Consultations on adoption of European Union guidelines in Australia: Outcome of previous consultation

3 June 2015

Following consultation within the TGA and with relevant external stakeholders including Industry and Consumer groups, ending 22 May 2015, the following EU/ICH guidelines have been adopted by the TGA, effective 25 May 2015 unless indicated otherwise:

- Quality guidelines
- Biological medicines guidelines
- Clinical efficacy and safety guidelines
- Nonclinical guidelines

How to access a pdf document

Quality guidelines

Pharmaceutical development

EMA/CHMP/ICH/24235/2006 (pdf,70kb)
ICH guideline Q9 on quality risk management.
See also EMA/CHMP/ICH/265145/2009 questions and answers on the guideline (pdf,173kb)

EMA/CHMP/ICH/214732/2007 (pdf,82kb)
ICH guideline Q10 on pharmaceutical quality system.
See also EMA/CHMP/ICH/265145/2009 questions and answers on the guideline (pdf,173kb)

Stability

EMA/CHMP/CVMP/QWP/441071/2011 Rev 2 (pdf,167kb)
Guideline on stability testing for applications for variations to a marketing authorisation.
TGA annotation:
EU-specific procedural requirements stated in this Guideline do not apply in Australia

Active substance

CHMP/QWP/227/02 Rev. 3 Corr (pdf,232kb)
Guideline on Active Substance Master File Procedure.
Replaces: CPMP/QWP/227/02 Rev 2 (adopted by TGA June 2013)
TGA annotation:

EU-specific procedural requirements stated in this Guideline do not apply in Australia

Specific types of products

EMA/CHMP/QWP/608924/2014 (pdf,242kb)
Guideline on the quality of transdermal patches.
Replaces: CPMP/QWP/604/96. Note for Guidance on Quality of Modified Release Products: [B: Transdermal Dosage Forms] (adopted by TGA April 2001)
Effective: June 2015

Biological medicines guidelines

Overarching biosimilar guidelines

CHMP/437/04 Rev. 1 (pdf,120kb)
Guideline on similar biological medicinal products.
Replace: CHMP/437/04 (adopted by TGA 15 June 2000).

EMEA/CHMP/BMWP/42832/2005 Rev1 (pdf,165kb)
Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues
Replaces: EMEA/CHMP/BMWP/42832/2005 (adopted by TGA Sept 2006)
Effective: July 2015

Clinical efficacy and safety guidelines

Alimentary tract and metabolism

CPMP/EWP/785/97 Rev. 1 (pdf,231kb)
Guideline on the evaluation of medicinal products for the treatment of irritable bowel syndrome
Replaces: CPMP/EWP/785/97 Points to consider on the evaluation of medicinal products for the treatment of Irritable Bowel Syndrome (adopted by TGA Sept 2004).

Clinical pharmacology and pharmacokinetics

EMA/CHMP/EWP/280/96 (pdf,499kb)
Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms (EMA/CPMP/EWP/280/96 Corr1)
Replaces: CPMP/EWP/280/96 Corr. Note for Guidance on Modified Release Oral and Transdermal dosage forms: Section II (Pharmacokinetic and Clinical Evaluation) (corrected version adopted by TGA 1 June 2014)
Effective: June 2015
TGA annotation:
For multiple strengths of generic TDDS products, bioequivalence studies should be performed at least on the lowest and highest strengths versus the corresponding innovator products. If an applicant considers that this is unnecessary in a particular case, a justification for not submitting bioequivalence data should be submitted in accordance with the ARGPM guidance on Biopharmaceutic studies.

Nonclinical guidelines

General guidelines

CPMP/SWP/2592/02 Rev 1 (pdf,238kb)

CHMP SWP Conclusions and recommendations on the use of genetically modified animal models for carcinogenicity assessment

Category: Prescription medicines
Tags: medicines, regulation, european union, eu, guidance, Adopted / adoption, non-adoption, consultant / consultation
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