

# SME Office NEWSLETTER

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

<a href="#">Scientific guidelines for human medicines</a>	1
<a href="#">Regulatory and procedural guidelines for human medicines</a>	2
<a href="#">Clinical trials guidelines</a>	2
<a href="#">Paediatric medicines</a>	2
<a href="#">Priority medicines (PRIME)</a>	3
<a href="#">Veterinary medicines</a>	3
<a href="#">Fees payable to the EMA</a>	4
<a href="#">Events and reports of interest</a>	4
<a href="#">Registered SMEs</a>	5
<a href="#">Contact details</a>	5

## Scientific guidelines for human medicines

### Quality guidelines

**A**n ICH guideline Q13 on continuous manufacturing of active substances and finished products will come into effect on 10 July 2023 ([EMA/CHMP/ICH/427817/2021](#)). It sets out scientific and regulatory considerations for the development, implementation, operation and lifecycle management of continuous manufacturing (CM), including clarifications on concepts such as 'state of control' and 'process dynamics'. The guideline applies to chemical entities, therapeutic proteins, new and generic medicines, biosimilars and conversion of batch manufacturing to CM for existing products and may also apply to other biological/biotechnological products.

A revised ICH guideline Q9(R1) on quality risk management (QRM) will come into effect on 26 July 2023 ([EMA/CHMP/ICH/24235/2006](#)). It covers QRM principles and process, risk management methodology, integration of QRM into industry and regulatory operations, includes a new section on managing subjectivity and annexes on methods and tools and potential QRM applications.

### Clinical guidelines

**A** revised guideline on the clinical evaluation of new vaccines intended for the prevention of infectious diseases ([EMA/CHMP/VWP/164653/05 Rev. 1](#)) will come into effect on 1 August 2023. It merges guidelines on the clinical evaluation of new vaccines ([EMA/CHMP/VWP/164653/2005](#)) and on adjuvants in vaccines for human use ([EMA/CHMP/](#)

[VEG/134716/2004](#)). The guideline includes revisions on topics such as vaccine efficacy and safety evaluation, effectiveness data, disease and patient-related factors for comparative immunogenicity trials and other topics arising from recent vaccine developments and approvals.

A paediatric addendum to guidelines on the clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease will come into effect on 1 August 2023 ([EMA/CHMP/20507/2023](#)). It provides guidance on endpoints and imaging techniques according to venous thromboembolism localisation, clinical trials methodologies, and efficacy and safety adults data extrapolation.

A draft EMA reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation was released for consultation until 30 September 2023. It includes definitions of key concepts and provide guidance on the choice of endpoints, the target and trial population, the role of external information, statistical principles, and sources of bias and potential mitigation ([EMA/CHMP/564424/2021](#)).

### Multidisciplinary guidelines

**A** draft ICH guideline M13A on bioequivalence for immediate-release (IR) solid oral dosage forms was released for consultation until 26 May 2023 ([EMA/CHMP/ICH953493/2022](#)). It provides scientific and technical recommendations for study designs to support bioequivalence assessments on topics including study population, sample size, comparator and test products, fasting and fed conditions, single- and multiple-doses studies.

## Regulatory and procedural guidelines for human medicines

As from 16 January 2023, EMA is implementing for electronic certificates of medicinal products the new WHO certificate template under the World Health Organization certification scheme. Further information and detailed procedural guidance can be found on a dedicated webpage ([Link](#)).

A Q&A document on the joint EMA-HMA statement on interchangeability of biosimilar medicinal products approved in the EU ([EMA/627319/2022](#)) was released on 20 January 2023 ([Link](#)). It addresses questions relating to interchangeability and switching.

A statement on the amended policy on orphan designations for inherited retinal dystrophies was published on 24 January 2023 ([Link](#)). It sets out a new approach for designating conditions depending on the orphan condition and type of therapy.

A Q&A document clarifying regulatory requirements of cannabis-derived medicinal products and the scope of EU herbal monographs for herbal medicinal products within the EU medicines legislation was published on 25 January 2023 ([EMA/HMPC/176770/2022](#)).

A pilot project to support academic and non-profit organisations developing advanced therapy medicinal products was launched in September 2022. Guidance including, an application form and Q&A document ([EMA/797476/2022](#)) were released in January 2023. For more information, please refer to [EMA's dedicated webpage](#) and a dedicated webinar ([Link](#)).

A Q&A document on the raw data proof-of-concept pilot was published on 7 March ([EMA/658116/2022](#)). It includes details on the scope, terms of participation and data submission process. For further information see also 'Information about the raw data proof-of-concept pilot for industry' ([EMA/174598/2022](#)).

## Clinical trials

Guidance on the management of ongoing clinical trials impacted by political conflicts, natural disasters or other major disruptions was released on 30 March 2023 ([Link](#)). It aims to help sponsors address challenges, mitigate risks to the rights, safety, dignity, and well-being of trial participants which may impact on the scientific value of clinical trials.

A guideline on computerised systems and electronic data in clinical trials will come into effect on 9 September 2023 ([EMA/INS/GCP/112288/2023](#)). It includes general principles, definitions of key concepts, requirements and elaborates on expectations for computerised systems including validation, user management, security, and electronic data for the data life cycle. The document supersedes the previous 'Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials' ([EMA/INS/GCP/454280/2010](#)).

A Q&A document on the protection of commercially confidential information and personal data in Clinical Trial Information System CTIS ([EMA/898965/2022](#)) was released on 27 March 2023. It addresses a number of questions related to the transparency aspects of CTIS.



## Paediatric medicines

A closing report on EMA-European Commission paediatrics action plan ([EMA/635567/2022](#)) was published on 6 February 2023. It highlights the main achievements of the plan on a series of topic areas, one which relates to improving the handling of PIP applications. As a deliverable a new framework that allows for changes to be made to PIPs as more evidence becomes available over time has been launched. A stepwise PIP will allow in selected cases to leave some elements of an initially agreed PIP open to further

amendments conditional on a full PIP developed once more evidence becomes available. More information on the pilot project is available in a guidance ([EMA/768685/2022](#)).

## PRiority MEDicines (PRIME)

EMA's PRiority MEDicines (PRIME) scheme was set up in March 2016 to provide early and enhanced scientific and regulatory support to medicines that have the potential to significantly address patients' unmet medical needs. EMA published a five-year analysis of the scheme ([Link](#), [press release](#)) which includes recommendations and new measures to strengthen PRIME as follows:

- Expedited follow-up scientific advice with shortened timelines;
- New regulatory roadmap and product development tracker to facilitate continuous dialogue between regulators and developers ([Link](#));
- Submission readiness meetings to discuss development programmes, marketing authorisation applications (MAA) plans and accelerated assessments ([Link](#));
- Pre-submission support and virtual pre-submission meeting for all applicants.

Guidance for applicants has been updated to reflect these changes ([EMA/191104/2015](#)). More information can be found in the dedicated [press release](#).

A draft multidisciplinary guideline on veterinary medicinal products specifically designed for phage therapy was released for public consultation until 31 May 2023 ([EMA/CVMP/NTWP/32862/2022](#)). It sets out quality, safety, and efficacy requirements applicable to bacteriophages-based products for prophylactic, metaphylactic and/or therapeutic treatment of specific infectious diseases caused by bacteria or dysbiotic conditions.

A draft multidisciplinary guideline on plasmid DNA vaccines for veterinary use was released for public consultation until 23 June 2023 ([EMA/CVMP/IWP/365817/2022](#)). It sets out quality, safety and efficacy requirements for vaccines consisting of bacterial or synthetic DNA plasmid(s). This guideline replaces the 'Note for guidance: DNA vaccines non-amplifiable in eukaryotic cell for veterinary use' ([CVMP/IWP/07/98-FINAL](#)).

A draft annex to guidance on quality data requirements for veterinary medicinal products that are administered in drinking water of animals, was released for public consultation until 30 June 2023 ([EMA/CVMP/QWP/592906/2022](#)). The annex provides guidance on compatibility studies between veterinary medicinal products and biocidal products.

A Q&A document ([EMA/CVMP/SWP/32272/2022](#)) on the guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products ([EMA/CVMP/SWP/377245/2016](#)) was published. It includes an extensive list of clarifications on topics such as the scope of the guideline, terminologies, impurity limits calculations, interpretation of results.

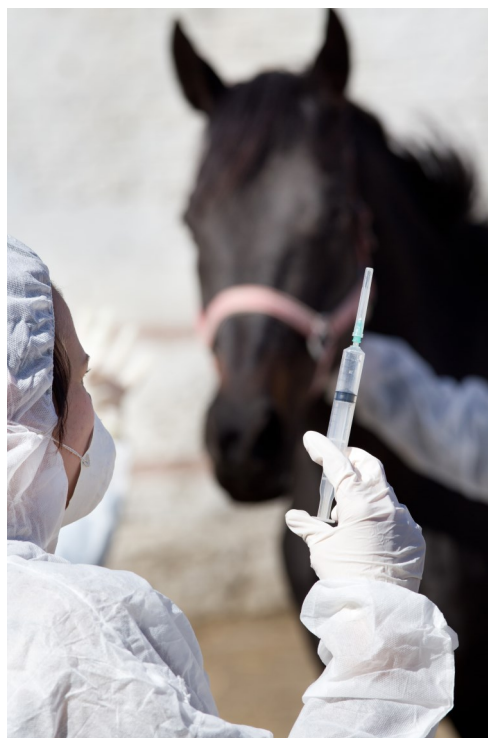
## Veterinary medicines

### Scientific guidelines

A guideline on the application of Article 34 of Regulation (EU) 2019/6 (the veterinary medicinal products regulation) came into effect on 27 January 2023 ([EMA/CVMP/273040/2022](#)). It elaborates on the scientific criteria within the various provisions of Article 34 to enable a consistent decision-making process for initial marketing authorisation applications as well as for variations to change the prescription status of a veterinary medicinal product.

The following guidance documents came into effect on 17 February (revised to align with Regulation (EU) 2019/6):

- Chemistry of active substances for veterinary medicinal products ([EMA/CVMP/QWP/707366/2017-Rev.1](#));
- Chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances ([EMA/CVMP/QWP/3629/2016-Rev.1](#)).



## Regulatory and procedural guidelines

**P**rocedural advice for vaccine platform technology master file certification was published on 27 January 2023. The document provides advice to marketing authorisation applicants and marketing authorisation holders (MAHs) on issues associated with the submission, evaluation, certification and use of a veterinary vaccine platform technology master file ([EMA/CVMP/184591/2022](#)).

The following guidance documents were updated:

- Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regards to residues of veterinary medicinal products in foodstuffs of animal origin ([EMA/CVMP/519714/2009-Rev.57](#));
- Guidance on changing the (invented) name of a veterinary medicine; revised on name checking procedure application and process ([Link](#));
- EVVet3 EVWeb Production release notes ([Link](#)); EVVET - EVWEB user manual ([Link](#)); revised following changes in DWH system with regards to new IRIS line listing (list of signals) and 'All cases' and 'New cases' filters;
- Q&A document on adverse events description in the product information ([Link](#)); revised to align with QRDv9 template.

- Pilot project for expert panels' scientific advice to manufacturers of high-risk medical devices (25/01/2023) ([Link](#)).
- EIC / EMA Info Day: Regulatory support for the development of innovative medicines and technologies (31/01/2023) ([Link](#)).
- Regulatory and scientific virtual conference on RNA-based medicines (03/02/2023) ([Link](#); [Media briefing](#))
- Fifth EMA-EFPIA annual bilateral meeting (07/02/2023) ([Link](#))
- EMA veterinary medicines info day 2023 (16/02/2023-17/02/2023) ([Link](#))
- 2022 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission (03/2023) ([Link](#))
- Fourth Industry Standing Group (ISG) meeting (21/03/2023) ([Link](#))
- EMA multistakeholder workshop on qualification of novel methodologies (17/04/2023-18/04/2023) ([Link](#))
- Union Product Database – Volume of sales webinar for UPD industry users (24/04/2023) ([Link](#))
- Information about all EMA events can be found on a dedicated webpage ([Link](#)).

## Fees payable to the EMA

**A**djusted fees for human and veterinary applications, except for pharmacovigilance procedures came into effect on 1 April 2023 (see Explanatory note on general fees payable to the European Medicines Agency; [Link](#)).



## Presentations, videos and reports of events

- Second Veterinary Big Data stakeholder forum (23/11/2022) ([Link](#))
- Ninth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines (24/11/2022) ([Link](#))
- EFSA report (European Food Safety Authority) on development of a harmonized approach to assess dietary exposure to residues of veterinary medicines, feed additives, and pesticides in food of animal origin in the EU (12/2022) ([Link](#)).
- Ninth meeting of industry stakeholder platform on research and development support (05/12/2022) ([Link](#))
- Big Data Steering Group (BDSG) 2022 report (01/2023) ([Link](#))

## Registered SMEs

Currently, 1770 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 \(veterinary medicines\)](#)

### Contact the SME Office

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