

Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance)

PART III

DISEASE AWARENESS, PREPAREDNESS AND CONTROL

TITLE I

DISEASE AWARENESS AND PREPAREDNESS

CHAPTER 2

The use of veterinary medicinal products for disease prevention and control

Article 46

The use of veterinary medicinal products for disease prevention and control

1 The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient prevention or control of those diseases, provided that such measures are appropriate or necessary.

Those measures may cover the following:

- a prohibitions and restrictions on the use of veterinary medicinal products;
- b the compulsory use of veterinary medicinal products.

2 Member States shall take the following criteria into consideration when determining whether or not to use, and how to use, veterinary medicinal products as prevention and control measures for a specific listed disease:

- a the disease profile;
- b the distribution of the listed disease in:
 - (i) the Member State concerned;
 - (ii) the Union;
 - (iii) where relevant, neighbouring third countries and territories;
 - (iv) third countries and territories from which animals and products are brought into the Union;
- c the availability and effectiveness of the veterinary medicinal products in question, and the risks attaching to them;
- d the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products concerned;
- e the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products concerned compared to other available disease prevention and control strategies.

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3 Member States shall take appropriate preventive measures concerning the use of veterinary medicinal products for scientific studies or for the purposes of developing and testing them under controlled conditions to protect animal and public health.

Article 47

Delegation of powers for the use of veterinary medicinal products

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning what might constitute appropriate and necessary measures as set out in Article 46, in relation to:

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

2 The Commission shall take into account the criteria set out in Article 46(2) when laying down the rules provided for in paragraph 1 of this Article.

3 Where, in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 265 shall apply to rules adopted pursuant to paragraph 1 of this Article.

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