



Joint EMA/HMA workshop on requirements for the authorisation of veterinary vaccines in the EU

**European Commission
Directorate Health and Food Safety
Health systems and products
Medicinal products - quality, safety and efficacy**

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- 1. Requirements for authorisation of vaccines**
- 2. Problems with availability of veterinary medicines**
- 3. Measures to promote the availability**

1. Requirements for authorisation of vaccines

- In the scope of the Directive 2001/82/EC:
 - immunological veterinary medicinal products
- Out of scope:
 - Art 3(b) of Directive 2001/82/EC
 - Art 4 (1) of Directive 2001/82/EC

1. Requirements for authorisation of vaccines

- Out of scope - Art 3 (b) of Directive 2001/82/EC:

This Directive shall not apply to:

(b) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or animals of that holding in the same locality

1. Requirements for authorisation of vaccines

- Out of scope - Art 4 of Directive 2001/82/EC:

Member States may provide that this Directive shall not apply to non-inactivated immunological veterinary products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality.

1. Requirements for authorisation of vaccines

- Proposal for a Regulation on veterinary medicinal products:
 - In the scope: - immunological veterinary medicinal products
 - ✓ Annex II Part 2 of the Proposal – technical requirements for biological veterinary medicinal products
 - Out of scope: Article 2(4)(a)

1. Requirements for authorisation of vaccines

- Proposal for a Regulation on veterinary medicinal products - out of scope:
 - Article 2(4)(a)
 - ✓ This Regulation shall not apply to:
 - (a) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or those animals in the same locality

2. Problem with availability

- Lack of availability of veterinary medicines – main problem identified and driver for revising the veterinary medicines legislation

3. Measures to promote the availability

- Under the current legal set-up:
 - Flexibility - MS can apply the legislation taking on board the particular animal health situation in the regions
 - Use of veterinary medicines which have a marketing authorisation is always preferable

3. Measures to promote the availability

- Proposal for a Regulation on veterinary medicinal products:
 - centralised procedure for all types of veterinary medicines
 - incentives for the industry to develop products in particular for minor species:
 - ✓ protection of technical documentation
 - ✓ limited market MA

Thank you for your attention!

