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 IV

POST-MARKETING AUTHORISATION MEASURES

Section 3

Changes to the terms of the marketing authorisations

Article 60

Variations

1 The Commission shall, by means of implementing acts, establish a list of variations not requiring assessment. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2 The Commission shall take account of the following criteria when adopting the implementing acts referred to in paragraph 1:

a the need for a scientific assessment of changes in order to determine the risk to public or animal health or to the environment;

b whether changes have an impact on the quality, safety or efficacy of the veterinary medicinal product;

c whether changes imply no more than a minor alteration to the summary of product characteristics;

d whether changes are of an administrative nature.

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Point in time view as at 11/12/2018.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 60.