Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

CHAPTER VII

SUPPLY AND USE

Section 3

Use

Article 107

Use of antimicrobial medicinal products

1 Antimicrobial medicinal products shall not be applied routinely nor used to compensate for poor hygiene, inadequate animal husbandry or lack of care or to compensate for poor farm management.

2 Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield.

3 Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.

In such cases, the use of antibiotic medicinal products for prophylaxis shall be limited to the administration to an individual animal only, under the conditions laid down in the first subparagraph.

4 Antimicrobial medicinal products shall be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available. Member States may provide guidance regarding such other appropriate alternatives and shall actively support the development and application of guidelines which promote the understanding of risk factors associated with metaphylaxis and include criteria for its initiation.

5 Medicinal products which contain the designated antimicrobials referred to in Article 37(5) shall not be used in accordance with Articles 112, 113 and 114.

6 The Commission may, by means of implementing acts, and taking into consideration scientific advice of the Agency, establish a list of antimicrobials which:

a shall not be used in accordance with Articles 112, 113 and 114; or

b shall only be used in accordance with Articles 112, 113 and 114 subject to certain conditions.

When adopting those implementing acts, the Commission shall take account of the following criteria:

a risks to animal or public health if the antimicrobial is used in accordance with Articles 112, 113 and 114;

b risk for animal or public health in case of development of antimicrobial resistance;

c availability of other treatments for animals;

d availability of other antimicrobial treatments for humans;

e impact on aquaculture and farming if the animal affected by the condition receives no treatment.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

7 A Member State may further restrict or prohibit the use of certain antimicrobials in animals on its territory if the administration of such antimicrobials to animals is contrary to the implementation of a national policy on prudent use of antimicrobials.

8 Measures adopted by the Member States on the basis of paragraph 7 shall be proportionate and justified.

9 The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph 7.

Status:
Point in time view as at 11/12/2018.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council, Article 107.