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Regulatory landscape of VMPs in Europe and the role of EMA

DISCONTOOLS meeting
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What does this presentation include

- Introduction to the regulatory framework
- The role of EMA and the centralised procedure
- Specific types of MAs
- Available support to developers

Why is this information relevant for you

DISCONTOOLS identifies gaps in knowledge to speed up the development of disease control tools;

- aimed to reduce the burden of animal diseases, delivering benefits for animal health and welfare, public health, and food security.

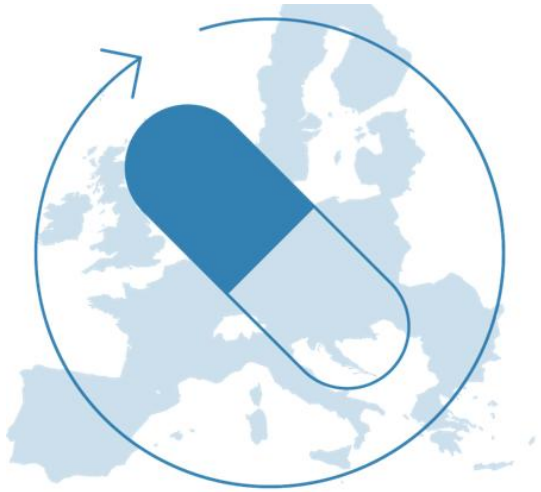
- Gaps for the development and authorisation of a product is not only about science, but also regulatory.
- Understanding the authorisation requirements can help researchers and developers to design studies that are fit for regulatory purposes from the outset.
- Closing the regulatory gap between development and authorisation is a shared goal.

EMA and DISCONTOOLS share a common goal: getting effective products to market.

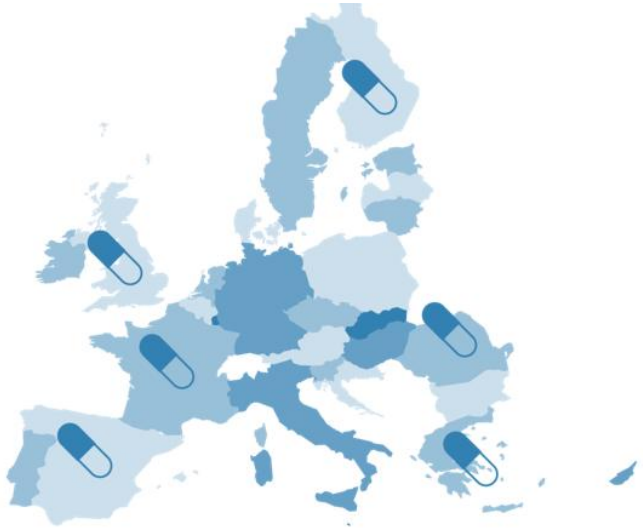
Current regulatory landscape: Regulation (EU) 2019/6

The Veterinary Medicines **Regulation (EU) 2019/6** provides incentives to stimulate innovation and increase the availability of veterinary medicinal products.

- Definition of different types of products: biologicals other than immunologicals (e.g. stem cells, phages), immunologicals and products other than biologicals (e.g. pharmaceuticals).



Centralised procedure (via EMA)

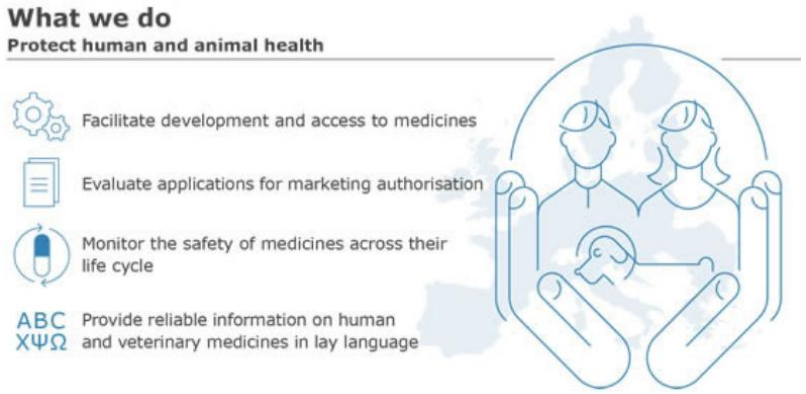


National procedures (via Member States)

European Medicines Agency (EMA)

Centralised authorisations:

- Issued by European Commission
- Assessment lead by EMA
- Committee of Veterinary Medicinal Products (CVMP): scientific opinion
- European Commission grants the marketing authorisation
- Validity through Europe
- Network of 27 national competent authorities (plus 3 non-EU)
  - ➢ Vaccine use is nationally controlled



The CVMP, working parties and groups

CMDv
Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products

Safety

3Rs*

*Joint CVMP/CHMP

Efficacy

Quality*

Immunologicals

Antimicrobials

Committee for Veterinary Medicinal Products (CVMP)

Scientific Advice

Pharmacovigilance

Environmental Risk Assessment

Novel Therapies and Technologies

European Sales and Use of Antimicrobials for Veterinary Medicines

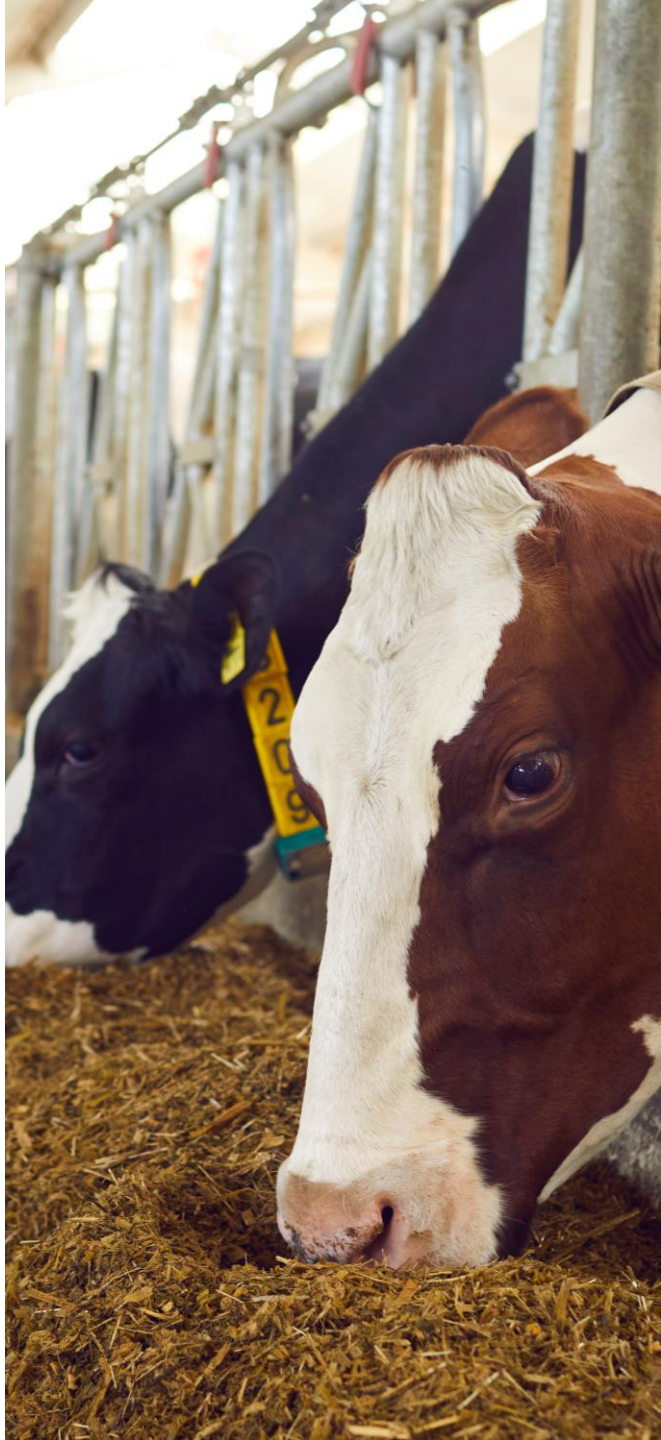
EMA

Scopes for the centralised route

- **Compulsory**:
  - VMPs involving biotechnological processes
  - Growth promoters
  - VMPs containing new active substances
  - Biological VMPs containing/consisting of engineered allogeneic tissues or cells
  - Novel therapy VMPs
- **Optional**:
  - VMPs for which a marketing authorisation has not been granted within EU.

Specific types of Marketing Authorisations

- Applications for authorisation in Exceptional Circumstances
- Applications for authorisation for Limited Markets
- Applications for Vaccine Antigen Master File
- Applications for Vaccine Platform Technology
- Applications for Multistrain dossier
- Applications for novel therapies/(novel technologies)



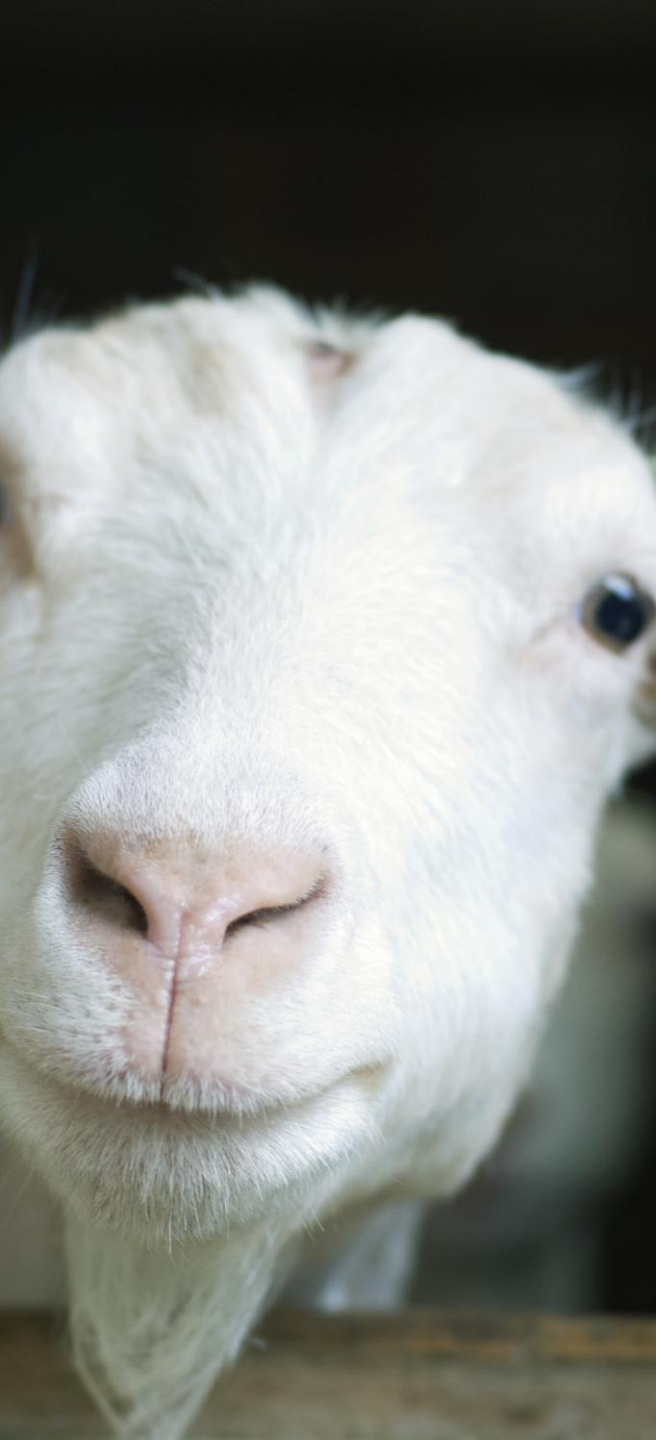
Applications for authorisation in Exceptional Circumstances (Art 25)

- Justification that immediate availability on the market outweighs the risk of lack of certain documentation (positive B-R balance).
- Eligibility to be confirmed by CVMP).
- Certain data on quality, safety and efficacy can be missing at the time of submission.
- Authorisation subject to specific obligations, conditions and/or restrictions (e.g. conduct of post-authorisation studies).
- CVMP guideline on data requirements for authorisation of IVMPs under exceptional circumstances revised and published.

Examples: from submission to opinion

Disease	Vaccine	Submission date	CVMP opinion date
BTV-3	Bluevac 3	30 September 2024	15 January 2025
BTV-3	Syvazul BTV-3	1 October 2024	15 January 2025
Avian influenza	Vectormune HVT AIV	28 February 2023*	12 February 2025
EHD	Hepizovac	29 November 2024	13 March 2025
Avian influenza	Vaxxitek HVT+IBD+H5	27 June 2025	9 October 2025
Avian influenza	Vaxxinact H5	17 July 2025	6 November 2025
EHD	EHD vaccine	27 June 2025	4 December 2025

3.5 months on average



Applications for authorisation for Limited Markets (Art 23)

- MA may be granted in the absence of comprehensive safety and/or efficacy data when the product is intended for use in a limited market.
- The benefit of availability of the new product outweighs the risk associated with the omission of some of the safety or efficacy data.
- Limited market means a market for one of the following medicinal product types:
  - veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;
  - veterinary medicinal products for animal species other than cattle, sheep for meat production, pigs, chickens, dogs and cats.

Applications for Multistrain dossier

- Single dossier containing data for an assessment of the different options of strains/combinations of strains.
- Scope widened to all inactivated vaccines against antigenically variable viruses or bacteria for which rapid or frequent change in the strains in the final product is needed to ensure efficacy in regard to the epidemiological situation in the field.

➢ Each dossier applicable only to one virus species, bacteria genus or vector.

➢ Eligibility for the multi-strain dossier will be confirmed by the Agency before submission of the application.

➢ Existing guideline on data requirements has been revised and published.

Available support to developers and applicants (EMA/CVMP)

- Early enquiries (AskEMA)
- Micro-, small- and medium-sized enterprise (SME) office and incentives
- Innovation Task Force (ITF)
- Limited markets provision (LMs)
- Scientific Advice (CVMP SAWP-V)
- Pre-submission meetings
- Guidance and guidelines on EMA website on procedural, regulatory and scientific issues
- Novel Therapies and Technologies Working Party (NTWP)
- IWP (Immunologicals Working Party)

ITF briefing meetings

The ITF holds briefing meetings with applicants covering regulatory, technical and scientific issues arising from the development of innovative medicines, new technologies and borderline products.

- Intended to facilitate the informal exchange of information and the provision of guidance early in the development process.
- Experts from the Agency's network, working parties and committees, with the best available scientific expertise being represented.
- Are intended to complement and reinforce existing formal regulatory procedures.
- Within 60 days of receipt of a valid request from an applicant.
- Free of charge.
- ITF briefing meetings in veterinary medicines were initiated 2014.

Scientific Advice (CVMP SAWP-V)

- Scientific advice may be requested for all veterinary medicinal products.
- A 60-90d procedure after validation.
- It may also be requested regarding the establishment of maximum residue limits (MRLs).
- SA should be requested during the initial development of the veterinary medicinal product.

➢ Can be requested also during the evaluation phase (not common)

- The question(s) should be as precise and clear and should address specific scientific issues concerning quality, safety, efficacy, MRLs.

Main take aways

- EMA is the centralised body coordinating the scientific assessment of dossiers for veterinary medicines.
- Different pathways for authorisation of medicines in EU

(scope is important).

- Specific types of MAs can facilitate the authorisation process (different requirements).
- Specific tools can be used for the authorisation of vaccines

(VAMF, vPTMF, multistrain dossier).

- There is some flexibility for emerging threats and potentially novel technologies.
- Early engagement with regulators is highly recommended.
- Support available to facilitate interaction from an early stage.

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Thank you for your attention!

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