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EMA plans to tackle lack of veterinary vaccines in Europe

BY DR TAMSIN DAWSON

The recent Veterinary Medicines Directorate (VMD) Biologicals Information Day heard feedback from European Medicines Agency (EMA)/Heads of Medicines Agencies (HMA) Workshop on Requirements for the Authorisation of Veterinary Vaccines in the EU. Dr Tamsin Dawson highlights the key points.

According to the EMA/HMA workshop, the lack of veterinary vaccines is a major issue, especially in the case of products for limited markets and for emergency situations.

The reasons why more vet vaccines are not available in the EU are complex and may relate to: technical requirements that are too demanding or not updated; authorisation procedures that are too complex; financial issues, including insufficient incentives; and the approach to management of risk and uncertainty.

The animal health industry has highlighted a range of concerns to the EMA regarding the complicated regulations and guidelines currently in place for vet vaccines. The veterinary medicine industry has underlined the lack of flexibility, differences in interpretation and slow update of current guidelines.

There is a need for better communication with regulators at the early stages of guideline development for a better understanding of future implications. The EMA also pinpointed a lack of regulatory expertise amongst Europe's small-to-medium-sized enterprises and a need for training in this area.

Data requirements in the EU are higher compared to other regions. For example, there is a requirement for the demonstration of field efficacy, correlation between serology and protection, as well as provision of consistency batches.

EMA solutions

The EMA's recommendations to improve availability of veterinary vaccines include the adoption of a more flexible and pragmatic approach in the interpretation of the current regulatory framework – it was argued that there is already flexibility such as reduced requirements for emergency vaccines, multi-strain dossiers and minor-use/minor species (MUMS).

The Agency also recommends a better approach to the management of risk and uncertainty. Vaccines could be grouped on the basis of risk tolerance with tailored data requirements according to category and need of vaccine. For example: vaccines for large versus limited markets; live versus inactivated; use for food-producing animals versus companion animals; and emergency vaccines. Low-risk groups could comply with reduced data requirements similar to MUMS products.

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The EMA also suggested the harmonisation of regulatory requirements globally. In the US, evidence of efficacy is based on laboratory work pre-authorisation with field data supplied post-authorisation. This is considered a more pragmatic approach to adopt in other regions.

Another recommendation was the facilitation of administrative procedures to make them easier and faster. For example: the proposal for a centralised authorisation procedure; provisional authorisation; and limited market approvals.

The EMA also highlighted incentives to the industry as a stimulus for developing minor use products such as protection of technical documentation, limited market authorisations and financial incentives to invest in pre-pandemic activities.

The workshop concluded, if availability is promoted, it is necessary to ensure that the final outcome is expanding the range of diseases that can be effectively prevented rather than just allowing an increased number of products of uncertain efficacy. If data requirements are reduced, there must be a global benefit outweighing the risks taken because of lack of data. By encouraging development of vet vaccines, antimicrobial use should reduce.

Action plan

The EMA/HMA action plan for vet vaccines aims to examine and define types of vaccines for which reduced data requirements may be permitted pre-authorisation, and how to define, acquire and assess the data post-authorisation. This would be similar to efficacy requirements in the US.

The plan will consider when appropriate to revise the benefit/risk assessment to reflect the particular need of vaccines.

The action plan also aims to explore the use of ad hoc expert groups to provide advice on conflicting topics such as the extrapolation of serology data and usefulness of field data.

The EMA/HMA aims to draft a list of diseases for which vaccines are required together with expectations on requirements for authorisation. The authorities will also make proposals for specific training in the area of immunologicals. The action plan will develop proposals to improve communication, cooperation and transparency between industry and regulators.

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