Industry challenges for developing emergency vaccines

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Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards, 31st January 2017

Regulatory Basis

National

- **Article 8, 2001/82/EC**

  In the event of serious disease epidemic, Member States may provisionally allow the use of immunological veterinary medicinal products without an authorization for placing on the market, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

- **Article 26.3, 2001/82/EC**

  In exceptional circumstances, and following consultation with the applicant, an authorization may be granted subject to certain specific obligations…...

- **Article 7, 2001/82/EC**

  Where the health situation so requires, a Member State may authorise the marketing … of veterinary medicinal products which have been authorized by another Member State in accordance with this Directive.

Regulatory Basis

European

- **Article 39.7., 726/2004/EC**

  In exceptional circumstances and following consultation with the applicant, authorisation may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning product safety, notification to the relevant authorities of any incident relating to its use, and action to be taken. This authorisation may be granted only for objective, verifiable reasons. Continuation of the authorization shall be linked to the annual reassessment of these conditions.

Experience

National

- **Handled efficiently, pragmatically and with urgency.**
- **Authorities flexible**
- **Licences (various regulatory procedures) granted in 1-4 months**
- **Non-harmonisation of claims/SPC**
- **High administrative burden due to multiple procedures**
- **If Article 8 is used there is a commercial risk due to its nature**

Experience

European

- No action by EC to allow rapid authorisation
- Advice from EMA was useful
- 1-3 years R&D to qualify for MA under exceptional circumstances
- EMA/CVMP moved procedures as quickly as possible, but this could not match urgent field needs
- Formal variation required to update SPC
- Increase in demands as urgency receded

What could be changed ?

- **Harmonised/EU use of Article 8**
- **Decrease time to MA under exceptional circumstances by:**
  - **Step-wise approach.**
  - **Combination with an EU Article 8 approach.**
  - **Flexibility in CVMP meeting dates / timelines.**
- **Use of National assessments and National Assessor as Rapporteur.**
- **Ability to place licence “on hold”, maintain but suspend development and data provision.**
- **New Technology Vaccines, Live Vaccines**

Disease Monitoring

- **ECDC does good work but human focused by regulation.**
- **EFSA does good work but food safety focused.**
- **OIE monitors certain diseases.**
- **Good work done at MS level and by companies.**

- **Veterinary diseases a need for:**
  - **Improved co-ordination at EU level**
  - **Improved surveillance at EU level**
  - **Improved threat prediction at EU level**

- **UNLESS disease is zoonotic/food safety**

EU ABS Regulation

Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

Member states are expected to be pragmatic.

- **But need to negotiate Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) prior to starting work could cause delays.**

Conclusions

- **Need for a vaccine identified as early as possible.**
- **Companies need the clearest possible understanding of the European position on vaccination.**
- **EU authorisation/permission as article 8 with**
  - **Agreed initial acceptable data package**
  - **Step-wise development to MA under exceptional circumstances or full MA**
  - **Option to place “on hold”.**

Thank you

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THANK YOU