News bulletin for small and medium-sized enterprises

Issue 1 May 2007

This news bulletin is the first published by the SME Office of the European Medicines Agency. It will be published three 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.

Inside this issue:

European scientific advice for human and veterinary medicines

Revised 'EMEA guidance for companies requesting scientific advice or protocol assistance' (EMEA/H/4260/01 Rev 4) for human medicines was released in January 2007.

This updated version of the guidance was amended in the light of the 'New framework for scientific advice & protocol assistance' (EMEA/267187/2005/Rev.1), which introduced significant changes to the way the Agency provides scientific advice on the research and development of new medicines.

The new framework was implemented in July 2006. The main aspects of the new framework include:

- Earlier and greater involvement of experts throughout the procedure
- Faster delivery of advice to sponsors (within a maximum of 70 days)
- Broader scope for requesting scientific advice
- Enlarged Scientific Advice Working Party
- Reinforced role of the EMEA secretariat in quality assurance
- Increased transparency and communication with stakeholders.

Revised 'EMEA guidance for companies requesting scientific advice' (EMEA/CVMP/172329/04 EMEA rev 2), for medicines for veterinary use, was released in March 2007.

This updated version was amended to include information on fees and SMEs.

Medicines for children

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (the 'Paediatric Regulation') was published in the Official Journal on 27 December 2006 and entered into force on 26 January 2007.

The main aims of the Paediatric Regulation are to increase the development of medicines for use in paediatrics and to increase the information about these medicines available to patients and prescribers.

All language versions of the regulation can be found on the European Commission's Pharmaceuticals website at:

http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm#g1901

A frequently-asked-questions document on the regulation is available from the European Commission at:

http://ec.europa.eu/enterprise/pharmaceuticals/paediatrics/docs/paeds_qa_october_28.pdf

Further European Commission information and guidance: http://ec.europa.eu/enterprise/pharmaceuticals/paediatrics/index.htm

Further EMEA information and guidance: http://www.emea.europa.eu/htms/human/peg/pegfaq.htm

New scientific guidelines for human medicines

A draft CHMP 'Guideline on requirements for first-in-man clinical trials for potential high-risk medicinal products' (EMEA/CHMP/SWP/28367/2007 Corr.) was published on 26 March 2007.

The guideline aims to provide a common approach across EU Member States to the design and conduct of such trials. It is released for public consultation until 23 May 2007.

Link to press release: http://www.emea.europa.eu/pdfs/general/direct/pr/12283307en.pdf

See 'Workshops' for information on an upcoming workshop related to this guideline.

The draft 'Guideline on scientific requirements for the environmental risk assessment of gene-therapy medicinal products' (EMEA/CHMP/GTWP/125491/2006) was published on 8 February 2007.

This guideline deals with the scientific principles and methodology for the environmental risk assessment of GMO-containing gene-therapy medicinal products required for centralised marketing authorisations. Guidance is given on application of the methodology laid down in Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

It is released for public consultation until 31 August 2007.

A draft CHMP 'Guideline on human cell-based medicinal products' (EMEA/CHMP/410869/2006) was published on 25 January 2007.

This multidisciplinary guideline adopted by the CHMP replaces the 'Points to consider on the manufacture and quality-control of human somatic cell-therapy medicinal products' (CPMP/BWP/41450/98). It is released for public consultation until 31 July 2007.

Application procedures for human medicines

The EMEA Management Board released on 21 March 2007 the 'Survey 2006 on the performance of EMEA scientific procedures for medicines for human use' (EMEA/489472/2006).

This report gives key performance measures for a range of scientific procedures managed by the EMEA units for medicines for human use. The report also focuses on the scientific review of marketing authorisation applications, scientific advice and orphan designations.

An updated 'Checklist for sponsors applying for the transfer of orphan medicinal product (OMP) designation' (EMEA/41277/2007) was released on 7 February 2007.

Updated 'EMEA guidance on pre-submission meetings for initial marketing-authorisation applications for human medicinal products in the centralised procedure' (EMEA/382712/06) was released on 12 January 2007.

The EMEA is involved in many meetings with applicants who seek guidance on their drug development or the preparation of a centralised application for marketing authorisation. These meetings represent critical points in the development and approval process.

The EMEA is currently reviewing the different types of meetings offered, with a view to better defining and improving them.

As a first step, the EMEA guidance on pre-submission meetings for marketing-authorisation applications, which usually take place 6-7 months before submission, was revised and released for consultation in January 2007.

Guidance on the various other meeting opportunities with the EMEA will be published in order to increase awareness and promote such interaction with sponsors.

Further pre-submission guidance is available on the EMEA website at:

http://www.emea.europa.eu/htms/human/presub/list.htm

A revised 'Guideline on the acceptability of names for human medicinal products processed through the centralised procedure' (CMP/328/98 rev 5) was published on 5 February 2007.

This guideline aims to provide guidance on the criteria applied by the EMEA when reviewing the invented names for medicinal products processed through the centralised procedure. It has been updated to take into account experience gathered since its last update in April 2005 and further clarifies aspects related to 'non-prescription' and 'generic/hybrid/similar biological' medicinal products.

An update of the 'Guideline on the packaging information of medicinal products for human use authorised by the Community' (Volume 2C of Notice to Applicants) was published on 30 March 2007 to include information requirements for the new Member States and updates from Italy and Sweden.

It is available on the European Commission's Pharmaceuticals website at: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm#g1901

New scientific guidelines for veterinary medicines

Three guidelines from the Veterinary International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH) were published on 19 February 2007, and will come into effect in January 2008:

VICH Topic GL10: Impurities in new veterinary drug substances (CVMP/VICH/837/99-Rev 1), providing guidance for registration applications on the content and qualification of impurities in new drug substances for new veterinary medicinal products, produced by chemical syntheses and not previously registered in a region (EU, Japan or the United States) or member state.

VICH Topic GL11: Impurities in new veterinary medicinal products (CVMP/VICH/838/99-Rev 1), providing guidance for registration applications on the content and qualification of impurities in new veterinary medicinal products produced from chemically synthesised new drug substances not previously registered in a region or member state.

VICH Topic GL3: Stability testing of new veterinary drug substances and medicinal products Feb 2007 (CVMP/VICH/899/99-Rev 1), providing guidance on the stability data package for a new drug substance or medicinal product for a registration application within the three regions (EU, Japan and the United States).

Link to documents: http://www.emea.europa.eu/htms/vet/vetguidelines/quality.htm

The 'Revised guideline on the SPC for antimicrobial products' (EMEA/CVMP/SAGAM/383441/2005) was released for consultation in January 2007.

This revision replaces the 'Guideline on the SPC for antimicrobial products' (EMEA/CVMP/612/01-FINAL), and takes into account recent developments and the feedback obtained from users of the previous guideline. The revised document is released for consultation until 31 July 2007.

Application procedures for veterinary medicines

'The revised checking process of mock-ups and specimens of outer/immediate labelling and package leaflets in the centralised procedure for veterinary medicinal products' (EMEA/14522/2007) was released on 1 February 2007.

The checking process has been simplified, taking into account previous experience and in view of the revised translation-checking policy agreed with the Member States at the end of 2005. The revised policy reinforces the linguistic checking of the product information annexes before the granting of the Commission Decision. The revised policy came into effect on 15 February 2007.

Pharmacovigilance

Volume 9A of the 'Rules Governing Medicinal Products in the European Union: Pharmacovigilance for medicinal products for human use' has been extensively revised and updated.

The guideline is divided into Volume 9A, relating to medicinal products for human use, and Volume 9B, on medicinal products for veterinary use. Volume 9A underwent public consultations during 2005 and 2006. The final version has now been made public, and takes effect immediately.

Volume 9A can be found at: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev9.htm.

Volume 9B is not yet available. The version of Volume 9 made public in June 2004 remains valid for veterinary medicines. It is available at: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev9.htm

Workshops

This upcoming workshop may be of interest to SMEs:

- *Workshop on draft guideline on requirements for first-in-man clinical trials for potential high-risk medicinal products, to be held on 22 June 2007*

The objective of the workshop is to consider the feedback received on the draft guideline in order to ensure the clarity and acceptability of the guideline before it is finalised.

A registration form and further information are available at: http://www.emea.europa.eu/conference.htm

Information presented during the following workshops has recently been published on the EMEA website:

- *1st EMEA workshop for small and medium-sized enterprises, titled 'Navigating the regulatory maze', held on 2 February 2007*

The objective of the workshop was to provide information, practical advice and tips for SMEs on a series of topics including orphan designation, scientific advice, and the centralised procedure.

- *2nd EMEA/EFPIA workshop on biomarkers, held on 15 December 2006*

This workshop looked at the current state of development and application of biomarkers, and how they are being deployed from research to the clinic. The current views on validation of biomarkers were examined, as was the influence of pharmacogenomics on new drug therapies.

Link to more information: http://www.emea.europa.eu/postconference.htm

SME companies registered with the EMEA

One hundred and seventy-two companies companies currently have SME status assigned by the EMEA. The list of companies is published on the EMEA 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 should also be forwarded to the SME Office:

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