Preparedness and Response to Emerging Veterinary Disease Outbreaks

March 25-26, 2025
Brussels, Belgium

Point of view of EU Pharmaceutical Industry on the preparedness and response to emerging disease outbreaks

Ely Bénéré, AnimalHealthEurope, Belgium

The presentation of the EU pharmaceutical industry will consist of 2 sessions.

In the first session, industry will present its views on the status and the perceived obstacles for developing, licensing (or otherwise gaining authorization for use), and supplying adequate quantities of vaccines for emerging veterinary diseases "in the hurry". In this discussion, particular attention will be given to the specifics of the veterinary vaccine industry for emerging infectious disease (EID) vaccine's investment decisions and manufacturing capabilities. The pros and cons of regulatory pathways described in Regulation 2019/6 (i.e. exceptional use, vaccine Platform Technology Master File and Multi-Strain dossier concepts) will be reviewed, considering recent experiences with Bluetongue virus serotype 3, Highly pathogenic Avian Influenza and other EID's outbreaks. The benefits and drawbacks of national *versus* European approval approaches will also be discussed.

In the second session, industry will provide its perspective and suggestions for possible improvements. In high level terms, it will be proposed that the concept of platform technologies is expanded, that the risk/benefit approach for vaccines against EIDs is reconsidered and that opportunities for "pre-approval discussions/processes" with authorities to accelerate vaccine approval for emergency use are maximized. Especially for BTV vaccines, industry will provide concrete suggestions for new incentives towards (early) vaccine development. The suggestions will include a range of proposals, either short-term and long-term, ranging from the need for new or revised technical guidelines, to more ambitious proposals requiring changes in the current legislation.