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 VI

MANUFACTURING, IMPORT AND EXPORT

Article 88

Manufacturing authorisations

1 A manufacturing authorisation shall be required in order to carry out any of the following activities:

a to manufacture veterinary medicinal products even if intended only for export;

b to engage in any part of the process of manufacturing a veterinary medicinal product or of bringing a veterinary medicinal product to its final state, including engagement in the processing, assembling, packaging and repackaging, labelling and relabelling, storing, sterilising, testing or releasing it for supply as part of that process; or

c to import veterinary medicinal products.

2 Notwithstanding paragraph 1 of this Article, Member States may decide that a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation of veterinary medicinal products, where those processes are carried out solely for retail directly to the public in accordance with Articles 103 and 104.

3 Where paragraph 2 applies, the package leaflet shall be given with each divided part and the batch number and expiry date shall be clearly indicated.

4 The competent authorities shall record the manufacturing authorisations granted by them in the database on manufacturing and wholesale distribution set up in accordance with Article 91.

5 Manufacturing authorisations shall be valid throughout the Union.

Article 89

Application for manufacturing authorisation

1 An application for a manufacturing authorisation shall be submitted to a competent authority in the Member State in which the manufacturing site is located.

2 An application for a manufacturing authorisation shall contain at least the following information:

a veterinary medicinal products which are to be manufactured or imported;

b name or company name and permanent address or registered place of business of the applicant;

c pharmaceutical forms which are to be manufactured or imported;

d details about the manufacturing site where the veterinary medicinal products are to be manufactured or imported;

e a statement to the effect that the applicant fulfils the requirements laid down in Articles 93 and 97.

Article 90

Procedure for granting of manufacturing authorisations

1 Before granting a manufacturing authorisation, the competent authority shall carry out an inspection of the manufacturing site.

2 The competent authority may require the applicant to submit further information in addition to that supplied in the application pursuant to Article 89. Where the competent authority exercises that right, the time limit referred to in paragraph 4 of this Article shall be suspended or revoked until the applicant has submitted the additional data required.

3 A manufacturing authorisation shall apply only to the manufacturing site and the pharmaceutical forms specified in the application referred to in Article 89.

4 Member States shall lay down procedures for granting or refusing manufacturing authorisations. Such procedures shall not exceed 90 days from receipt by the competent authority of an application for manufacturing authorisation.

5 A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to undertake actions or introduce specific procedures within a given time period. Where a manufacturing authorisation has been conditionally granted, it shall be suspended or revoked if the requirements are not complied with.

Article 91

Database on manufacturing and wholesale distribution

1 The Agency shall establish and maintain a Union database on manufacturing, import and wholesale distribution (‘manufacturing and wholesale distribution database’).

2 The manufacturing and wholesale distribution database shall include information regarding the grant, suspension or revocation by competent authorities of any manufacturing authorisations, wholesale distribution authorisations, certificates of good manufacturing practice, and registrations of manufacturers, importers and distributors of active substances.

3 Competent authorities shall record in the manufacturing and wholesale distribution database information on manufacturing and wholesale distribution authorisations and certificates granted in accordance with Articles 90, 94 and 100 together with information on importers, manufacturers and distributors of active substances registered in accordance with Article 95.

4 The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications, including the format for electronic submissions of data, for the manufacturing and wholesale distribution database.

5 The Agency shall ensure that information reported to the manufacturing and wholesale distribution database is collated and made accessible and that the information is shared.

6 The competent authorities shall have full access to the manufacturing and wholesale distribution database.

7 The general public shall have access to information in the manufacturing and wholesale distribution database, without the possibility to change that information therein.

Article 92

Changes to manufacturing authorisations on request

1 If the holder of a manufacturing authorisation requests a change in that manufacturing authorisation, the procedure for examining such a request shall not exceed 30 days from the day on which the competent authority receives the request. In justified cases, including when an inspection is necessary, that period of time may be extended by the competent authority to 90 days.

2 The request referred to in paragraph 1 shall contain a description of the requested change.

3 Within the period referred to in paragraph 1, the competent authority may require the holder of the manufacturing authorisation to provide supplementary information within a set time limit and may decide to perform an inspection. The procedure shall be suspended until such time as the supplementary information has been provided.

4 The competent authority shall assess the request referred to in paragraph 1, inform the holder of the manufacturing authorisation of the outcome of the assessment and, where appropriate, amend the manufacturing authorisation, and update, where appropriate, the manufacturing and wholesale distribution database.

Article 93

Obligations of the holder of a manufacturing authorisation

1 The holder of a manufacturing authorisation shall:

a have at its disposal suitable and sufficient premises, technical equipment and testing facilities, for the activities stated in its manufacturing authorisation;

b have at its disposal the services of at least one qualified person referred to in Article 97 and ensure that the qualified person operates in compliance with that Article;

c enable the qualified person referred to in Article 97 to carry out his or her duties, particularly by providing access to all the necessary documents and premises, and by placing at his or her disposal all the necessary technical equipment and testing facilities;

d give at least a 30 days prior notice to the competent authority before the replacement of the qualified person referred to in Article 97 or, if prior notice is not possible because the replacement is unexpected, inform the competent authority immediately;

e have at its disposal the services of staff complying with the legal requirements existing in the relevant Member State as regards both manufacture and controls;

f allow the representatives of the competent authority access to the premises at any time;

g keep detailed records of all veterinary medicinal products which the holder of a manufacturing authorisation supplies in accordance with Article 96, and keep samples of each batch;

h only supply veterinary medicinal products to wholesale distributors of veterinary medicinal products;

i inform the competent authority and the marketing authorisation holder immediately if the holder of a manufacturing authorisation obtains information that veterinary

medicinal products which fall within the scope of its manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those veterinary medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale by means of information society services;

j comply with good manufacturing practice for veterinary medicinal products and use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practice for active substances;

k verify that each manufacturer, distributor and importer within the Union from whom the holder of a manufacturing authorisation obtains active substances is registered with the competent authority of the Member State in which the manufacturer, distributor and importer are established, in accordance with Article 95;

l perform audits based on a risk assessment on the manufacturers, distributors and importers from whom the holder of a manufacturing authorisation obtains active substances.

2 The Commission shall, by means of implementing acts, adopt measures on good manufacturing practice for veterinary medicinal products and active substances used as starting materials, referred to in point (j) of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 94

Certificates of good manufacturing practice

1 Within 90 days of an inspection, the competent authority shall issue a certificate of good manufacturing practice of the manufacturer for the manufacturing site concerned if the inspection establishes that the manufacturer in question is in compliance with the requirements laid down in this Regulation and with the implementing act referred to in Article 93(2).

2 If the outcome of the inspection referred to in paragraph 1 of this Article is that the manufacturer does not comply with good manufacturing practice, such information shall be entered into the manufacturing and wholesale distribution database referred to in Article 91.

3 The conclusions reached following an inspection of a manufacturer shall be valid throughout the Union.

4 A competent authority, the Commission or the Agency may require a manufacturer established in a third country to undergo an inspection as referred to in paragraph 1, without prejudice to any arrangements which may have been concluded between the Union and a third country.

5 Importers of veterinary medicinal products shall ensure, before those products are supplied to the Union, that the manufacturer established in a third country is in possession of a certificate of good manufacturing practice issued by a competent authority or, where the third country is party to an arrangement concluded between the Union and the third country, there is an equivalent confirmation.

Article 95

Importers, manufacturers and distributors of active substances established in the Union

1 Importers, manufacturers and distributors of active substances used as starting materials in veterinary medicinal products, that are established in the Union, shall register their activity with the competent authority of the Member State in which they are established and shall comply with good manufacturing practice or good distribution practice, as applicable.

2 The registration form for registering the activity with the competent authority shall include at least the following information:

a name or company name and permanent address or registered place of business;

b the active substances which are to be imported, manufactured or distributed;

c particulars regarding the premises and the technical equipment.

3 The importers, manufacturers and distributors of active substances referred to in paragraph 1 shall submit the registration form to the competent authority at least 60 days prior to the intended start of their activity. The importers, manufacturers and distributors of active substances in operation before 28 January 2022 shall submit the registration form to the competent authority by 29 March 2022.

4 The competent authority may, based on a risk assessment, decide to carry out an inspection. If the competent authority notifies within 60 days of receipt of the registration form that an inspection will be carried out, the activity shall not begin before the competent authority has notified that the activity may start. In such a case, the competent authority shall carry out the inspection and communicate to the importers, manufacturers and distributors of active substances referred to in paragraph 1 the results of the inspection within 60 days of the notification of its intention to carry out the inspection. If within 60 days of receipt of the registration form the competent authority has not notified that an inspection will be carried out, the activity may start.

5 The importers, manufacturers and distributors of active substances referred to in paragraph 1 shall communicate annually to the competent authority the changes which have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed shall be notified immediately.

6 Competent authorities shall enter the information provided in accordance with paragraph 2 of this Article and with Article 132 in the manufacturing and wholesale distribution database referred to in Article 91.

7 This Article shall be without prejudice to Article 94.

8 The Commission shall, by means of implementing acts, adopt measures on good distribution practice for active substances used as starting materials in veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 96

Record keeping

1 The holder of a manufacturing authorisation shall record the following information in respect of all veterinary medicinal products that it supplies:

a date of the transaction;

b name of the veterinary medicinal product, and marketing authorisation number if applicable, as well as pharmaceutical form and strength, as appropriate;

c quantity supplied;

d name or company name and permanent address or registered place of business of the recipient;

e batch number;

f date of expiry.

2 The records referred to in paragraph 1 shall be available for inspection by competent authorities for one year after the date of expiry of the batch or at least five years from recording, whichever is longer.

Article 97

Qualified person responsible for manufacturing and batch release

1 The holder of a manufacturing authorisation shall have permanently at its disposal the services of at least one qualified person who fulfils the conditions laid down in this Article and is responsible, in particular, for carrying out the duties specified in this Article.

2 The qualified person referred to in paragraph 1 shall hold a university degree in one or more of the following scientific disciplines: pharmacy, human medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology.

3 The qualified person referred to in paragraph 1 shall have acquired practical experience over at least two years, in one or more undertakings which are authorised manufacturers, in the activities of quality assurance of medicinal products, of qualitative analysis of medicinal products, of quantitative analysis of active substances and the checking necessary to ensure the quality of veterinary medicinal products.

The duration of practical experience required in the first subparagraph may be reduced by one year where a university course lasts for at least five years and by a year and a half where the university course lasts for at least six years.

4 The holder of the manufacturing authorisation, if a natural person, may assume the responsibility referred to in paragraph 1, if he or she personally fulfils the conditions referred to in paragraphs 2 and 3.

5 The competent authority may lay down appropriate administrative procedures to verify that a qualified person referred to in paragraph 1 fulfils the conditions referred to in paragraphs 2 and 3.

6 The qualified person referred to in paragraph 1 shall ensure that each batch of the veterinary medicinal products is manufactured in compliance with good manufacturing practice, and tested in compliance with the terms of the marketing authorisation. That qualified person

shall draw up a control report to that effect. Such control reports shall be valid throughout the Union.

7 Where veterinary medicinal products are imported, the qualified person referred to in paragraph 1 shall ensure that each imported production batch has undergone in the Union a full qualitative and a quantitative analysis of at least all the active substances, and all the other tests necessary to ensure the quality of the veterinary medicinal products in accordance with the requirements of the marketing authorisation and that the batch manufactured is in compliance with good manufacturing practice.

8 The qualified person referred to in paragraph 1 shall keep records in respect of each released production batch. Those records shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for one year after the date of expiry of the batch or at least five years from recording, whichever is longer.

9 Where veterinary medicinal products manufactured in the Union are exported and subsequently imported back into the Union from a third country, paragraph 6 shall apply.

10 Where veterinary medicinal products are imported from third countries with which the Union has made arrangements regarding application of standards of good manufacturing practice at least equivalent to those laid down in accordance with Article 93(2) and it is demonstrated that the tests referred to in paragraph 6 of this Article have been carried out in the exporting country, the qualified person may draw up the control report referred to in paragraph 6 of this Article without the necessary tests referred to in paragraph 7 of this Article being carried out, unless the competent authority of the Member State of importation decides otherwise.

Article 98

Certificates of veterinary medicinal products

1 On the request of a manufacturer or an exporter of veterinary medicinal products, or of the authorities of an importing third country, the competent authority or the Agency shall certify that:

a the manufacturer holds a manufacturing authorisation;

b the manufacturer possesses a certificate of good manufacturing practice as referred to in Article 94; or

c the veterinary medicinal product concerned has been granted a marketing authorisation in that Member State or, in the case of a request to the Agency, that it has been granted a centralised marketing authorisation.

2 When issuing such certificates, the competent authority or the Agency, as applicable, shall take into account the relevant prevailing administrative arrangements with regard to the content and format of such certificates.

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