COMMISSION IMPLEMENTING REGULATION (EU) 2021/1248

of 29 July 2021

as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 99(6) thereof,

Whereas:

(1) Article 101(5) of Regulation (EU) 2019/6 requires wholesale distributors to comply with good distribution practice for veterinary medicinal products, as adopted by the Commission.

(2) Measures on good distribution practice should ensure the identity, integrity, traceability and quality of veterinary medicinal products across the supply chain. Furthermore, those measures should guarantee that veterinary medicinal products are appropriately stored, transported and handled, as well as ensure that they remain within the legal supply chain during storage and transport.

(3) Several international standards and guidelines on good distribution practice exist for medicinal products for human use ([2]) ([3]) ([4]) ([5]). At Union level, guidelines on good distribution practice have been adopted only in respect of medicinal products for human use ([6]). Corresponding measures in the veterinary domain should take into account the experience gained with the application of the current system under Directive 2001/83/EC of the European Parliament and of the Council ([7]) in light of the similarities and potential differences between the requirements on good distribution practice for medicinal products for human use and for veterinary medicinal products.

(4) Wholesale distributors often deal with both medicinal products for human use and veterinary medicinal products. In addition, good distribution practice inspections for both types of medicinal products are often to be performed by the same competent authority experts. Therefore, in order to avoid unnecessary administrative burden on the industry and the competent authorities, it is practical to apply similar measures to the veterinary domain as in the human domain, unless specific needs dictate otherwise.

(5) In order not to affect negatively the availability of veterinary medicinal products in the Union, the good distribution practice requirements for veterinary medicinal products should not be more stringent than the corresponding ones for medicinal products for human use.

([1]) OJ L 4, 7.1.2019, p. 43.

([2]) Good storage and distribution practices for medical products, In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020: Annex 7 (WHO Technical Report Series, No 1025).

([3]) Guide to good storage practices for pharmaceuticals. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-seventh report. Geneva: World Health Organization; 2003: Annex 9 (WHO Technical Report Series, No 908).

([4]) Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fifth report. Geneva: World Health Organization; 2011: Annex 9 (WHO Technical Report Series, No 961).

([5]) PIC/S Guide to good distribution practice for medicinal products, PIC/S, PE 011-1, 1.6.2014.

([6]) Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01) (OJ C 343, 23.11.2013, p. 1).

([7]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(6) The measures on good distribution practice for veterinary medicinal products laid down in this Regulation should ensure consistency with and complement the implementing measures on good manufacturing practice for veterinary medicinal products and active substances used as starting materials provided for in Article 93(2) of Regulation (EU) 2019/6 and good distribution practice for active substances used as starting materials in veterinary medicinal products provided for in Article 95(8) of that Regulation.

(7) Any person acting as a wholesale distributor of veterinary medicinal products must hold a wholesale distribution authorisation in accordance with Article 99(1) of Regulation (EU) 2019/6 and comply with good distribution practice for veterinary medicinal products in accordance with Article 101(5) of that Regulation. In accordance with Article 99(5) of that Regulation, a manufacturing authorisation allows for the wholesale distribution of the veterinary medicinal products covered by that manufacturing authorisation. Therefore, manufacturers performing any such distribution activities with their own veterinary medicinal products are also to comply with good distribution practice for veterinary medicinal products.

(8) The definition of wholesale distribution as laid down in Article 4(36) of Regulation (EU) 2019/6 does not exclude wholesale distributors established or operating under specific customs regimes, such as free zones or customs warehouses. Therefore, all obligations related to wholesale distribution activities (such as exporting, holding or supplying) also apply to those wholesale distributors in respect of good distribution practice for veterinary medicinal products.

(9) Relevant sections of good distribution practice for veterinary medicinal products should also be adhered to by third-party actors involved in the wholesale distribution of veterinary medicinal products and should be part of their contractual obligations. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified veterinary medicinal products.

(10) A quality system is required to ensure that the objectives of good distribution practice are achieved and should clearly set out responsibilities, processes and risk management principles in relation to the wholesale distributor's activities. That quality system should be the responsibility of the organisation's management, requires their leadership and active participation, and should be supported by personnel commitment.

(11) The correct distribution of veterinary medicinal products relies significantly on an adequate number of competent personnel to carry out all the tasks for which the wholesale distributor is responsible. Individual responsibilities should be clearly understood by personnel and be recorded.

(12) The persons distributing veterinary medicinal products should have suitable and adequate premises, installations and equipment, in order to ensure proper storage and distribution of veterinary medicinal products.

(13) Good documentation should be an essential part of any quality system. Written documentation should be required in order to prevent errors from oral communication and permit the tracking of relevant operations during the wholesale distribution of veterinary medicinal products. All types of documents should be defined and adhered to.

(14) Procedures should describe all distribution activities that affect the identity, traceability and quality of the veterinary medicinal products.

(15) Records of all significant activities or events should be made and kept to ensure the traceability of the origin and destination of veterinary medicinal products, as well as the identification of all suppliers of, or those supplied with, such veterinary medicinal products. Such records should facilitate the recall of a batch of a veterinary medicinal product, if necessary, as well as the investigation of falsified or suspected falsified veterinary medicinal products.

(16) With regard to the processing of personal data of employees, complainants or any other natural person, Regulation (EU) 2016/679 of the European Parliament and of the Council ([8]) on the protection of natural persons should apply to the processing of personal data and on the free movement of such data.

(17) The quality system should fully describe all key operations in appropriate documentation.

(18) Complaints, returns, suspected falsified veterinary medicinal products and recalls should be recorded and handled carefully in accordance with established procedures. Records should be made available to the competent authorities. An assessment of returned veterinary medicinal products should be performed before any approval for resale.

(19) Any activity covered by good distribution practice for veterinary medicinal products that is outsourced should be defined, agreed and controlled in order to avoid misunderstandings that could affect the integrity of the veterinary medicinal product. A written contract between the contract giver and the contract acceptor should clearly establish the duties of each party.

(20) Regardless of the mode of transport, it should be possible to demonstrate that the veterinary medicinal products have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be used when planning transport of and for transporting veterinary medicinal products.

(21) Regular self-inspections are necessary to monitor the implementation of and compliance with good distribution practice for veterinary medicinal products and to propose necessary corrective and preventive measures.

(22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down the measures on good distribution practice for veterinary medicinal products.

2. This Regulation shall apply to holders of a manufacturing authorisation performing wholesale distribution of the veterinary medicinal products covered by that manufacturing authorisation, and to holders of a wholesale distribution authorisation, including those established or operating under specific customs regimes, such as free zones or customs warehouses.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'good distribution practice for veterinary medicinal products' means the part of the quality assurance throughout the supply chain which ensures that the quality of veterinary medicinal products is maintained throughout all stages of the supply chain from the site of their manufacturer to the persons referred to in Article 101(2) of Regulation (EU) 2019/6;

([8]) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

(b) 'free zone' means any free zone designated by the Member States in accordance with Article 243 of Regulation (EU) No 952/2013 of the European Parliament and of the Council ([9]);

(c) 'customs warehouse' means any of the warehouses referred to in Article 240(1) of Regulation (EU) No 952/2013;

(d) 'quality system' means the sum of all aspects of a system that implements quality policy and ensures that quality objectives are met;

(e) 'quality risk management' means a systematic process, applied both proactively and retrospectively, for the assessment, control, communication and review of risks to the quality of the veterinary medicinal product across the product's lifecycle;

(f) 'validation' means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria;

(g) 'procedure' means a documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the distribution of veterinary medicinal products;

(h) 'documentation' means written procedures, instructions, contracts, records and data, in paper or in electronic form;

(i) 'procuring' means obtaining, acquiring or purchasing veterinary medicinal products from manufacturers, importers or other wholesale distributors;

(j) 'holding' means storing veterinary medicinal products;

(k) 'supplying' means all activities of providing, selling or donating veterinary medicinal products to the persons referred to in Article 101(2) of Regulation (EU) 2019/6;

(l) 'transport' means moving veterinary medicinal products between two locations without storing them for unjustified periods of time;

(m) 'deviation' means departure from approved documentation or an established standard;

(n) 'falsified veterinary medicinal product' means any veterinary medicinal product with a false representation of any of the following:

(i) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(ii) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(iii) its history, including the records and documents relating to the distribution channels used;

(o) 'contamination' means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a veterinary medicinal product during production, sampling, packaging or repackaging, storage or transport;

(p) 'calibration' means the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard;

(q) 'qualification' means the action of proving that any equipment works correctly and actually leads to the expected results;

([9]) Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

(r) 'signed' means the record of the individual who performed a particular action or review. This record can be initials, a full handwritten signature, a personal seal, or an advanced electronic signature as defined in Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council ([10]);

(s) 'batch' means a defined quantity of starting material, packaging material or product processed in a single process or series of processes, so that it is expected to be homogeneous;

(t) 'expiry date' means the date placed on the packaging of a veterinary medicinal product designating the time during which that veterinary medicinal product is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used;

(u) 'batch number' means a distinctive combination of numbers or letters that uniquely identifies a batch.

CHAPTER II

QUALITY MANAGEMENT

Article 3

Development and maintenance of a quality system

1. The persons referred to in Article 1(2) shall develop and maintain a quality system.

2. The quality system shall take into account the size, structure and complexity of the activities of those persons and the changes foreseen for those activities.

3. The persons referred to in Article 1(2) shall ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

Article 4

Requirements for the quality system

1. The quality system shall set out responsibilities, processes and quality risk management principles in relation to the activities of the persons referred to in Article 1(2). All wholesale distribution activities shall be clearly defined and systematically reviewed. All critical steps of wholesale distribution activities and significant changes shall be justified and, where relevant, subject to validation.

2. The quality system shall encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure that the veterinary medicinal products delivered maintain their quality and integrity and remain within the legal supply chain during storage or transport.

3. The quality system shall be fully documented. Its effectiveness shall be monitored. All quality-system-related activities shall be defined and documented.

4. A quality manual or equivalent documentation approach shall be established and include a description of any differences in the quality system regarding handling of veterinary medicinal products of different types.

5. A change control system shall be established and incorporate the principles of quality risk management and be proportionate and effective.

([10]) Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

6. The quality system shall ensure that the following obligations are fulfilled:

(a) the procuring, holding, supplying, transport or export of veterinary medicinal products comply with the requirements of good distribution practice for veterinary medicinal products laid down in this Regulation;

(b) management responsibilities are clearly specified;

(c) veterinary medicinal products are delivered to the correct consignees within an appropriate time period;

(d) records are made contemporaneously;

(e) deviations are documented and investigated;

(f) appropriate corrective and preventive actions ('CAPA') are taken in line with the principles of quality risk management;

(g) changes that may affect the storage and distribution of veterinary medicinal products are evaluated.

Article 5

Management of outsourced activities

The quality system shall cover the control and review of any outsourced activities related to the wholesale distribution of veterinary medicinal products. Such control and review shall incorporate quality risk management and shall include:

(a) assessment of the suitability and competence of the contract acceptor to carry out the activity and checking authorisation status, if required;

(b) definition of the responsibilities and communication processes for the quality-related activities of the parties involved;

(c) regular monitoring and review of the performance of the contract acceptor, and the identification and implementation of any required improvements on a regular basis.

Article 6

Management review and monitoring

1. The management of the persons referred to in Article 1(2) shall establish and implement a formal process for reviewing the quality system on a periodic basis.

2. The review shall include the following:

(a) a measurement of achievement of the objectives of the quality system;

(b) an assessment of:

  (i) performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, deviations, CAPA, changes to processes;

  (ii) feedback on outsourced activities;

  (iii) self-assessment processes including risk assessments and audits; and

  (iv) results of external assessments such as inspections, findings and customer audits;

(c) emerging regulations, guidance and quality issues that can impact the quality system;

(d) innovations that might enhance the quality system;

(e) changes in business environment and objectives.

3. The outcome of each management review of the quality system shall be documented in a timely manner and communicated effectively internally.

Article 7

Quality risk management

1. The persons referred to in Article 1(2) shall apply quality risk management.

2. Quality risk management shall ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the treated animal or animal group, the persons responsible for the animal and the treatment, the consumer of a food producing animal and the environment.

3. The level of detail and documentation of the quality risk management process shall be proportionate to the level of risk to quality.

CHAPTER III

PERSONNEL REQUIREMENTS

Article 8

Obligations of persons responsible for wholesale distribution

1. The persons responsible for wholesale distribution referred to in Article 101(3) of Regulation (EU) 2019/6 ('the responsible persons') shall ensure compliance with good distribution practice for veterinary medicinal products. In addition to the requirement laid down in Article 100(2)(a) of that Regulation, the responsible persons shall have appropriate competence and experience as well as knowledge of, and training in, compliance with good distribution practice for veterinary medicinal products.

2. The responsible persons shall be personally responsible for fulfilling their obligations and shall be contactable at any time.

3. The responsible persons may delegate their tasks but not their responsibilities.

4. If the responsible persons are not available, the persons referred to in Article 1(2) shall appoint a substitute for the necessary time period so that continuity of business is ensured.

5. A written job description of the responsible persons shall define their authority to take decisions with regard to their responsibilities. The persons referred to in Article 1(2) shall give the responsible persons the defined authority, resources and responsibility needed to fulfil their duties.

6. The responsible persons shall carry out their tasks in such a way as to ensure that the relevant persons referred to in Article 1(2) can demonstrate compliance with good distribution practice for veterinary medicinal products and that the obligations referred to in Article 101(4) of Regulation (EU) 2019/6 are met.

7. The obligations of the responsible persons shall include:

(a) ensuring that a quality system is implemented and maintained;

(b) focusing on the management of authorised activities and the accuracy and quality of records;

(c) ensuring that initial and continuous training programmes are implemented and maintained;

(d) coordinating and promptly performing any recall operations for veterinary medicinal products;

(e) ensuring that relevant customer complaints are dealt with effectively;

(f) ensuring that suppliers and customers are approved;

(g) approving any subcontracted activities which may impact on good distribution practice for veterinary medicinal products;

(h) ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and ensuring that the necessary CAPA are put in place;

(i) keeping appropriate records of any delegated tasks;

(j) deciding on the final disposition of returned, rejected, recalled or falsified veterinary medicinal products;

(k) approving any returns to saleable stock;

(l) ensuring that any additional requirements imposed on certain veterinary medicinal products by national law are adhered to;

(m) documenting deviations and deciding on CAPA to correct deviations and avoid their reoccurrence and monitoring of the effectiveness of those CAPA.

Article 9

Other personnel

1. There shall be an adequate number of competent personnel involved in all stages of the wholesale distribution of veterinary medicinal products. That number shall be proportionate to the volume and scope of activities.

2. The organisational structure of the persons referred to in Article 1(2) shall be set out in an organisation chart. The individual roles, responsibilities, and interrelationships of all members of personnel shall be clearly indicated in that chart. Each member of personnel shall understand their own role and responsibilities.

3. The role and responsibilities of employees working in key positions shall be set out in written job descriptions, along with any arrangements for deputising.

Article 10

Training of personnel

1. All personnel involved in wholesale distribution activities shall be trained in the requirements of good distribution practice for veterinary medicinal products. Furthermore, personnel shall have the appropriate competence and experience prior to commencing their tasks.

2. Personnel shall receive initial and continuing training relevant to their role, based on procedures and in accordance with a written training program. The responsible persons shall maintain their competence in good distribution practice for veterinary medicinal products through regular training.

3. Training shall include identifying and preventing falsified veterinary medicinal products from entering the supply chain.

4. Personnel dealing with veterinary medicinal products requiring more stringent handling conditions, such as hazardous products, products presenting special risks of abuse, including narcotic and psychotropic substances, and temperature-sensitive products, shall receive specific training.

5. The persons referred to in Article 1(2) shall keep a record of all training and periodically assess and document its effectiveness.

Article 11

Hygiene

The persons referred to in Article 1(2) shall establish appropriate procedures relating to personnel hygiene, including personal health and appropriate clothing, relevant to the activities carried out. Personnel shall comply with those procedures.

CHAPTER IV

PREMISES AND EQUIPMENT

Article 12

Premises

1. The premises shall be designed or adapted to ensure that the required storage conditions are maintained. They shall be suitably secure, structurally sound and of sufficient capacity to allow safe storage and handling of the veterinary medicinal products. Storage areas shall be provided with adequate lighting to enable all operations to be carried out accurately and safely. Veterinary medicinal products shall be stored suitably spaced to permit cleaning and inspection. Pallets shall be kept in a good state of cleanliness and repair.

2. Where premises are not directly operated by the persons referred to in Article 1(2), a contract shall be in place. The persons referred to in Article 1(2) may only use contracted premises if those premises are covered by a separate wholesale distribution authorisation.

3. Veterinary medicinal products shall be stored in segregated areas that are clearly marked and have access restricted to authorised personnel.

4. Any system replacing physical segregation, as applicable, such as electronic segregation based on a computerised system, shall provide equivalent security and shall be subject to appropriate validation.

5. Veterinary medicinal products pending a decision as to their disposal, or veterinary medicinal products that have been removed from saleable stock, shall be segregated physically or, if an equivalent electronic system is available, electronically, including returned veterinary medicinal products.

6. Veterinary medicinal products received from a third country but not intended for the Union market shall be segregated physically and electronically, if an electronic system is available.

7. Any expired veterinary medicinal products, recalled veterinary medicinal products and rejected veterinary medicinal products shall immediately be segregated physically and stored in a dedicated area away from all other veterinary medicinal products. The appropriate degree of security shall be applied in those areas to ensure that such items remain separate from saleable stock. Those areas shall be clearly identified.

8. The premises shall be designed or adapted to ensure that veterinary medicinal products subject to specific storage and handling measures, such as narcotics and psychotropic substances, are stored in accordance with written instructions and subject to appropriate security measures.

9. One or more dedicated areas shall be provided and appropriate safety and security measures shall be in place for the storage of hazardous veterinary medicinal products, as well as veterinary medicinal products presenting special safety risks of fire or explosion, such as medicinal gases, combustibles, flammable liquids and solids.

10. Receiving and dispatch bays shall protect veterinary medicinal products from prevailing weather conditions. There shall be adequate separation between the receipt and dispatch and storage areas. Procedures shall be in place to maintain control of inbound and outbound goods. Reception areas where deliveries are examined following receipt shall be designated and suitably equipped.

11. Unauthorised access to all areas of the authorised premises shall be prevented by appropriate devices such as a monitored intruder alarm system and appropriate access control. Visitors shall be accompanied at all times.

12. Premises and storage facilities shall be clean and free from litter and dust. Cleaning programmes, instructions and records shall be in place. Appropriate cleaning equipment and cleaning agents shall be chosen and used so as not to present a source of contamination.

13. The premises shall be dry and maintained within acceptable temperature limits.

14. There shall be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

15. Vehicles shall be cleaned regularly. Equipment chosen and used for the cleaning of vehicles shall not constitute a source of contamination.

16. Premises shall be designed and equipped in order to afford protection against the entry of insects, rodents or other animals. A preventive pest control programme shall be in place.

17. Rest, wash and refreshment rooms for employees shall be adequately separated from the storage areas. The presence of food, drink, smoking material or medicinal products for personal use shall be prohibited in the storage areas.

Article 13

Temperature and environmental control

1. Suitable equipment and procedures shall be in place to check the environment where veterinary medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.

2. An initial temperature mapping exercise shall be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment shall be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise shall be repeated according to the results of a risk assessment exercise or whenever significant modifications are made to the facility or the temperature controlling equipment. For small premises of a few square meters that are at room temperature, an assessment of potential risks, such as heaters, shall be conducted and temperature monitors shall be placed accordingly.

Article 14

Equipment

1. All equipment with an impact on storage and distribution of veterinary medicinal products shall be designed, located and maintained to a standard suitable for its intended purpose. Planned maintenance shall be in place for key equipment vital to the functionality of the operation.

2. Equipment used to control or to monitor the environment where the veterinary medicinal products are stored shall be subject to calibration at defined intervals based on a risk and reliability assessment.

3. Calibration of equipment shall be traceable to a national or international measurement standard. Appropriate alarm systems shall be in place to provide alerts when there are excursions from pre-defined storage conditions. Alarm levels shall be appropriately set and alarms shall be regularly tested to ensure adequate functionality.

4. Equipment repair, maintenance and calibration operations shall be carried out in such a way that the integrity of the veterinary medicinal products is not compromised.

5. Defective vehicles and equipment shall not be used and shall either be labelled as such or removed from service.

6. Equipment not relevant for the wholesale activities shall not be stored in the area where veterinary medicinal products are stored.

7. Adequate records of repair, maintenance and calibration activities for key equipment, such as cold stores, monitored intruder alarm and access control systems, refrigerators, thermohygrometers, or other temperature and humidity recording devices, air handling units and any equipment used in conjunction with the onward supply chain, shall be made and the results shall be retained.

Article 15

Computerised systems

1. Before a computerised system is brought into use, it shall be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

2. A written, detailed description of the computerised system shall be available, including diagrams where appropriate. That description shall be kept up to date. The document shall describe principles, objectives, security measures, system scope and main features, how the system is used and the way it interacts with other systems.

3. Data shall only be entered into the computerised system or amended by persons authorised to do so.

4. Data shall be secured by physical or electronic means and protected against accidental or unauthorised modifications. Stored data shall be checked periodically for accessibility. Data shall be backed up at regular intervals. Backup data shall be retained at a separate and secure location for at least 5 years or for the period stated in the applicable national law, if that period is longer than 5 years.

5. Procedures to be followed if the system fails or breaks down shall be defined. This shall include systems for the restoration of data.

Article 16

Qualification and validation

1. The persons referred to in Article 1(2) shall identify what key equipment qualification and key process validation is necessary to ensure their correct installation and operation. The scope and extent of such qualification and validation activities such as storage, picking and packing processes, shall be determined using a documented risk assessment approach.

2. Equipment and processes shall be subject to qualification or validation, respectively, before commencing use and after any significant changes, such as repair or maintenance.

3. Qualification and validation reports shall be prepared summarising the results obtained and commenting on any deviations observed. The principles of CAPA shall be applied, where necessary. Evidence of satisfactory validation and acceptance of a process or piece of equipment shall be produced and approved by appropriate personnel.

CHAPTER V

DOCUMENTATION, PROCEDURES AND RECORD-KEEPING

Article 17

Documentation requirements

1. Documentation shall fulfil the following requirements:

(a) be readily available or retrievable;

(b) be sufficiently comprehensive with respect to the scope of the activities of the persons referred to in Article 1(2);

(c) be written in a language understood by personnel;

(d) be written in clear, unambiguous language.

2. Documentation shall be approved, signed and dated by appropriate authorised persons, as required. It shall not be handwritten, unless handwritten records are justified for practical reasons. In that case, sufficient space shall be provided to make those records.

3. When errors in the documentation are identified, they shall be corrected without delay, with clear traceability of who corrected them and when.

4. Any alteration made in the documentation shall be signed and dated. The alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.

5. Documents shall be retained for at least 5 years or for the period stated in the applicable national law, if that period is longer than 5 years. Personal data shall be deleted as soon as their storage is no longer necessary for the purpose of distribution activities.

6. Each employee shall have ready access to all necessary documentation for the tasks executed.

7. Relationships and control measures for original documents and official copies, data handling and records shall be stated for all paper-based, electronic and hybrid systems.

Article 18

Procedures

1. Procedures shall describe the wholesale distribution activities affecting the quality of veterinary medicinal products. Those activities include:

(a) receipt and checking of deliveries; suppliers and customers control;

(b) storage;

(c) cleaning and maintenance of the premises and equipment, including pest control;

(d) checking and recording of storage conditions;

(e) protection of veterinary medicinal products during transport;

(f) security of stocks on site and of consignments in transit;

(g) withdrawal from saleable stock;

(h) handling of returned veterinary medicinal products;

(i) recall plans;

(j) qualification and validation;

(k) procedures and measures for the disposal of unusable veterinary medicinal products;

(l) procedures for investigating and resolving complaints;

(m) procedures for identifying veterinary medicinal products suspected of falsification.

2. Procedures shall be approved, signed and dated by the responsible persons.

3. Valid and approved procedures shall be used. Documents shall be clear and appropriately detailed. The title, nature and purpose of documents shall be stated. Documents shall be reviewed regularly and kept up to date. Version control shall be applied to procedures. After revision of a document, a system shall exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures shall be removed from workstations and archived.

Article 19

Records

1. Records shall be kept either in the form of purchase or sales invoices, delivery slips, or in electronic form, for any transaction in veterinary medicinal products received or supplied.

2. In addition to the detailed records referred to in Article 101(7) of Regulation (EU) 2019/6, records shall include any additional requirements specified by national law, as appropriate.

3. Records shall be made at the time each operation is performed. If handwritten, they shall be made in clear, legible and indelible handwriting.

CHAPTER VI

OPERATIONS

Article 20

Requirements for operations

1. The persons referred to in Article 1(2) shall ensure that the identity of the veterinary medicinal product is not lost during wholesale distribution and shall use all means available to minimise the risk of falsified veterinary medicinal products entering the legal supply chain.

2. The persons referred to in Article 1(2) shall ensure that the wholesale distribution of veterinary medicinal products is performed according to the information on the outer packaging.

3. The persons referred to in Article 1(2) shall ensure that all veterinary medicinal products they distribute in the Union are:

(a) covered by a marketing authorisation granted by a competent authority or the Commission, as applicable;

(b) covered by a registration granted by a competent authority;

(c) covered by an exemption, granted by a competent authority, from the requirements for marketing authorisation;

(d) covered by an approval for parallel trade issued by the competent authority of the destination Member State;

(e) covered by a permission to use in accordance with Articles 110(2) and (3) of Regulation (EU) 2019/6; or

(f) in the case of products to be used under Articles 112(2), 113(2) or 114(4) of Regulation (EU) 2019/6, imported by holders of a manufacturing authorisation issued in accordance with Article 90 of that Regulation or in accordance with the procedures referred to in Article 106(3) of that Regulation, as applicable.

4. All key operations of the persons referred to in Article 1(2) shall be fully described in the quality system in appropriate documentation.

Article 21

Verification of eligibility and approval of suppliers

1. Where veterinary medicinal products are obtained from a person referred to in Article 1(2), the receiving wholesale distributor shall verify that the supplier complies with good distribution practice for veterinary medicinal products as laid down in this Regulation and that they hold an authorisation. This information shall be obtained from the national competent authorities or the Union database on manufacturing, import and wholesale distribution referred to in Article 91(1) of Regulation (EU) 2019/6. Appropriate verification of eligibility and approval of suppliers shall be performed prior to any procurement of veterinary medicinal products. This process shall be controlled by a procedure and the results documented and periodically checked based on quality risk management principles.

2. When entering into a contract with new suppliers, the persons referred to in Article 1(2) shall carry out so called due diligence checks in order to assess the suitability, competence and reliability of the other party. The due diligence checks shall consider:

(a) the reputation or reliability of the supplier;

(b) offers of veterinary medicinal products more likely to be falsified;

(c) large offers of veterinary medicinal products which are generally only available in limited quantities;

(d) unusually high diversity of veterinary medicinal products handled by supplier;

(e) abnormally low prices.

Article 22

Verification of eligibility and approval of customers

1. The persons referred to in Article 1(2) shall perform initial and, as appropriate, periodic checks to establish whether their customers meet the requirements laid down in Article 101(2) of Regulation (EU) 2019/6. This may include requesting copies of a customer's authorisations issued in accordance with national law, verifying status on a competent authority website and requesting evidence of qualifications or entitlement in accordance with national law.

2. The persons referred to in Article 1(2) shall monitor their transactions and investigate any irregularity in the sales patterns of narcotics, psychotropic substances or other dangerous substances. Unusual sales patterns that may constitute diversion or misuse of veterinary medicinal products shall be investigated and reported to competent authorities where necessary.

Article 23

Receipt of veterinary medicinal products

1. The persons responsible for receiving veterinary medicinal products shall ensure that the arriving consignment is correct, that the veterinary medicinal products originate from approved suppliers and that they have not been damaged during transport.

2. Veterinary medicinal products requiring special storage or security measures shall be prioritised and, once appropriate checks have been conducted, those products shall immediately be transferred to appropriate storage facilities.

3. Batches of veterinary medicinal products intended for the Union market shall not be transferred to saleable stock before assurance has been obtained in accordance with procedures, that they are authorised for sale. For batches coming from another Member State, prior to their transfer to saleable stock, the control report referred to in Article 97(6) and (9) of Regulation (EU) 2019/6, the results of necessary tests, as applicable, referred to in Article 97(7) of that Regulation or another proof of release to the market in question based on an equivalent system, shall be carefully checked by appropriately trained personnel.

Article 24

Storage

1. Veterinary medicinal products shall be stored separately from other products likely to alter them and shall be protected from the harmful effects of light, temperature, moisture and other external factors. Particular attention shall be paid to veterinary medicinal products requiring special storage conditions.

2. Incoming containers of veterinary medicinal products shall be cleaned, if necessary, before storage. Any activities performed on the incoming goods shall not impact on the quality of the veterinary medicinal products.

3. Warehousing operations shall be performed so as to ensure that appropriate storage conditions are maintained and allow for appropriate security of stocks.

4. Stock shall be rotated according to the 'first expiry, first out' principle. Exceptions shall be documented.

5. Veterinary medicinal products shall be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Veterinary medicinal products shall not be stored directly on the floor unless the package is designed to allow for such storage, such as for some medicinal gas cylinders.

6. Veterinary medicinal products that are nearing their expiry date shall immediately be segregated from saleable stock physically or, if an equivalent electronic system is available, electronically.

7. Stock inventories shall be performed regularly taking into account the requirements of national law. Stock irregularities shall be investigated and documented.

Article 25

Destruction of obsolete veterinary medicinal products

1. Veterinary medicinal products intended for destruction shall be appropriately identified, kept separately and handled in accordance with a procedure.

2. Destruction of veterinary medicinal products shall be carried out in accordance with the applicable requirements for handling, transport and disposal of such products.

3. Records of all destroyed veterinary medicinal products shall be retained for a period defined in the quality system referred to in Article 3.

Article 26

Picking

Controls shall be in place to ensure that the correct veterinary medicinal product is picked. The veterinary medicinal product picked shall have an appropriate remaining shelf life and shall not have been damaged during storage.

Article 27

Supply

1. An electronic or physical document shall accompany all supplies and include, in addition to the information referred to in Article 101(7) of Regulation (EU) 2019/6, a unique number to allow identification of the delivery order, the applicable transport and storage conditions and additional requirements specified by national law.

2. Electronic or physical records shall be kept so that the location of the veterinary medicinal product is known.

Article 28

Export

1. When exporting veterinary medicinal products for which neither a national competent authority, nor the Commission, as applicable, has granted a marketing authorisation in accordance with Chapter III of Regulation (EU) 2019/6, wholesale distributors shall take appropriate measures to prevent those veterinary medicinal products reaching the Union market.

2. Where the persons referred to in Article 1(2) supply veterinary medicinal products to persons in third countries, they shall only supply those products to persons who are authorised or entitled to receive veterinary medicinal products for wholesale distribution or for supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned.

CHAPTER VII

COMPLAINTS, RETURNS, SUSPECTED FALSIFIED VETERINARY MEDICINAL PRODUCTS AND RECALLS

Article 29

Complaints

1. Complaints shall be recorded with all the original details. A distinction shall be made between complaints related to the quality of a veterinary medicinal product and those related to wholesale distribution.

In the event of a complaint about the quality of a veterinary medicinal product and a potential product defect, the manufacturer or marketing authorisation holder shall be informed without delay.

Any veterinary medicinal product distribution complaint shall be thoroughly investigated to identify the origin of or the reason for the complaint.

2. A person shall be appointed to handle complaints and sufficient personnel shall be allocated to support that person.

3. If necessary, appropriate follow-up actions (including CAPA) shall be taken after investigation and evaluation of the complaint, including, where required, notification to the national competent authorities.

Article 30

Returns

1. Returned veterinary medicinal products shall be handled according to a written, risk-based process taking into account the nature of the veterinary medicinal product concerned, any special storage conditions it requires and the time elapsed since it was supplied. Returns shall be conducted in accordance with national law and contractual arrangements between the parties.

2. Veterinary medicinal products which have left the care of the persons referred to in Article 1(2) shall only be returned to saleable stock if all of the following conditions are met:

(a) the veterinary medicinal products are in their unopened and undamaged secondary packaging and are in good condition;

(b) the veterinary medicinal products have not expired and have not been recalled;

(c) the veterinary medicinal products returned from a customer not holding a wholesale distribution authorisation or from pharmacies or persons authorised to supply veterinary medicinal products to the public in accordance with national law of the Member State concerned have been returned within a defined acceptable time limit determined by using quality risk management principles;

(d) the veterinary medicinal products have not been returned by the animal owner to the pharmacy or to other persons authorised to supply veterinary medicinal products to the public in accordance with national law of the Member State concerned, unless such return is permitted under national law of that Member State;

(e) it has been demonstrated by the customer that the veterinary medicinal products have been transported, stored and handled in compliance with their specific storage requirements;

(f) the veterinary medicinal products have been examined and assessed by a sufficiently trained and competent person authorised to do so;

(g) the persons referred to in Article 1(2) have reasonable evidence that the veterinary medicinal product was supplied to the customer returning the veterinary medicinal product, as evidenced by copies of the original delivery note or by referencing invoice numbers, batch numbers, expiry date etc., as required by national law, and that there is no reason to believe that the veterinary medicinal product has been falsified.

3. For veterinary medicinal products requiring specific temperature storage conditions such as low temperature, returns to saleable stock shall only be made if there is documented evidence that the product has been stored under the authorised storage conditions throughout the periods in points (a) to (f). If any deviation has occurred, a risk assessment shall be performed, which shall demonstrate the integrity of the veterinary medicinal product. The evidence shall cover all the following steps:

(a) delivery to the customer;

(b) examination of the veterinary medicinal product;

(c) opening of the transport packaging;

(d) return of the veterinary medicinal product to the packaging;

(e) collection and return to the persons referred to in Article 1(2);

(f) return to the wholesale distribution site refrigerator.

4. Products returned to saleable stock shall be placed so that the 'first expiry, first out' system operates effectively.

5. Stolen veterinary medicinal products that have been recovered shall not be returned to saleable stock nor sold to customers.

Article 31

Falsified veterinary medicinal products

1. In addition to the notification referred to in Article 101(6) of Regulation (EU) 2019/6, wholesale distributors shall immediately stop the distribution of any veterinary medicinal products they identify as falsified or suspected to be falsified and act on the instructions as specified by the competent authorities. A procedure shall be in place to this effect. The incident shall be recorded with all the original details and investigated.

2. Any suspected falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically or, if an equivalent electronic system is available, electronically. Any falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically, stored in a dedicated area away from all other veterinary medicinal products and appropriately labelled. All relevant activities in relation to such products shall be documented and records retained.

Article 32

Recalls

1. There shall be documentation and procedures in place to ensure that veterinary medicinal products received and distributed are traceable for the purposes of any product recall.

2. In the event of a veterinary medicinal product recall, the persons referred to in Article 1(2) shall inform, with the appropriate degree of urgency and clear actionable instructions, all affected customers to whom the product has been distributed.

3. The persons referred to in Article 1(2) shall inform the relevant national competent authority of all veterinary medicinal product recalls. If the veterinary medicinal product is exported, the persons referred to in Article 1(2) shall inform the third country clients or the third country competent authorities of the recall as required by national law.

4. The persons referred to in Article 1(2) shall regularly evaluate the effectiveness of the arrangements for veterinary medicinal product recall on the basis of quality risk management principles.

5. The persons referred to in Article 1(2) shall ensure that recall operations can be initiated promptly and at any time.

6. The persons referred to in Article 1(2) shall follow the instructions of a recall message, which shall be approved, if required, by the competent authorities.

7. Any recall operation shall be recorded at the time it is carried out. Records shall be made readily available to the competent authorities.

8. The distribution records shall be readily accessible to the persons responsible for the recall and shall contain sufficient information on distributors and directly supplied customers (with addresses, phone numbers and means of electronic communication inside and outside working hours, batch numbers as required by national law and quantities delivered), including those records for exported veterinary medicinal products and veterinary medicinal product samples.

9. The progress of the recall process shall be recorded in a final report including reconciliation between the delivered and recovered quantities of the recalled veterinary medicinal product.

CHAPTER VIII

OUTSOURCED ACTIVITIES

Article 33

Obligations of contract giver

1. The contract giver shall be responsible for any activities contracted out.

2. The contract giver shall be responsible for assessing the competence of the contract acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles of good distribution practice for veterinary medicinal products are followed. The contract giver shall perform an audit of the contract acceptor before commencement of the outsourced activities and shall monitor and review the performance of the contract acceptor. The frequency of audit shall be defined based on risk, depending on the nature of the outsourced activities. Where there has been a change to outsourced activities, the contract giver shall apply risk assessment as part of change control to determine if re-audit is required. The contract acceptor shall permit the contract giver to audit the outsourced activities.

3. The contract giver shall provide the contract acceptor with all the information necessary to carry out the contracted operations in accordance with the specific veterinary medicinal product requirements and any other relevant requirements.

Article 34

Obligations of contract acceptor

1. The contract acceptor shall have adequate equipment, procedures, knowledge and experience, competent personnel to carry out the work ordered by the contract giver and if required for the activity, premises.

2. The contract acceptor shall not subcontract out any of the work under the contract to a third party without the contract giver's prior evaluation and approval of the arrangements and an audit of the third party by the contract giver or the contract acceptor. Arrangements made between the contract acceptor and any third party shall provide that the wholesale distribution information is made available in the same way as between the original contract giver and contract acceptor.

3. The contract acceptor shall refrain from any activity that may adversely affect the quality of the veterinary medicinal products handled for the contract giver.

4. The contract acceptor shall forward any information that may influence the quality of the veterinary medicinal products to the contract giver in accordance with the requirements of the contract.

CHAPTER IX

SELF-INSPECTIONS

Article 35

Self-inspection programme

A self-inspection programme shall be implemented covering all aspects of good distribution practice for veterinary medicinal products and compliance with this Regulation and procedures within a defined time frame.

Article 36

Conduct and recording of self-inspections

1. Self-inspections may be divided into several individual self-inspections of limited scope.

2. Self-inspections shall be conducted in an impartial and detailed way by designated competent personnel. Audits by independent external experts may not be used as a substitute for self-inspection.

3. All self-inspections shall be recorded. Reports shall contain all the observations made during the inspection. A copy of the report shall be provided to the management and other relevant persons.

4. In the event that irregularities or deficiencies are observed, their cause shall be determined and the CAPA shall be documented and followed up. The effectiveness of the CAPA shall be reviewed.

CHAPTER X

TRANSPORT

Article 37

Transport requirements

1. The persons referred to in Article 1(2) supplying veterinary medicinal products shall be responsible for protecting those veterinary medicinal products against breakage, adulteration and theft, and for ensuring that temperature conditions are maintained within acceptable limits during transport and shall, whenever possible, monitor such conditions.

2. During transport, the required storage or transport conditions, as appropriate, for veterinary medicinal products shall be maintained within the defined limits as described by the manufacturers and marketing authorisation holders or as stated on the outer packaging.

3. If a deviation such as temperature excursion or veterinary medicinal product damage has occurred during transport, this shall be reported to the persons referred to in Article 1(2) and to the consignee of the affected veterinary medicinal products in order for them to assess the potential impact on the quality of the veterinary medicinal products concerned. A procedure shall be in place for investigating and handling temperature excursions.

4. The persons referred to in Article 1(2) shall ensure that vehicles and equipment used to distribute, store or handle veterinary medicinal products are suitable for their use and appropriately equipped to prevent exposure of the veterinary medicinal products to conditions that could affect their quality and packaging integrity.

5. There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

6. Equipment chosen and used for the cleaning of vehicles shall not constitute a source of contamination.

7. Risk assessment of delivery routes shall be used to determine where temperature controls are required. Equipment used for temperature monitoring during transport within vehicles or containers shall be maintained and subject to calibration at regular intervals determined on the basis of quality risk management principles.

8. Dedicated vehicles and equipment shall be used, where possible, when handling both veterinary medicinal products and medicinal products for human use. Where non-dedicated vehicles and equipment are used, procedures shall be in place to ensure that the quality of the veterinary medicinal products will not be compromised.

9. Deliveries shall be made to the address stated on the delivery note and into the care or the premises of the consignee. Veterinary medicinal products shall never be left on alternative premises.

10. For emergency deliveries outside normal business hours, persons shall be designated and procedures shall be available.

11. Where transport is performed by a third party, the contract in place shall encompass the requirements of Articles 33 and 34 and clearly state that third party's obligations for ensuring compliance with good distribution practice for veterinary medicinal products. The persons referred to in Article 1(2) shall make transport providers aware of the relevant transport conditions applicable to the consignment.

12. Where the transport route includes unloading and reloading or transit storage at a transport hub, any intermediate storage facilities shall be clean and secure and shall allow for temperature monitoring, as applicable.

13. Provision shall be made to minimise the duration of temporary storage while awaiting the next stage of the transport route.

Article 38

Containers, packaging and labelling

1. Veterinary medicinal products shall be transported in containers that have no adverse effect on the quality of the veterinary medicinal products and that offer adequate protection from external influences, including contamination.

2. Selection of a container and packaging shall be based on the following:

(a) the storage and transport requirements for the veterinary medicinal products;

(b) the space required for the amount of veterinary medicinal products;

(c) the pharmaceutical forms, also including medicated premixes;

(d) the anticipated external temperature extremes;

(e) the estimated maximum time for transport including transit storage at customs;

(f) the qualification status of the packaging;

(g) the validation status of the shipping containers.

3. Containers shall bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the veterinary medicinal products are properly handled and secured at all times. The containers shall enable identification of the contents of the containers and the source.

Article 39

Products requiring special conditions

1. In relation to deliveries containing veterinary medicinal products requiring special conditions such as narcotics or psychotropic substances, the persons referred to in Article 1(2) shall maintain a safe and secure supply chain for these products in accordance with requirements laid down by the Member States concerned. There shall be additional control systems in place for delivery of these products. There shall be a protocol to address the occurrence of any theft.

2. Veterinary medicinal products comprising highly active materials shall be transported in safe, dedicated and secure containers and vehicles in accordance with the applicable safety measures.

3. For temperature-sensitive veterinary medicinal products, equipment subject to qualification, such as thermal packaging, temperature-controlled containers or temperature-controlled vehicles, shall be used to ensure that correct transport conditions are maintained between the manufacturer, wholesale distributor and customer, unless stability of the product has been demonstrated with other transport conditions.

4. If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport shall be maintained and subject to calibration at regular intervals. Temperature mapping under representative conditions shall be carried out and shall take into account seasonal variations.

5. If requested by customers with adequate justification and in any case in the event of incident, the persons referred to in Article 1(2) shall provide the customers with information to demonstrate that veterinary medicinal products have complied with the temperature storage or transport conditions.

6. If cool-packs are used in insulated boxes, they shall be placed in such a way to ensure the veterinary medicinal product does not come in direct contact with the cool-pack.

7. Personnel shall be trained on the procedures for assembly of insulated boxes, including in function of the season, and on the reuse of cool-packs.

8. The persons referred to in Article 1(2) shall have a system in place to control the re-use of cool-packs to ensure that incompletely cooled packs are not used in error. The persons referred to in Article 1(2) shall ensure that there is adequate physical segregation between frozen and chilled ice packs.

9. The persons referred to in Article 1(2) shall describe the process for delivery of sensitive veterinary medicinal products and control of seasonal temperature variations in a procedure.

CHAPTER XI

FINAL PROVISIONS

Article 40

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 July 2021.

For the Commission
The President
Ursula VON DER LEYEN