

SME Office NEWSLETTER

Information for SMEs on the EU regulatory environment for medicines.
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Scientific guidelines for human medicines

Non-clinical guidelines

A n ICH guideline S12 on nonclinical biodistribution considerations for gene therapy products will come into effect on 30 September 2023 ([EMA/CHMP/ICH/318372/2021](#)). It provides harmonised recommendations for the conduct of such studies to facilitate development of gene therapy medicinal products while avoiding unnecessary use of animals in accordance with the 3Rs (reduce/refine/replace) principles.

Clinical guidelines

A draft revised ICH guideline E6 (R3) on good clinical practice (GCP) for clinical trials of investigational products was released for public consultation until 26 September 2023 ([EMA/CHMP/ICH/135/1995](#)). It was revised to address innovative trial designs, advances in technologies used in clinical practice, diverse data sources and technology interoperability across the data life cycle, and align it with E8(R1) on 'General Considerations for Clinical Studies'. It also includes an annex which focuses on interventional clinical trials (see dedicated multi-stakeholder workshop [event webpage](#)).

A points to consider document on the management of ongoing clinical trials impacted by political conflicts, natural disasters or other major disruptions ([EMA/INS/GCP/622198/2022](#)) was published on 30 March 2023. It supplements the [CTCG recommendation to sponsors on managing the impact of the war in Ukraine on clinical trials](#),



the [points to consider on the impact of the war in Ukraine on methodological aspects of ongoing clinical trials](#), and the [guidance on the management of clinical trials during the Covid-19 \(coronavirus\) pandemic](#).

A revised guideline on the clinical investigation of medicinal products intended for the treatment or prevention of diabetes will come into effect in January 2024 ([CPMP/EWP/1080/00 Rev.2](#)). Revisions include an update of the safety section with respect to cardiovascular safety, guidance on estimands, requirements for monotherapy indications, studies in children, high strength insulin preparations, definitions of hypoglycaemia and the development of oral treatments for patients with type 1 diabetes.

A questions and answers document on good clinical practice (GCP) has been updated on service providers' subcontracted activities by sponsors, productivity applications in clinical trials and direct remote access of identifiable personal and health data ([Link](#)).

Regulatory and procedural guidelines for human medicines

EMA & CMDh's questions and answers document on nitrosamines in medicines was updated to include the carcinogenic potency categorisation approach (CPCA) and the enhanced Ames test (EAT) for establishing acceptable intake (AIs) for N-nitrosamines ([EMA/409815/2020 Rev.16](#)). For more information please refer to the [nitrosamine dedicated webpage](#).

A one-year pilot project on the use of electronic product information (ePI) has been launched. ePI refers to the product information for medicines (i.e. summary of product characteristics, package leaflet and labelling) adapted for handling in electronic format and dissemination via the web, e-platforms and in print. Information is available in the quarterly system 'demo' events accessible [here](#).

The following documents were updated:

- EMA pre-authorisation guidance (on e.g. dossier submissions, risk management plan, marketing authorisation withdrawal) ([EMA/821278/2015](#)).
- EMA post-authorisation guidance (on e.g. type 2 variation withdrawal, line-extension submission and withdrawal) ([EMA-H-19984/03 Rev. 103](#)).

Veterinary medicines

Regulatory and scientific guidelines

The European Commission (EC) issued on 28 March 2023 a decision based on CVMP recommendations on measures to reduce risks to human and animal health from exposure to N-methyl pyrrolidone in veterinary medicines ([EMA/131536/2023](#)). More information is available on the [dedicated press release](#).

The EC issued on 23 May 2023 an implementing Regulation (EU) 2023/997 amending Regulation (EU) 2021/17. It establishes a list of variations *not requiring* assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council' ([Link](#)) with guidance on requirements, conditions for each variation type. More information available on the [dedicated webpage](#). Guidance on variations *requiring assessment* according to Regulation (EU) 2019/6 is available under [Link](#).

EMA issued on 15 June 2023 scientific advice on antimicrobials reserved for the treatment of certain infections in humans and which cannot be authorised in veterinary medicines. The advice's objectives aim to help preserve efficacy of certain antimicrobials for humans and animals by promoting prudent antimicrobial use and reducing the risk from antimicrobial resistance ([Link](#)).

A guideline on the development and data requirements of potency assays for veterinary cell-based therapy products and links to clinical efficacy came into effect on 23 June 2023 ([EMA/CVMP/NTWP/179287/2022](#)). It sets out requirements to develop suitable potency assays linked to biological activity and clinical efficacy, and to detect quantitative and qualitative active ingredient changes due to manufacturing variability or changes upon stability.



A revised guidance '*VICH GL18(R2) impurities: residual solvents in new veterinary medicinal products, active substances and excipients - Revision 2*' will come into effect in April 2024 ([EMA/CVMP/VICH/502/1999](#)). It recommends acceptable amounts for residual solvents in pharmaceuticals for the safety of the target animal and of residues in products derived from treated food producing animals.

A draft guideline on reporting of antimicrobial sales and use in animals in the EU is open for public consultation until 31 July ([EMA/CVMP/882931/2022](#)). It outlines animal population data to be reported by Member States and adjustments for the calculation of population-adjusted volume of sales and of the use of antimicrobials.

Pharmacovigilance

Updates have been made in the EU Implementation Guide on veterinary medicines product data in the Union Product Database:

- Chapter 2 'Format for the electronic submission of veterinary medicinal product information' ([EMA/772581/2022](#)) on product information documents requirements and data on strength.
- Chapter 7 'Submission of other post-authorisation data information', section 2.1 Volume of Sales data fields and new annex (B) added on how to handle CSV files and configure 'date format' of workstation ([EMA/772580/2022](#)).

Clinical Data Publication (Policy 0070)

EMA will resume its policy for publication of clinical data ([Link](#)) included in marketing authorisation applications from September 2023. This will apply to products containing new active substances that receive an opinion (irrespective of outcome), with Covid-19 and other public health emergency clinical data publication continuing as currently done. Additional information can be found on a webpage for industry ([Link](#)) and a [dedicated webinar](#).

Accelerating Clinical trials in the EU (ACT EU)

The Accelerating Clinical Trials in the EU (ACT EU) initiative aims to develop the European Union (EU) as a competitive location for innovative clinical research. An EU multi-stakeholder platform is being established with a series of workshops where stakeholders involved in designing, regulating, performing and participating in clinical trials can identify scientific, methodological and technological advances to develop the clinical trials environment in the EU. A first workshop was held in June 2023 ([link](#) to event including videos).

PRIME

EMA requires medicines developers to use IRIS to apply for PRIME eligibility, transfer or withdraw an existing PRIME eligibility. Before carrying any activity on the IRIS platform for the first time, applicants are advised to complete a few registration steps described in the [IRIS guide to registration and RPIs](#). More information is available on a [dedicated IRIS website](#).

Scientific Advice pilot for high-risk medical devices

EMA is running a pilot project to enable the expert panels on medical devices managed by EMA to provide scientific advice for manufacturers of high-risk medical devices. In the first round of the project, six applications were selected and a second phase is being launched. EU-based manufacturers and authorised representatives are invited to apply [here](#).

Medicines shortages

EMA has published recommendations on good practices to ensure continuity in the supply of human medicines, prevent shortages and reduce their impact ([EMA/760980/2022](#)). The guidance describes the various stakeholders involved in the medicine supply chain, their responsibilities and roles in the prevention and management of medicine shortages. More information can be found in a dedicated [press release](#) and on [Availability of medicines webpage](#).



Events of interest

Upcoming events

- EMA Veterinary Awareness Day on 12-13 September 2023 ([Link](#)).
- Shaping a European innovation ecosystem: EU-Innovation network multi-stakeholder meeting on 26 September 2023 ([Link](#)).
- Clinical Trials Information System (CTIS) Information Day on 17 October 2023 ([Link](#)).

Past events

- HMA/EMA multi-stakeholder workshop on shortages on 01-02 March 2023 ([Link](#)).
- Listen-and-learn focus group meeting of the Quality Innovation Group on 13 March 2023 ([Link](#)).
- Second European Medicines Agency & MedTech Europe bilateral meeting on 11 April 2023 ([Link](#)).
- EMA multi-stakeholder workshop on qualification of novel methodologies on 17-18 April 2023 ([Link](#)).
- Fourth EMA and Association of the European Self-Medication Industry (AESGP) annual bilateral meeting on 18 April 2023 ([Link](#)).
- Focus group meeting on bacteriophages as veterinary medicines on 11 May 2023 ([Link](#)).
- Clinical Trials Information System Webinar: Second Year of Transition on 04 July 2023 ([Link](#)).



Reports

- EMA annual report 2022 ([Link](#); [Webpage](#); [Annexes](#)).
- Real-world evidence framework to support EU regulatory decision-making: report on experience gained with regulator-led studies ([Link](#)).
- Guide to information on human medicines evaluated by EMA ([Link](#); [Webpage](#)).



SME office annual report 2022

The annual report highlights achievements of the Agency's support to SMEs during the last year. The report also features key facts and figures of companies that registered as SMEs with EMA in 2022 ([Link](#)).

Registered SMEs

Currently, 1835 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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