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SME Office NEWSLETTER

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Scientific guidelines for human medicines

Quality guidelines

A document setting out how the European medicines regulatory network will be implementing the outcome of CHMP's review on the risk of nitrosamine impurities in human medicines was published on 19 February 2021 (EMA/425645/2020). It elaborates on operational, organisational, scientific and communication aspects for the implementation of CHMP scientific review (see dedicated webpage and updated questions & answers (Q&A) – EMA/409815/2020 Rev.2 – for additional information as well as specific Q&A for sartan medicines – EMA/86733/2021).

A Q&A on GMP requirements applicable to early manufacturing steps for comminuted plants and herbal extracts used as active substances was published on 5 February 2021 (EMA/INS/GMP/48514/202).

Guidance on quality data for PRIME MAAs

EMA has launched a public consultation until 31 July 2021 on a draft guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications (MAAs) (EMA/CHMP/BWP/QWP/IWG/694114/2019). Additional information can be found in a dedicated section of the PRIME webpage (Link).

Clinical guidelines

A product-specific bioequivalence guidance was released for public consultation for sorafenib (Link).

Clinical trials (CTs)

The European network of paediatric research at EMA (Enpr-EMA) published on 26 January 2021 a guidance on assent/ informed consent for paediatric CTs conducted in Europe (EU/EEA) (Link). The aim of this document is to provide an informed consent and assent overview tool, publicly available for all stakeholders, in order to support the design and conduct of high-quality ethical paediatric CTs in Europe.

Q&A on good clinical practice (GCP) was updated on the topic of GCP inspectors' authority to inspect trial participants' medical records and other data (Link).

A dedicated webpage on the Clinical Trials Information System (CTIS) training programme is now available (Link). The training material consists of eLearning courses, quick guides, infographics, short videos demonstrating CTIS functionalities, frequently asked questions (FAQs) and instructor guides to facilitate the future use of CTIS. The webpage will be regularly updated throughout 2021. It includes the SME and academia CTIS two-part training webinar – 22 February (Link) and 4 March 2021 (Link).

SPOR – EU IDMP Implementation Guide

EMA has published an update (version 2) of the EU Identification of Medicinal Products (IDMP) implementation guide (EU IG) (Link). The guide defines the implementation requirements of ISO IDMP standards and terminologies in the EU. It sets out high level principles of the target operating model for submitting, maintaining and exchanging medicinal product data and provides guidance on how to populate product management service (PMS) data elements.

Pharmacovigilance

New or updated guidance have been published:

- Pharmacovigilance fees Q&A updated on medicinal products authorised in the UK and calculation of chargeable units (Link).
- Q&A on signal management (EMA/261758/2013 Rev 4) updated on requirements for the submission of additional data.
- EudraVigilance User Manual for MAHs (EMA/167839/2016) including a new section on EVDAS outputs changes related to Brexit.
- EMA pharmacovigilance system manual (EMA/623550/2013) updated in light of EMA latest organisational structure.

A revised good pharmacovigilance practices (GVP) – Module XVI guideline and annex have been released for public consultation until 28 April 2021:

- 'Risk minimisation measures: selection of tools and effectiveness indicators' (EMA/204715/2012 Rev 3), updated on evaluation methodologies, educational material classification, communication, healthcare professionals and patients' engagement.
- Addendum II – Methods for effectiveness evaluation (EMA/419982/2019).
- Updated introductory cover note on GVP (EMA/54854/2021).

A revised list of important medical event (IME) terms was published on 18 March 2021 (MedDRA version 24.0). The list aims to facilitate the classification of suspected adverse reactions for pharmacovigilance activities in the EU. It was revised to consider the latest version of MedDRA and the ICH definition of seriousness and important medical event (EMA/126913/2021).

Regulatory guidance

The following documents have been updated:

- Dossier requirements for centrally authorised products (EMA/497021/2012 Rev. 26).
- Dossier requirements for nationally authorised products (NAPs) (referral, 'PASS107', workshare, signal detection procedures) and ancillary medicinal substances in a medical device (EMA/13015/2014 Rev.10).
- Pre-authorisation procedural guidance for generic/hybrid applications (EMEA/CHMP/225411/2006) on MAA legal basis.
- Pre-authorisation guidance (EMA/821278/2015) on topics including paediatric use marketing authorisation (PUMA) application, centralised procedure eligibility, product name, EEA batch release arrangements, product information and prescription status.
- Post-authorisation guidance (EMEA-H-19984/03 Rev. 90) on topics including type IA/IAIN-IB-II variations, pre-submission queries service, risk management plan (RMP), extension of indication, post-authorisation efficacy studies (PAES), labelling and package leaflet change – Article 61(3) notifications.
- Guidance on the application form for centralised type IA and IB variations (EMA/233564/2014-Rev. 3).
- IRIS guide for applicants (EMA/444925/2018) on new functionality to update the contact person assigned to a regulatory 'entitlement' (e.g. orphan designation) (Link); IRIS guide to registration (EMA/31242/2019) and Quick interactive guide to IRIS registration process (Link).
- Guidance on parallel consultation EMA/European Network for Health technology Assessment (EUnetHTA) (EMA/410962/2017 Rev 4.).
- Revised accelerated assessment (AA) request template updated to include enhanced guidance for sponsors (Link ; AA timetable for ATMPs).
- Q&A on EMA consultation procedure by notified bodies on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device (EMA/144066/2021 Rev. 1), on initial- and post-consultation as well as fee-related aspects. See dedicated webpage for additional information.

Product information (PI)

Updated PI-related guidance, templates and checklists have been published on 8 February 2021, including aspects related to personal data protection (see product information and linguistic review webpages).

EMA, NCAs and the European Commission (EC) have started an electronic PI (ePI) initiative. It aims at developing a common electronic standard for ePI, and will start with a proof-of-concept exercise which will be followed by an EU implementation roadmap. EMA will publish progress updates and details of stakeholder consultations with patients, healthcare professionals, academia and the pharmaceutical industry (Link).

Authenticity verification for electronic certificates

EMA launched an authenticity verification system for electronic certificates of medicinal products. The validity of an electronic certificated issued by EMA can be verified using the new online system. EMA's electronic system for issuing certificates permanently replaces the previous paper-based system as part of EMA's digitalisation strategy (Link).

Pilot phase for early CHMP engagement with patient/consumer organisations

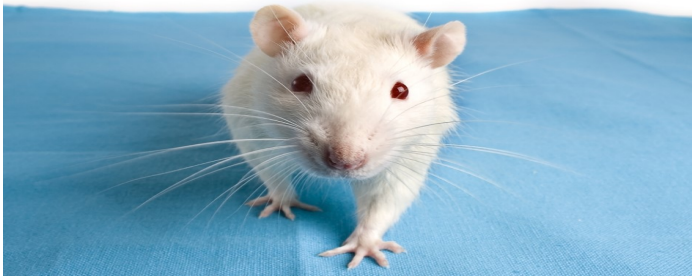
A new pilot project to enhance CHMP engagement with patient groups during the assessment of new medicines was published on 19 February 2021. The initiative aims to engage with patient organisations at the start of new MAAs evaluation (EMA/97615/20212021).

EMA publishes plain language description of medical terms

A manual of plain language descriptions for medical terms commonly used in medicines information ('EMA's medical terms simplifier') was published on 19 March 2021 (Link). The tool used by EMA's communications team to prepare documents about medicines for the public may be of interest to medicines communication professionals.

Pilot project 'Market launch of Centrally Authorised Medicinal Products'

From 25 March 2021 until August 2022, EMA will invite MA applicants for orphan medicines and cancer medicines to participate in a pilot project by making a declaration of market launch plans on a voluntary and confidential basis (see EC website and practical Q&A). The initiative aims to help regulators understand reasons behind delayed EU market launches of certain medicines.



Veterinary medicines

New veterinary medicines regulation (VMR)

The final access policy for the union product database (UPD) was released on 27 January 2021 (EMA/198149/2020-Corr). The document sets out the types of information different user groups will be allowed to access once the database becomes operational in 2022.

Draft guidance documents on the implementation of requirements of Regulation (EU) 2019/6 – the new VMR – for the UPD on veterinary medicinal products were published on 21 January 2021 for public consultation until end of March 2021:

- Introduction (EMA/536780/2020).
- Chapter 1: Registration and data access requirements for the User Interface and Application Programming Interface (EMA/562455/2020).
- Chapter 2: Format for the electronic submission of veterinary medicinal product information (EMA/106051/2020).
- Chapter 3: Process for the initial submission and maintenance of veterinary medicinal products information (EMA/590669/2020-Corr).
- Chapter 4: Process and format for the submission of legacy data on veterinary medicinal products (EMA/557461/2020).
- Chapter 5: Technical specifications (EMA/597691/2020).

A new draft QRD veterinary annotated PI template implementing the requirements of the VMR (EMA/176485/2021) was released for public consultation until 14 May 2021. Additional information can be found in the dedicated webpage (Link).

EMA is publishing a bimonthly newsletter including news and updates on the progress of the VMR implementation (Link). See also dedicated VMR webpage (Link).

To stimulate the development of innovative veterinary medicines for small markets, increase the availability of treatments for serious or life-threatening animal diseases and unmet veterinary medical needs, the VMR contains new legal provisions for veterinary medicines intended for minor use minor species (MUMS)/limited markets. The current classification in EMA's MUMS/limited market will cease to apply once the Regulation becomes applicable on 28 January 2022 (Link). Eligibility criteria and guidelines on reduced data requirements that will apply under the Regulation are available for public consultation until 15 May 2021:

- Classification of a product intended for a limited market and eligibility for authorisation under Article 23 of Regulation (EU) 2019/6 (Applications for limited markets) (Link).
- Safety and residue data requirements for the establishment of maximum residue limits in minor species (Link).
- Safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (Link).
- Data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (Link).
- Efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 (Link).

Scientific guidelines

EMA published on 13 January 2021 a reflection paper on dose review and adjustment of established veterinary antibiotics in the context of summary of product characteristics' (SPC) harmonisation (EMA/CVMP/849775/2017; Link). It outlines non-experimental approaches for dose review and adjustment, and evaluates impact on target animal safety, withdrawal periods, environmental risk assessment and user safety assessment.

A revised list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009 ('maximum residue limit (MRL) regulation'), with regards to residues of veterinary medicinal products in foodstuffs of animal origin was published on 3 February 2021 (EMA/CVMP/519714/2009Rev.48).

A dedicated section 'Biological substances not requiring an MRL evaluation' of the MRL webpage was updated on 1 March 2021 (Link). It includes information and timelines to submit a CVMP application to evaluate the need for an MRL assessment in case of 'chemical-unlike' biological substance.

EMA published several reflection papers on 1 March 2021 on:

- Use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the EU: development of resistance and impact on human and animal health (EMA/CVMP/AWP/842786/2015).
- Antimicrobial resistance (AMR) in the environment: considerations for current and future risk assessment of veterinary medicinal products (EMA/CVMP/ERA/632109/2014).

Regulatory guidance

EMA published a CVMP strategy on antimicrobials 2021-2025 on 2 February 2021 (EMA/CVMP/179874/2020). The document focuses on the implementation of VMR provisions that take account of EU's one health action plan against AMR. More information can be found in the dedicated AMR's webpage (Link).

Draft concept paper documents were released on 29 January 2021 for public consultation until end of March 2021 on:

- The development of a guideline on data requirements for the authorisation of immunological veterinary medicinal products under exceptional circumstances (EMA/CVMP/IWP/630533/2020).
- The development of a guideline on data requirements for vaccine antigen master files (VAMF) (EMA/CVMP/IWP/674640/2020).
- The development of a guideline on data requirements for vaccine platform technology master files (PTMF) (EMA/CVMP/IWP/582191/2020).
- The revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD) (EMA/CVMP/IWP/600275/2020).
- Requirements for field efficacy studies in support of MAAs for immunological veterinary medicinal products and indications for veterinary vaccines (EMA/CVMP/IWP/671155/2020).

The following documents have been updated:

- Dossier requirements for submission of MAA and MRL applications to EMA and CVMP members (EMA/466102/2007Rev.33).
- Veterinary pre-submission Q&A 1-20 (Link) on topics including centralised procedure eligibility.

COVID-19

EMA has extended free scientific advice incentives for COVID-19 treatments and vaccines to 15 September 2021 (Link).

The Agency published two guidance documents on:

- Labelling flexibilities for COVID-19 therapeutics (EMA/35618/2021).
- Reflection paper on regulatory requirements for vaccines intended to provide protection against variant strain(s) of SARS-CoV-2 (EMA/117973/2021).

Latest updates, guidance for companies (e.g. on research and development, assessment, marketing authorisation, pharmacovigilance), information on treatments and vaccines, medicines availability, public-health advice and transparency are regularly updated on EMA's dedicated webpage (Link).

Events of interest and Other news

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

- Workshop on the General Data Protection Regulation (GDPR) and secondary use of data for medicines and public health purposes – 29 September 2020 (Link).
- Meeting summary - PCWP/HCPWP meeting with all eligible organisations: COVID-19 pandemic update – 16 November 2020 (EMA/693425/2020).
- Workshop on support for orphan medicines development – 30 November 2020 (Link; Summary Report).
- 5th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines – 3 December 2020 (Link; Highlights report).
- EU big data stakeholder virtual forum – 15 December 2020 (Link; Summary Report).
- Annual report on EMA's interaction with industry stakeholders 2018-2019 – 21 January 2021 (EMA/17744/2021).
- Orphan Medicines Figures : 2000 – 2020 (Link).
- Orphan Medicines 2020 annual report (EMA/30719/2021).
- Industry Webinar: Introduction to OMS services and activities – 3 February 2021 (Video); Introduction to RMS services and activities – 4 February 2021 (Video).
- ICMRA Pregnancy and Lactation Workshop – 9 February 2021 (Summary Report).
- Enpr-EMA Coordinating Group and networks meeting – 2 March 2021 (Link).
- SME and academia CTIS two-part training webinar – 22 February (Link) and 4 March 2021 (Link).
- Real world research on medicines: contribution of the European Network of Centres in Pharmacoepidemiology and Pharmacovigilance (ENCePP) – 8 March 2021 (Link).
- 11th annual report on MUMS/limited market scheme for veterinary medicinal products – 11 March 2021 (EMA/553359/2020).
- Third public stakeholder meeting on approval, safety monitoring and impact of COVID-19 vaccines in the EU - 26 March 2021 (Link).

Upcoming events:

- Joint HMA/EMA workshop on artificial intelligence in medicines regulation – 19-20 April 2021 (Link).
- Data standards strategy workshop – 18 May 2021 (Link).
- Veterinary Big Data stakeholder forum – 01-02 June 2021 (Link).

UK's withdrawal from the EU

New and updated Brexit-related guidance for companies have been published: Q&As to stakeholders on the implementation of the Protocol on Ireland/Northern Ireland (EMA/520875/2020), impact of EU-UK trade and cooperation agreement (Link); EU-UK international collaboration on GMP inspections (Link). See also dedicated webpage on Brexit-related guidance (Link).

Registered SMEs

Currently, 1534 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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