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SME Office NEWSLETTER

Information for SMEs on the EU regulatory environment for medicines.
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IN THIS ISSUE

Scientific guidelines

Clinical guidelines

A revised addendum to the guideline on the evaluation of products for the treatment of diseases due to mycobacterium tuberculosis (EMA/CHMP/EWP/14377/2008 Rev. 1) came into effect on 1 February 2018. It focuses on the development of new regimens that include one or more new agents that allow for a shortening of the duration of therapy.

A revised guideline on the clinical investigation of medicines for Alzheimer's disease (CPMP/EWP/553/95 Rev.2) will come into effect on 1 September 2018. It elaborates on new diagnostic criteria for early or asymptomatic disease outcome parameters, biomarkers in different disease stages and design and analysis of long-term efficacy and safety studies.

A guidance on Good Pharmacogenomic Practice (EMA/CHMP/718998/2016) will come into effect on 1 September 2018. It provides details on principles and methods for the evaluation of genetic variations related to pharmacokinetics, efficacy and safety. It complements the guidance included in the Reflection paper on methodological issues associated with pharmacogenomic biomarkers in relation to clinical development and patient selection.

A reflection paper on physical frailty (EMA/CHMP/778709/2015) was published in February 2018. It describes instruments for the characterisation of baseline physical frailty in older patients (≥ 65 years) enrolled in a clinical trial or other clinical investigation (e.g. registry) and supplements ICH guidance E7 on 'Studies in support of special populations (Geriatrics)' (CPMP/ICH/379/95) and the related Questions and Answers (EMEA/CHMP/ICH/604661/2009).

A revised guideline on the clinical investigation of vaccines (EMEA/CHMP/VWP/164653/05 Rev. 1) is open for consultation until 30 October 2018. It includes specific considerations for clinical trials with vaccines in special populations, such as pregnant women and the elderly, and provides details on priming and boosting strategies.

A draft guideline on the clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00 Rev. 2) was released for consultation until 15 August 2018. It includes updated recommendations on cardiovascular safety, first-line indications requirements, high-strength insulin preparations, definitions of hypoglycaemia and the development of oral treatments for patients with type 1 diabetes.

An addendum to the guideline on the clinical evaluation of medicinal products indicated for the treatment of bacterial infections to address paediatric-specific clinical data (EMA/CHMP/187859/2017) was released for consultation until 30 October 2018. It provides details on strategies for the extrapolation of efficacy and safety data from adults to paediatric patients for the approval of antibacterial agents in a paediatric population.

Quality guidance

European Pharmacopoeia recommendations for manufacturers of vaccines for human use came into force on 1 January 2018. They highlight recent measures to promote replacement, reduction, and refinement (3Rs) measures through new or revised recommendations (e.g. substitution of in vivo method(s) by in vitro method(s) for quality control, tests for extraneous agents in viral vaccines (2.6.16) and cell substrates for the production of vaccines) (Link).

A guidance on the transfer and acceptance of quality control methods validated in collaborative trials between laboratories with a view to implementing 3Rs was published on 24 January 2018 (EMA/CHMP/CVMP/3Rs/94436/2014). It applies to regulatory testing used for quality control of human and veterinary medicinal products where animals have been traditionally used.

A draft guideline on quality information to be included in the product information of vaccines (EMA/CHMP/BWP/133540/2017) was released for consultation until 31 July 2018.

A guidance to report quality defects to EMA has been updated to streamline processes for reporting and investigating product quality defects of centrally authorised medicines. The reporting template was also updated to be more user-friendly and use standardised terminology from the Medical Dictionary for Regulatory Activities (MedDRA) (Link).

Regulatory Guidance

Chapter 1 of the Notice to Applicants (Link) was revised to introduce changes relating to use of marketing authorisations granted under exceptional circumstances as reference in generic applications, requirements for hybrid and fixed-dose combination applications, and global developments of biosimilar products.

A revised guideline on excipients in labelling and package leaflet was released (EMA/CHMP/302620/2017). It replaces the annex previously included in the guideline CPMP/463/00 Rev. 1. and is part of the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668).

Pre-authorisation guidance was updated with a new topic regarding multipack presentations and details to be included on the outer and inner packaging (EMA/821278/2015).

A revised "Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices" (Link) has been released. It includes updated recommendations on product classifications for consideration by regulators and stakeholders.

Veterinary medicines

A guidance on the use of QR codes in the packaging and labelling of veterinary medicines (EMA/364980/2017 rev.1) was published on 7 December 2017. It sets out the general principles of acceptability and procedural steps for the submission and assessment of QR code proposals (EMA/818103/2017).

Guidance on reporting antimicrobial data by animal species was published on 21 February 2018 (EMA/489035/2016; Q&A EMA/716249/2016-Rev.1). It defines the data which could be provided in the future to EMA by countries collecting antimicrobial use data by animal species.

The following guidance documents were released:

- Q&A (EMEA/CVMP/ERA/172074/2008 Rev. 6) on the implementation of CVMP guidelines on environmental impact assessment.
- List of substances considered as not falling within the scope of Regulation (EC) No. 470/20091 (The "Maximum Residue Limits" Regulation) (EMA/CVMP/519714/2009–Rev.38).

A VICH GL57 guideline on marker residue depletion studies to establish product withdrawal periods in aquatic species (EMA/CVMP/VICH/517152/2013) was released for consultation until 15 June 2018. It is an extension to the parent residue guidance VICH GL48 "Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods", and provides recommendations on the design of such studies.

Pharmacovigilance

Updated guidance on the new EudraVigilance system have been published: EudraVigilance release notes (EMA/234295/2018), user manual for EVWEB (EMA/ 765279/2017), stakeholders Q&A (EMA/132042/2018), QPPVs or trusted deputies registration (EMA/260914/2017 Rev.1).

EU news

The European Commission and the European Investment Fund (EIF) have launched a pan-European Venture Capital Funds-of-Funds programme (VentureEU) to boost venture capital investment in innovative SMEs, start-up and scale-up companies in sectors such as information and communication technologies, digital, life sciences and medical technologies (Link).

The European Commission has launched a series of initiatives to increase the availability of data in the EU (Link). In healthcare, an action plan is proposed which focuses on cross-border access to healthcare records, a shared European Data infrastructure and digital tools to facilitate integration of healthcare systems (Link).

Public consultation on EMA's fees system

A public consultation as part of a study on the evaluation of the EMA's fees system has been launched (Link). An online questionnaire is available for stakeholders to provide contributions until 2 August 2018 (Link).

UK's withdrawal from the European Union ("Brexit")

Latest information on the Agency's relocation to Amsterdam and 'Brexit preparedness' (Link) are available on the EMA website (Link). SMEs are advised to consult Brexit-related regulatory and procedural guidance (Link) and address any questions relating to Brexit to SME@ema.europa.eu.

Reports of interest

2017 EMA and SME Office Annual Reports

The EMA annual report provides an overview of the work of the Agency in 2017 and highlights the major achievements in protecting and promoting public and animal health in the EU (Link).

The SME annual report (EMA/123438/2018) provides details on SME activities including SMEs' experience with marketing authorisation applications and early interactions with the Agency.

- Report on the operation of the Steering Group for the Joint EMA/HMA action plan on availability of veterinary vaccines (EMA/565300/2017).
- Report of the joint CVMP/CHMP Working group on the Application of the 3Rs in regulatory testing of medicinal products (Link).
- Annual report on the Minor Use Minor Species/limited market scheme (EMA/795802/2017).
- Report on the International Active Pharmaceutical Ingredient Inspection Programme 2011 – 2016 (Link).
- Report from the survey of centralised marketing authorisation procedures (EMA/338870/2017).

Past meetings

Presentations, reports and videos of the following events have been published:

- Twelfth industry stakeholder platform on the operation of pharmacovigilance in the European Union – 24 November 2017 (Link).
- Substance, product, organisation and referential (SPOR) data services: questions and answers webinar with industry – 7 December 2017 (Link).
- A common data model in Europe? Why? Which? How? – 11-12 December 2017 (Link).
- Workshop on site and histology-independent indications in oncology - 14-15 December 2017 (Link)
- 14th Joint EMA/European network for Health Technology Assessment dialogue meeting – 15 December 2017 (Link)
- Industry associations webinar: update on the implementation of EMA policy on publication of clinical data - Policy 0070 – 29 January 2018 (Link)
- Substance, product, organisation and referential data (SPOR) impact on veterinary stakeholders – 20 February 2018 (Link)
- Multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation - 20 March 2018 (Link)

Future events

- Haemophilia registries workshop - 8 June 2018 (Link)
- Paediatric strategy forum for medicinal product development of checkpoint inhibitors for use in combination therapy in paediatric patients – 5-6 September 2018 (Link)

Registered SMEs

Currently, 1763 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)

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