ANIMAL HEALTH ADVISORY COMMITTEE

Future rules for the use of VMPs for disease prevention and control

Brussels, 28 October 2022

Draft Delegated act

on the use of veterinary medicinal products for disease prevention and control

European Commission

AHL: Rules for the use of VMPs for disease prevention and control

Article 46(1)

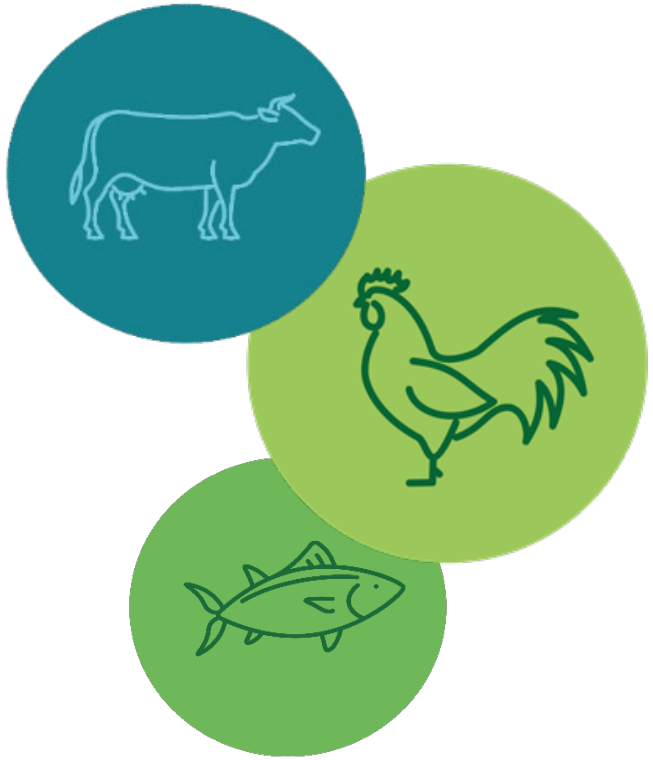
Provides for the possibility for the Member States to take measures concerning **the use of (ALL) veterinary medicinal products** to ensure the most efficient **prevention or control** of **(ALL)** listed diseases. These measures may cover prohibitions, restrictions and compulsory use of veterinary medicinal products and must be previously assessed as proportionate and necessary.

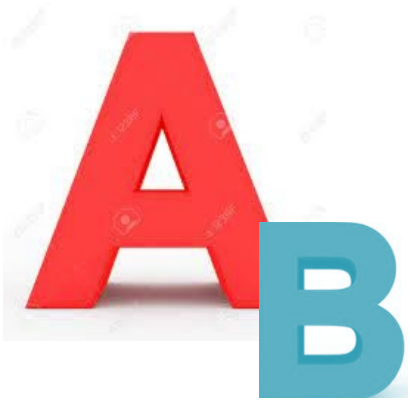
Article 47(1) (empowerment)

Empowers the Commission to adopt delegated acts concerning:

- ✓ prohibitions and restrictions on the use of veterinary medicinal products;
- ✓ specific conditions for the use of veterinary medicinal products for a specific listed disease;
- ✓ risk-mitigation measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;
- ✓ surveillance for specific listed diseases following the use of vaccines and other veterinary medicinal products.

Future rules for the use of VMPs for disease prevention and control





Category C and D diseases

Article 46 of AHL, CDR (EU) 2020/688 (for movements within the Union) and CDR (EU) 2020/689 (for eradication programmes and freedom status) apply

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Proposed approach

Rules on the use of **certain VMPs** for prevention and control of **certain listed diseases - Terrestrial and Aquatic animals**

Circumstances under which **vaccines for category A** diseases can be used

Which **VMPs cannot be used for category A and B** diseases *(including some vaccines, i.e. Rinderpest and Mycobacterium tuberculosis complex)*

Rules on the use of **vaccines** for prevention and control of category A diseases **– Terrestrial animals (partially Aquatic)**

- Preconditions
- Strategies
- General rules
- Risk-mitigation measures (movement restrictions)

Disease-specific conditions

- Implementation + post vaccination surveillance
- Measures (movement prohibitions for animals and products) in the vaccination zone
- Recovery of the previous animal health status

This (draft) Act does not interfere with the scope of **Regulation (EU) 2019/6**

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Progress since the last AHAC meeting (07 June 2022)

Finalisation of internal consultation/final modifications: early August 2022

Amendments to the text :

- **Restructuring of the body and annexes** in line with the instructions of the legal service to ensure that :
  - All rules are laid down in the articles
  - Annexes list only the conditions for the implementation of the rules

- **No major factual changes** on the rules /conditions *(e.g. who and how decides vaccination, what vaccines may be used against which diseases, risk mitigating measures for each disease etc.)*

- **Uniform structure** across all disease-specific Annexes

- Necessary amendments in view of the recent adoption of the **new name of the World Organisation for Animal Health** (WOAH, founded as OIE)

Progress since the last AHAC meeting (07 June 2022)

Public feedback: 5 August – 2 September 2022

Online procedure, through the dedicated EU website:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12173-Veterinary-medicines-vaccines-conditions-for-use_en

26 Feedbacks received (numerous stakeholders + few anonymous)
Various points /concerns raised *(e.g. post-vaccination surveillance, types of vaccines used, trade implications of vaccination, decision mechanisms for the initiation of vaccination, movement restrictions for vaccinated animals and products thereof).*

MANY THANKS TO ALL WHO PROVIDED THEIR FEEDBACK !!

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Progress since the last AHAC meeting (07 June 2022)

Public feedback: 5 August – 2 September 2022

Careful examination of all contributions after public feedback

- Some comments already taken on board in the final text (*e.g. type of vaccines for HPAI, to ensure that they do not contain live avian influenza virus)*
- Some comments kept in reserve, to reconsider once new/sufficient scientific evidence becomes available *(e.g. post vaccination surveillance / risk mitigating measures etc.)*
- Some comments outside the scope of the regulation but kept under the Commission "radar", for future actions *(e.g. contacts with non-EU trade partners)*

Progress since the last AHAC meeting (07 June 2022)

Translation: August - October 2022

Final fine tuning of the draft , in close cooperation with DG Translation

- Correction of typos
- Correction of clerical errors *(e.g. cross references, numbering of paragraphs – sub-paragraphs etc.)*
- Minor textual amendments to improve clarity of the text in all EU Official Languages

SPECIAL THANKS TO DGT FOR THEIR EFFORT AND SUPPORT !

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State of play – Updated timeline

- Rules discussed in 8 Expert Group meetings (incl. a questionnaire to MS experts) (Doc SANTE 7144/2020) from March 2020 until May 2022
- Finalisation of internal consultation and final modifications: early August 2022
- Public feedback: 5 August – 2 September 2022
- Translation: completed 25 October 2022
- Adoption by the COMM: October-November 2022
- EP and Council objection period: November-December 2022
- OJ Publication: January 2023

Thank you

European Commission