EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

News bulletin for small and medium-sized enterprises

ISSUE 10 DECEMBER 2009

INSIDE THIS ISSUE:

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

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

Advanced Therapies

A reflection paper on in-vitro cultured chondrocyte containing products for cartilage repair of the knee was published on 5 October 2009 (EMEA/CAT/CPWP/288934/2009). It addresses specific points related to these products and complements the 'Guideline on human cell based medicinal products' (EMEA/CHMP/410869/2006). It is released for consultation until 31 December 2009.

An ICH 'considerations' document on oncolytic viruses was released on 21 October 2009 (EMEA/CHMP/ICH/607698/2008). It includes general principles for the development of oncolytic viruses and elaborates on issues relating to product characterization, non-clinical and clinical development.

Information on products classified as advanced therapies medicines by the Agency has been updated on 3 November (Link). The webpage provides details about the type of products classified by the Committee on Advanced Therapies (CAT), the therapeutic area and the classification as gene, cell or tissue engineered product. SME companies developing gene, cell or tissue engineered products are advised to seek CAT advice should there be any issue related to regulatory classification of such products. Contact: AdvancedTherapies@emea.europa.eu or the SME Office.

A guideline on the follow-up of patients administered gene therapy medicinal products was published on 22 October 2009 (EMEA/CHMP/GTWP/60436/2007). It includes recommendations for the clinical monitoring and follow-up after gene therapy treatment to e.g. detect signals of adverse reactions or prevent clinical consequences of such reactions. It will come into effect on 1 May 2010.

A guideline on xenogeneic cell-based medicinal products was released on 22 October 2009 (EMEA/CHMP/CPWP/83508/2009). It addresses the requirements for the development and marketing authorisation of xenogeneic cell-based medicinal products for human use. These products contain viable animal cells or tissues which might be sourced from (non)transgenic animals or are genetically modified cells. It replaces the 'Points to consider on xenogeneic cell-therapy medicinal products' (CPMP/1199/02) and will come into effect on 1 January 2010.

Veterinary Medicines

A Question and Answers document on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 (phase I) and GL38 (phase II) was released on 29 September 2009 (Link).

A draft guideline on the change of classification of veterinary medicinal products authorised by the EU was released on 29 September 2009 (EMEA/CVMP/430509/2009). It details the criteria to be met and the documentation to be provided to change the classification of a centrally authorised veterinary medicinal product from prescription-only medicine to non-prescription medicine. It is released for consultation until 31 March 2010.

An updated guidance document outlining the appointment and responsibilities of rapporteurs for centralised veterinary authorisations procedures was published on 29 September 2009 (EMEA/CVMP/468877/2009). It was revised to take into account the provisions of Council Regulation (EC) No. 726/2004, expand on the appointment principles for referral procedures, and take into account the new MRL Regulation (EC) No 470/2009.

A draft reflection paper on risk management plans for centrally authorised veterinary medicinal products was released on 18 November 2009 (EMEA/CVMP/126726/2007). The current legislation foresees that applicants may need to develop risk management systems to be submitted with veterinary marketing authorisation applications. The document intends to initiate a reflection with stakeholders on the extent of guidance needed and the timing for developing such guidance. It is released for consultation until 31 March 2010.

A draft guideline on the 'Data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009' (the 'MRL regulation') was released on 18 November 2009 (EMEA/CVMP/516817/2009). The 'MRL Regulation' requires that evaluations are undertaken for pharmacologically active substances present in veterinary medicinal products for use in food-producing species. The draft guideline describes the approach for evaluating whether or not excipients can be included in the list of substances considered as not falling within the scope of the MRL regulation. It is released for consultation until 31 May 2010.

Regulatory Guidance

Information on the implementation of the Product information Management (PIM) system for products registered in Europe via the Centralised Procedure was published on 28 September 2009. PIM is a project initiated to improve the management efficiency of product information documents in the centralised procedure by the adoption of a structured XML format document replacing the current Word format files. The Agency has developed a PIM authoring application, called the Light Authoring Tool (LAT) which can be used to create and manage PIM submissions. It is primarily designed to support SMEs and provides basic functionalities to create and maintain product information in PIM format. Further information is available in the Statement of Intent (EMEA/132166/2009) and the Questions and Answers document (EMEA/127652/2009).

Updated information on the fees payable to the EMEA was published on 5 October 2009. The details are specified in the document 'Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures (EMEA/MB/170391/2009/Rev.3) adopted by the EMEA Management Board and in the Explanatory note on Fees payable to the EMEA (EMEA/421353/2009). For further information please refer to the relevant section of the Agency 's website (Link).

Pre- and post-authorisation guidance was updated with respect to:

- Implementation date and transitional period of transfers of marketing authorisations (Link)
- Guideline on Summary of Product Characteristics Rev. 2 (Link). It provides advice on the principles of presenting information in the Summary of Product Characteristics in a consistent manner and shall apply as from 1 May 2010. Submissions in line with the guidance may also be done prior to that date.
- A report on the international cooperation between the European Medicines Agency and FDA in the area of Scientific Advice was published in October 2009 (EMEA/24517/2009 and Link). SMEs planning the submission of a parallel scientific advice are advised to contact the Scientific Advice Section of the Agency: scientificadvice@ema.europa.eu.
- Letter of intent for of scientific advice/protocol assistance request (Link)
- Dates of 2010 SAWP meetings and deadlines for scientific advice or protocol assistance request submissions (Link)

Regulatory Guidance continued

- Variation guidelines published by the European Commission (Procedural guideline and Categorisation guideline). Variations submitted before 1 January 2010 will be finalised in line with previous variation regulations 1084/2003 and 1085/2003; variations submitted on or after 1 January 2010 will be processed in line with the new variation Regulation 1234/2008. The guidelines apply to human and veterinary medicinal products authorised through the Centralised Procedure or Mutual Recognition/ Decentralised procedure.
- GCP Questions and Answers with respect to investigational medicinal products in bioavailability and bioequivalence trials (Link)
- Concept paper on the revision of Chapter 7 of the GMP Guide concerning 'outsourced GMP activities' (EMEA/INS/GMP/648678/2009) released for consultation until 31 January 2010.

Clinical Trials

An update of the Questions and Answers document on ICH guidance E7 'Studies in Support of Special Populations: Geriatrics' was published on 21 October 2009 (EMEA/CHMP/ICH/604661/2009). It is released for consultation until 31 January 2010.

A reflection paper on the 'extrapolation of results from clinical studies conducted outside Europe to the EU population' was adopted on 22 October 2009 (EMEA/CHMP/EWP/692702/2008). The paper should be considered as a reinforcement of the ICH E5 guideline to be used when deciding whether clinical trials conducted in a specific area of the world would be relevant to the EU setting or if there is a need to perform additional clinical trials within the EU. It will come into effect in May 2010.

A concept paper on the development of a guideline on 'biosimilar' monoclonal antibodies was released on 18 November 2009 (EMEA/CHMP/BMWP/632613/2009). The guideline to be developed will outline the non-clinical and clinical requirements and may also include a chapter on quality aspects. The concept paper is released for consultation until 31 January 2010.

An updated note for guidance on 'Eudravigilance Human - Processing of safety messages and individual case safety reports (ICSRs)' was released on 20 November 2009 (EMEA/H/20665/04). It updates and replaces previous guidance (EMEA/H/20665/04) to improve the quality and consistency of ICSRs reported electronically to EudraVigilance. This will be achieved by strengthening the validation process of ICH E2B (R2) data elements and making mandatory the population of certain ICH E2B(R2) data elements in the ICSRs. Details about the implementation are included in the following plan EMEA/665231/2008.

A public consultation paper on the functioning of the Clinical Trials Directive was released by the European Commission on 9 October 2009. It outlines various options to improve the functioning of the Directive while taking the global dimension of clinical trials into account. SMEs are particularly invited to provide comments by 8 January 2010 (ENTR/F/2/SF D(2009) 32674).

The SME Office would like to draw the sponsors' attention to the 'Guidance document for a Voluntary Harmonisation Procedure (VHP) for the assessment of multinational Clinical Trial Applications' published by the Clinical Trials Facilitation Group (CTFG) (Link). The CTFG is a working group set up by the Heads of National Regulatory Medicines Agencies to support harmonisation activities relating to clinical trials. The document outlines a harmonised and coordinated procedure for assessing multinational clinical trials by the EU national competent authorities. Selection criteria may apply during the pilot phase of the initiative targeting e.g. multinational clinical trial involving an investigational medicinal product without a marketing authorisation in the EU, or with novel modes of action, intended for orphan, cancer, paediatrics populations, or tested in large phase 3 trials with several member states concerned.

Meetings

Reports and/or presentations from the following meetings were published on the Agency's website:

- Workshop for SMEs on Paediatric Medicines held on 23 October 2009 (Link)
- European Medicines Agency-EFPIA 'Quality by Design' application workshop held on 28-29 September 2009 (Link)
- Training of Quality assessors held on 26-27 October 2009 (Link)
- GMP training program for inspectors held on 20-21 October 2009 (Link)

SME companies registered with the European Medicines Agency

460 companies currently have SME status assigned by the Agency. The list of companies is published on the Agency's website at: http://www.emea.europa.eu/pdfs/SME/registeredcompanies.pdf

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:

E-mail: smeoffice@ema.europa.eu

Direct telephone: (44-20) 74 18 85 75/84 63
Fax: (44-20) 75 23 70 40

Please note that our email address has changed:
firstname.lastname@ema.europa.eu