

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 5

Pharmacovigilance

Article 77

Pharmacovigilance responsibilities of the marketing authorisation holder

1 Marketing authorisation holders shall establish and maintain a system for collecting, collating and evaluating information on the suspected adverse events concerning their authorised veterinary medicinal products, enabling them to fulfil their pharmacovigilance responsibilities ('pharmacovigilance system').

2 The marketing authorisation holder shall have in place one or more pharmacovigilance system master files describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products. For each veterinary medicinal product, the marketing authorisation holder shall not have more than one pharmacovigilance system master file.

3 The marketing authorisation holder shall designate a local or regional representative for the purpose of receiving reports of suspected adverse events who is able to communicate in the languages of the relevant Member States.

4 The marketing authorisation holder shall be responsible for the pharmacovigilance of the veterinary medicinal product for which it holds a marketing authorisation and shall continuously evaluate by appropriate means the benefit-risk balance of this veterinary medicinal product and, if necessary, take appropriate measures.

5 The marketing authorisation holder shall comply with good pharmacovigilance practice for veterinary medicinal products.

6 The Commission shall, by means of implementing acts, adopt necessary measures on good pharmacovigilance practice for veterinary medicinal products and also on the format and content of the pharmacovigilance system master file and its summary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

7 Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in detail in the pharmacovigilance system master file.

8 The marketing authorisation holder shall designate one or more qualified persons responsible for pharmacovigilance to carry out the tasks provided for in Article 78. Those qualified persons shall reside and operate in the Union and shall be appropriately qualified and

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be permanently at the disposal of the marketing authorisation holder. Only one such qualified person shall be designated for each pharmacovigilance system master file.

9 The tasks, set out in Article 78, of the qualified person responsible for pharmacovigilance referred to in paragraph 8 of this Article may be outsourced to a third party under the conditions set out in that paragraph. In such cases, those arrangements shall be specified in detail in the contract and included in the pharmacovigilance system master file.

10 The marketing authorisation holder shall, based on the assessment of the pharmacovigilance data, and where necessary, submit without undue delay an application for a variation to the terms of a marketing authorisation in accordance with Article 62.

11 The marketing authorisation holder shall not make a public announcement on pharmacovigilance information in relation to its veterinary medicinal products without giving prior or simultaneous notification of its intention to the competent authority having granted the marketing authorisation or to the Agency, as applicable.

The marketing authorisation holder shall ensure that such public announcement is presented objectively and is not misleading.