EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Veterinary Awareness Day

September 2023

European Medicines Agency, Amsterdam

Availability of VMPs

Promoting the authorisation of alternatives to antimicrobials

Dr Noemi Garcia del Blanco
Head of Veterinary Biologicals and Emerging Therapies
Evaluation and Innovation, Veterinary Medicines Division

Road map

- Promoting the authorisation of alternatives to antimicrobials Veterinary Medicinal Products (VMPs)
- Opportunities created by the current Regulation
- International cooperation
- Existing support to developers and applicants
- Challenges presented to the authorisation of alternatives
- Moving forward

1 Availability of Veterinary Medicinal Products - September 2023

Promoting the authorisation of alternatives to antimicrobials VMPs

Why is it important?

Support the development and authorisation of VMPs which provide an alternative treatment approach to the use of antimicrobials in animals, or that reduces the need for the use of antimicrobials by preventing or controlling infectious diseases:

- VMPs that can be used as substitute treatment to antimicrobials for the treatment of infectious disease (e.g., bacteriophages)
- VMPs that are not a substitute treatment, but could help reducing the need for antimicrobial use, by acting in a preventive targeted way (e.g., vaccines)

Promoting the authorisation of alternatives to antimicrobials VMPs **How?**

Recognising the importance of alternatives and adopting a pro-active approach to promote their authorisation:

- Considering the provisions in the new Regulation (EU) 2019/6 that are applicable and ensuring that the necessary guidance is in place for authorisation of those categories
- Promoting international cooperation and exchange of information with other regulatory regions to assist global development of alternatives and to align the approach to authorisation where possible
- Providing advice and support to developers and applicants seeking to authorise alternatives within the EU.

New regulatory landscape: Regulation (EU) 2019/6

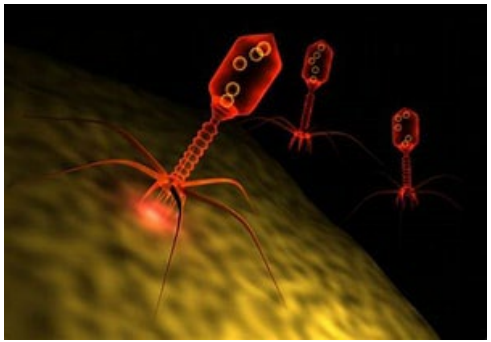
The Veterinary Medicines Regulation (EU) 2019 provides incentives to stimulate innovation and increase the availability of veterinary medicinal products

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

Applications for authorisation for Limited Markets

- A marketing authorisation may be granted for a limited market in the absence of comprehensive safety and/or efficacy data when the applicant can demonstrate that the product is intended for use in a limited market and that 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 novel therapies



Novel therapies can fall under:

- Products other than biologicals (pharmaceuticals)
- Biologicals
- Immunologicals

➢ Deviations from the requirements in the annex may be possible when scientifically justified (or additional requirements may be relevant for particular types of products).

➢ To address data gaps or uncertainties at the time of product authorisation, implementation of post-authorisation measures or studies may be considered on a case-by-case basis.

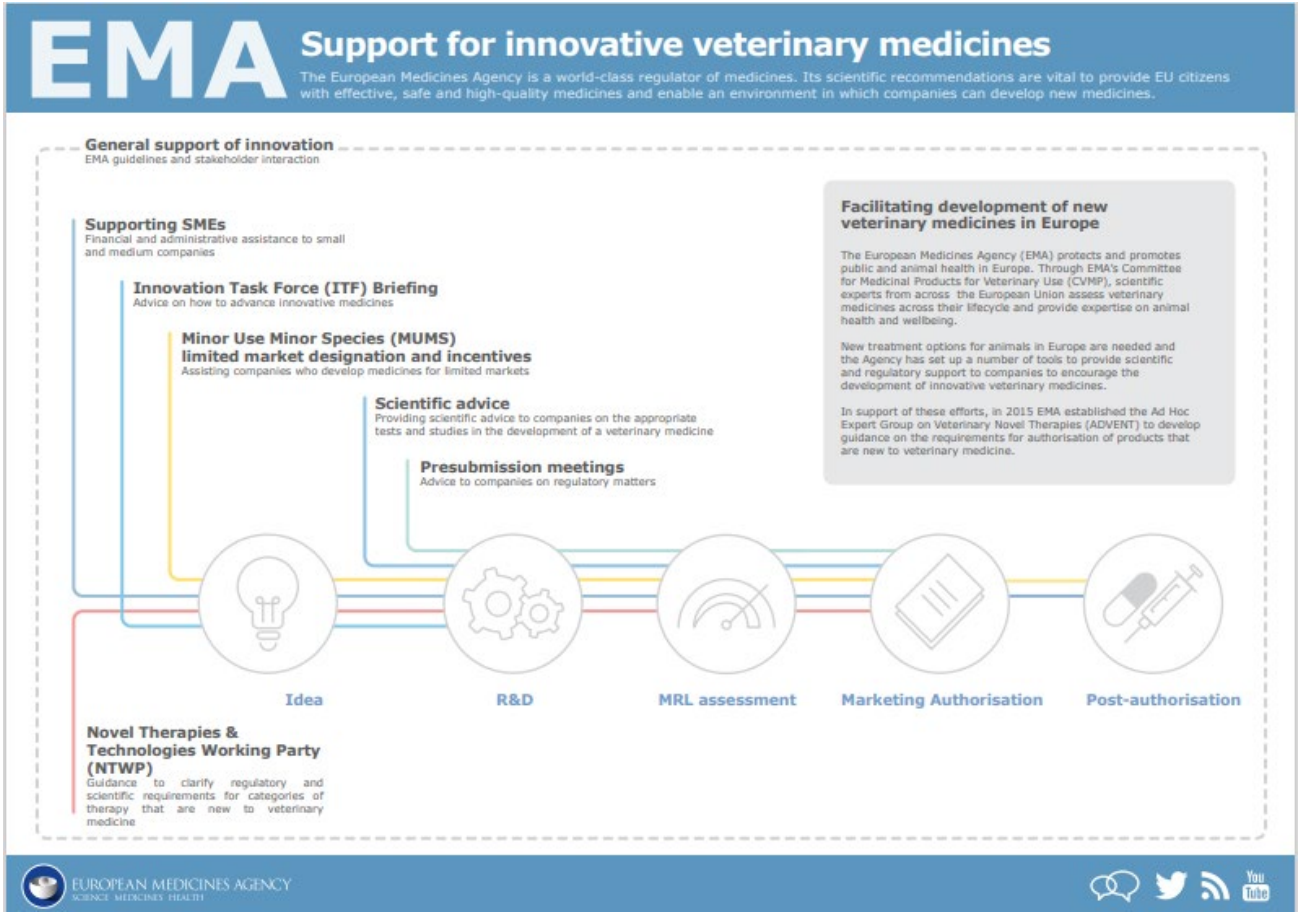
International cooperation and exchange of information

- EMA exchanges information with both the Food and Drug Administration (FDA) Centre for Veterinary Medicines and the USDA Centre for Veterinary Biologics
- Collaboration with other European agencies: European Food Safety Authority (EFSA)
- Authorisation of novel veterinary therapies (and its challenges) are included as specific action items in the work plan of the Trans-Atlantic Task Force on AMR (TATFAR)

Available support to developers and applicants (EMA/CVMP)

- Early enquiries (**AskEMA**)
- Innovation task force (**ITF**): Early stages of development, general or product-specific, advice on legal, regulatory and /or scientific aspects
- **Scientific advice**: Later stages of development, pre-submission or during evaluation
- **Pre-submission** meetings: Final stages of development, product-specific
- **Guidance and guidelines** on EMA website, on procedural, regulatory and scientific issues
- **IWP** (Immunologicals Working Party)
- **NTWP** (Novel Therapies and Technologies Working Party)

- **SME Office**: provides regulatory, financial and administrative assistance to companies designated as micro, small and medium-sized enterprises.



Authorisation of alternatives to antimicrobials VMPs

Challenges presented

- Lack of consistent terminology: definition of 'alternatives to antimicrobials' in the context of measures to promote their authorisation
  - 'Products to reduce the need for the use of antimicrobials' or 'Products that can contribute to the reduction of the need for antimicrobials'

- Borderline products: certain products containing the same active substance could be classified as a VMP, a feed additive or a biocide depending on the intended use and claims; this is important for the consideration of the appropriate regulatory framework (standards for evaluation)
  - Provide clarity to applicants (EU agencies, national competent authorities)

Authorisation of alternatives to antimicrobials VMPs

Challenges presented

Adequate regulatory framework to support authorisation of alternatives to antimicrobials VMPs

- Regulation (EU) 2019 provides new framework for authorisation of alternative VMPs:
  - ✓ European Medicines Agency's scientific guidelines on immunologicals (more than 10 GDLs finalised and published since 2021)
  - ✓ European Medicines Agency's scientific guidelines on novel therapies (GDLs on stem cells products; bacteriophages)
  - ✓ European Medicines Agency's scientific guidelines on limited markets (quality, safety and efficacy of immunologicals, biologicals and non biologicals)

Authorisation of alternatives to antimicrobials VMPs

Challenges presented

- Need for additional guidance specifically intended to clarify requirements for different types of products which can be used as alternative to antimicrobials (e.g. peptides, immunomodulators, gene-editing products).
  - ➢ CVMP through its Working Parties

16 December 2022
EMA/CVMP/617330/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products (CVMP)
Work Plan 2023

Overcoming challenge

- Promote EMA and National Competent Authorities' incentives to SMEs working in the area of alternatives.
- Increase communication with stakeholders on development and authorisation of alternatives to the use of antimicrobials.
- Foster dialogue between the EU regulatory network, industry, veterinary professionals and other relevant parties to identify priorities:
  - diseases with highest need for alternative treatments
  - types of VMPs that show greatest promise for future development and potential medicinal claims.

Overcoming challenges (II)

- Increase international cooperation and exchange of information with other regulatory regions to facilitate global development of alternative VMPs and alignment of requirements for authorisation.
- Promote and strengthen support to developers and applicants (e.g. ITF, SA, NTWP) as the appropriate forum for scientific, regulatory and procedural advice related to development of innovative VMP
- Horizon scanning meetings with industry/developers.

Overcoming challenges (III)

- Develop further guidance on data requirements (as needed) and potential claims for alternative VMPs
- Specific calls for projects on alternatives to antimicrobials (for veterinary use) as an incentive and stimulus
- Develop objective targets to monitor success of measures to promote alternatives.

Further information

askema@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

Follow us on **@EMA_News**