

L.N. 3 of 2018

**VETERINARY SERVICES ACT
(CAP. 437)**

**Good Manufacturing Practice for Veterinary
Medicinal Products Rules, 2018**

IN exercise of the powers conferred by articles 30 and 31 of the Veterinary Services Act, the Minister for the Environment, Sustainable Development and Climate Change in concurrence with the Minister for Health, after consultation with the Head of the National Veterinary Laboratory, has made the following rules:-

1. (1) The title of these rules is the Good Manufacturing Practice for Veterinary Medicinal Products Rules, 2018. Citation and scope.

(2) The scope of these rules is to transpose Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

(3) These rules lay down the principles and guidelines of good manufacturing practice for veterinary medicinal products whose manufacture requires the authorisation referred to in Article 44 of Directive 2001/82/EC.

2. (1) For the purposes of these regulations and unless the context otherwise requires, the following definitions shall apply: Interpretation.

"the Act" means the Veterinary Services Act;

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"the Commission" means the European Commission;

"competent authority" means the Department of Veterinary Services, or any other authority or authorities authorised by the Department of Veterinary Services to act on its behalf;

"good manufacturing practice" shall mean the part of quality assurance with ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use;

"manufacturer" shall mean any holder of the authorization referred to in Article 44 of Directive 2001/82/EC;

"pharmaceutical quality assurance" means the sum total of the organized arrangements made with the object of ensuring that veterinary medicinal products are of the quality required for their intended use;

"qualified person" shall mean the person referred to in Article 52 of Directive 2001/82/EC;

"veterinary medicinal products" means veterinary medicinal products as set out in Article 1(2) of Council Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products.

(2) Unless the context otherwise requires, words and phrases used in these rules which are not defined herein shall have the same meaning assigned to them in article 2 of the Act.

Inspections.

3. (1) The competent authority shall, by means of the repeated inspections referred to in Article 80 of Directive 2001/82/EC, ensure that manufacturers respect the principles and guidelines of good manufacturing practice laid down by these rules.

(2) For the interpretation of these principles and guidelines of good manufacturing practice, the manufacturers and the competent authority shall refer to the detailed guidelines referred to in Article 51 of Directive 2001/82/EC.

(3) The detailed guidelines referred to in sub-rule (2) are published by the Commission in the "Guide to good manufacturing practice for medicinal products" and in its annexes.

Conformity with good manufacturing practice.

4. (1) The manufacturers shall ensure that the manufacturing operations are carried out in accordance with good manufacturing practice and with the manufacturing authorisation.

(2) For veterinary medicinal products imported from third countries, the importer shall ensure that the veterinary medicinal products have been manufactured by manufacturers duly authorized and conforming to good manufacturing practice standards, at least equivalent to those laid down by the Community.

Manufacturing operations subject to an authorisation for marketing.

5. (1) The manufacturer shall ensure that all manufacturing operations subject to an authorization for marketing are carried out in accordance with the information given in the application for marketing authorization as accepted by the relevant competent authorities.

(2) The manufacturers shall regularly review their manufacturing methods in the light of scientific and technical progress.

(3) When a modification to the marketing authorization dossier is necessary, the application for modification must be

submitted to the competent authorities.

6. (1) The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different services involved. Quality management.

7. It shall be the duty of the manufacturer to ensure that: Personnel.

(a) at each manufacturing site there are a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the pharmaceutical quality assurance objectives;

(b) the duties of managerial and supervisory staff, including the qualified person(s), responsible for implementing and operating good manufacturing practice:

(i) are defined in job descriptions;

(ii) their hierarchical relationships are defined in an organisational chart;

(iii) the job descriptions and organisational chart mentioned in sub-rule (b)(i) and (ii) respectively are approved in accordance with the manufacturer's internal procedures;

(c) the staff referred to in paragraph (b) shall be given sufficient authority to carry out their responsibilities correctly;

(d) personnel shall receive initial and continuing training including the theory and application of the concept of quality assurance and good manufacturing practice;

(e) hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes include procedures relating to health, hygiene and clothing of personnel.

8. (1) Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations. Premises and equipment.

(2) Layout, design and operation must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.

(3) Premises and equipment intended to be used for manufacturing operations which are critical for the quality of the products shall be subjected to appropriate qualification.

Documentation.

9. (1) (a) The manufacturer shall have a system of documentation based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the different manufacturing operations that they perform.

(b) Documents shall be clear, free from errors and kept up to-date.

(c) Pre-established procedures for general manufacturing operations and conditions shall be available, together with specific documents, for the manufacture of each batch. This set of documents shall make it possible to trace the history of the manufacture of each batch.

(d) The batch documentation shall be retained for at least one year after the expiry date of the batches to which it relates, or at least five years after the certification referred to in Article 55 (3) of Directive 2001/82/EC, whichever is the longer.

(2) (a) When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall have validated the system by proving that the data will be appropriately stored during the anticipated period of storage.

(b) Data stored by these systems shall be made readily available in legible form. The electronically stored data shall be protected against loss or damage of data which may be done by duplication or back-up and transfer onto another storage system.

Production.

10. (1) The different production operations shall be carried out according to pre-established instructions and procedures and in accordance with good manufacturing practice.

(2) Adequate and sufficient resources shall be made available for the in-process controls.

(3) Appropriate technical and, or organizational measures shall be taken to avoid cross contamination and mix-ups.

(4) Any new manufacture or important modification of a manufacturing process shall be validated.

(5) Critical phases of manufacturing process shall be regularly revalidated.

11. (1) The manufacturer shall establish and maintain a quality control department: Quality control.

Provided that this department shall be placed under the authority of a person having the required qualifications and shall be independent of the other departments.

(2) The quality control department shall have at its disposal one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of starting materials, packaging materials and intermediate and finished products testing:

Provided that, resorting to outside laboratories is authorized in accordance with rule 12 and after the authorization referred to in Article 24(b) of Directive 2001/82/EC has been granted.

(3) During the final control of finished products before their release for the sale or distribution, in addition to analytical results, the quality control department shall take into account essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of the products to their specifications including the final finished pack.

(4) (a) Samples of each batch of finished products shall be retained for at least one year after the expiry date.

(b) Samples of starting materials other than solvents, gases and water used shall be retained for at least two years after the release of the product:

Provided that this period may be shortened if their stability, as mentioned in the relevant specification, is shorter.

(c) All the samples shall be maintained at the disposal of the competent authority.

(d) For certain veterinary medicinal products manufactured individually or in small quantities, or when their storage could raise special problems, other sampling and retaining conditions may be defined in agreement with the competent authority.

12. (1) Any manufacturing operation or operation linked with the manufacture, which is carried out under contract, shall be the subject of a written contract between the contract giver and the contract acceptor. Work contracted out.

(2) The contract shall clearly define the responsibilities of each party and in particular the observance of good manufacturing practice by the contract acceptor and the manner in which the qualified person responsible for releasing each batch shall undertake his full responsibilities.

(3) The contract acceptor shall not further sub-contract any of the work entrusted to him by the contract giver without the written authorization of the contract giver.

(4) The contract acceptor shall respect the principles and guidelines of good manufacturing practice and shall submit to inspections carried out by the competent authorities as provided for by Article 80 of Directive 2001/82/EC.

Complaints and
product recall.

13. (1) The manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time the veterinary medicinal products in the distribution network.

(2) Any complaint concerning a quality defect shall be recorded and investigated by the manufacturer.

(3) The competent authority shall be informed by the manufacturer of any quality defect that could result in a recall or abnormal restriction on the supply. In so far as possible, the countries of destination shall also be indicated.

(4) Any recall shall be made in accordance with the requirements referred to in Article 91 of Directive 2001/82/EC.

Self-inspection.

14. (1) The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures.

(2) Records of self-inspections and any further corrective action shall be maintained.