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 VIII

INSPECTIONS AND CONTROLS

Article 123

Controls

1 Competent authorities shall carry out controls of the following persons:

- a manufacturers and importers of veterinary medicinal products and active substances;
- b distributors of active substances;
- c marketing authorisation holders;
- d holders of a wholesale distribution authorisation;
- e retailers;
- f owners and keepers of food-producing animals;
- g veterinarians;
- h holders of a registration for homeopathic veterinary medicinal products;
- i holders of veterinary medicinal products referred to in Article 5(6); and
- j any other persons having obligations under this Regulation.

2 The controls referred to in paragraph 1 shall be carried out regularly, on a risk-basis, in order to verify that the persons referred to in paragraph 1 comply with this Regulation.

3 The risk-based controls referred to in paragraph 2 shall be carried out by the competent authorities taking account of at least:

- a the intrinsic risks associated with the activities of the persons referred to in paragraph 1 and the location of their activities;
- b the past record of the persons referred to paragraph 1 as regards the results of controls performed on them and their previous compliance;
- c any information that might indicate non-compliance;
- d the potential impact of non-compliance on public health, animal health, animal welfare and the environment.

4 Controls may also be carried out on the request of a competent authority of another Member State, the Commission or the Agency.

5 Controls shall be carried out by representatives of the competent authority.

6 Inspections may be carried out as part of the controls. Such inspections may be made unannounced. During those inspections the representatives of a competent authority shall at least be empowered to:

- a inspect the premises, equipment, means of transport, records, documents and systems, related to the objective of the inspection;

b inspect and take samples with a view to submitting them for an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by a Member State;

c document any evidence deemed necessary by the representatives;

d carry out the same controls on any parties performing the tasks required under this Regulation with, for or on behalf of the persons referred to in paragraph 1.

7 The representatives of the competent authorities shall keep a record of every control that they carry out and where necessary shall draw up a report. The person referred to in paragraph 1 shall be promptly informed in writing by the competent authority of any case of non-compliance identified through the controls and shall have the opportunity to submit comments within a time limit set by the competent authority.

8 The competent authorities shall have procedures or arrangements in place to ensure that staff performing controls are free from any conflict of interest.

Article 124

Audits by the Commission

The Commission may carry out audits in Member States on their competent authorities for the purpose of confirming the appropriateness of the controls carried out by those competent authorities. Such audits shall be coordinated with the relevant Member State and shall be carried out in a manner which avoids unnecessary administrative burden.

After each audit, the Commission shall draft a report containing, where appropriate, recommendations to the relevant Member State. The Commission shall send the draft report to the competent authority for comments and shall take into account any such comments in drawing up the final report. The final report and the comments shall be made public by the Commission.

Article 125

Certificate of suitability

In order to verify whether the data submitted for obtaining a certificate of suitability complies with the monographs of the *European Pharmacopoeia*, the standardisation body for nomenclatures and quality norms within the meaning of the Convention on the elaboration of a *European Pharmacopoeia* accepted by Council Decision 94/358/EC[(1)] (European Directorate for the Quality of Medicines and Healthcare ('EDQM')) may ask the Commission or the Agency to request an inspection by a competent authority when the starting material concerned is subject to a *European Pharmacopoeia* monograph.

Article 126

Specific rules on pharmacovigilance inspections

1 The competent authorities and the Agency shall ensure that all pharmacovigilance system master files in the Union are regularly checked and that the pharmacovigilance systems are being correctly applied.

2 The Agency shall coordinate and the competent authorities shall carry out inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 44.

3 The competent authorities shall carry out inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Articles 47, 49, 52 and 53.

4 The competent authorities of the Member States in which the pharmacovigilance system master files are located shall carry out inspections of the pharmacovigilance systems master files.

5 Notwithstanding paragraph 4 of this Article and pursuant to Article 80, a competent authority may enter into any work-sharing initiatives and delegation of responsibilities with other competent authorities to avoid the duplication of inspections of pharmacovigilance systems.

6 The results of the pharmacovigilance inspections shall be recorded in the pharmacovigilance database as referred to in Article 74.

Article 127

Proof of the product quality for veterinary medicinal products

1 The marketing authorisation holder shall have at its disposal the results of the control tests carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in the marketing authorisation.

2 If a competent authority concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take measures in relation to the marketing authorisation holder and the manufacturer, and shall inform accordingly the competent authorities of other Member States in which the veterinary medicinal product is authorised, and also the Agency in case the veterinary medicinal product is authorised under the centralised procedure.

Article 128

Proof of the product quality specific for immunological veterinary medicinal products

1 For the purposes of application of Article 127(1), competent authorities may require the holder of a marketing authorisation for immunological veterinary medicinal products to submit to the competent authorities the copies of all the control reports signed by the qualified person in accordance with Article 97.

2 The holder of a marketing authorisation for immunological veterinary medicinal products shall ensure that an adequate number of representative samples of each batch of veterinary medical products is held in stock at least up to the expiry date, and provide samples promptly to the competent authorities on request.

3 Where necessary for reasons of human or animal health, a competent authority may require the holder of a marketing authorisation for an immunological veterinary medicinal product to submit samples of batches of the bulk product or of the immunological veterinary

medicinal product for control by an Official Medicines Control Laboratory before the product is placed on the market.

4 On the request of a competent authority, the marketing authorisation holder shall promptly supply the samples referred to in paragraph 2, together with the control reports referred to in paragraph 1, for control testing. The competent authority shall inform the competent authorities in other Member States in which the immunological veterinary medicinal product is authorised, as well as the EDQM and the Agency in case the immunological veterinary medicinal product is authorised under the centralised procedure, of its intention to control batches of the immunological veterinary medicinal product.

5 On the basis of the control reports referred to in this Chapter, the laboratory responsible for the control shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished immunological veterinary medicinal product, in accordance with the relevant specifications in its dossier for marketing authorisation.

6 The list of tests to be repeated by the laboratory responsible for the control shall be restricted to justified tests, provided that all competent authorities in the relevant Member States, and, if appropriate, the EDQM, agree to such a restriction.

For immunological veterinary medicinal products authorised under the centralised procedure, the list of tests to be repeated by the control laboratory may be reduced only upon agreement of the Agency.

7 The competent authorities shall recognise the results of the tests referred to in paragraph 5.

8 Unless the Commission is informed that a longer period is necessary to conduct the tests, the competent authorities shall ensure that the control is completed within 60 days of receipt of the samples and control reports.

9 The competent authority shall notify the competent authorities of other relevant Member States, the EDQM, the marketing authorisation holder and, if appropriate, the manufacturer, of the results of the tests within the same period of time.

10 The competent authority shall verify that the manufacturing processes used in the manufacture of immunological veterinary medicinal products are validated and that batch-to-batch consistency is ensured.

(**1**) Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).