EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Promote and support development of veterinary vaccines

Underlying actions

EMA's Regulatory Science Strategy to 2025 – Veterinary Stakeholder Workshop

Chaired by Esther Werner, IWP
Presented by Javier Pozo Gonzalez, EMA on 6 December 2019

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Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

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Promote and support development of veterinary vaccines

Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types, especially zoonotic vaccines, minor-use-minor-species vaccines, and vaccines for exceptional circumstances

Develop criteria for epidemiological modelling to demonstrate vaccine efficacy against epizootic disease

Interact collaboratively with industry to focus development on areas where vaccines are most needed

Clarify the criteria required for field efficacy trials to support marketing authorisation applications for new vaccines

High level concerns/recommendations

- Availability of vaccines
- Development of novel vaccines
- Minimum requirements for demonstration of field efficacy of vaccines
- Improve communication EMA - Industry
- Joint contingency plan and immediate reaction in emergencies and exceptional circumstances (EMA – Industry - Academia)

General comment

- “Veterinary vaccines play a major role in protecting animal health by preventing and controlling serious epizootic diseases. They also have an impact on human health by ensuring safe food supplies and preventing animal-to-human transmission of infectious diseases. Veterinary vaccines can be an efficient tool in reducing the need for using antibiotics in animals, thereby contributing to the fight against antimicrobial resistance.”

Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types, especially zoonotic vaccines, minor-use-minor-species vaccines, and vaccines for exceptional circumstances

- Preparedness is crucial to prevent an EU disease outbreak, specially for those where there are no vaccines authorised in the EU and they should be imported (…) e.g. LSD. The benefit-risk assessment should take into account different epidemiological scenarios. Risk-mitigation measures should be considered and worked on.

- A standardized methodology for the benefit-risk assessment should be developed, considering the scientific and policy development of each Member State.

Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types, especially zoonotic vaccines, minor-use-minor-species vaccines, and vaccines for exceptional circumstances

- The new veterinary regulation allows the setting of requirements for innovative vaccines, limited markets and vaccines for use in emergency situations. There is currently a unique opportunity to adapt the scientific requirements to state of the art development and manufacture of IVMPs. The need for cooperation with OIE and Ph. Eur. on harmonized requirements is stressed.

- 'Cross-fertilization' between vet and human approaches would help developing more quickly medicinal products (vaccines in particular) in emergency situations. (…) In practice, both humans and animals are facing the same microorganisms and commonalities between approaches should be more closely inter-related for the benefit of both.

Develop criteria for epidemiological modelling to demonstrate vaccine efficacy against epizootic disease

- Develop methodology for the benefit-risk evaluation of novel medicines intended to promote, or manage, the health of farms/herds/flocks, rather than the health of the individual animal.

- Collaborate with regulators of human medicinal products to develop methodology, including biomarkers, to evaluate the efficacy of a veterinary medicine which is used to produce an improvement in human health.

Interact collaboratively with industry to focus development on areas where vaccines are most needed

- The need for additional veterinary vaccines in particular those where the return of investment is low is underlined.
- The strategy should not overlook that in many new scientific areas the experts lie within companies (…). Therefore the strategy should include more reference to finding ways to engage also with industry experts.
- A goal is missing on ensuring availability and meeting therapeutic challenges. Ways need to be found to monitor availability gaps and to try to address the worst of them.

Clarify the criteria required for field efficacy trials to support marketing authorisation applications for new vaccines

- "Clarify the criteria required for field efficacy trials" would be better phrased as "clarify criteria for field trials and when efficacy field trials are needed."

- Develop standards for novel vaccines and the promotion of new endpoints for the evaluation of efficacy.

Other underlying actions identified by EMA Secretariat

- How can the approval of vaccines to be used under emergencies/exceptional circumstances be accelerated (e.g. African swine fever)
- Vaccine antigen master file
- Platform technology master file
- Multi-strain dossier
- Advance understanding of science behind novel manufacturing technologies and regulatory implications of novel approaches (e.g. NGS). Gaps in regulatory framework should be identified and strategies established to address them.

Any questions?

Further information

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