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 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.

Pharmaceutical guidelines

A guideline on the "Status of EMEA scientific guidelines and European Pharmacopoeia monographs and chapters in the regulatory framework applicable to medicinal products" was released on 6 October 2008 (EMEA/42371/2008). It describes the complementary roles of these documents as instruments to ensure the quality of medicinal products in the European Union.

Clinical guidelines

A guideline on the investigation of bioequivalence was released on 21 August 2008 (CPMP/EWP/QWP/1401/98 Rev. 1). It defines when bioequivalence studies are necessary and formulates requirements for their design, conduct, and evaluation with a focus on bioequivalence for immediate release dosage forms with systemic action. It is released for consultation until 31 January 2009.

Orphan Medicines

A guideline on the application of Article 8(1) and (3) of Regulation (EC) No 141/2000 (Orphan Regulation) was released on 23 September 2008 (C(2008) 4077 final). It concerns the granting of market exclusivity for authorised orphan medicinal products according to Article 8(1) of the 'Orphan Regulation', (so-called 10 year market exclusivity), in particular the assessment of the similarity criterion and the granting of derogations from that market exclusivity under Article 8(3).

A guideline on the application of Article 8(2) of the 'Orphan Regulation' was published on 24 September 2008 (C(2008) 4051 final). It sets out the general principles and procedures by which the period of market exclusivity of orphan medicinal products is reviewed and may be reduced to six years.

A communication and a proposal for a Council recommendation on rare diseases were released by the European Commission on 11 November (Link). It sets out a European strategy to support Member States in diagnosing, treating and caring for patients with rare diseases in three areas:

a) improving recognition and visibility of rare diseases
b) supporting national plans for rare diseases in the Member States and
c) strengthening cooperation and coordination for rare diseases at European level.

Further information on the Community actions for rare diseases can be found the EC website (Link).

Paediatric medicines

An update of the frequently asked questions (FAQ) on regulatory aspects of Regulation (EC) No 1901/2006 ('Paediatric Regulation') was released on 4 September 2008 (EMEA/520085/2006 Version 2.0).

A European Commission guideline on the implementation of the 'Paediatric Regulation' was finalised on 25 September 2008 (2008/C 243/01). It includes information about:

a) the format and content of applications for agreement or modification of a paediatric investigation plan ('PIP') and requests for waivers or deferrals and
b) the operation of the compliance check and
c) the criteria for assessing significant studies.

Further information on the implementation of the 'Paediatric Regulation' can be found here.

Regulatory guidance for veterinary medicines

An updated questions and answers ('Q&A) on regulatory guidance for MRL applications was released on 14 August 2008 (Link).

A guidance (VICH GL44) on target animal safety ('TAS') for veterinary live and inactivated vaccines was released on 24 September 2008 (EMEA/CVMP/VICH/359665/2005). It establishes criteria and recommendations for the conduct of studies that evaluate the safety of final formulation of veterinary live and inactivated vaccines to be marketed for use in target animals. It will come into effect in July 2009.

A guidance (VICH GL43) on target animal safety for veterinary medicines was released on 24 September 2008 (EMEA/CVMP/VICH/393388/2006). It provides recommendations on the TAS evaluation for regulatory submission of an investigational veterinary pharmaceutical product (IVPP) to determine the safety in the target animal, identify target organs and confirm safety margins with a view to minimizing the number of animals used in the studies. It will come into effect in July 2009.

A recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products was released on 23 October 2008 (EMEA/CVMP/248499/2007-Consultation-Rev.1). It aims to improve the methodology for benefit-risk evaluations, provide a more systematic approach to improve the consistency and transparency of decisions taken at European and National level, clarify the definitions of a benefit-risk evaluation and give guidance on when and how to perform a benefit-risk assessment. It is addressed to regulators, applicants or marketing authorisation holders and released for consultation until January 2009.

Pharmacovigilance

"EudraLex Volume 9A of 'The Rules Governing Medicinal Products in the European Union' was updated on 7 October 2008 (Link). It contains all guidelines on pharmacovigilance for medicinal products for human use revised in relation to the 'Paediatric Regulation', the identification of biological products in adverse reaction reports and clarifications for vaccines. An updated questions and answers document ('Q&A') related to Volume 9A was also released on 4 October 2008 (Link). Several sections of Volume 9A (e.g. electronic reporting post-authorisation safety) were revised and released for consultation until January 2009 (Link).

Inspections/Good Manufacturing Practices

The following sections of the GMP Guide/EudraLex Volume 4 were released in September 2008:

- GMP Annex 3 "Manufacture of Radiopharmaceuticals" revised in light of new requirements for actives substances used as starting materials and updated for radiopharmaceuticals. It will come into effect in March 2009 (Link).
- GMP Annex 7 "Manufacture of Herbal Medicinal Products" revised to specify provisions for active substances used as starting materials and for the manufacture of herbal medicinal products. It will come into effect in September 2009 (Link).

Workshops

3rd Workshop for SMEs
The 3rd SME workshop focussing on "Non-Clinical Aspects will be held at the EMEA on 2 February 2009. It will include an overview of non-clinical data requirements, highlighting key success factors and practical advice from an EU assessors' perspective. It is open to SME companies that have been assigned SME status by the EMEA and representatives of stakeholder organisations. There is no registration fee for participating in this meeting. The registration form and more information can be found here.
Please note that the deadline for registration is **18 December 2008**.

1st Workshop on Advanced Therapy Medicinal Products (ATMP)
The 1st workshop on Advanced Therapy Medicinal Products will be held at the EMEA on 3 February 2009. It is open to all companies in the ATMP field and representatives of stakeholder organisations. Representatives of the Agency's new Committee on Advanced Therapies and EMEA scientific staff will present an overview of the new EU legislation on ATMPs and its implementation, dossier requirements for ATMPs and the evaluation procedure for marketing authorisation. There will also be a session on how to obtain classification as an ATMP and request EMEA certification of quality and non-clinical data.
There is no registration fee for participating in this meeting. The registration form and more information can be found here. Please note that the deadline for registration is also **18 December 2008**.

SME companies registered with the EMEA

367 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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