



SME Office NEWSLETTER

Information for SMEs on the EU regulatory environment for medicines.
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Please subscribe [here](#) to receive future issues of the SME newsletter.

The SME newsletter is moving to a new platform – Newsroom, which is used by European institutions and agencies to create and disseminate information online. Newsroom is a user-friendly tool that allows more efficient subscriber management.

The next issue due in Q1 2024 will only be sent, via email, to readers who signed up and agreed to data privacy policy using the [link](#) provided.

Scientific guidelines for human medicines

Quality guidelines

A joint CHMP/CVMP ICH M7(R2) guideline on the assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals came into effect on 30 September 2023 ([EMA/CHMP/ICH/83812/2013](#)). The guidance provides a framework for the identification, categorisation, qualification, and control of such impurities to limit potential carcinogenic risk.

A joint CHMP/CVMP draft guideline on the development, manufacture and control of synthetic peptides was released for public consultation until 31 April 2024 ([EMA/CHMP/CVMP/QWP/387541/2023](#)). Synthetic peptides are at the interface of small molecules and proteins and from a quality point of view specific considerations apply to this class of medicines. The document provides guidance on characterisation, specifications and analytical control which are not covered in guidelines on the chemistry of active substances ([EMA/454576/2016](#); [EMA/CVMP/QWP/707366/2017](#)).

A new questions and answers (Q&A) document on biologic medicines has been published ([Link](#)). It provides clarifications on quality related topics encountered during the assessment of marketing authorisations applications of such products and covers topics such as process validation, host cell proteins testing, active substance specifications and biosimilarity.

A new section on remote batch certification/confirmation by the qualified person (QP) has been added to the Q&A on good manufacturing practice and good distribution practice ([Link](#)).

Clinical guidelines

A draft guideline on the clinical investigation of medicinal products for the treatment of major depressive disorder was released for public consultation until 31 March 2024 ([EMA/CHMP/185423/2010, Rev.3](#)). It was revised in light of experience with scientific advice, PRIME, marketing authorisations, clinical guidelines and the release of DSM-5 and [ICD-11](#). Methodological, efficacy and safety issues regarding special populations such as children and adolescents, young adults and older people are also addressed.



A Q&A on modelling and simulation ([Link](#)) was updated on a series of topics relating to model informed drug development approaches for pharmacokinetics and dose selection in neonates.

Multi-disciplinary guidelines

A draft joint reflection paper on the use of artificial intelligence in the lifecycle of human and veterinary medicines is open for a public consultation until 31 December 2023 ([EMA/CHMP/CVMP/83833/2023](#)). The paper provides considerations on the use of artificial intelligence in medicines development, authorisation and post-authorisation and elaborates on topics relating to technical, governance, data protection, integrity and ethical considerations.



Regulatory and procedural guidelines for human medicines

Guidance on parallel EMA/Health technology assessment (HTA) bodies scientific advice has been published ([EMA/250551/2023](#)). It sets out the support available to developers to discuss development plans and evidence generation to meet regulators and HTA bodies needs, until the HTA regulation becomes applicable in January 2025.

Guidance on how to plan, organise and execute effective PRIME-related meetings, such as pre-submission, 'kick-off' and submission readiness meetings has been published ([EMA/7874/2021](#)).

The following procedural guidance have been updated:

- Pre-authorisation procedural advice for users of the centralised procedure; on e.g. paediatric use marketing authorisations, eligibility, rapporteurs appointments, accelerated assessment, application submission and assessment, pre-submission interactions, withdrawal of planned application, data exclusivity/marketing

protection/market exclusivity, risk management plans ([Link](#)).

- Post-authorisation procedural advice for users of the centralised procedure; on e.g. Type IA, IB, II variation applications, variations work-sharing, line-extensions, pre-submission queries, post-authorisation safety studies, risk management plans, paediatric study submissions, Article 61(3) notifications ([Link](#)). For information about contact points in the post-authorisation phase, see [Link](#).
- Q&A on the consultation procedure to EMA by notified bodies on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device; on e.g. notification of submission ([Link](#)).

Clinical trials

A Q&A document on Good Clinical Practice ([Link](#)) has been released with new and revised sections on study subject data records, clinical trials service providers, productivity applications used in clinical trials, distribution of investigator's brochures and informed consent forms to clinical sites/investigators.

EMA has adopted revised transparency rules for the publication of information on clinical trials submitted through CTIS ([EMA/263067/2023](#)). The rules will apply after technical implementation in CTIS, including its public portal, which is expected in the second quarter of 2024. More information can be found in the [dedicated press release](#).

OPEN Initiative

The Opening Procedures at EMA to Non-EU authorities (OPEN) initiative was established in December 2020 as a pilot program to enhance global collaboration concerning COVID-19 vaccines and treatments ([Link](#)). It allows non-EU regulators to conduct near-concurrent reviews of certain new medicines and exchange views and reports on evaluations. This aims to help accelerate and align regulatory decisions in several regions in the world. The initiative has now been extended to a wider range of medicines, such as medicines with a potential to address antimicrobial resistance (AMR), respiratory syncytial virus (RSV) infections or newly diagnosed myelodysplastic syndromes (and other hereditary diseases). More information can be found in a [Q&A document](#) and the [dedicated press release](#).

Medicines shortages

Marketing authorisation holders for all authorised medicines in the EU are required to appoint a so-called industry single point of contact (i-SPOC) responsible to provide information directly to EMA about supply and availability of critical medicines identified in the context of a major event or a public health emergency. SMEs are advised to refer to the [IRIS user guide](#) and the [video](#) which provides details on the registration process.

Veterinary medicines

Scientific guidelines

A guideline on excipients in veterinary marketing authorisations applications came into effect on 13 July 2023 ([EMA/CVMP/QWP/307647/2023](#)). It was revised to align it with the Regulation (EU) 2019/6 (the veterinary medicines regulation).

A guideline on quality, safety and efficacy of bacteriophages as veterinary medicines came into effect on 13 October 2023 ([EMA/CVMP/NTWP/32862/2022](#)). It establishes quality, safety and efficacy requirements for initial marketing authorisation applications for phase therapy medicines as well as post-marketing authorisation changes.

A guideline on allergen products for use in horses, dogs and cats will come into effect on 13 January 2024 ([EMA/CVMP/IWP/170689/2016](#)). It lays down quality, safety and efficacy requirements for allergen products of biological origin, including allergen extracts derived from natural source material and allergens produced through recombinant DNA technology, used for immunotherapy treatment or in vivo diagnosis of immunoglobulin E (IgE)-mediated allergic diseases in horses, dogs and cats.

Guidelines on quality data requirements for applications of biological medicinal products intended for limited markets ([EMA/CVMP/IWP/228730/2022](#)) and medicinal products other than biologicals intended for limited markets ([EMA/CVMP/QWP/47285/2022](#)) will come into effect on 31 January 2024. The documents sets out which data flexibilities provided in Annex II of Regulation (EU) 2019/6 may be applied to marketing authorisation applications where scientifically justified for 'limited markets' products.

A draft guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6 ([EMA/CVMP/SWP/32027/2022](#)) is open for public consultation

until 31 January 2024. It sets out where adaptations within Annex II of Regulation (EU) 2019/6 may be acceptable provided that the data submitted in the dossier are sufficient to demonstrate the safety of a medicinal product.

A draft guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6 ([EMA/CVMP/IWP/224724/2022](#)) is open for public consultation until 31 January 2024. It defines acceptable data requirements for the demonstration of safety and efficacy of immunological veterinary medicinal products classified as limited markets.

A registration guide on the Union Product Database (UPD) has been published ([EMA/362250/2023](#)). The UPD serves as a single source of information on all authorised veterinary medicines and their availability in the European Union (EU) and European Economic Area (EEA).



Events of interest

Upcoming events

- Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) AI workshop – Smart regulation in a rapidly evolving world 20 – 21 November 2023 ([Link](#))
- EudraVigilance and Signal Management information day - 21 November 2023 ([Link](#))
- Strengthening life-sciences innovation across Europe: EU-Innovation Network conference - 21 November 2023 ([Link](#))
- Focus group on veterinary pharmacovigilance reporting in aquaculture - 22 November 2023 ([Link](#))

Awareness session for SMEs on the reform of the EU pharmaceutical legislation
24 November 2023 ([Link](#))

The EMA's SME office in collaboration with the European Commission is organising a webinar to raise awareness of the proposed changes that will mostly impact small and medium-sized enterprises (SMEs).



Newsletters and reports

- Clinical Trials Information System (CTIS) newsflash ([Link](#))
- Veterinary Medicines Highlights ([Link](#))
- Big Data Highlights ([Link](#))
- Clinical Trials Highlights ([Link](#))
- Infosheet on review of real-world data studies ([Link](#))
- Real-world evidence framework to support EU regulatory decision-making ([Link](#))

Past events

- European Medicines Agency / Emergency Task Force and European Commission workshop on lessons learned on clinical trials in public health emergencies ([Link](#)) (09/06/2023)
- ACT EU multi-stakeholder platform kick off workshop ([Link](#)) (22 – 23/06/2023)
- Multi-stakeholder workshop on Real World Data (RWD) quality and Real World Evidence (RWE) use ([Link](#)) (26 – 27/06/2023)
- Clinical Trials Information System Webinar: Second Year of Transition ([Link](#)) (04/07/2023)
- ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation ([Link](#)) (13 – 14/07/2023)
- EMA Veterinary Awareness Day ([Link](#)) (12/09/2023)
- Webinar on Regulatory Procedure Management for Product Lifecycle Management 1st roll-out on IRIS ([Link](#)) (15/09/2023)
- Shaping a European innovation ecosystem: EU-Innovation network multi-stakeholder meeting ([Link](#)) (26/09/2023)
- Focus group on veterinary pharmacovigilance reporting in poultry ([Link](#)) (11/10/2023)
- Clinical Trials Information System (CTIS): Information day ([Link](#)) (17/10/2023)
- Update on human variations web-based electronic application form implementation on product lifecycle management portal ([Link](#)) (06/11/2023)



Registered SMEs

Currently, 1892 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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