Rs)

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/CVMP/JEG-3Rs/252137/2012 | Recommendation to marketing authorisation holders, highlighting the need to ensure compliance with 3Rs methods described in the European Pharmacopoeia | **adopted**<br><br>Publication subject to CVMP adoption. |

## Quality Working Party (QWP)

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/QWP/911254/2011 | Guideline on quality of transdermal patches | **6-month public consultation** |
| EMA/CHMP/QWP/283491/2012 | Guideline on quality of oral modified release products | **6-month public consultation** |

## Radiopharmaceutical Drafting Group

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/448228/2012 | Guideline on core SmPC and Package Leaflet for fludeoxyglucose<br>• Overview of comments (EMA/CHMP/448578/2012) | **adopted** |
| EMA/CHMP/448591/2012 | Guideline on core SmPC and Package Leaflet for technetium ($^{99m}$Tc) sestamibi | **3-month public consultation** |

## Respiratory Drafting Group

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/436065/2012 Rev. 2 | Guideline on clinical investigation of medicinal products in the treatment of Chronic Obstructive Pulmonary Disease (COPD) | **adopted** |

## Safety Working Party (SWP)

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/SWP/169430/2012 | Guideline on setting health based exposure limits for use in risk identification in the manufacture of different drug products in shared facilities | **6-month public consultation**<br><br>Publication subject to CVMP adoption. |