Europe

IABS-EU Meeting on Preparedness and Response to Emerging Veterinary Disease Outbreaks

Date: 25-26 March 2025 - **Venue**: Pullman Hotel Centre Midi, Brussels, Belgium

CONCLUSIONS & RECOMMENDATIONS

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Key learnings for improved preparedness against Emerging Infectious Diseases (EID) in animals.

Definition of Emerging Disease (WOAH, Terrestrial Animal Health Code, 2025): *new occurrence in an animal of a disease, infection or infestation, causing a significant impact on animal or public health resulting from a change of a known pathogenic agent* ***or*** *its spread to a new geographic area or species;* ***or*** *a previously unrecognised pathogenic agent or disease diagnosed for the first time*.

In the context of "preparedness", we have to distinguish 2 types of events and associated actions:

For « expected events » *(observed only for slow spreading infectious diseases)*

- Anticipated planning.
- Rational selection of best pragmatic and existing solutions.

For « unexpected events » (most of the events), *all timelines become critical*:

- Need to design the best vaccine approach and vaccination strategy.
- Need to push our scientific knowledge to the next level for immunogens.

Development of « *universal vaccines* »: achievable dream or pure fantasy?

Universal for: which target disease(s)?

which target animal species?

What are the perspectives for a new strategy? Several questions are facing us:

How to get fast to an efficacious vaccine product? (and not the « *ideal vaccine* »).

What do we need for the Target Product Profile? (not always easy to determine up front)

Do we want (or need) to be:

« ready to react » vaccine preparedness?

or « ready to act » vaccine preparedness?

RECOMMENDATIONS

1) <u>Necessity to build a collective decision matrix</u>

- Need to build collectively (regulators, industry, veterinarians, animal health surveillance systems) a decision matrix (according to the disease category, drivers and economic consequences) for optimal preparedness.
- This is a complex matrix with many dimensions… but it should certainly consider industrial manufacturing feasibility and registrability (Pre-authorised Vaccine Concept)
- Clear and transparent vaccine plan policies to be based on WOAH recommendations and requirements and, where relevant, aligned with the EU animal health law.
- Better connect CVOs and regulatory agencies.

2) <u>Specific funding for R&D on EIDs</u>

Today, there is no emergency funding system for veterinary vaccine development at EU level but incentives have to be developed for accelerating our preparedness level.

- Multiple dilemmas exist for industry to decide to invest in vaccines against emerging infectious diseases (including the outbreak's scale, its economic impact, its duration and the feasibility of developing an effective vaccine in time). Very difficult to "guestimate" all these uncertainties at the crisis start and thus to predict the return on investment. However, currently, industry carries most investment risks and costs. This situation cannot be sustained.
- Solid orders are required for initiating batch manufacturing and establishing large scale industrial capacity.
- Need a specific funding organization for anticipating vaccine tools for animal health / One Health.
- The interest to set up a CEPI AH / BARDA AH / NIVI AH type of organization was mentioned several times during this meeting, and there is an obvious need to establish close links with human health since the same vaccine technologies and similar viral pathogens are shared (One Health global approach).
- The corresponding R&D budget is significant but corresponds actually to only a small fraction of the losses that can arise due to EIDs.

3) <u>Societal, logistical, and Political aspects</u>

- EID vaccines should be viewed as an insurance policy, rather than a Fire Department System as is currently the case, for animal production and the animal health industry, which may also ultimately benefit human health.
- There are new societal and political priorities / issues to address:
    - animal welfare / 3R policy,
    - ensuring food supply,

- Vaccine hesitancy / vaccine rejection (lack of information and education) (« societal vaccine sensitivity ») interfering strongly with the mass vaccination of livestock.

- And other items not to forget (beyond the scientific, industrial and regulatory timelines):
  - political time,
  - need for a robust, consistent, science-based communication strategy,
  - logistical aspects of vaccinating large number of animals and of surveillance,
  - Societal (social networks) time,
  - diplomacy time (for trade barriers).

4) <u>Regulations aspects</u>

There is already an important regulatory toolbox which has been adopted with the intent to cover all types of situations. However, limitations have been identified, especially in relation to EID pro-active threat preparedness which may lead to the perverse outcome of increased use of unauthorized products under Art 110 with a consequent increase in risk.

The following recommendations were made, about regulations aspects:

1. The development and authorization of vaccines should be encouraged to reduce the need for other types of permits for use or autogenous vaccines, taking into account the particular challenges that licensing EID vaccine brings to the vet vaccine industry.

2. Future approaches should include EU wide authorization options (versus a few member states) to improve the availability of vaccines, both pro-actively “in peace time” and re-actively “in emergency”.

3. The relevant technical/CVMP regulatory guidelines should be reviewed and adapted to address both the “in emergency” and “pro-active” needs. A pragmatic EID approach, using a revised risk benefit-balance, would be an incentive for industry to invest. A specific proposal to address a new serotype for inactivated BTV vaccines has been made. The example of how human industry addresses updates to Influenza vaccines has also been suggested as an option to look at. In addition, it would be beneficial to investigate if the exceptional circumstances guideline (EMA/CVMP/IWP/251947/2021) could be reviewed and adapted so that this could be implemented “in peace time”. In addition, competent authorities should consider establishing (based on pre-set objective criteria) a list of diseases considered as “priority” from a vaccine development standpoint (associated with reduced data requirements), similar to the “MUMS vaccine table” in the past. Such a list would ideally be an “European” list. It is acknowledged that such a list would be expected to evolve over time.

4. There is a need for an improved productive collaboration between the different regulatory bodies in EU to facilitate approval and access to EID vaccines for the relevant Member States.

5. Numerous regulations beyond regulatory requirements (Nagoya/ABS, GMOs (easier implementation of field trials), biosafety, training, etc.) need to be taken into account, which adds complexity.

6. Duplicates in regulation relevant for IVMPs should best be deleted. E.g. ERA and other quality and safety requirements laid down in Regulations 2019/6 cover provisions laid down in Directive 2001/18. IVMPs should be deleted from the latter Directive.

7. The exceptional circumstances requirements should be encouraged and be leveraged to manage emergency crises (see also point 3 above).

8. There is a need to increase autogenous vaccine quality requirements. Although autogenous vaccines may be useful at local level when there is no vaccine authorized against the corresponding disease, autogenous vaccines should not be the first choice as a tool against EID, especially viral EID.

9. Vaccines against many diseases that are considered as EID within Europe are already widely used and approved in countries where the corresponding diseases are endemic. European preparedness would be improved by evaluating the quality of such vaccines in advance of need through a suitable system of prequalification and supporting vaccine manufacturers in low to middle income countries to improve the quality of the vaccines they produce.