Preparedness and Response to Emerging Veterinary Disease Outbreaks

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A regulatory perspective on authorisation under exceptional circumstances, the BTV-3/NET2023 case
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Soon after the first BTV 3 cases appeared in the Netherlands in September 2024 it became clear that a vaccine was desperately needed in order to save the sheep population from being decimated by the BTV 3 outbreak and to prevent significant losses in cattle. The CBG-MEB veterinary unit was asked by the Dutch Ministry of Agriculture to evaluate BTV vaccines available outside the EU, but none were found suitable. In March and April 2024 data were provided by three manufacturers that had requested authorisation for use in accordance with Art.110(2) of the regulation 2019/6. The data were assessed within 2.5 to 5.5 weeks depending on the level of completeness of the dossier at the first submission. Generally this was achieved by using a 'rolling' submission. The reduced data requirements as identified in the IWP Guideline on authorization of IVMPs in exceptional circumstances were taken as the basis for the assessment and a pragmatic approach was taken. Where possible, details concerning the minimum data considered necessary will be highlighted. A pragmatic approach was also taken for the initial packaging and labelling in order to not delay the marketing process. Overall, this approach meant that vaccines were on the market in the Netherlands within 2 months from the first request for authorisation for use.