EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

News bulletin for small and medium-sized enterprises

ISSUE 15 MARCH 2011

This news bulletin is published four times a year by the SME Office of the European Medicines Agency.

The news bulletin aims to bring to the attention of SMEs, and their stakeholders, documents and activities related to the European regulatory environment.

IN THIS ISSUE:

CMC guidance

The 'question and answers document on ICH guideline Q8, Q9 and Q10-volume 4' was updated in December 2010 (EMA/CHMP/ICH/265145/2009).

A revision of ICH guideline Q4B annex 7 (R2) on dissolution test–general chapter was published in December 2010 (EMA/CHMP/ICH/645469/2008). It recommends that the official pharmacopoeial texts, Ph.Eur. 2.9.3. Dissolution Test for Solid Dosage Forms, JP 6.10 Dissolution Test, and USP <711> Dissolution, can be used as interchangeable in the ICH regions subject to certain conditions outlined in the guidance.

Clinical guidance

A revised guideline on clinical investigation of medicinal products in the treatment of hypertension came into effect on 18 February (EMA/238/1995/Rev. 3). The revision addresses mainly the requirements for the different types of indications of fixed dose combinations products (i.e. first line, second line, substitution indication).

A draft reflection paper on the need for active control trials was published on 11 January 2011 (EMA/759784/2010). It elaborates on regulatory aspects to be considered in a centralised marketing authorisation application when discussing the importance of a direct comparison to active control. The scope is limited to those therapeutic areas where placebo is deemed ethical and one or more established medicines are available. The principles outlined in the document are applicable to pivotal trials to establish efficacy and safety, for 'add-on' trials as well as trials without background treatment. The paper is written mainly with respect to applications for marketing authorisation, although it also applies to justifications on the need for active control during a scientific advice application which remains the forum for discussing a specific development program. It is released for consultation until 31 March 2011.

A draft guideline on clinical evaluation of medicinal products for the treatment of chronic hepatitis C was published on 20 January 2011 (EMEA/CHMP/51240/2011). It provides guidance on the clinical development of compounds for the treatment of chronic hepatitis C, including directly acting antivirals as well as host targeting antivirals. It is released for consultation until 31 August 2011.

Advanced therapies

A multidisciplinary reflection paper on stem cell-based medicinal products was released on 4 February 2011 (EMA/CAT/571134/2009). It includes quality, non-clinical and clinical considerations for companies developing such products specifying aspects related to marketing authorisation application requirements. The document should be read in conjunction with existing guidance on cell-based medicinal products (EMEA/CHMP/410869/2006) which addresses general aspects of cell-based medicinal products.

Veterinary guidance

A draft 'VICH GL34: Guideline on testing for the detection of mycoplasma contamination' was released on 15 December 2010 (EMA/CVMP/VICH/463/02). This guideline describes the manner in which tests conducted to detect the presence of mycoplasma contamination in cell culture and *in ovo* origin biological products for veterinary use shall be done to assure the absence of mycoplasma contamination. It is released for consultation until 31 March 2011.

Regulatory guidance

The following updated regulatory and procedural guidance for users of the centralised procedure was released in December 2010:

- Pre-submission procedural advice for users of the centralised procedure-Human medicines (EMA/339324/2007)
- Specific guidance for users of the centralised procedure for generic/hybrid applications -Human medicines (EMEA/CHMP/225411/2006).
- Veterinary post-authorisation guidance questions (Link).

An updated 'Manual on borderline and classification in the Community Regulatory framework for medical *devices'* was released by the European Commission (version 1.8).

A 'Questions and answers' document on the procedure of PIP compliance verification at EMA was released on 8 March 2011 (EMA/PDCO/179892/2011)

Meetings

The following meetings have been announced:

- Global animal health conference on availability of veterinary medicines at the EMA premises on 23-24 March 2011. Further information about the conference including registration details is available under Link. Special discount for SME is available (Contact: diaeurope@diaeurope.org).
- Open Information Day on Framework Program 7 Health Research organised by the European Commission (Research & Innovation DG - Directorate Health) on 9-10 June 2011 in Brussels. Further information about the conference is available under Link.
- Annual SME Workshop 'Focus on Regulatory and Scientific Advice', at the EMA premises on 26 May 2011. Further information about the conference will be made available from the EMA SME Office shortly.
- Fourth European Conference for Clinical Nanomedicine on 23-25 May 2011, Basel. The conference is organised by the European Foundation for Clinical Nanomedicine in collaboration with the European Medicines Agency. It aims to highlight the joint European approach in the development of nanomedicines and provide a platform for discussion on nanomedical tools, techniques and materials. Further information is available under Link.

SME companies registered with the Agency

469 companies currently have SME status assigned by the Agency. The companies are published in the Agency's public SME registry at: http://fmapps.emea.europa.eu/SME/

Contact the SME Office

The SME Office has been set up within the Agency to address the particular needs of smaller companies. The Office aims to facilitate communication with SMEs through dedicated personnel who will respond to practical or procedural enquiries, monitor applications, and organise workshops and training sessions for SMEs. Any comments on this news bulletin can be forwarded to the SME Office:

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