News bulletin for small and medium-sized enterprises

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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 quality, non-clinical and clinical issues relating to recombinant adeno-associated viral vectors was released on 24 March 2009 (Link). It discusses specific issues of recombinant adeno-associated viral vectors developed as medicinal products e.g. the complex methods for manufacture and quality control, and the currently unknown long-term fate of the administered vector. It is released for consultation until 30 September 2009.

A procedural guidance on the scientific classification of advanced therapy medicinal products in accordance with Article 17 of Regulation (EC) no 1394/2007 was released on 23 April 2009 (EMEA/99623/2009). It provides guidance to applicants on how to prepare a request for advice on the classification of a given product based on genes, cells or tissues as an advanced therapy medicinal product. The procedure is recommended before regulatory procedures such as scientific advice, Paediatric Investigation Plan (PIP), certification of advanced therapies (see below), orphan drug designation and submission of a marketing authorisation application.

A draft regulation laying down the provisions for the certification of quality and non-clinical data for small and medium-sized companies developing advanced therapies was released on 2 April 2009 by the European Commission (Link). It specifies the requirements to be provided by small and medium-sized enterprises that intend to seek certification of quality and non-clinical data for their advanced therapy medicinal products. The regulation will enter into force once it has been formally adopted by the Commission after consultation of the European Parliament.

A draft directive amending Annex I of directive 2001/83/EC relating to advanced therapies was released on 2 April 2009 by the European Commission (Link). It includes detailed definitions of advanced therapies and specific requirements for Modules 3, 4 and 5 of marketing authorisations dossiers. The draft directive will need to be formally adopted by the Commission after consultation of the European Parliament to be become effective.

A procedural guidance on the centralised evaluation process of advanced therapies was released on 12 May 2009 (EMEA/630043/2008). It describes the evaluation process, the timetable, the interactions, the roles and responsibilities of all parties involved. It is released for consultation until 6 July 2009. SMEs are particularly invited to provide comments.

The presentations from the first EMEA workshop on advanced therapies held on 3 April 2009 are available on the website (Link).

Regulatory Guidance

A guideline on the categorisation of regulatory documents was released on 23 March 2009 (EMEA/P/24143/2004 Rev. 1 corr). It intends to define the different guidelines that support the European pharmaceutical legislative framework and to describe a harmonised procedure for their development.

A guideline on the status of EMEA scientific guidelines and European Pharmacopoeia monographs/Chapters in the regulatory framework applicable to medicinal products was released on 27 March 2009 (EMEA/42371/2008). It clarifies the complementary roles of EMEA scientific guidelines and European Pharmacopoeia Monographs/ Chapters applicable to medicinal products.

EMEA guidance was published relating to:

- New fees payable to EMEA applicable as of 1 April 2009 (Link). The new fees were introduced following the publication of Commission Regulation (EC) No 249/2009 on 23 March 2009 and the adoption of the Implementing Rules by the EMEA Management Board.
- New guidance on 'Article 58 opinions' i.e. medicinal products intended exclusively for markets outside the community under article 58 of regulation (EC) no 726/2004 in the context of co-operation with the World Health Organization (WHO) (Link).
- New guidance on 'Unforeseen variations' according to Article 5 of Commission Regulation (EC) No 1234/2008. It outlines a procedure for marketing authorisation holders to request classification of variations for human and veterinary centrally authorized products whose classification is not provided for in the variation regulation or guideline.
- Updated pre-authorisation procedures (Link).
- Updated post-authorisation procedures (Link).
- Updated guidance on Paediatric investigation plans/Waivers/Modifications including information on e.g. electronic submissions, new templates and procedural deadlines (Link).

Documents supporting the preparation of regulatory documentation were released in April 2009:

- Data providers and sources to identify existing authorised medicinal products in the European Union and European Economic Area (Link).
- List of frequently used non-standard abbreviations to be used in SmPC and labelling (Link).

Veterinary Medicines

A draft guideline on the conduct of bioequivalence studies for veterinary medicines was released on 11 March 2009 (EMEA/CVMP/016/00-Rev.1). It defines when bioequivalence studies could be used to demonstrate that two products will show similar systemic safety and efficacy in a certain target animal species and formulates recommendations for the design, the conduct, and the evaluation of such studies. It is released for consultation until 30 September 2009.

A draft guideline on data requirements to support in-use stability claims for veterinary vaccines was released on 16 March 2009 (EMEA/CVMP/IWP/250147/2008). It is released for consultation until 30 September 2009.

An e-submission roadmap of veterinary medicinal products was released on 17 March 2009. It aims at developing a harmonised approach to the compilation and submission of regulatory documents taking into account the specific nature and limited resources of companies in the veterinary sector (EMEA/152972/2009).

A draft guideline on user safety for veterinary medicines was adopted on 17 April 2009 (EMEA/CVMP/543/03-Rev.1). It was revised to provide clearer guidance on user safety and the conduct of user safety risk assessments. It is released for consultation until 31 August 2009.

A VICH guideline on 'Safety studies for veterinary drug residues in human food/general approach to testing' was released on 20 April 2009 (EMEA/CVMP/VICH/486/02-Rev.2/GL33). It will come into effect on 1 February 2010.

A 'Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products' was released on 17 April 2009 (EMEA/CVMP/248499/2007). It aims at improving the methodology for benefit-risk evaluations in a systematic approach and ensuring the consistency and transparency of decisions taken at EU and Member State level. It will come into effect on 1 February 2009.

Pharmaceutical Development

A concept paper on the implementation of ICH Q10 was released on 11 March 2009 (EMEA/INS/GMP/34212/2009). It aims at aligning Chapters 1 and 2 of the EU GMP Guide with the modern quality terminology and concepts used in ICH Q10 that are now well established in many pharmaceutical companies.

A guideline on the replacement of rabbit pyrogen testing by an alternative test for plasma derived medicinal products was adopted on 23 April 2009 (EMEA/CHMP/BWP/452081/2007). It will come into effect on 1 November 2009.

The questions and answers webpage maintained by the joint CHMP/CVMP Quality Working Party provides harmonised position on issues that can be subject to different interpretation or require clarification on matters related to quality. It was updated in May 2009 to include e.g. information on the need for in vitro dissolution studies with alcohol for modified release oral products including opioid drug products, and endotoxin and sterility testing at the end of shelf-life (Link).

A questions and answers document on ICH Topic Q8, Q9 and Q10 Note for guidance on pharmaceutical development/quality risk management/pharmaceutical quality system was released on 2 June 2009 (EMEA/CHMP/ICH/265145/2009). It aims at facilitating the implementation of the guidelines in a consistent way across the three ICH regions.

A guideline on plasma-derived medicinal products was released on 8 April 2009 (CPMP/BWP/269/95 rev. 4). It includes the requirements for the collection of starting material, the manufacturing, the quality control and the viral safety of plasma-derived medicinal products. It was revised in light of EU technical directives, European Pharmacopoeia and EMEA guidelines. It is released for consultation until 30 September 2009.

Clinical Development

A guideline on missing data in confirmatory clinical trials was released on 18 May 2009 (CPMP/EWP/1776/99 Rev. 1 Corr*). It provides advice on how the presence of missing data in a confirmatory clinical trial should be addressed in a regulatory submission. It is released for consultation until 31 October 2009.

A concept paper on immunogenicity assessment of monoclonal antibodies intended for in vivo clinical use was released on 1 April 2009 (EMEA/CHMP/BMWP/114720/2009). It identifies the topics that will be developed in the future guideline e.g. variability of immunogenicity, confirmatory assays, neutralizing antibodies and immunogenicity prediction.

A concept paper on the development of a guideline on the use of pharmacogenomics in the pharmacokinetic evaluation of medicinal products was released on 12 May 2009 (EMEA/CHMP/PGxWP/63270/2009). It identifies the topics that will be developed in the future guideline e.g. pharmacogenetic effects on drug exposure, genotyping for clinical use and polymorphisms effect at transporter level.

Meetings

The report of the 'EMEA/EFPIA Pharmacogenetics Workshop on Integrating Pharmacogenetics Early into Drug Development: PK as a working example' are available on the EMEA website (Link).

SME companies registered with the EMEA

385 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 can be forwarded to the SME Office:
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