EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Support and assistance offered by EMA to veterinary academic stakeholders

EMA Veterinary Awareness Day

Presented by Valentin Nicorescu on 13 September 2023
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Agency tools available for veterinary academic stakeholders

Support and assistance

1. Innovation Task Force (ITF) briefing meetings
2. Scientific guidance for veterinary medicines
3. Scientific Advice procedures
4. Support to small and medium-sized enterprises (SMEs)

Information and communication

1. Newsletters
2. EMA website
3. Social media

1 Support and assistance offered by EMA to veterinary academic stakeholders

Support and assistance

Fostering research and innovation

A strategic goal

- One of EMA's strategic goals is ***to foster research and the uptake of innovative methods in the development of human and veterinary medicines***.
- The Agency supports the development of innovative methodologies by fostering collaboration across the regulatory network and with academia.

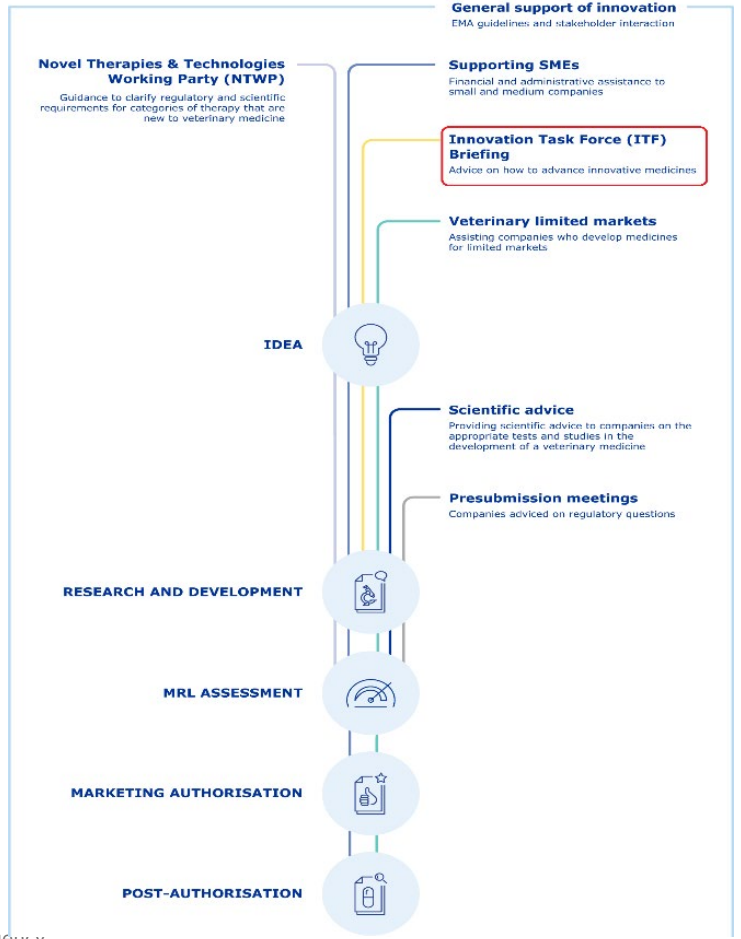
1. Innovation Task Force (ITF)

- ITF is a multidisciplinary group that includes scientific, regulatory and legal competences, set up to ensure coordination across the Agency.

- Two-fold objectives:
  - i. clarify aspects regarding the road to market of innovative medicines
  - ii. ensure EMA awareness and preparedness for assessment of the most recent developments in innovative medicine

ITF briefing meetings

- Forum for *early* dialogue on medicines innovation, **very early** in the product development.
- Cover issues arising from innovative medicines development, new technologies and borderline products.
- Informal exchange of information and guidance in the development process.
- Attended by experts from the Agency network, scientific committees (CVMP) and working parties (e.g. NTWP).
- Free of charge.



ITF briefings

How to request a meeting

Request → **Review** → Submission → **Early interaction**

- A request form to be completed and sent via ITFvet@ema.europa.eu
- EMA reviews the form and advises applicants on how to proceed
- Applicants prepare submission via a dedicated platform
- A meeting takes place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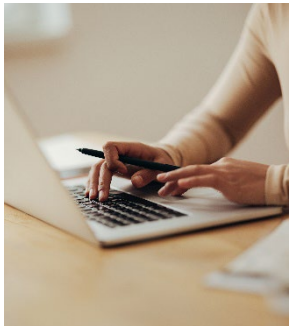
Request for early interaction on innovative developments
Innovation Task Force Briefing Meeting (ITF BM) request form



Detailed information in the step-by-step guide and here.

2. Scientific guidance for veterinary medicines

- Designed to help applicants **prepare their marketing authorisation applications** for veterinary medicines (VMPs).
- Applicants and marketing authorisation holders are strongly encouraged to **follow scientific guidelines** while developing VMPs.
- Scientific guidelines for veterinary medicines available for different sections: quality, safety and residues, efficacy, antimicrobials, immunologicals, novel therapies.
- Stakeholders are encouraged to comment on the draft guidelines during the **public consultation,** as it ensures that their opinion and scientific input are captured and good quality documents can be made available.

Scientific guidance for veterinary medicines

Public consultation

- Concept papers, reflection papers, scientific guidelines
- Draft guidance documents are published on EMA website
- Stakeholders are invited to review these documents and provide their general and specific comments in a specified timeframe – **public consultation**
- Stakeholders' comments are considered when the final version of the document is prepared
- An 'Overview of comments' document is also prepared and published, where feedback is given to all comments received

Data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats - Scientific guideline

Table of contents

- Current version
- Document history - First version

This guideline provides recommendations for the design and conduct of studies to support the efficacy of veterinary medicinal products (VMPs) intended for the reduction of the risk of transmission of vector-borne pathogens (VBPs) in dogs and cats, which can be transferred by blood-feeding arthropods. The guideline outlines the requirements for pre-clinical studies and clinical trials.

Keywords: Vector-borne disease (VBD), vector-borne pathogen (VBP), blood-feeding arthropods, reduction of the risk of transmission of VBPs, efficacy, veterinary medicinal product (VMP), ectoparasiticides, repellent effect, dog, cat

Current version

Guideline on data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats (PDF/422.33 KB)
Adopted
First published: 24/06/2022
Legal effective date: 01/01/2023
EMA/CVMP/EWP/278031/2015

Overview of comments received on the 'Guideline on data requirements for veterinary medicinal products for the prevention of transmission of vector-borne diseases in dogs and cats' (EMA/CVMP/EWP/278031/2015) (PDF/364.95 KB)
First published: 24/06/2022
EMA/CVMP/EWP/552708/2018

Document history - First version

Draft guideline on data requirements for veterinary medicinal products for the prevention of transmission of vector- borne diseases in dogs and cats (PDF/181.1 KB)
Draft: consultation closed
First published: 27/07/2018
Last updated: 27/07/2018
Consultation dates: 27/07/2018 to 31/08/2019
EMA/CVMP/EWP/278031/2015

Concept paper for a guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases (PDF/81.29 KB)
Draft: consultation closed
First published: 18/11/2014
Last updated: 18/11/2014
Consultation dates: 18/11/2014 to 28/02/2015
EMA/CVMP/EWP/309734/2014

More information on scientific guidelines: here

3. Scientific Advice procedures

- EMA can provide scientific advice on the appropriate tests and studies to be conducted in the development of a VMP.
- Available to applicants including commercial enterprises, but **also research organisations and academics**.
- Scientific advice can be requested at any stage.
- For veterinary medicines, scientific advice is given by the CVMP on the recommendation of the Scientific Advice Working Party (SAWP-V).

Scientific Advice procedures

How it works

- The applicant poses specific questions on the development of a VMP.
  - *Questions should be clear as possible and address quality, safety and efficacy issues*.
- The applicant presents the VMP development plan and identifies possible solutions.

- CVMP gives advice on the developer's proposals.

Scientific advice from EMA is not legally binding on EMA or on the medicine developer.

- Guidance for applicants requesting scientific advice
- Request for scientific advice form
- More information: here

4. Small and medium-sized enterprises (SMEs)

- SMEs are considered an important source of innovation and development of new medicines.
- EMA provides incentives and support for SMEs developing medicines for human or veterinary use.

- The **EMA's SME office** provides advice, guidance and assistance to SMEs to help to find their way through the centralised authorisation procedure.
- SME briefing meetings possible; questions on regulations, administrative requirements or procedures can be addressed.

Agency’s support to SMEs

- Enterprises should have **SME status assigned** by EMA.
- Once the SME status has been granted, the company is included in **EMA's public SME register**.

- The support for SMEs includes:
  - **fee exemptions** and **reductions** for regulatory procedures.
  - **translation assistance**.

More information can be found in the EMA's SME user guide.
Guidance on applying for SME status and financial advantages for SMEs is also available.

Information and communication

1. Newsletters

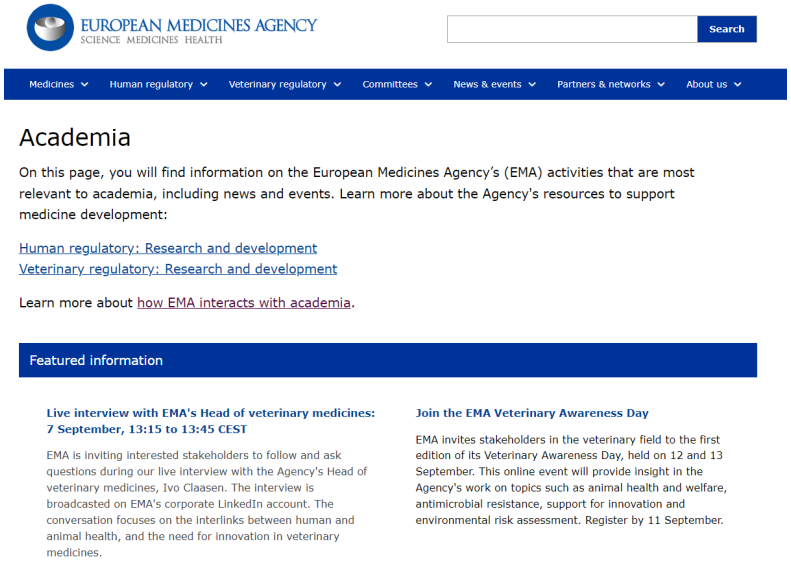
Veterinary Medicines Highlights:

- published quarterly;
- focuses on news, activities and interviews from the Veterinary Medicines Division of the EMA.

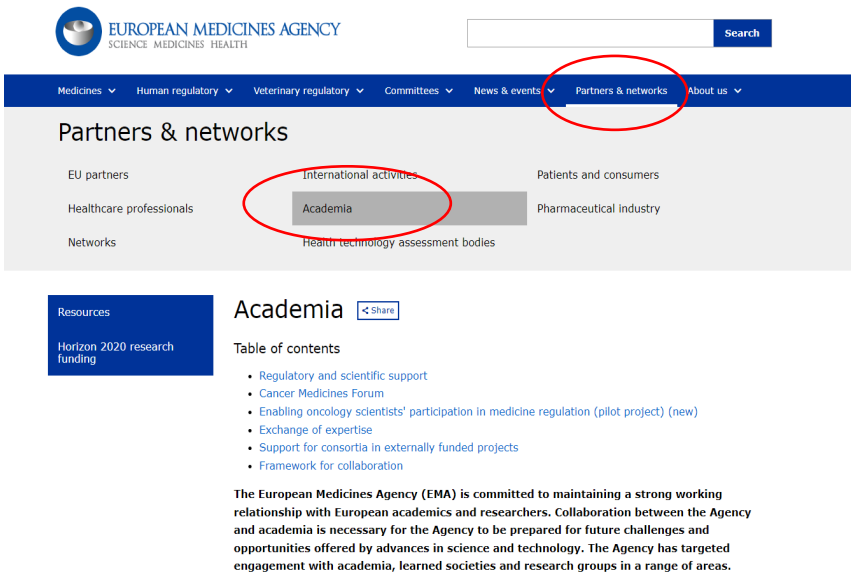
SME Office Newsletter:

- news and guidance of relevance to SMEs and their stakeholders;
- developments in EU regulations and regulatory environment;
- events and training opportunities.

2. EMA's corporate website - www.ema.europa.eu



Academia news page



Academia dedicated landing page

3. LinkedIn, X, YouTube

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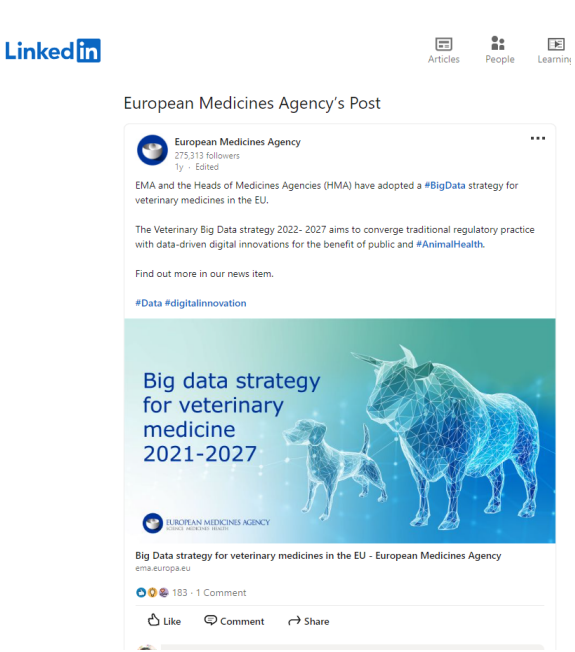

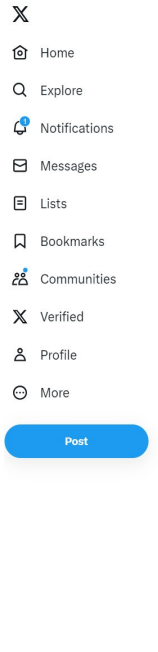

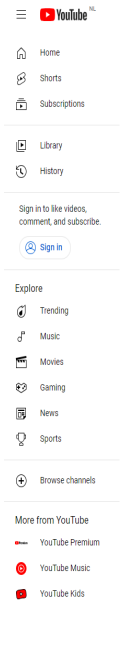

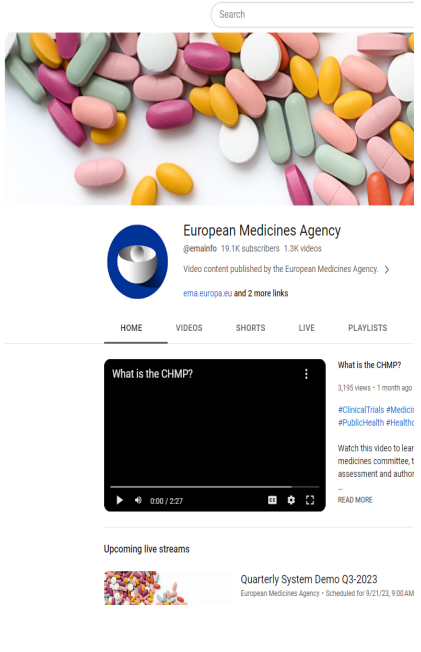

Any questions?

Further information

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