VMPs in the Biotech Act

Rocio Salvador Roldan
DG SANTE, Unit D4

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

{SWD(2025) 1055 final}

(Text with EEA relevance)

Chapter IX – Art 59

Amendments to Regulation 2019/6:

- GMO-VMPs: Streamlined regulatory requirement
- VNRAs: Reduction of administrative burden
- Sandboxes
- SPC extension
- Updates to Annex II

GMO-VMPs: Streamlined regulatory requirements

- Reduction of administrative burden.
- Sandboxes.
- SPC Extension
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Micro-organisms in medicine

1796

Jenner's **small pox vaccine** (based on infection with cowpox).

1870-80s

Pasteur develops the first live **attenuated vaccine** (cholera in chickens). Subsequently developed anthrax and rabbies vaccine.

1940's

First influenza vaccine authorised for civilian use in US.

1980's

A **recombinant DNA** vaccine developed against hepatitis B, still in use today.

1990s

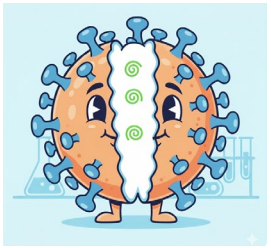
First GMO veterinary vaccines authorised in the Union.

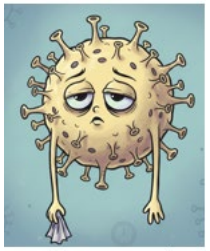
2019

Vaccine against ebola (**viral vector approach**) authorized in the Union.

Micro-organisms as medicines (cont)

GMO vaccines



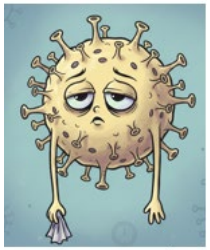


Attenuated

Wildtype micro-organism

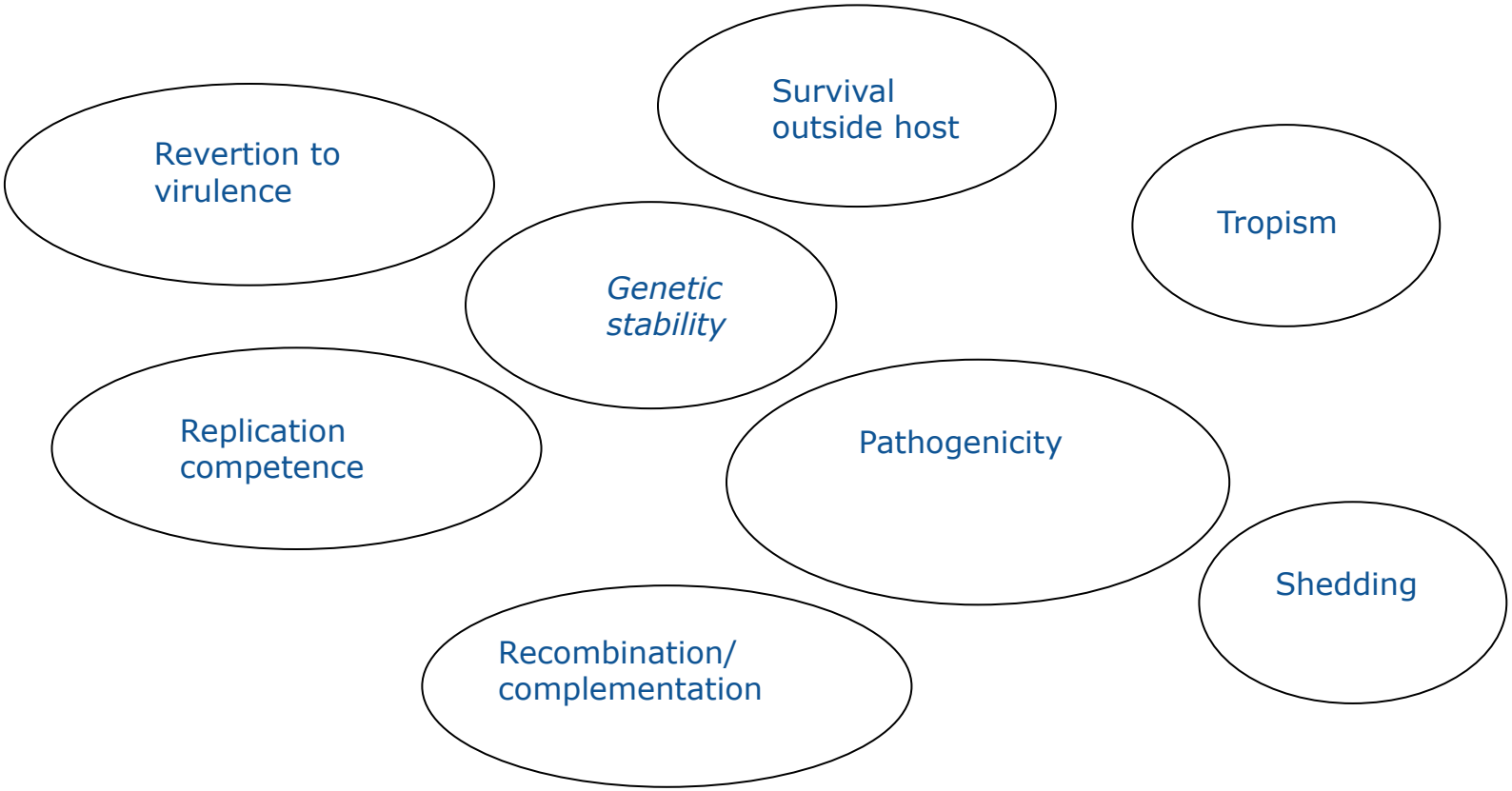
Traditional vaccines

Inactivated



Attenuated

Safety aspects for (live) modified micro-organisms used in medicine



Annex II – Regulation 2019/6

For live attenuated vaccines, confirmation of the stability of the attenuation

Spread of the vaccine strain from vaccinated to unvaccinated target animals shall be investigated
investigate the spread to non-target animal species which could be highly susceptible

Increase in or reversion to virulence shall be investigated

Dissemination in the vaccinated animal

the risk of changing the tropism or virulence of the strain

The probability of recombination or genomic reassortment

European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2026
EMEA/CVMP/074/95–Rev.1*
Committee for Veterinary Medicinal Products (CVMP)

Guideline on environmental risk assessment for immunological veterinary medicinal products

3. Framework for risk assessment

The aim of the risk assessment is to identify hazards, to estimate the likelihood that the hazardswill lead to actual harm and to take decisions regarding the appropriate control measures. The main elements of a risk assessment are therefore:

(i) hazard identification;

(ii) assessment of exposure to the hazard and the likelihood that the hazard will occur;

(iii) assessment of the consequences of that exposure;

(iv) assessment of the level of risk (by consideration of the severity of any adverse consequences and the likelihood that they will occur);

(v) selection and assignment of appropriate control measures (risk management), as far aspossible.

Capacity of live organisms to transmit to non-target species

Capacity to survive, establish and disseminate

Pathogenicity to other organisms

Shedding

recombination.

Toxic effects of excreted metabolites

European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 December 2024
EMA/CVMP/IWP/390313/2023
Committee for Veterinary Medicinal Products (CVMP)

Guideline on live recombinant vector vaccines for veterinary use

possible changes of tissue tropism

Spread of the recombinant vector vaccine

Vectors must be non-pathogenic or low pathogenic

- Host-range specificity.
- Potential for establishment in the environment

potential of recombination

- Study of virulence to target and non-target species at risk

insertion of foreign gene(s) does not lead to an increase in virulence

GMO legislation not fit for medicines

REGULATION (EU) 2020/1043 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 July 2020

on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19)

Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

The complexity of that procedure increases greatly in the case of multi-centre clinical trials conducted in several Member States, as sponsors of clinical trials need to submit multiple requests for authorisation to multiple competent authorities in different Member States in parallel. In addition, national requirements and procedures for the environmental risk assessment and written consent by competent authorities for the deliberate release of GMOs under Directive 2001/18/EC vary greatly from one Member State to another. Whereas in some Member States a single request for authorisation concerning the conduct of the clinical trial and the GMO aspects can be submitted to a single competent authority, in other Member States parallel requests need to be submitted to different competent authorities. Furthermore, some Member States apply Directive 2001/18/EC, others apply Directive 2009/41/EC and there are Member States that apply either Directive 2009/41/EC or 2001/18/EC depending on the specific circumstances of a clinical trial, so it is not possible to determine *a priori* the national procedure that is to be followed. Other Member States apply both Directives simultaneously to different operations within the same clinical trial. Attempts to streamline the process through informal coordination between Member States' competent authorities have been unsuccessful. There are also variations between national requirements as to the content of the technical dossier.

GMO approaches in the development of novel vaccines

- 3/8 vaccines authorised in exceptional circumstances are based on GMO approaches.
- 4/4 vaccine platform technologies certified are based on GMO approaches.

OIE/FAO/WHO

- The standard of safety should not be different between GE vaccines and conventional vaccines.
- Animals vaccinated with GE vaccines should not be considered GM animals.

OIE/FAO/WHO meeting on the assessment of food safety related to the use of recombinant vaccines in food-producing animals (2011)

BTA proposals

1. Streamlining procedures for safety assessment.

2. Increased legal certainty for users.

1. Streamlining safety assessment

- GMO framework not applicable to VMPs authorised or manufactured in accordance with Regulation 2019/6.
- Sole assessment under Regulation 2019/6:
  - Clinical trials
  - Marketing authorisation

a) The clinical trial phase

BTA proposal:

- RMMs to be implemented by applicants where a risk to the environment is identified, having regard to the specific characteristics of the product, magnitude of relevant hazard and likelihood of AE occurring.
- NCA authorising CT to assess potential adverse effects on human health and the environment, having regard to the specific characteristics of the product and to require RMMs, where appropriate.
- Consultation with GMO authorities possible.

a) The clinical trial phase (cont)

Regulation 2019/6 (current)

- ***Art 9(4):***

4. The clinical trials shall be carried out taking due account of the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ('VICH').

2. THE PRINCIPLES OF VICH GCP

2.1. The purpose of the VICH GCP is to establish guidance for the conduct of clinical studies that ensures the accuracy, integrity and correctness of data. Due regard should be given to the welfare of the study animals, the effects on the environment and the study personnel and to residues in the edible products derived from food-producing study animals.

2.5. The relevant regulatory authority should provide procedures that independently assure that the study animals and the human and animal food chains are protected. The relevant regulatory authority should also assure that informed consent has been obtained from the owner of the study animals.

a) The clinical trial phase (cont)

VICH (cont):

4.2. Responsibilities. The sponsor should:

4.2.1. Ascertain that sufficient scientifically valid information exists with respect to the effectiveness and safety of the investigational veterinary product to justify conduct of the clinical study. The sponsor should also determine from this information that there are no environmental, welfare, ethical or scientific grounds which might preclude the conduct of a clinical study.

3.2. Responsibilities. The investigator should:

3.2.15. Document any veterinary care and procedures, changes in animal health, or significant environmental changes.

8. STUDY DOCUMENTATION

8.2.2.4. Facility and equipment records. As appropriate, descriptions of the study site, e.g. diagrams and photographs, equipment identification and specifications, equipment calibration and maintenance records, equipment failure and repair records, meteorological records and environmental observations.

b) Marketing authorisation

BTA proposal:

- ✓ Dataset as per Directive 2001/18 no longer in MAA.
- ✓ Consultations with GMO authorities no longer mandatory.

2. Increased legal certainty for users

- Administration of VMPs does not bring animals (or their products) under GMO rules:

- GMO-VMPs: Streamlined regulatory requirements
- **VNRAs: Reduction of administrative burden.**
- Sandboxes.
- SPC Extension
- Updates to Annex II

2. Regulation 2019/6

(5) This Regulation aims to reduce the administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.

Article 60

Variations

1. The Commission shall, by means of implementing acts, establish a list of variations not requiring assessment. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2. The Commission shall take account of the following criteria when adopting the implementing acts referred to in paragraph 1:

(a) the need for a scientific assessment of changes in order to determine the risk to public or animal health or to the environment;

(b) whether changes have an impact on the quality, safety or efficacy of the veterinary medicinal product;

(c) whether changes imply no more than a minor alteration to the summary of product characteristics;

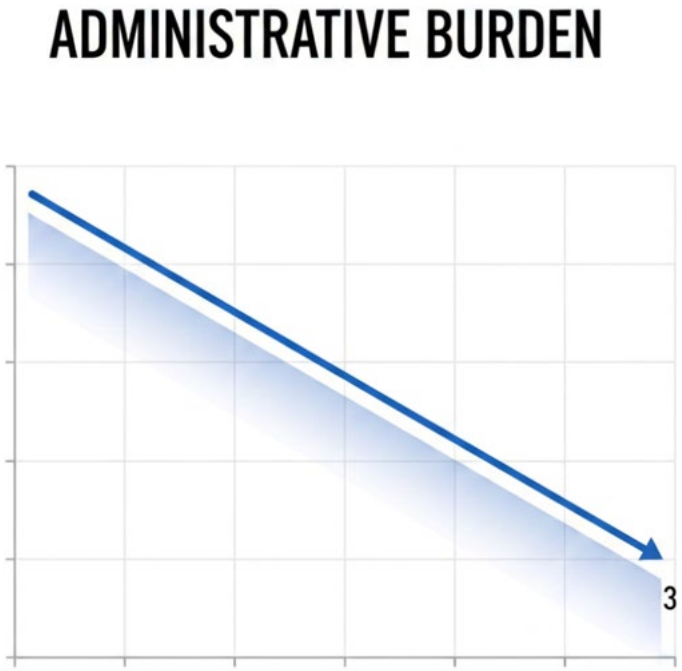
(d) whether changes are of an administrative nature.

2. Administrative burden has increased

- Possibility to consolidate notifications within 12 months (“yearly update”) lost.
- Confirmation step by competent authorities.

2. VNRAs: Reduction of administrative burden

- MAHs can consolidate submissions to UPD on a yearly basis, if the VNRA does not affect PI.
- Confirmation by competent authorities not required.



GMO-VMPs: Streamlined regulatory requirements

Reduction of administrative burden.

Sandboxes.

SPC Extension

Updates to Annex II

Scope and objective

- Aim: facilitate development and marketing/use of innovation under proportionate requirements.
- Scope: **technologies, methods or products related to animal health** directly or indirectly related to the development, manufacturing or use of veterinary medicinal products **not regulated under other Union legislation**.

How?

- Sandboxes are set up by COM (following EMA's recommendation). They are limited in time.
- ***Development phase:***
  - ✓ development of technical/scientific requirements by EMA;
  - ✓ scientific advice by EMA.
- ***Authorisation phase:***
  - ✓ assessment of specific applications by EMA;
  - ✓ authorisation by COM (comitology);
  - ✓ surveillance by NCAs – possibility to take interim measures in case of serious risks.

Termination

- **Earlier termination:**
  - ✓ identification of serious risks to public or animal health or the environment by CAs;
  - ✓ benefit-risk negative and RMMs not possible.
- **End of sandbox (end date reached):**
  - ✓ COM to take appropriate action as regards regulatory framework for such innovation having regard to assessment performed by EMA;
  - ✓ authorisations granted under the sandbox continue to be valid (except termination due to serious risks).

- GMO-VMPs: Streamlined regulatory requirements
- Reduction of administrative burden.
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Overview

- 12 months extension of SPC protection.
- Conditions:
  - biotechnology VMPs (art 42 (2a) Regulation 2019/6);
  - intended to treat zoonotic diseases;
  - new active substance;
  - new MoA with efficacy/safety at least equal to relevant authorised VMPs;
  - at least one manufacturing step in the EU (excluding packaging, testing and batch certification).

- GMO-VMPs: Streamlined regulatory requirements
- Reduction of administrative burden.25 MAA.
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'Article 146

Amendments to Annex II

'The Commission is empowered to adopt delegated acts in accordance with Article 147(2) in order to amend Annex II to take due account of technical and scientific progress.'

Thank you!