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# Guidelines and concept papers

## Adopted during the CHMP meeting 18-21 May 2015

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.

### Biologics Working Party

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/BWP/126802/2012 | Guideline on the adventitious agent safety of urine-derived medicinal products | Adopted |
| EMA/CHMP/BWP/548524/2008 | Guideline on epidemiological data on blood transmissible infections | Adopted for 3-months public consultation |

### Vaccines Working Party

| Reference number | Document | Status |
|---|---|---|
| EMA/56793/2014 | Guideline on influenza vaccines – submission and procedural requirements | Adopted |

### Blood Products Working Party

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/BPWP/144552/2009 rev 1 | Guideline on clinical investigation of recombinant and human plasma-derived factor IX products | Adopted |

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| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/BPWP/144533/2009 rev 1 | Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products | Adopted for 1 month public consultation |
| EMA/CHMP/BPWP/1619/1999 rev. 2 | Guideline on core SmPC for human plasma derived and recombinant coagulation factor VIII products | Adopted for 1 month public consultation |

## Cardiovascular Working Party

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/707532/2013 | Paediatric Addendum on the CHMP Guideline on clinical investigation of medicinal products for the treatment of acute heart failure | Adopted for 6-months public consultation |
| EMA/CHMP/50549/2015 | Reflection paper on assessment of cardiovascular risk of medicinal products for the treatment of cardiovascular and metabolic diseases | Adopted for 3-months public consultation |
| EMA/CHMP/35576/2015 | Guideline on clinical investigation of medicinal products for the treatment of acute heart failure | Adopted |

## Pharmacokinetics Working Party

| Reference number | Document | Status |
|---|---|---|
| EMEA/CHMP/EWP/192217/2009 Rev.1 Corr | Guideline on bioanalytical method validation | Adopted |
| CPMP/EWP/560/95/Rev. 1 Corr | Guideline on the Investigation of Drug Interactions | Adopted |

## Excipients Drafting Group

| Reference number | Document | Status |
|---|---|---|
| EMA/CHMP/338679/2014 | Questions and answers on Sodium as excipient in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1) | Adopted for 3-months public consultation |

| Reference number | Document | Status |
| --- | --- | --- |
| EMA/CHMP/704219/2013 | Questions and Answers on Wheat starch (containing gluten) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev. 1) | Adopted |