17 November 2011
EMA/CHMP/877164/2011
Press Office

# Guidelines and concept papers

Adopted during the CHMP meeting 14-17 November 2011

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 website of the European Medicines Agency.

## Biosimilar Medicinal Product Working Party (BMWP)

| Reference number | Document | Status[1] |
|---|---|---|
| EMA/CHMP/BMWP/671292/2010 | Guideline on Non-Clinical and Clinical development of similar biological medicinal products containing recombinant human follicle stimulating hormone (r-hFSH) | **6-month public consultation** |
| EMA/CHMP/EMA/572643/2011 | Concept paper on the revision of the Guideline on similar biological medicinal products | **3-month public consultation** |

## Pharmacovigilance Working Party (PhVWP)

| Reference number | Document | Status[1] |
|---|---|---|
| EMA/13432/2009 | Guideline on Detection and Management of Duplicate Individual Cases and Individual Case Safety Reports (ICSRs) | **Adopted** |

[1] Adopted or released for consultation documents can be found at the European Medicines Agency website (under "Document library-Public Consultations" or under "Regulatory-Human Medicines").

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

## Pharmacokinetics Working Party (PKWP)

| Reference number | Document | Status[1] |
|---|---|---|
| EMA/CHMP/600958/2010 | Appendix IV of the Guideline on the Investigation on Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1): Presentation of Biopharmaceutical and Bioanalytical Data in Module 2.7.1<br>• Overview of comments (EMA/CHMP/643484/2011) | **Adopted** |

## Quality Working Party (QWP)

| Reference number | Document | Status[1] |
|---|---|---|
| EMA/CHMP/CVMP/QWP/862730/2011 | Revised Q/A: Stability Issues of Pharmaceutical Bulk Products for use in manufacture of drug product (Human and Veterinary) | **Adopted** Publication of this Q/A is subject to adoption by CVMP |
| EMA/CHMP/CVMP/QWP/862689/2011 | Revised Q/A: Revised questions how to handle some ICH Harmonised Ph. Eur. Chapters under the new variations system | **Adopted** Publication of this Q/A is subject to adoption by CVMP |

## Urology Drafting Group

| Reference number | Document | Status[1] |
|---|---|---|
| CPMP/EWP/18/01/Rev. 1 | Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence | **6-month public consultation** |

[1] Adopted or released for consultation documents can be found at the European Medicines Agency website (under "Document library-Public Consultations" or under "Regulatory-Human Medicines").