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SCIENCE MEDICINES HEALTH

SME Office NEWSLETTER

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

COVID-19

Updated guidance for companies, information on treatments and vaccines, medicines availability and public-health advice have been published on EMA's website (see dedicated webpage).

Clinical trials

A Q&A on good clinical practice (GCP) was updated on several topics including principal investigator requirements review and sign-off of data (Link).

Scientific guidelines for human medicines

Quality guidelines

An outcome of a lessons learned exercise on the presence of nitrosamines in sartan medicines has been published. It includes recommendations to help reduce the risk of impurities in medicines, and to ensure that regulators are better prepared to manage cases of unexpected impurities (see dedicated webpage and press release for additional information).

An updated guideline on the quality of water for pharmaceutical use (EMA/CHMP/CVMP/QWP/496873/2018) will come into effect on 1 February 2021. It includes a revised monograph for water for injections and reflects current expectations for the minimum acceptable quality of water used in the manufacture of active substances and medicinal products for human and veterinary use.

Preclinical and clinical guidelines

Draft product-specific bioequivalence guidance (Link) were released for public consultation for: Abiraterone, Dasatinib, Lapatinib and Levothyroxine.

A questions and answers document (Q&A) on clinical pharmacology and pharmacokinetics was updated on several topics including general and product-specific bioequivalence, biowaiver and biosimilars (Link).

A Q&A document in support of the ICH guideline M7 on '*assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk*' was released for consultation until 3 October 2020 (EMA/CHMP/ICH/321999/2020). It clarifies the guidance on the assessment and control of DNA reactive (mutagenic) impurities and the information that should be provided during drug development, marketing authorisation applications (MAAs) and master files.

A Q&A document in support of ICH guideline E14/S7B on '*clinical and nonclinical evaluation of QT/QTc interval prolongation and proarrhythmic potential*' was released for consultation until 28 November 2020 (EMA/CHMP/ICH/415588/202).

Digital technology-based methodologies

A Q&A on qualification of digital technology-based methodologies to support approval of medicinal products was published on 6 June 2020 (EMA/219860/2020). It highlights key points to consider for the successful qualification of digital technology-based methodologies intended to support approval of medicinal products.

Evaluation of the medicines for rare diseases and children legislation

On 11 August 2020, the European Commission (EC) published its evaluation on the legislation for medicines for rare diseases and for children. This is the first comprehensive evaluation of the two regulations since their adoption in 2000 and 2006, respectively. The evaluation found that both Regulations fostered the development and availability of medicines for patients with rare diseases and for children, but they have not adequately managed to support development in all areas of rare and paediatric diseases where the need for medicines is greatest. Additional information can be found in the EC dedicated webpage.

Regulatory guidance

The following documents have been updated:

- Pre- and post-procedural guidance for orphan medicinal product designation (EMA/420706/2018 Rev 9; EMA/469917/2018).
- Pre-authorisation guidance (EMA/24037/2019) on topics including applicant's EEA establishment, steps prior to submitting an MAA, orphan designation, submission, validation, assessment and fees.
- Post-authorisation guidance (EMEA-H-19984/03 Rev. 86) on topics including IA/IAIN-IB-II variations, extension of indication, grouping of variations, pre-submission queries service, annual re-assessment, renewal application, post-authorisation safety studies (PASS), post-authorisation measures (PAMs), risk management plan (RMP), periodic safety update reports (PSURs), article 46 paediatric study submission and transfer of MA.
- IRIS guide to registration (EMA/31242/2019) and a quick interactive guide to IRIS registration process (Link).
- Validation issues frequently seen with initial MAAs (EMA/454165/2015).

Product information

A revised overview document listing scientific guidelines which include summary of product characteristics recommendations (EMA/813125/2012 rev. 6) and an updated training presentation on 'Section 4.8: Undesirable effects' (Link) were published on 25 June 2020. Additional information can be found in the webpage 'How to prepare and review a summary of product characteristics'.

Academia fee waiver for scientific advice (SA) for orphan medicines

As of 19 June 2020, EMA is waiving all fees for SA for academia developing orphan medicines (Link). More information can be found in the academia dedicated webpage.

What EMA publishes and when?

A guide to information on human medicines evaluated by EMA was published on 10 June 2020 (Link). It describes the different types of information the Agency currently publishes for both centrally and non-centrally authorised medicines, as well as publication times and location on EMA's website. It aims to help stakeholders know what kind of information to expect on medicines undergoing evaluations and other regulatory procedures. Additional information can be found in the dedicated webpage.

Pharmacovigilance

New or updated guidance have been published:

- Addendum I to the guideline on pharmacovigilance practices (GVP) Module VIII – requirements and recommendations for the submission of information on non-interventional PASS (EMA/395730/2012 Rev 3).
- A revised explanatory note to GVP Module VII (EMA/670256/2017 Rev. 2).

Veterinary medicines

New veterinary medicines regulation

A draft access policy for the union product database (UPD) was released for consultation until 18 September 2020 (EMA/198149/2020; Link). The policy has been drafted to provide transparency and visibility of information on veterinary medicinal products while protecting commercially confidential information, as required in the new veterinary medicines regulation (VMR).

Advice documents on implementing measures under various articles of Regulation (EU) 2019/6 (VMR) were published on 8 July 2020 relating to:

- Good distribution practices (GDP) for veterinary medicinal products (EMA/567192/2019).
- GDP for active substances used as starting materials in veterinary medicinal products (EMA/87754/2020).
- Report on the format of the data to be collected on antimicrobial medicinal products used in animals (EMA/CVMP/586518/2019).

The dedicated webpage on the VMR should be consulted regularly (Link).

Scientific guidelines

A list of biological substances considered as not requiring a maximum residue limits (MRL) evaluation as per Regulation (EU) No. 2018/782, with regards to residues of veterinary medicinal products in foodstuffs of animal origin was published on 29 May 2020 (EMA/CVMP/572629/2019). Additional information can be found in the dedicated section 'Biological substances not requiring an MRL evaluation' in the MRL webpage.

A revised list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009 ('MRL regulation'), with regards to residues of veterinary medicinal products in foodstuffs of animal origin was published on 1 July 2020 (EMA/CVMP/519714/2009–Rev.44).

A Q&A document on the management of extraneous agents in immunological veterinary medicinal products (IVMPs) has been published on 26 June 2020 (EMA/CVMP/IWP/669993/2019).

A Q&A document on stem cell-based products for veterinary use on target animal safety was published on 24 July 2020 (EMA/CVMP/ADVENT/791717/2016).

Regulatory guidance

A draft strategy on antimicrobials for 2021-2025 was released for public consultation until 30 September 2020 (Link). It will support the implementation of the VMR on the EU's one health action plan against antimicrobial resistance (AMR).

A concept paper for the development of a reflection paper on criteria for the application of Article 40(5) of the VMR (EMA/CVMP/340959/2020) was released for consultation until 21 September 2020. The reflection paper aims to detail the criteria to be fulfilled to gain the 4-year period of protection for (pre-)clinical data submitted in support of a variation to change the pharmaceutical form, administration route dosage.

Pre-authorisation procedural Q&As have been updated on topics including eligibility, rapporteurs/co-rapporteurs and GMP compliance (Q&A: 1-20; Q&A: 21-40).

Pharmacovigilance

A revised combined veterinary dictionary for drug regulatory activities (VeDDRA) list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products was published on 14 July 2020 (Link). It should be read in conjunction with the guidance notes on the use of VeDDRA terminology (EMA/CVMP/PhVWP/288284/2007-Rev.12) and the list of changes to combined VeDDRA list of clinical terms (EMA/CVMP/PhVWP/239225/2020; Link).

New or updated guidance have been published:

- Scientific recommendations for implementing measures under Article 77(6) of VMR Regulation (EU) 2019/6 on veterinary medicinal products regarding good pharmacovigilance practice (EMA/CVMP/111028/2020) and the pharmacovigilance system master file (EMA/CVMP/123178/2019).
- Q&A on adverse event reporting (EMA/CVMP/PhVWP/145186/2013-Rev.4).

Other news

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

- EMA's SME 2019 Office annual report (Link).
- EMA's 2019 annual report (Link).
- Paediatric strategy forum for medicinal product development for epigenetic modifiers in children and adolescents; 23-24/01/2020 (Link).
- European network of paediatric research at the EMA (Enpr -EMA) Coordinating Group and networks meeting – 21 February 2020 (Link).
- EMA, in collaboration with other parties, has published two scientific articles outlining the importance of prospective dialogue between developers and regulators for better evidence generation (Link).
- ICH E6(R3) Good Clinical Practice workshop with Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties – 3 June 2020 (Link).

Registered SMEs

Currently, 1823 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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