40 Issue 40
August 2017

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SME Office NEWSLETTER

Information for SMEs on the EU regulatory environment for medicines.
Published four times a year by the European Medicines Agency.

An agency of the European Union

IN THIS ISSUE

Scientific Guidelines

A draft guideline on the *'notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol'* has been released for consultation until 22 August 2017 (EMA/430909/2016). It provides details on the notification process of serious breaches of clinical trials and possible actions that may be taken by Member States in response to such notifications.

A concept paper on the revision of the guideline on **clinical development of vaccines** has been released for consultation until 30 September 2017 (EMA/CHMP/VWP/124350/2017). The planned revisions include the design of clinical development programs for new vaccines intended to provide pre- and post-exposure prophylaxis against infectious diseases.

EUnetHTA/EMA Parallel Consultation

A guidance document on **parallel consultations between EMA and EUnetHTA** has been published (EMA/410962/2017). The new platform provides a single gateway for requests for parallel consultations with EMA and HTA bodies in the Member States on evidence-generation plans to support decision-making on marketing authorisation and health technology assessment. It replaces the parallel scientific advice procedure by EMA and HTA bodies. Further information is available on the EMA website (Link).

Pharmacovigilance

A **new version of EudraVigilance** will be launched on 22 November 2017. It provides enhanced functionalities for the reporting and analysis of suspected adverse reactions and increased transparency. Further information for marketing authorisation holders and clinical trials sponsors is available in the Link.

An updated guidance on **electronic submission of information on medicinal products** for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article

57(2) of Regulation (EC) No. 726/2004 was published (EMA/135580/2012; Q&A EMA/159776/2013). It was revised on a series of topics including submission dates for type II variations, maintenance of details of the marketing authorisation holder and pharmacovigilance system master file location.

Regulatory and Administrative Guidance

The following guidance, documents and questions and answers were updated or released:

- Scientific advice and protocol assistance (EMA/4260/2001 Rev. 8) on e.g. new EMA and EUnetHTA platform.
- Post-authorisation safety studies (PASS) (Link) on e.g. non-interventional imposed PASS.
- Post-authorisation measures (Link) on e.g. contact points and timelines.
- Quality of medicines (Link) on e.g. dry powder inhaler product information.
- Type-II variations (Link) on e.g. dossier presentation.
- Paediatric investigation plans (Link) on e.g. PIP modifications and dossiers submissions.
- Post-authorisation procedural advice for users of the centralised procedure (EMEA-H-19984/03 Rev. 71) on e.g. type II variations, post-authorisation safety studies, post-authorisation measures, PSURs and transparency.
- Establishment requirements within the framework of the United Kingdom's withdrawal from the EU topics for centralised procedures (human and veterinary) (Link).

Scientific Guidelines (Veterinary Medicines)

A revised guideline on data requirements for **immunological veterinary medicinal products** intended for minor use or minor species (MUMS)/limited market will come into effect on 1 November 2017 (EMA/CVMP/IWP/123243/2006-Rev.3). It clarifies the requirements for demonstrating quality, safety and efficacy of new marketing authorisations applications, line-extensions and variation applications of products classified as MUMS/limited market.

A draft revised guideline on the **conduct of bioequivalence studies** for veterinary medicinal products has been released for consultation until 31 October 2017 (EMA/CVMP/EWP/016/00-Rev.3). It specifies the requirements for the conduct, design and evaluation of bioequivalence studies for pharmaceutical forms with systemic action, and in vitro dissolution tests.

A question-and-answer document on **allogenic stem cell-based products** for veterinary use was adopted on 15 June 2017 (EMA/CVMP/ADVENT/751229/2016). It addresses a series of topics relating to sterility aspects of stem cell-based therapies for veterinary use.

A CVMP reflection paper on **non-spontaneous adverse event reporting** for veterinary medicinal products was published on 23 May 2017 (EMA/CVMP/PhVWP/357539/2015). It analyses how pharmacovigilance information from non-spontaneous sources is currently gathered (literature, internet and social media) with a view to develop future guidance on the topic.

A CVMP reflection paper on the *'authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances'* was adopted on 11 May 2017 (EMA/CVMP/448211/2015). It describes the tools to address the use of PBT/vPvB substances in veterinary medicines in line with CVMP guideline on 'Environmental impact assessment for veterinary medicinal products, VICH guidelines GL6 and GL38' (EMEA/CVMP/ERA/418282/2005-Rev.1).

A CVMP reflection paper on **anthelmintic resistance** was adopted in April 2017. It focuses on food producing animals and horses and describes monitoring systems for detecting resistance and strategies to delay resistance development (EMA/CVMP/EWP/573536/2013).

The following guidance documents and questions and answers were updated or released:

- Type-IA variations (Link) and Type-IB variations (Link) on e.g. classification for new pack size.
- Application of the 'sunset clause' to centrally authorised veterinary medicinal products (Link).
- Electronic submission of veterinary dossiers (Link) on e.g. submission media and structure of the dossier.
- Extension applications (Link) on e.g. format of submissions.

Fees (Human and Veterinary)

The explanatory note on general fees payable to the European Medicines Agency was updated to provide clarifications on charging variations on pack sizes for human and veterinary medicinal products (Link). An updated Q&A document on pharmacovigilance fees (human medicines) was also released (EMA/175299/2015 Rev.3).

SMEs and Industry Stakeholders Interactions

An **EMA action plan for small and medium-sized enterprises** was published on 31 May 2017 (EMA/337458/2017). It sets out a series of actions for implementation over 2017-2020 to address challenges identified by SMEs in a report published on the 10th anniversary of the SME initiative (EMA/155560/2016). The actions cover education, training and enhanced interactions with SMEs, EU partners, and public and private stakeholders.

The **2016 SME Office report** was released on 31 May 2017. It provides an overview of SME activities, highlights platforms that SMEs can leverage to advance innovative developments and regulatory strategies, and provides details on SMEs' experience with human and veterinary marketing-authorisation applications (Link).

The **EMA 2016 report on 'Interaction with industry stakeholders'** was released on 16 June 2017. It highlights topic-driven events and targeted consultations carried out throughout the year with pharmaceutical industry organisations (Link).

EU Public Consultation

A public consultation on the **EU blood and tissues and cells legislation** (Directives 2002/98/EC and 2004/23/EC) was launched on 29 May 2017 (deadline for comments 31 August 2017). The consultation aims to support an evaluation of the legislation on blood and tissues and cells, its functioning across the EU and provide evidence to consider any future changes to the legislation (Link).

Workshops, Meetings and Reports

Reports, presentations and/or videos of the following meetings have been published:

May 2017

- Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) joint workshop on personalised medicines (Link).
- Industry stakeholder platform on research and development support (Link).
- European Union International Organization for Standardization (ISO) for the identification of medicinal products (IDMP) / Substance, Product, Organisation and Referential data (SPOR) task force meeting (Link).

June 2017

- First anniversary of PRIME: experience so far (Link).
- Second meeting held between EMA, PMDA and FDA to discuss regulatory approaches for the evaluation of antibacterial agents (Link).
- EMA/FDA/Health Canada joint workshop addressing unmet needs of children with pulmonary arterial hypertension (Link).

July 2017

- Report and video of the 2017 annual workshop of the European Network of Paediatric Research at the EMA (Enpr-EMA) - (Link). See also webinar on Enpr-EMA activities (Link).

EMA Annual report 2016

The EMA 2016 annual report has been published. It elaborates on the EMA's key achievements in the areas of medicine evaluation, support to research and development of new and innovative treatments and the safety monitoring of medicines in real life. It also highlights other initiatives including the PRIME scheme, the policy on publication of clinical trial data, developments in big data, patient registries and real world data, and antimicrobial resistance (Link).

Selection of upcoming events

September 2017

- Introduction to the European Union (EU) regulatory system and EMA for international regulators and non-governmental organisations – 18 &19 September 2017 (Link).

November 2017

- Second paediatric strategy forum on medicine development for mature B cell malignancies in children – 13 & 14 November 2017 (Link).
- SME info day "Supporting innovative medicines' development and early access" – 17 November 2017 (Link).
- Joint EMA/DIA Information Day on measuring the impact of pharmacovigilance activities – 17 November 2017 (Link).

Registered SMEs

Currently, 1778 companies have SME status assigned by the Agency.

The names and profiles of these companies are published in the Agency's public SME Register.

If you would like to have your company details included in the SME Register, you must first apply for SME status at the Agency.

See the Applying for SME status section of the SME Office pages on the Agency's website for information on how to do this.

About the SME Office

The SME Office was set up within the European Medicines Agency to address the particular needs of smaller companies.

The Office has dedicated personnel who can help SMEs by:

- responding to practical or procedural enquiries;
- setting up briefing meetings to discuss their regulatory strategy;
- organising info days and training sessions.

Need more information?

Visit the European Medicines Agency website:

http://www.ema.europa.eu

In particular, these sections may interest you:

SME Office
Pre-authorisation (human medicines)
Pre-authorisation (veterinary medicines)

Contact the SME Office

E-mail: sme@ema.europa.eu
Tel: +44 (0)20 3660 8787

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact