EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Focus on veterinary vaccine availability and emerging diseases

EMA Veterinary Medicines Info Day 2024

Presented by Dr Javier Pozo Gonzalez on 15 March 2024
Veterinary Medicines Division

Content

- Introduction
- Regulatory tools to promote vaccine availability
- Availability of vaccines for emerging diseases
- EMA support to applicants/developers

Importance of veterinary vaccines

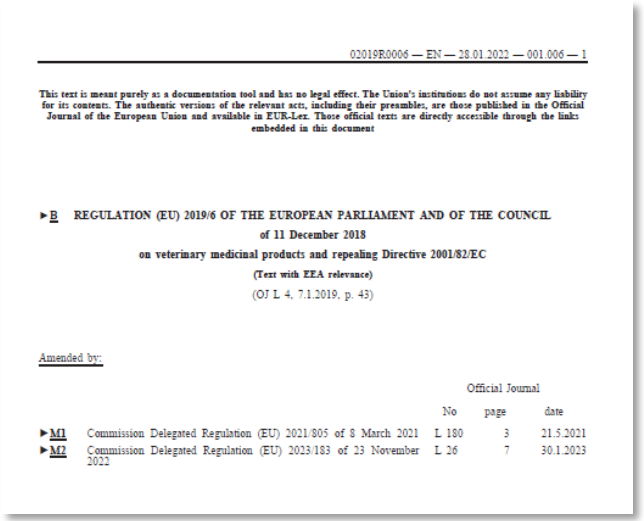
- Vaccination is one of the most effective tools for:
  - Preventing and controlling animal disease
  - Promoting animal health and welfare
  - Protecting public health (zoonosis)
  - Ensuring safe food production
  - Reducing the need to use antibiotics in animals (AMR)
- Challenges to ensuring availability of suitable veterinary vaccines in a timely manner in the EU market.
- Increasing availability of veterinary vaccines is a key priority area for EU medicines regulatory network.

Regulatory tools to support availability of veterinary vaccines

Regulation (EU) 2019/6 aims to stimulate innovation, increase availability of veterinary medicines, fight AMR and reduce administrative burden on industry and regulators

Regulatory tools:

- Applications for Limited Markets
- Applications in Exceptional Circumstances
- Vaccine Antigen Master File
- Vaccine Platform Technology Master File
- Multi-strain dossiers
- Novel therapies



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►B REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 December 2018
on veterinary medicinal products and repealing Directive 2001/82/EC
(Text with EEA relevance)
(OJ L 4, 7.1.2019, p. 43)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Delegated Regulation (EU) 2021/805 of 8 March 2021	L 180	3	21.5.2021
►M2	Commission Delegated Regulation (EU) 2023/183 of 23 November 2022	L 26	7	30.1.2023

Limited Markets (Art. 23)

NEW

Definition LM

- VMPs for diseases that occur infrequently or in a limited geographical area ***or***
- VMPs for species other than cattle, sheep (meat), pigs, chickens, dogs and cats

Applications under Article 23

- Marketing authorisation (MA) can be granted if benefit of availability outweighs certain **gaps in safety or efficacy**
- Validity limited to 5 years (renewable)

Eligibility

- Eligibility to be confirmed by EMA

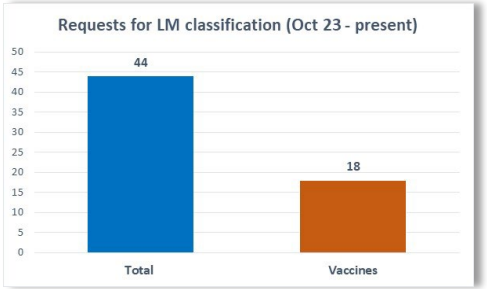
Applications for Limited Markets under Art. 23

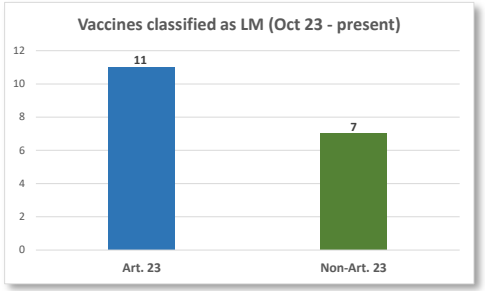
NEW

EMA Guidance

- Reflection paper on eligibility (currently under revision)
- GL on data requirements for IVMPs for LM Art. 23
- GLs on data requirements for LM non-Art. 23 (in progress)

LM Requests





Challenges

- Criteria for classification for Article 23
- Flexibilities for LM not eligible under Art. 23
- Specific data reductions may require scientific advice

Vaccine Antigen Master File

VAMF definition

- Stand-alone part of MAA dossier containing all **quality data** for an antigen
- Common to one or more MAs

Certification

- Centralised evaluation procedure handled by EMA
- As part of an initial marketing authorisation application (MAA) or as a separate procedure
- Certificate valid throughout the EU *(for any authorisation route)*

Use of VAMF

- VAMF certificate can be used to support future applications for vaccines containing the same antigen

Vaccine Antigen Master File

Main benefits

- Single assessment for authorities
- Single dossier to be handled by applicants
- Speed up assessment procedure – data in VAMF not reassessed
- Increase predictability

EMA Guidance

- Procedural advice for VAMF certification (link)
- Guideline on data requirements for VAMFs (link)

Experience to date

- First applications for VAMFs currently under assessment
- Evaluation procedure run smoothly

Vaccine Platform Technology Master File (vPTMF)

What is a PT

- Technologies with common backbone carrier/vector that can be modified with different antigens/inserts for each vaccine

What is a vPTMF

- Stand-alone part of MAA dossier containing all data that will be common to the vaccines based on the platform (Q, S, E)

Certification

- Centralised evaluation procedure handled by EMA
- As part of an initial full MAA or as a separate procedure
- Certificate valid throughout the EU (for any authorisation route)

Use of vPTMF

- vPTMF certificate can be used to support future MAAs for vaccines based on the same platform

Vaccine Platform Technology Master File (vPTMF)

Benefits

- Single assessment for authorities
- Single dossier to be handled by applicants
- Speed up assessment procedure – data in MF not reassessed
- Increase predictability
- Reductions in data requirements for vaccines using the same PT
- Foster the use of platforms for development of vaccines

EMA Guidance

- Procedural advice for vPTMF certification (link)
- Guideline on data requirements for vPTMF (link)

Experience to date

- First applications for certification ongoing
- Main challenge: define constant and variable parts of the PT

Application for Multi-strain dossiers

What is a MS dossier

- A single MA dossier with data for different antigens/strains allowing different combinations of final formulation adapted to the epidemiological situation

Scope (expanded)

- Any inactivated vaccine against antigenically variable viruses or bacteria requiring rapid or frequent change in composition
- Each dossier is only applicable to one virus species, bacteria genus or vector

Eligibility

- Eligibility for the MS approach to be confirmed by EMA
- Not necessary for vaccines against FMD, AI, BTV and diseases for which a MS has already been authorised

Applications for multi-strain dossiers

Benefits

- Flexible vaccine composition tailored to field situation
- Handling all relevant strains in a single dossier
- Reduction in data requirements for additional strains
- Possibility to add, replace strains to MS dossier via variation
- Possibility to convert a standard MA dossier in a MS dossier

EMA Guidance

- Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines (link)

Experience to date

- Very positive
- 4 centrally-authorised MS dossiers for BTV vaccines
- 4 nationally-authorised MS dossiers for FMD vaccines
- Increasing interest in the expanded scope of the MS approach

Emerging and re-emerging diseases

- Significance of emerging and re-emerging animal diseases is increasing:
  - Outbreaks with serious consequences for animal and human health
  - Increased risk of spill-over of zoonotic disease to humans
  - Animal welfare
  - Economic (food supply, trade)
- Timely availability of safe and effective vaccines is key to tackle emerging threats – One Health approach

Availability of vaccines for emerging diseases - Challenges

- **Technical/scientific challenges**
  - Complexity of pathogen (ASFV)
  - Breadth of protection (serotype or strain-specific)
  - Access to high containment facilities (FMD, HPAI)
  - Manufacturing capacity
- **Regulatory challenges**
  - Meeting minimum requirements for authorisation
  - Maintaining relevance of strains
  - Regulatory mechanisms for updating strains
  - Uncertainty around vaccination policy

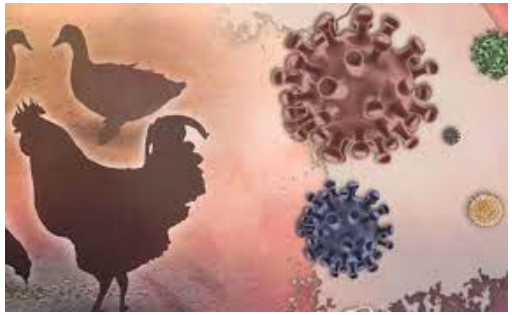
- **Economic challenges**
  - Unpredictable market return
  - Lack of incentives
  - Costs of maintaining vaccine stocks

Multi-faceted approach required to address these challenges

Increase preparedness

Vaccines for emerging diseases – EMA contribution

- Awareness on animal disease situation EU/global
- Dialogue with vaccine manufacturers
- Collaboration with EC and other stakeholders (e.g. EFSA, WOAH)
- Role in centralised MAAs in exceptional circumstances
- Accelerated assessment for centralised MAA
  - Reduced timetable to facilitate faster access to the market (from 210 to 150 days of assessment)
- Role in variations for addition of new strains to existing MS dossiers



Applications in Exceptional circumstances (Art. 25)

Exceptional circumstances

- Related to animal or public health
- Benefit of immediate availability outweighs risks of gaps in data provided

Data requirements

- Reduced data requirements (Q, S and E) possible if justified
- Subject to specific obligations, conditions and/or restrictions
- Validity 1 year (annual re-assessment)

Eligibility

- To be confirmed (national or centralised routes)
- Accelerated assessment may be applicable

Applications in Exceptional circumstances (Art. 25)

EMA Guidance

- Guideline on data requirements for authorisation of IVMPs in exceptional circumstances (link)

Previous experience

- 3 centralised MAs for AI vaccines (2006-2008)
- 11 centralised MAs for BTV vaccines (2008-2010)
- Time from submission to authorisation (5 to 11 months)

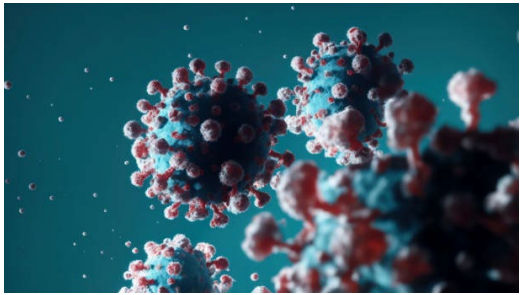
Currently

- 2 applications for vaccines against HPAI under assessment
- Vaccines against HPAI, ASF, BTV-3, EHD may be eligible for Art. 25 in the current context

Future trends in veterinary vaccinology - Innovation

- **Vaccine platforms** (DNA, RNA, vector)
- **New delivery systems** (nanoparticles)
- **New adjuvants and immunomodulators**
- **Vaccines against parasitic diseases**

Innovative vaccines may be classified as novel therapy



EMA support to vaccine developers and applicants

- **AskEMA**: early enquiries
- **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
- **EMA website:** procedural guidance and technical guidance on requirements for IVMPs (IWP) (Link)
- **SME office:** Regulatory, financial and administrative to companies designated as micro, small or medium-sized enterprises

EMA SME Office

EUROPEAN MEDICINES AGENCY

Specific incentives and support for micro, small and medium enterprises (SMEs)

EU SME regulation(EC) No 2049/2005 of 15 December 2005

Aiming to promote **innovation and development** of new medicines by SMEs.

Dedicated contact point

Administrative and procedural support

Regulatory assistance

Consultation & advice

SME briefing meeting

Early dialogue

Regulatory guidance

Fee incentives

Deferrals

Waivers

Conditional fee exemptions

Reductions

Training & awareness

SME user guide *(new vet legislation)*

Newsletters (*subscribe*)

Mailings

Info days

Webinars

Awareness sessions

Partnering and networking

Collaborations with EU bodies & stakeholders

Participation to conferences and events

Public SME Registry

Translation assistance

For Product Information, in all EU languages free of charge

2024 :

- **60** veterinary SMEs registered at EMA
- **77** veterinary and human SMEs registered at EMA

SME@ema.europa.eu

SME Helpline : +31 (0)88 781 8787

Support to SMEs | European Medicines Agency (europa.eu)

More information on how to apply for SME status here

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
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