



Council of the  
European Union

Brussels, 17 September 2014  
(OR. en)

13289/14

---

---

**Interinstitutional File:  
2014/0257 (COD)**

---

---

**AGRILEG 185  
VETER 87  
PHARM 70  
MI 665  
CODEC 1838  
IA 2**

**PROPOSAL**

---

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	16 September 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2014) 558 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on veterinary medicinal products

---

Delegations will find attached document COM(2014) 558 final.

---

Encl.: COM(2014) 558 final



Brussels, 10.9.2014  
COM(2014) 558 final

2014/0257 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on veterinary medicinal products**

(Text with EEA relevance)

{SWD(2014) 273 final}

{SWD(2014) 274 final}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### **Justification and objectives**

Work on a European legal framework for veterinary medicinal products started in 1965 with the adoption of Directive 65/65/EEC,<sup>1</sup> which required that marketing authorisations be issued before such products could be placed on the market. Since then, numerous other directives and regulations have been adopted to extend and refine the rules, and a harmonised framework has gradually been established. In 2001, all the rules on production, marketing, distribution and use were consolidated in a veterinary medicines code (Directive 2001/82/EC);<sup>2</sup> this was followed by Regulation (EC) No 726/2004.<sup>3</sup> These two acts regulate the authorisation, manufacturing, marketing, distribution, pharmacovigilance and use of veterinary medicinal products over their lifetime. The annex to the Directive 2001/82/EC specifies the data to be submitted in applications for marketing authorisations. Among other things, the Regulation (EC) No 726/2004 lays down the EU procedures applying to medicinal products for human and veterinary use and establishes the European Medicines Agency ('the Agency').

In the course of the co-decision procedure for its proposal for a regulation on residue limits of pharmacological active substances in foodstuffs, the Commission submitted a declaration<sup>4</sup> recognising the importance of problems linked to the availability of veterinary medicinal products, the use of veterinary medicinal products in species for which they are not authorised, and disproportionate regulatory burden hampering innovation. The present proposal is the Commission's follow-up to its declaration.

Stakeholders and Member States have expressed concern that the current legislation does not fully deliver a single market in veterinary medicinal products and fails to meet the Union's needs as regards the regulation of medicines. In particular, the private and public sectors have indicated the following areas for improvement:

- regulatory burden;
- the lack of availability of veterinary medicinal products, especially for small markets such as that for bees; and
- the functioning of the internal market.

---

<sup>1</sup> Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ 22, 9.2.1965, p. 369–373).

<sup>2</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

<sup>3</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

<sup>4</sup> Communication from the Commission to the European Parliament pursuant to the second subparagraph of Article 251(2) of the EC Treaty concerning the common position of the Council on the adoption of a proposal for a Regulation of the European Parliament and the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, and repealing Regulation (EEC) No 2377/90 (COM(2008) 912, 8.1.2009).

In this regard, it is important to recall that needs of the veterinary sector differ substantially from those of the human sector in relation to medicines. In particular, the drivers for investment for the human and the veterinary medicines markets are different. For example, in the veterinary sector there are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of medicines existing for one animal species to another. Moreover, the price-setting mechanisms in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicines are typically substantially lower than for medicinal products for human use. The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines. It is therefore considered appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.

The revision of Directive 2001/82/EC and other legislation on veterinary medicinal products is in line with the principles set out in the Commission's 2013 and 2014 work programmes. The proposal seeks to put in place, while safeguarding public health, animal health, food safety and the environment, an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector, aiming in particular to:

- increase the availability of veterinary medicinal products;
- reduce administrative burdens;
- stimulate competitiveness and innovation;
- improve the functioning of the internal market; and
- address the public health risk of antimicrobial resistance (AMR).

These objectives are not only complementary, but also interlinked, as innovation will provide new and better medicines to treat and prevent diseases in animals, while avoiding damage to the environment.

The spread of AMR is a major threat to public and animal health. In November 2011, the Commission launched a five-year action plan,<sup>5</sup> which seeks to mobilise all stakeholders in a joint effort to combat AMR; in particular, Action 2 in the plan aims to strengthen the regulatory framework for veterinary medicinal products. This proposal implements this action.

The Commission's Communication on honeybee health<sup>6</sup> stresses the importance of proactively protecting bee health, while taking into account the particularities of beekeeping, and acknowledges the limited availability of medicines to treat the diseases that afflict bees. As regards measures to increase availability, the Communication refers to the revision of the legislation on veterinary medicinal products.

---

<sup>5</sup> Communication from the Commission to the European Parliament and the Council on an *Action Plan against the rising threats of antimicrobial resistance* (COM 2011/748, 15.11.2011).

<sup>6</sup> Commission *Communication on honeybee health* (COM 2010/714, 6.12.2010).

## Legal basis

The legal bases for legislative measures on animal health, which are essential to public and animal health, environmental protection, trade and single market policy are:

- Article 114 of the Treaty on the Functioning of the European Union (TFEU), which provides for the establishment and functioning of the internal market and the approximation of relevant legal, regulatory and administrative provisions; and
- Article 168(4)(b) TFEU, which covers measures in the veterinary field directly aimed at protecting public health.

## 2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

*Better regulation of veterinary pharmaceuticals: how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies*, a public consultation on the key issues of the envisaged legal proposal, was launched on the Commission's website on 13 April 2010 and was available through the interactive policy-making (IPM) tool until 15 July 2010.<sup>7</sup>

The consultation and a study, *An assessment of the impact of the revision of veterinary pharmaceutical legislation*, formed the basis of an impact assessment carried out for the Commission between November 2009 and June 2011.<sup>8</sup>

The Commission's Impact Assessment Board (IAB) released its final opinion in September 2013.

## 3. LEGAL ELEMENTS OF THE PROPOSAL

### Chapter I: Subject matter, scope and definitions

This part contains provisions on the scope of the Regulation. It also sets out clear definitions reflecting the proposed changes.

### Chapter II: Marketing authorisations — general provisions and rules on applications

In the Union, only veterinary medicinal products that meet standards of safety, quality and efficacy are authorised. The proposal lays down rules for obtaining a marketing authorisation, specifying that the product in question can be marketed for the approved indications only. The indications are listed in the summary of product characteristics (SPC) included in the terms of the marketing authorisation. Those terms also contain a description of the product's properties and the conditions attached to its use. Before a marketing authorisation can be granted for a veterinary medicinal product for food-producing species, the Commission has to establish a maximum residue limit for the pharmacologically active substance it contains.

---

<sup>7</sup> For a summary of the responses, see: [http://ec.europa.eu/health/files/veterinary/vet\\_pubcons\\_rep2011.pdf](http://ec.europa.eu/health/files/veterinary/vet_pubcons_rep2011.pdf).

<sup>8</sup> Study carried out by GHK Consulting, a member of the European Policy Evaluation Consortium (EPEC), assisted by Triveritas.

An applicant has to provide certain details on the packaging and labelling of the medicine. The proposal introduces a major simplification of the rules by reducing the compulsory information and introducing harmonised pictograms and abbreviations. This should reduce translation and packaging costs and encourage multilingual packages and labelling. Member States will have a degree of flexibility as to the languages used.

In principle, applicants must prove the quality, safety and efficacy of the veterinary medicinal product. In exceptional circumstances (e.g. in emergencies) and where limited markets are concerned, however, temporary authorisation may be granted without comprehensive data in order to fill therapeutic gaps on the market.

This part of the proposal also includes provisions for generic applications. If a product meets the conditions for a generic veterinary medicinal product, the applicant is not required to prove safety and efficacy and the application will rely on the data provided for the reference product. The proposal contains a definition of generic veterinary medicinal products.

This part also regulates the ‘protection period’ applying to technical documentation submitted in order to obtain or amend a marketing authorisation. It addresses the characteristics and specificities of the veterinary sector. Experience has shown that the needs of the veterinary sector differ substantially from those of the human sector. Also the drivers for investment differ for the human and veterinary medicines market, for example in animal health there is more than one species, creating a fragmented market and necessitating major investments to add other animal species. Therefore, the provisions in this proposal to stimulate innovation cannot be considered as a model for the human medicines market. The protection arrangements prevent applicants for a generic product from referring to the documentation submitted for the reference product. Data provided to extend the generic product to another animal species should also be protected according to the same principle.

Extending the protection periods provided for in Directive 2001/82/EC should create incentives and stimulate innovation in the animal health sector. The current ten-year period would be maintained for the initial marketing authorisation. In order to encourage industry to extend already authorised products to other species, a further 1 year would be added for any extension of the veterinary medicinal products to another species (up to a maximum of 18 years).

In order to encourage the animal health industry to develop products for minor species, increased protection will apply: 14 years for the initial marketing authorisation for a minor species, and 4 additional years for an extension to a minor species.

So as to secure data protection, any application for an extension must be submitted at least 3 years before expiry of the data protection period. This ensures that companies can place a generic product on the market immediately after expiry of the protection period for the reference product. Product developments for bee medicines will receive increased data protection because of the small size of the market for bee medicines and the lack of effective medicines to treat diseases in bees. The protection applying to environmental data would be the same as that for safety and efficacy data.

The results of clinical trials comprise much of the data required to demonstrate the quality, safety and efficacy of a product. A Union procedure for the authorisation of clinical trials is provided for (this is currently not harmonised).

It is important to safeguard the effectiveness of certain antimicrobials that are essential for the treatment of human infections. Therefore, it is proposed that the Commission be empowered to establish rules excluding or restricting the use of certain antimicrobials in the veterinary sector.

### **Chapter III: Procedures for granting marketing authorisations**

Various marketing authorisation procedures are provided for:

- a centralised procedure, in which the Commission grants an authorisation;
- procedures in which Member States grant the authorisation:
  - a national procedure;
  - a mutual recognition procedure; and
  - a decentralised procedure.

Regardless of whether the authorisation is obtained at Union or national level, the requirements for the safety, efficacy and quality of the product are the same. In all authorisation procedures, a key part of the assessment of an application is the benefit-risk analysis of a product.

The centralised procedure is mandatory for all veterinary medicinal products derived from biotechnology and optional with any other type of veterinary medicinal product. For products that are of interest in the majority of the Member States, access to the centralised procedure can lead to savings for the marketing authorisation holder.

The mutual recognition procedure applies for veterinary medicinal products already authorised in one Member State for which authorisation is requested in respect of two or more Member States. This procedure is based on the principle that a product authorised in one Member State should be recognised by another.

The decentralised procedure applies in cases where a medicine has not received a marketing authorisation in any Member State. It enables applicants to target their product to a limited group of Member States. After a marketing authorisation has been granted for the group of Member States in the original application, marketing authorisation holders can obtain an authorisation for additional Member States without repeated scientific assessment. This should mean that unnecessary duplication of work by competent authorities can be avoided, ease the rolling-out of national marketing authorisations to other Member States and therefore increase the availability of veterinary medicinal products in the Union.

For the decentralised and mutual recognition procedures, an arbitration mechanism applies if a Member State cannot agree with the scientific assessment. If an applicant cannot agree with the outcome of a Member State's assessment, it may request re-examination by the Agency. In such cases, the Agency will deliver a scientific opinion to the coordination group of Member States, which will act by consensus or by a majority of votes cast.

Currently, marketing authorisations have to be renewed every five years. The proposal provides for unlimited validity, which will reduce the regulatory burden.

## Chapter IV: Post-marketing authorisation measures

This part establishes a single product database for all authorised veterinary medicinal products in the Union. Competent authorities will be obliged to upload data on national marketing authorisations. Having a readily accessible, up-to-date database of all authorised medicines will mean *inter alia* improved application of the provisions on the use of veterinary medicinal products outside the terms of the marketing authorisation, as veterinarians will be able to identify the products they need from other Member States.

Post-marketing authorisation measures include amending marketing authorisations and monitoring products after they have been on the market (pharmacovigilance). The terms of the authorisation may need to be amended where, for example, a change to the SPC is proposed. The provisions of Regulation (EC) No 1234/2008 should no longer apply to variations to veterinary medicinal products. The Regulation lays down a system for varying the terms of marketing authorisations that takes account of the level of risk involved. Only changes that substantially affect product safety or efficacy will still require prior authorisation by the competent authorities or the Commission before being implemented.

Veterinary medicinal products tend to have unintended effects when actually brought into use. Pharmacovigilance involves identifying adverse events and determining what action, if any, is required. The objective is to ensure the continuous safety of products once they are authorised. This proposal introduces a risk-based approach to pharmacovigilance whereby certain requirements that do not contribute effectively to public health, animal health or environmental protection (e.g. submitting periodic safety update reports) are relaxed. The Agency will manage a database of adverse events linked to medicines authorised in the Union. It will work together with competent authorities to monitor and evaluate collated data on adverse events linked to similar groups of veterinary medicinal products (signal management process).

Many SPCs of nationally authorised products may differ in some respects between Member States. As a result, dosage, uses and warnings may also differ. This lack of harmonisation could result in discrepancies between the SPCs of the originator and the generic product on the same national market. This part also seeks to harmonise the SPCs for products on the Union market that have been authorised at national level by means of a dual procedure:

- products considered low-risk will be subject to an administrative procedure; and
- products that are by nature more likely to present a risk to animal or public health or the environment will be scientifically re-assessed.

This harmonisation should increase the availability of products in the Union.

Member States or the Commission can request a re-evaluation of veterinary medicinal products available on the market on the grounds that they may pose a risk to animal or public health or the environment. Once this ‘Union referral procedure’ is triggered, the Agency adopts an opinion on the case and the Commission adopts a decision that will apply throughout the Union.

In addition, a system will be set up to record and report the use of antimicrobials. This is one of measures in the Commission’s AMR action plan.

## Chapter V: Homeopathic veterinary medicinal products



This part lays down requirements and a simplified registration procedure for homeopathic veterinary medicinal products.

## **Chapter VI: Manufacturing, import and export**

This part covers the procedure and requirements for obtaining an authorisation to manufacture, import or export veterinary medicinal products. It lays down the obligations of a manufacturing authorisation holder. These rules will ensure the quality of the medicine available on the Union market.

## **Chapter VII: Supply and use**

This part covers the supply and use of veterinary medicinal products after a marketing authorisation has been granted. It imposes new restrictions on the supply of antimicrobial veterinary medicinal products and lays down rules on prescriptions and online sales of veterinary medicinal products.

In order to improve access to veterinary medicinal products in the Union, retailers should be allowed to sell products via the internet if they are authorised to supply them in the Member State in which the buyer is established. Online sales of veterinary medicinal products throughout the Union must be harmonised and ring-fenced, as falsified or substandard veterinary medicinal products represent a threat to public and animal health. Member States may impose conditions, for public health reasons, on supplying veterinary medicinal products to the public via the internet.

The provisions on the use of veterinary medicinal products for species or indications outside the terms of the marketing authorisation are improved as follows:

- the ranking system is abolished and more flexibility introduced, enabling veterinarians to choose the best available treatment for animals under their care;
- withdrawal periods are determined according to a multiplication factor system which takes account of relevant available information;
- specific provisions are included for the use of products in an aquatic environment in order to better protect the environment; and
- the Commission is empowered to exclude or restrict the use of certain antimicrobials.

## **Chapter VIII: Controls**

Inspections by Member States' competent authorities should ensure that the Union rules are complied with and enforced at national level. The Agency should coordinate the controls of veterinary medicinal products authorised by the centralised procedure. The key change is that the Commission will be able to check Member States' inspection systems to ensure that the legislation is enforced consistently. This brings the arrangements for veterinary medicinal products into line with those in the food sector.

## **Chapter IX: Restrictions and sanctions**

This part deals with Member State and Union-level measures to tackle risks to public or animal health or the environment. It provides for:

- a procedure for temporary safety restrictions; and
- suspending, withdrawing and varying marketing authorisations; or
- prohibiting the supply of veterinary medicinal products.

## **Chapter X: Regulatory network**

This part regulates the Union regulatory network on veterinary medicinal products. Responsibility for veterinary medicinal products is shared between the Member States and the Commission. The fully fledged European network between the competent authorities of the Member States, the Agency and the Commission should ensure that:

- veterinary medicinal products are available on the Union market;
- they are properly evaluated before being authorised for use; and
- their safety and efficacy is constantly monitored.

This part of the proposal specifies the functioning and the tasks of the Agency's Committee for Medicinal Products for Veterinary Use (CVMP) and the Coordination Group for Mutual Recognition and Decentralised Procedures (veterinary) (CMDv). The main changes are to clarify the remit of the CMDv, which will have more responsibility under the new arrangements and will take decisions by majority voting. These changes should improve the functioning of the network. The CVMP's tasks are amended to reflect the proposed changes to marketing authorisation procedures and post-marketing measures.

## **Chapter XI: Final provisions**

This proposal repeals and replaces Directive 2001/82/EC. To give those affected sufficient time to adapt to the new legislation, the Regulation will apply as from two years after its publication.

Regulation (EC) No 726/2004 must be amended to take account of the fact that centralised marketing authorisation for veterinary medicinal products is being decoupled from that for medicines for humans. The amendments are proposed in a separate act accompanying this proposal.

### **4. BUDGETARY IMPLICATION**

It is planned that the costs for the Agency for implementing and applying the new rules are entirely covered by fees charged to industry.

Therefore, the proposal is not expected to have any financial impact on the budget of the EU.

As set out in the legislative financial statement the additional resource needs for the European Medicines Agency are approximately 8 staff plus expenditure for meetings, translation, IT, etc.

The level of fees, their structure, modalities and exceptions will be set at a later stage by the Commission by way of implementing acts. This holds not only for the fees for new tasks for the Agency set out in this proposal, but for all fees in general.

## **5. OPTIONAL ELEMENTS**

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**on veterinary medicinal products**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>9</sup>,

Having regard to the opinion of the Committee of the Regions<sup>10</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Directive 2001/82/EC of the European Parliament and of the Council<sup>11</sup> and Regulation (EC) No 726/2004 of the European Parliament and of the Council<sup>12</sup> constitute the Union regulatory framework for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and the use of veterinary medicinal products.
- (2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality.
- (3) The legal framework should take into account the needs of the businesses in the veterinary pharmaceutical sector and trade in veterinary medicinal products within the

---

<sup>9</sup> OJ C , , p. .

<sup>10</sup> OJ C , , p. .

<sup>11</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

<sup>12</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Union. It should also integrate the major policy objectives set out in the Communication from the Commission of 3 March 2010 "Europe 2020 A Strategy for smart, sustainable and inclusive growth"<sup>13</sup>.

- (4) Experience has shown that the needs of the veterinary sector differ substantially from those of the human sector in relation to medicines. In particular, the drivers for investment for the human and the veterinary medicines markets are different. For example, in the veterinary sector there are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of medicines existing for one animal species to another. Moreover, the price-setting mechanisms in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicines are typically substantially lower than for medicinal products for human use. The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines. It is therefore appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.
- (5) The provisions of this act aim to reduce administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.
- (6) Animals may suffer from a broad range of diseases which can be prevented or treated. The impact of animal diseases and the measures necessary to control them can be devastating for individual animals, animal populations, animal keepers and the economy. Animal diseases transmissible to humans may also have a significant impact on public health. Therefore sufficient and effective veterinary medicinal products should be available in the Union in order to ensure high standards of animal and public health, and for the development of the agriculture and aquaculture sectors.
- (7) This Regulation should set high standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health. At the same time, this Regulation should harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union market.
- (8) With a view to harmonising the internal market for veterinary medicinal products in the Union and improving their free movement, rules should be established concerning the procedures for authorisation of such products that ensure the same conditions for all applications and a transparent framework for all interested parties.
- (9) The scope of the mandatory use of a centralised authorisation procedure under which the authorisations are valid throughout the Union should cover *inter alia* products containing new active substances and products which contain or consist of engineered tissues or cells. At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the centralised authorisation procedure should be extended to allow for applications for authorisations under that procedure to

---

<sup>13</sup> COM(2010) 2020 final, 3.3.2010.

be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products.

- (10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs). It should be ensured that marketing authorisations granted in one Member State are recognised in other Member States.
- (11) In order to help applicants, and in particular SMEs, to comply with the requirements of this Regulation, Member States should provide advice to the applicants, for example by establishing helpdesks. This advice should be provided in addition to the operational guidance documents and other advice and assistance provided by the European Medicines Agency.
- (12) In order to avoid unnecessary administrative and financial burdens for applicants and competent authorities, a full in-depth assessment of an application for the authorisation of a veterinary medicinal product should be carried out only once. It is appropriate therefore to lay down special procedures for the mutual recognition of national authorisations.
- (13) Moreover, rules should be established under the mutual recognition procedure to resolve any disagreements between competent authorities in a coordination group of the Member States without undue delay.
- (14) Where a Member State or the Commission considers that there are reasons to believe that a veterinary medicinal product may present a potential serious risk to human or animal health or to the environment, a scientific evaluation of the product should be undertaken at Union level, leading to a single decision on the area of disagreement, binding on the Member States concerned, being taken on the basis of an overall benefit-risk assessment.
- (15) No veterinary medicinal product should be allowed to be placed on the market or used in the Union unless it has been authorised, and its quality, safety and efficacy have been demonstrated.
- (16) Where a veterinary medicinal product is intended for food-producing animal species, a marketing authorisation should only be granted if the pharmacologically active substances which the product contains are allowed in accordance with Commission Regulation (EU) No 37/2010<sup>14</sup> for the species for which the veterinary medicinal product is intended.
- (17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only. In case of food-producing animals, veterinarians should ensure that an

---

<sup>14</sup> Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain.

- (18) Member States should be able to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases and where the health situation in a Member State so requires.
- (19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that may affect animal health, public health or the environment should require a scientific assessment.
- (20) Directive 2010/63/EU of the European Parliament and of the Council<sup>15</sup> lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Clinical trials for veterinary medicinal products are exempted from that Directive. The design and performance of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should be such as to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be the least likely to cause pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU.
- (21) The principles of replacement, reduction and refinement concerning the care and use of live animals for scientific purposes should therefore be taken into account during the design and performance of clinical trials.
- (22) It is recognised that improved access to information contributes to public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. Regulation (EC) No 1049/2001 of the European Parliament and of the Council<sup>16</sup> gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The European Medicines Agency should therefore give the widest possible access to the documents carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as regarding the protection of personal data, or the protection of commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001.
- (23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.

---

<sup>15</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

<sup>16</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

- (24) Environmental risk assessments should be mandatory for all new applications for a marketing authorisation and should consist of two phases. In the first phase the extent of environmental exposure of the product, its active substances and other constituent should be estimated, while in the second phase the effects of the active residue should be assessed.
- (25) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorisation or to establish a maximum residue limit for pharmaceutical active substances in the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, so that it is ensured the necessary veterinary medicinal products are available in the Union. For that reason data submitted to a competent authority or the Agency should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition.
- (26) Certain particulars and documents that are normally to be submitted with an application for a marketing authorisation should not be required if a veterinary medicinal product is a generic medicinal product of a veterinary medicinal product that is authorised or has been authorised in the Union.
- (27) It is recognised that the potential effect of a product on the environment may depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, where there is evidence that a constituent of a medicinal product for which a generic application for a marketing authorisation is submitted is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to safeguard the environment. In such cases applicants should endeavour to join efforts in generating such data in order to reduce costs and to reduce testing on vertebrate animals.
- (28) The protection of technical documentation should be applied to new veterinary medicinal products, as well as to data developed for supporting innovations of products with or referring to an existing marketing authorisation, for example in the case of extending use of an existing product to an additional animal species. In this case the variation or marketing authorisation application may refer partly to data submitted in a former marketing authorisation or variation applications, and should include new data specifically developed to support the required innovation of the existing product.
- (29) Differences in the manufacturing process of biological products or a change in the excipient used may lead to differences in the generic product characteristics. In an application for generic biological veterinary medicinal product the bioequivalence should be demonstrated in order to ensure, based on the existing knowledge, that quality, safety and efficacy are similar.
- (30) In order to avoid unnecessary administrative and financial burdens both for the competent authorities and for the pharmaceutical industry, as a general rule a marketing authorisation for a veterinary medicinal product should be granted for an unlimited period of time. Conditions for renewing the approval of a marketing authorisation should be imposed only exceptionally and should be duly justified.



- (31) It is recognised that, in some cases, a scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and other relevant factors should be taken into account including societal, economical, ethical, environmental and welfare factors and the feasibility of controls.
- (32) In certain circumstances where a significant animal or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in the Communication from the Commission on the precautionary principle<sup>17</sup>. In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular concern and should review the measure accordingly within a reasonable period of time.
- (33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It needs to be ensured that appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use not covered by the terms of the marketing authorisation of certain new or critically important antimicrobials for humans should be restricted in the veterinary sector. The rules for advertising veterinary antimicrobials should be tightened, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.
- (34) It is necessary to mitigate the risk of development of antimicrobial resistance to human and veterinary medicinal products. Therefore, an application for an antimicrobial veterinary medicinal product should contain information about the potential risks that use of the product may lead to the development of antimicrobial resistance in humans or animals or in organisms associated with them. In order to ensure a high level of public and animal health, veterinary antimicrobials should only be authorised following a careful scientific benefit-risk assessment. If necessary, conditions should be laid down in the marketing authorisation in order to restrict the use of the product. This should include restrictions on the use of the veterinary medicinal product not in accordance with the terms of the marketing authorisation, in particular the summary of product characteristics of the veterinary medicinal product.
- (35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Combinations of antimicrobial substances should therefore only be authorised where evidence is provided that the benefit-risk balance of the combination is favourable.
- (36) The development of new antimicrobials has not kept pace with the increase of resistance to existing antimicrobials. Given the limited innovation in developing new antimicrobials it is essential that the efficacy of existing antimicrobials is maintained for as long as possible. The use of antimicrobials in veterinary medicinal products may accelerate the emergence and spread of resistant micro-organisms and may compromise the effective use of the already limited number of existing antimicrobials

---

<sup>17</sup> Communication from the Commission on the precautionary principle, COM (2000) 1 (final).

to treat human infections. Therefore the misuse of antimicrobials should not be allowed.

- (37) In order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it may be necessary to reserve those antimicrobials for humans only. Therefore it should be possible to decide that certain antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector.
- (38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. Persons having the right to prescribe have a key role in ensuring prudent use of antimicrobials and consequently they should not be influenced, directly or indirectly, by economic incentives when prescribing those products. Therefore the supply of veterinary antimicrobials by those health professionals should be restricted to the amount required for treatment of the animals under their care.
- (39) It is important to consider the international dimension of the development of antimicrobial resistance when assessing the benefit-risk balance of certain veterinary antimicrobials in the Union. Any measure restricting the use of those products may affect the trade of products of animal origin or the competitiveness of certain animal production sectors in the Union. Moreover, antimicrobial resistant organisms can spread to humans and animals in the Union through consumption of products of animal origin imported from third countries, from direct contact with animals or humans in third countries or by other means. Therefore, measures restricting the use of veterinary antimicrobials in the Union should be based on scientific advice and should be considered in the context of cooperation with third countries and international organisations addressing antimicrobial resistance in order to ensure consistency with their activities and policies.
- (40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. Therefore it is important to collect data on the sales and use of antimicrobials in animals, data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.
- (41) The majority of the veterinary medicinal products on the market have been authorised under national procedures. The lack of harmonisation of summary of product characteristics for veterinary medicinal products authorised nationally in more than one Member State creates additional and unnecessary barriers for the circulation of veterinary medicinal products within the Union. It is necessary to harmonise those summaries of product characteristics. In order to avoid unnecessary costs and burdens for the Member States, the Commission and the pharmaceutical industry, and in order to increase the availability of veterinary medicinal products as fast as possible, it should be possible to harmonise summaries of the products characteristics for certain

veterinary medicinal products in accordance with an administrative procedure, while taking on board the risk to public and animal health and to the environment. This harmonisation exercise should cover veterinary medicinal products authorised before 2004.<sup>18</sup>

- (42) In order to reduce administrative burden and maximise the availability of veterinary medicinal products in the Member States, simplified rules should be laid down as to how their packaging and labelling are to be presented. The textual information provided should be reduced and, if possible, replaced by pictograms and abbreviations. Pictograms and abbreviations should be standardised across the Union. Care should be taken so that those rules do not jeopardise public and animal health and environmental safety.
- (43) In addition, Member States should be empowered to choose the language of the text used in the packaging and labelling of veterinary medicinal products authorised in their territory. The package leaflet, however, should be provided in the official language or languages of the Member State.
- (44) With a view to increasing availability of veterinary medicinal products in the Union it should be possible to grant more than one marketing authorisation for a specific veterinary medicinal product to the same marketing authorisation holder in the same Member State. In that case all product-related characteristics of the product and data in support of the applications for the product should be identical. However, multiple applications for a specific product should not be used to circumvent the principles of mutual recognition, and therefore this type of applications in different Member States should take place inside the procedural framework for mutual recognition.
- (45) Pharmacovigilance rules are necessary for the protection of public and animal health and the environment. Collection of information on adverse events should contribute to the good usage of veterinary medicinal products.
- (46) In the light of the experience acquired it has become clear that it is necessary to take measures to improve the operation of the pharmacovigilance system. It should integrate and monitor data at Union level. It is the interest of the Union to ensure that the veterinary pharmacovigilance systems for all authorised veterinary medicinal products are consistent. At the same time, it is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.
- (47) Holders of marketing authorisations should be responsible for continuously carrying out pharmacovigilance of the veterinary medicinal products they place on the market. They should collect reports on adverse events relating to their products, including those concerning use outside the terms of the granted marketing authorisation.
- (48) It is necessary to increase the shared use of resources between authorities, and to enhance efficiency of the pharmacovigilance system. Data collected should be uploaded to a single reporting point to ensure that the information is shared. The

---

<sup>18</sup> Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).

competent authorities should use those data to ensure the continuous safety and efficacy of the veterinary medicinal products that are on the market.

- (49) It is necessary, in specific cases, or from a public health and animal health perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the market. Therefore the obligation to conduct post-authorisation studies should be imposed on the marketing authorisation holder.
- (50) A pharmacovigilance database at Union level should be established to record and integrate information of adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities.
- (51) It is necessary to exercise control over the entire chain of distribution of veterinary medicinal products, from manufacture or import into the Union through supply to the end-user. Veterinary medicinal products from third countries should comply with the same requirements which apply to products manufactured in the Union, or with requirements which are recognised to be at least equivalent thereto.
- (52) In order to facilitate the movement of veterinary medicinal products and to prevent checks carried out in one Member State being repeated in others, minimum requirements should be applied to veterinary medicinal products manufactured in or imported from third countries.
- (53) The quality of veterinary medicinal products manufactured within the Union should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products.
- (54) Companies should be in possession of an authorisation to be able to wholesale or retail veterinary medicinal products, so as to guarantee that such medicines are appropriately stored, transported and handled. It should be the responsibility of the Member States to ensure that those conditions are met. Those authorisations should be valid throughout the Union.
- (55) In order to ensure transparency, a database should be established at Union level for the purposes of publishing a list of wholesale distributors who have been found to comply with applicable Union legislation following an inspection by the competent authorities of a Member State.
- (56) The conditions governing the supply of veterinary medicinal products to the public should be harmonised in the Union. Veterinary medicinal products should only be supplied by persons authorised to do so by the Member State where they are established. At the same time, in order to improve access to veterinary medicinal products in the Union, retailers that are authorised to supply veterinary medicinal products by the competent authority in the Member State where they are established should be allowed to sell prescription and non-prescription veterinary medicinal products via the Internet to buyers in other Member States.

- (57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.
- (58) When examining the compatibility with Union law of the conditions for the supply of medicinal products, the Court of Justice of the European Union has recognised, in the context on medicinal products for human use, the very particular nature of medicinal products whose therapeutic effects distinguish them substantially from other goods. The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States must be allowed some discretion as regards the conditions for the supply on their territory of medicinal products to the public. Therefore Member States should be able to subject the supply of medicinal products offered for sale at a distance by means of information society services to conditions justified by the protection of public health. Such conditions should not unduly restrict the functioning of the internal market.
- (59) In order to ensure high standards and safety of the veterinary medicinal products offered for sale at a distance, the public should be assisted in identifying websites which are legally offering such medicinal products. A common logo should be established, which is recognisable throughout the Union, while allowing for the identification of the Member State where the person offering veterinary medicinal products for sale at a distance is established. The Commission should develop the design for such a logo. Websites offering veterinary medicinal products for sale at a distance to the public should be linked to the website of the competent authority concerned. The websites of the competent authorities of Member States, as well as that of the European Medicines Agency, should give an explanation of the use of the logo. All those websites should be linked in order to provide comprehensive information to the public.
- (60) Collection systems for the take-back of unused or expired veterinary medicinal products should continue to be in place in the Member States in order to control any risk that such products might raise with regard to the protection of animal, human health or the environment.
- (61) Advertising, even on non-prescription medicinal products, could affect public and animal health and distort competition. Therefore, advertising of veterinary medicinal products should satisfy certain criteria. Persons qualified to prescribe or supply can properly evaluate the information available in advertising because of their knowledge, training and experience in animal health. The advertising of veterinary medicinal products to persons who cannot properly appreciate the risk associated with their use may lead to medicine misuse or overconsumption which is liable to harm public or animal health, or the environment.

- (62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated animal health profession for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State. The removal of regulatory and administrative barriers to such recognition should not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.
- (63) The implementation of the principle of recognition of prescriptions should be facilitated by the adoption of a standard prescription, listing the essential information necessary to ensure the safe and efficacious use of the product. Nothing should prevent Member States from having further elements in their prescriptions, as long as this does not prevent prescriptions from other Member States from being recognised.
- (64) Information on veterinary medicinal products is essential in order to enable health professionals, authorities and undertakings to make informed decisions. A key aspect is the creation of a European database that should collate information on marketing authorisations granted in the Union. The database should enhance overall transparency, streamline and facilitate the flow of information between authorities and prevent multiple reporting requirements.
- (65) The verification of compliance with the legal requirements through controls is of fundamental importance to ensure that the objectives of the Regulation are effectively achieved across the Union. Therefore the competent authorities of the Member States should have the power to perform inspections at all stages of production, distribution and use of veterinary medicinal products. In order to preserve the effectiveness of the inspections, authorities should have the possibility to perform unannounced inspections.
- (66) The frequency of controls should be established by the competent authorities having regard to the risk and to the level of compliance expected in the different situations. This approach should allow authorities to allocate resources where the risk is the highest. In some cases, however, controls should be performed irrespective of the level of risk or expected non-compliance, for example prior to granting manufacturing authorisations.
- (67) In certain cases failures in Member States' control system can substantially hinder the achievement of the objectives of this Regulation and may lead to the emergence of risks to public and animal health and the environment. To ensure a harmonised approach to inspections throughout the Union, the Commission should be able to carry out audits in the Member States to verify the functioning of national control systems.
- (68) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework for penalties with a view to imposing effective, proportionate and dissuasive penalties for non-compliance, as non-compliance can result in damage to animal and public health and the environment.
- (69) At the same time, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of laying down the procedure for investigating the infringements and the imposition of fines to the holders of marketing

authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection.

- (70) Companies and authorities are frequently confronted with the need to distinguish between veterinary medicinal products, feed additives, biocidal products and other products. In order to avoid inconsistencies in the treatment of such products, to increase legal certainty, and to facilitate the decision process by Member States, a coordination group of Member States should be established, and among other tasks it should provide on a case-by-case basis a recommendation whether a product falls within the definition of a veterinary medicinal product. In order to ensure legal certainty the Commission may decide whether a specific product is a veterinary medicinal product.
- (71) Having regard to the special characteristics of homeopathic veterinary medicinal products, especially the constituents of these products, it is desirable to establish a special, simplified registration procedure and to provide specific provisions for labelling for certain homeopathic veterinary medicinal products which are placed on the market without therapeutic indications. Immunological homeopathic products cannot follow the simplified registration procedure as immunologicals may initiate a response at a high dilution rate. The quality aspect of a homeopathic medicinal product is independent of its use so no specific provisions should apply with regard to the necessary quality requirements and rules.
- (72) In order to follow the scientific developments of the sector, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of amending the rules on designation of homeopathic veterinary medicinal products for which registration procedure should be allowed.
- (73) In order to protect public health, animal health and the environment, the activities and tasks attributed to the Agency in this Regulation should be adequately funded. Those activities, services and tasks should be funded through fees charged to enterprises. Those fees, however, should not affect the right of Member States to charge fees for activities and tasks at national level.
- (74) In order to ensure that annexes to this Regulation are adapted to the technical and scientific developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission.
- (75) In order to adapt this Regulation to the scientific developments of the sector, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of the use of a product outside the terms of the granted marketing authorisation, in particular regarding establishing a list of antimicrobial veterinary medicinal products for which such use should be prohibited.
- (76) In order to adapt this Regulation to the scientific developments of the sector, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of amending the list of groups of veterinary medicinal products for which the centralised authorisation procedure shall be compulsory.
- (77) In order to adapt this Regulation to the scientific developments of the sector, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of establishing detailed rules on the principles for the

refusal or restriction of marketing authorisations of antimicrobial veterinary medicinal products, in particular with a view to preserving the efficacy of certain active substances in treating infections in humans.

- (78) In order to exercise its supervisory powers effectively, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of laying down the procedure for investigating the infringements and the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection.
- (79) In order to introduce harmonised standards within the Union for the methods of gathering data on the use of antimicrobials and the methods of transferring of these data to the Commission, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of establishing rules on these methods.
- (80) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>19</sup>.
- (81) Taking into account the main changes that should be made to the existing rules, and aiming to improve the functioning of the internal market, a regulation is the appropriate legal instrument to replace Directive 2001/82/EC in order to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.
- (82) Since the objectives of this Regulation, namely to establish rules on veterinary medicinal products ensuring the protection of human and animal health and the environment as well as the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

---

<sup>19</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).



HAVE ADOPTED THIS REGULATION:

## **Chapter I**

### **Subject matter, scope and definitions**

#### *Article 1* *Subject matter*

This Regulation lays down rules for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and use of veterinary medicinal products.

#### *Article 2* *Scope*

1. This Regulation shall apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market.
2. In addition to the products referred to in paragraph 1, Chapter VI shall also apply to active substances, intermediate products and excipients used as starting materials in veterinary medicinal products.
3. In addition to the products referred to in paragraph 1, Chapter VII shall also apply to:
  - (a) substances that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties and that may be used in animals;
  - (b) veterinary medicinal products prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals ('magistral formula');
  - (c) veterinary medicinal products prepared in a pharmacy in accordance with the directions of a pharmacopoeia and intended to be supplied directly to the end-user ('official formula').
4. This Regulation shall not apply to:
  - (a) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or those animals in the same locality;
  - (b) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;
  - (c) veterinary medicinal products based on radio-active isotopes;

- (d) feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and of the Council<sup>20</sup>;
- (e) veterinary medicinal products intended for research and development.

*Article 3*  
*Conflict of laws*

1. Where a veterinary medicinal product referred to in Article 2(1) also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council<sup>21</sup> or Regulation (EC) No 1831/2003 of the European Parliament and of the Council, and there is a conflict between the provisions of this Regulation and the provisions of Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, the provisions of this Regulation shall prevail.
2. The Commission may, by means of implementing acts, adopt decisions on whether a specific product or group of products is to be considered as a veterinary medicinal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

*Article 4*  
*Definitions*

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

- (1) ‘veterinary medicinal product’ means any substance or combination of substances which fulfils at least one of the following conditions:
  - (a) it is presented as having properties for treating or preventing disease in animals;
  - (b) its purpose is to be used in or administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;
  - (c) its purpose is to be used for euthanasia of animals;
- (2) ‘substance’ means any matter of the following origin:
  - (a) human,
  - (b) animal,
  - (c) vegetable,
  - (d) chemical;

---

<sup>20</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 55, 28.3.2011, p. 13).

<sup>21</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

- (3) 'immunological veterinary medicinal product' means a veterinary medicinal product consisting of vaccines, toxins, sera or allergen products and intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity;
- (4) 'biological veterinary medicinal product' means a veterinary medicinal product an active substance of which is a biological substance;
- (5) 'biological substance' means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with knowledge of the production process and its control;
- (6) 'generic veterinary medicinal product' means a veterinary medicinal product which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference medicinal product, and with regard to which appropriate bioavailability studies have demonstrated a bioequivalence with the reference veterinary medicinal product;
- (7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;
- (8) 'antimicrobial resistance' means the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species;
- (9) 'clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof;
- (10) 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof;
- (11) 'benefit-risk balance' means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:
  - (a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;
  - (b) any risk of undesirable effects on the environment;
  - (c) any risk relating to the development of antimicrobial resistance;
- (12) 'common name' means the international non-proprietary name recommended by the World Health Organisation for a veterinary medicinal product, or, if one does not exist, the name generally used;

- (13) ‘strength’ means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;
- (14) ‘competent authority’ means an authority designated by a Member State in accordance with Article 136;
- (15) ‘labelling’ means information on the immediate packaging or the outer packaging;
- (16) ‘outer packaging’ means packaging in which is placed the immediate packaging;
- (17) ‘immediate packaging’ means the container or any other form of packaging that is in direct contact with the veterinary medicinal product;
- (18) ‘package leaflet’ means a documentation leaflet on a veterinary medicinal product which contains information to ensure its safe and efficacious use;
- (19) ‘letter of access’ means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by the competent authorities, the Agency or the Commission for the purposes of this Regulation;
- (20) ‘limited market’ means a market for one of the following product types:
- (a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;
  - (b) veterinary medicinal products for animal species other than cattle, sheep, pigs, chickens, dogs and cats;
- (21) ‘pharmacovigilance’ means the process of monitoring and investigating adverse events;
- (22) ‘pharmacovigilance system master file’ means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products;
- (23) ‘control’ means any task performed by a competent authority, including inspections, for the verification of compliance with this Regulation;
- (24) ‘veterinary prescription’ means any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law;
- (25) ‘withdrawal period’ means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health;
- (26) ‘making available on the market’ means any supply of a veterinary medicinal product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

- (27) ‘placing on the market’ means the first making available of a veterinary medicinal product on the Union market.

## **Chapter II**

### **Marketing authorisations – general provisions and rules on applications**

#### **SECTION 1**

#### **GENERAL PROVISIONS**

##### *Article 5*

##### *Marketing authorisations*

1. A veterinary medicinal product shall be placed on the market only when a marketing authorisation has been granted in respect of the product by a competent authority in accordance with Articles 44, 46 or 48 or by the Commission in accordance with Article 40.
2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.
3. Decisions to grant, refuse, suspend, withdraw or vary a marketing authorisation shall be made public.
4. Applicants for marketing authorisations and marketing authorisation holders shall be established in the Union.

##### *Article 6*

##### *Submission of applications for marketing authorisations*

1. Applications shall be submitted to the competent authority where they concern the granting of marketing authorisations in accordance with any of the following procedures:
  - (a) the national procedure laid down in Articles 42, 43 and 44;
  - (b) the decentralised procedure laid down in Articles 45 and 46;
  - (c) the mutual recognition procedure laid down in Articles 47 and 48.
2. Applications for the granting of marketing authorisations in accordance with the centralised marketing authorisation procedure laid down in Articles 38 to 41 shall be submitted to the European Medicines Agency (‘the Agency’) established by Regulation (EC) No 726/2004.
3. Applications shall be submitted electronically. For applications submitted in accordance with the centralised marketing authorisation procedure, the formats made available by the Agency shall be used.

4. The applicant shall be responsible for the accuracy of the documents and data submitted.
5. Within 15 days of receipt of the application, the competent authority or the Agency shall notify the applicant of whether all data required in accordance with Article 7 have been presented.
6. Where the competent authority or the Agency considers that the application is incomplete, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information.

## **SECTION 2**

### **DOSSIER REQUIREMENTS**

#### *Article 7*

#### *Data to be submitted with the application*

1. An application for a marketing authorisation shall contain the following information:
  - (a) the administrative information set out in Annex I;
  - (b) technical documentation satisfying the requirements set out in Annex II;
  - (c) the information to be provided in the immediate packaging, outer packaging and the package leaflet in accordance with Articles 9 to 14.
2. Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information listed in paragraph 1:
  - (a) documentation on the direct or indirect risks to public or animal health of use of the antimicrobial veterinary medicinal product in animals,
  - (b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.
3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council<sup>22</sup> shall be submitted in addition to the information listed in paragraph 1.
4. Paragraph 3 shall not apply to veterinary medicinal products intended for animals of the equidae family that have been declared as not being intended for slaughter for

---

<sup>22</sup> Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

human consumption in accordance with Commission Regulation (EC) 504/2008<sup>23</sup> and the active substances contained in those veterinary medicinal products are not listed in Table 2 of the Annex to Regulation (EU) No 37/2010.

5. Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council<sup>24</sup> the application shall in addition to the documents listed in paragraph 1 be accompanied by:
  - (a) a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC;
  - (b) the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;
  - (c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and
  - (d) the results of any investigations performed for the purposes of research or development.
6. Where the application is submitted in accordance with the national procedure laid down in Articles 42, 43 and 44, the applicant shall, in addition to the information listed in paragraph 1, submit a declaration stating that he has not submitted an application for a marketing authorisation for the veterinary medicinal product in another Member State.
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend Annexes I and II to adapt the information and documentation requirements to technical and scientific progress.

### **SECTION 3**

#### **CLINICAL TRIALS**

##### *Article 8*

##### *Approval of clinical trials*

1. An application for the approval of a clinical trial shall be submitted to a competent authority of the Member State in which the clinical trial is to take place.
2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the human food chain unless:

---

<sup>23</sup> Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae (OJ L 149, 7.6.2008, p. 3).

<sup>24</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p.1).

- (a) the tested product is a veterinary medicinal product authorised for the food-producing species used in the clinical trial, and the withdrawal period set out in the summary of the product characteristics is respected, or
  - (b) the tested product is an authorised veterinary medicinal product for target species other than the food-producing species used in the clinical trial and the withdrawal period set out in accordance with Article 117 is respected.
3. The competent authority shall issue a decision on the approval of a clinical trial within 60 days after the receipt of an application. Where the competent authority has not notified the applicant of its decision within that time limit, the clinical trial shall be considered to have been approved.
4. The clinical trials referred to in paragraph 1 shall be carried out taking due account of the standards set by the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.
5. Results of clinical trials shall be submitted with the application for a marketing authorisation for the purposes of providing the documentation referred to in Article 7(1)(b).
6. Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with the standards set by the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

## **SECTION 4**

### **LABELLING AND PACKAGE LEAFLET**

#### *Article 9*

##### *Labelling of the immediate packaging of veterinary medicinal products*

1. The immediate packaging of a veterinary medicinal product shall contain only the following information:
  - (a) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;
  - (b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;
  - (c) the batch number, preceded by the word "Lot";
  - (d) the name or corporate name or logo name of the marketing authorisation holder;



- (e) the target species;
  - (f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.";
  - (g) special storage precautions, if any.
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.

#### *Article 10*

##### *Labelling of the outer packaging of veterinary medicinal products*

1. The outer packaging of a veterinary medicinal product shall contain only the following information:
- (a) the information listed in Article 9(1);
  - (b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;
  - (c) warning that the veterinary medicinal product must be kept out of the sight and reach of children;
  - (d) warning that the veterinary medicinal product is for animal treatment only;
  - (e) recommendation to read the package leaflet;
  - (f) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions as regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;
  - (g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.
3. Where there is no outer packaging, all the particulars listed in paragraph 1 shall appear on the immediate packaging.

#### *Article 11*

##### *Labelling of small immediate packaging units of veterinary medicinal products*

By way of derogation from Article 9, small immediate packaging units shall contain only the following information:

- (a) the name of veterinary medicinal product;
- (b) the quantitative particulars of the active substances;
- (c) the batch number, preceded by the word "Lot";
- (d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp."

#### *Article 12*

##### *Package leaflet of veterinary medicinal products*

1. The package leaflet shall be available for each veterinary medicinal product and shall contain at least the following information:
  - (a) the name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing authorisation holder;
  - (b) the name of the veterinary medicinal product or, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States;
  - (c) the strength and pharmaceutical form of the veterinary medicinal product;
  - (d) the target species, the dosage for each species, the method and route of administration and advice on correct administration, if necessary;
  - (e) the therapeutic indications;
  - (f) the contra-indications and adverse events in so far as this information is necessary for the use of the veterinary medicinal product;
  - (g) the withdrawal period, even if this is nil, in the event that the target species are food-producing animals;
  - (h) special storage precautions, if any;
  - (i) information essential for safety or health protection, including any special precautions relating to use and any other warnings;
  - (j) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;
  - (k) the marketing authorisation number;
  - (l) in case of generic veterinary medicinal products, the statement 'generic veterinary medicinal product';

- (m) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".
- 2. The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. This additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.
- 3. The package leaflet shall be written and designed to be clear and understandable, in terms that are comprehensible to the general public.

### *Article 13*

#### *Package leaflet of homeopathic veterinary medicinal products*

By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Articles 89 to 90 shall contain only the following information:

- (a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States;
- (b) name and address of the marketing authorisation holder and, where appropriate, of the manufacturer;
- (c) method of administration and, if necessary, route;
- (d) the expiry date, in the format "mm/yyyy", preceded by the abbreviation "Exp.";
- (e) pharmaceutical form;
- (f) special storage precautions, if any;
- (g) target species;
- (h) a special warning if necessary for the medicinal product;
- (i) the batch number, preceded by the word "Lot";
- (j) registration number;
- (k) withdrawal period, if applicable.
- (l) the statement "homeopathic veterinary medicinal product".

*Article 14*  
*Languages*

1. The language or languages of the information on the labelling shall be determined by Member State where the veterinary medicinal product is made available on the market.
2. Member States shall communicate the languages determined by them for the purpose of paragraph 1 to the Commission. The Commission shall make this information public.
3. Veterinary medicinal products may be labelled in several languages.

*Article 15*  
*Abbreviations and pictograms common throughout the Union*

The Commission shall, by means of implementing acts, adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Article 9(2) and Article 10(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

**SECTION 5**  
**DOSSIER REQUIREMENTS FOR GENERIC, COMBINATION AND HYBRID**  
**VETERINARY MEDICINAL PRODUCTS AND FOR APPLICATIONS BASED ON**  
**INFORMED CONSENT AND BIBLIOGRAPHIC DATA**

*Article 16*  
*Generic veterinary medicinal products*

1. By way of derogation from Article 7(1)(b), an application for a marketing authorisation for a generic veterinary medicinal products shall not contain the documentation on safety and efficacy if all the following conditions are fulfilled:
  - (a) the application satisfies the requirements set out in Annex III;
  - (b) the applicant can demonstrate that the application concerns a generic veterinary medicinal product of a veterinary medicinal product which has been authorised by a Member State or by the Commission, and the period of protection of the technical documentation in respect of that reference veterinary medicinal product laid down in Articles 34 and 35 has elapsed or is due to elapse in less than 2 years ('reference veterinary medicinal product');
  - (c) documentation referred to in Article 7(1)(b) is available for the reference veterinary medicinal product to the competent authority or to the Agency.
2. For the purpose of this Section, where the active substance consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the

active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.

3. Where the reference veterinary medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted, or the application is submitted in accordance with Article 38(3) where the reference medicinal product was authorised in a Member State, the applicant shall indicate in its application the Member State in which the reference veterinary medicinal product has been authorised.
4. The competent authority or the Agency may request information on the reference veterinary medicinal product from the competent authority of the Member State where it was authorised. Such information shall be transmitted to the requestor within 30 days of receipt of the request.
5. The summary of the product characteristics of the generic veterinary medicinal product shall be identical to that of the reference veterinary medicinal product. However, that requirement shall not apply to those parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still covered by patent law at the time when the generic veterinary medicinal product is authorised.
6. A competent authority or the Agency may require the applicant to provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment in case the marketing authorisation for the reference veterinary medicinal product was granted before 20 July 2000 or in case the second phase environmental risk assessment was required for the reference veterinary medicinal product.
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 concerning amendments to Annex III in order to adapt the requirements to technical and scientific progress.

#### *Article 17*

#### *Combination veterinary medicinal products*

By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances that have each already been used in authorised veterinary medicinal products, but have not hitherto been authorised in that combination ('combination veterinary medicinal product') shall satisfy the following criteria:

- (a) the application satisfies the requirements set out in Annex III;

- (b) the applicant can demonstrate that the veterinary medicinal product is a combination of reference veterinary medicinal products as referred to in Article 16(1)(b);
- (c) documentation referred to in Article 7(1)(b) is available for the reference veterinary medicinal products to the competent authority or to the Agency;
- (d) documentation on the safety of that combination is provided.

#### *Article 18*

##### *Hybrid veterinary medicinal products*

1. By way of derogation from Article 16(1), the results of appropriate pre-clinical studies and clinical trials shall be required when the product does not meet all the characteristics of a generic veterinary medicinal product because:
  - (a) there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic veterinary medicinal product compared to the reference veterinary medicinal product, or
  - (b) bioavailability studies cannot be used to demonstrate bioequivalence with the reference veterinary medicinal product, or
  - (c) there are differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product.
2. The pre-clinical studies or clinical trials may be conducted with batches of reference products manufactured in the Union or in third countries.

When the batches are manufactured in third countries, the applicant shall demonstrate by state of the art analytical tests that the two reference products are so highly similar that they can substitute to each other in the clinical trials.

#### *Article 19*

##### *Application based on informed consent*

By way of derogation from Article 16(1)(b), an applicant for a marketing authorisation for a generic veterinary medicinal product shall not be required to provide the documentation on safety and efficacy if he demonstrates in the form of a letter of access that he is allowed to use the documentation on safety and efficacy referred to in Article 7(1)(b) which is available for the reference veterinary medicinal product.

#### *Article 20*

##### *Application based on bibliographic data*

1. By way of derogation from Article 7(1)(b), the applicant shall not be required to provide the documentation referred to therein if he demonstrates that the active substances of the veterinary medicinal product have been in well-established

veterinary use within the Union for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety.

2. The application shall satisfy the requirements set out in Annex III.

## **SECTION 6**

### **DOSSIER REQUIREMENTS FOR APPLICATIONS FOR LIMITED MARKET AND IN EXCEPTIONAL CIRCUMSTANCES**

#### *Article 21*

##### *Reduced data requirements for applications for limited markets*

1. By way of derogation from Article 7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted although the quality and/or efficacy documentation required in accordance with Annex II has not been provided, if all the following conditions are met:
  - (a) the benefit of the immediate availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;
  - (b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.
2. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be granted for a period of 3 years.
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality and/or efficacy has been conducted due to the lack of comprehensive efficacy and/or quality data.

#### *Article 22*

##### *Data requirements for applications in exceptional circumstances*

1. By way of derogation from Article 7(1)(b), in exceptional circumstances related to animal or public health, where the applicant has demonstrated that for objective, verifiable reasons he is unable to provide the quality, safety and/or efficacy documentation required in accordance with Part 1, Part 2 and Part 3 of Annex II, a marketing authorisation may be granted subject to any of the following:
  - (a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;
  - (b) a requirement to notify the competent authorities of any incident relating to the use of the veterinary medicinal product;
  - (c) a requirement to conduct post-authorisation studies.

2. By way of derogation from Article 5(2), a marketing authorisation in exceptional circumstances shall be granted for a period of 1 year.
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data.

## **SECTION 7**

### **EXAMINATION OF APPLICATIONS AND GRANTING OF MARKETING AUTHORISATIONS**

#### *Article 23* *Examination of applications*

1. The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall:
  - (a) verify that the documentation submitted complies with the requirements laid down in Article 7(1) and is satisfactory for granting a marketing authorisation;
  - (b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.
2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the Agency with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.

#### *Article 24* *Requests to laboratories in the course of the examination of applications*

1. The competent authority or the Agency examining the application may require an applicant to provide samples of the veterinary medicinal product to the Union reference laboratory, an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose to:
  - (a) test the veterinary medicinal product, its starting materials and if necessary intermediate products or other constituent materials in order to ensure that the control methods employed by the manufacturer and described in the application documents are satisfactory;
  - (b) verify, using samples provided by the applicant, that the analytical detection method proposed by the applicant for the purposes of safety tests and residue tests is satisfactory and suitable for use to reveal the presence of residue levels, particularly those exceeding the maximum residue level of the pharmacologically active substance established by the Commission in



accordance with Regulation (EC) No 470/2009 and Commission Decision 2002/657/EC<sup>25</sup>.

2. The time limits laid down in Articles 40, 44, 46 and 48 shall be suspended until the samples requested in accordance with paragraph 1 have been provided.

*Article 25*  
*Information on manufacturers*

The competent authority shall ascertain that the manufacturers of veterinary medicinal products from third countries are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 7(1).

*Article 26*  
*Information to the applicant*

The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support of the application is insufficient. The competent authority or the Agency shall request the applicant to provide the documentation within a given deadline. In such case the time limits laid down in Articles 40, 44, 46 and 48 shall be suspended until the deadline has elapsed.

*Article 27*  
*Withdrawal of applications*

1. An applicant may withdraw his application for marketing authorisation submitted to a competent authority or the Agency at any time before the decision referred to in Article 31 or 32 has been taken.
2. If an applicant withdraws his application for marketing authorisation submitted to a competent authority or the Agency before the assessment of the application as referred to in Article 23 has been completed, the applicant shall communicate its reasons for doing so to the competent authority or the Agency to which the application was submitted in accordance with Article 6.
3. If an assessment report or, in case of the centralised authorisation procedure, the opinion, has been drawn up, it shall be made public by the competent authorities or the Agency, after deletion of any commercially confidential information.

---

<sup>25</sup> Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results, (OJ L 221, 17.8.2002, p. 8).

*Article 28*  
*Outcome of the assessment*

1. In case of favourable assessment to grant a marketing authorisation, the competent authority or the Agency examining the application shall prepare an opinion including the following documents:
  - (a) a summary of the product characteristics containing the information laid down in Article 30;
  - (b) details of any conditions or restrictions to be imposed as regards the supply or use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with Article 29;
  - (c) details of any conditions or restrictions which should be imposed as regards the safe and effective use of the veterinary medicinal product;
  - (d) the approved text of the labelling and package leaflet.
2. Where the application concerns a veterinary medicinal product for food-producing target species, the competent authority or the Agency shall prepare a statement related to the maximum residue levels of the pharmaceutical active substance in relation to specific foodstuffs and species, as established by the Commission in accordance with Regulation (EC) No 470/2009.
3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive with a view to the possible development of antimicrobial resistance.

*Article 29*  
*Requirement for a veterinary prescription*

1. A competent authority or the Commission shall classify the following veterinary medicinal products as subject to veterinary prescription:
  - (a) veterinary medicinal products which contain psychotropic drugs or narcotics, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the United Nations Convention on Psychotropic Substances of 1971;
  - (b) veterinary medicinal products for food-producing animals;
  - (c) antimicrobial veterinary medicinal products;
  - (d) products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures;
  - (e) officinal formulae intended for food-producing animals;

- (f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the Union.
2. A competent authority or the Commission may classify a veterinary medicinal product as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to:
- (a) the target species,
  - (b) the person administering the products to the animal,
  - (c) the environment.
3. By the way of derogation from paragraph 1, a competent authority or the Agency may not classify a veterinary medicinal product as subject to veterinary prescription if all of the following conditions are fulfilled:
- (a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;
  - (b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal(s) treated, to the person administering the product or to the environment;
  - (c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;
  - (d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;
  - (e) the summary of the product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;
  - (f) the veterinary medicinal product is not subject to special storage conditions;
  - (g) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;
  - (h) there is no risk to public or animal health as regards the development of resistance to anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

*Article 30*  
*Summary of the product characteristics*

1. The summary of the product characteristics referred to in Article 28(1)(a) shall contain the following information:
  - (a) name of the veterinary medicinal product followed by its strength and pharmaceutical form;
  - (b) qualitative and quantitative composition of the active substances or other constituents stating the common name or the chemical description of the substances or other constituents;
  - (c) clinical information:
    - (i) target species,
    - (ii) indications for use,
    - (iii) contra-indications,
    - (iv) special warnings for each target species,
    - (v) special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,
    - (vi) frequency and seriousness of adverse events,
    - (vii) use during pregnancy, lactation or lay,
    - (viii) interaction with other medicinal products and other forms of interaction,
    - (ix) administration route and amounts to be administered ,
    - (x) overdose symptoms and emergency procedures and antidotes in the event of overdose, where applicable,
    - (xi) where appropriate, special indications or restrictions for use in accordance with Articles 107 to 109,
    - (xii) where appropriate, an indication of classification of an antimicrobial regarding its strategic use,
    - (xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,
  - (d) withdrawal periods, including animal species/foodstuffs combinations;
  - (e) pharmacological information:
    - (i) pharmacodynamics,

- (ii) pharmacokinetics,
  - (iii) pharmaceutical particulars,
  - (iv) major incompatibilities,
  - (v) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time,
  - (vi) special precautions for storage,
  - (vii) nature and composition of immediate packaging,
  - (viii) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;
- (f) name of the marketing authorisation holder;
  - (g) marketing authorisation number(s);
  - (h) if applicable, date of the first authorisation;
  - (i) the date of the last revision of the summary of the product characteristics;
  - (j) if applicable, for products authorised in accordance with Article 21 or Article 22, the statement 'market authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised requirements for documentation'.
2. In case of generic veterinary medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in a Member State at the time of placing the generic veterinary medicinal product on the market may be omitted.

*Article 31*  
*Decisions granting marketing authorisations*

1. Decisions granting marketing authorisations shall be taken on the basis of the documents prepared in accordance with Article 28 and shall set out the conditions attached to the placing on the market of the veterinary medicinal product and the summary of the product characteristics ('terms of the marketing authorisation').
2. The competent authority or the Commission shall make the decision granting the marketing authorisation publicly available and record it in the database referred to in Article 51.

*Article 32*  
*Decisions refusing marketing authorisations*

1. The marketing authorisation shall be refused on any of the following grounds:
  - (a) the benefit-risk balance of the veterinary medicinal product is unfavourable;
  - (b) the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;
  - (c) the product is a zootechnical veterinary medicinal product or a performance enhancer, and the applicant has not sufficiently demonstrated the benefits of the product to the animal health and welfare or public health;
  - (d) the product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;
  - (e) the withdrawal period is not long enough to ensure food safety;
  - (f) information to be provided in the immediate packaging, the outer packaging and the package leaflet of the veterinary medicinal product does not comply with the requirements set out in Articles 9 to 11;
  - (g) risk for public health in case of development of antimicrobial resistance outweighs the benefits of the product to animal health;
  - (h) the product has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the target species;
  - (i) the qualitative or quantitative composition of the product is not as stated in the application.
2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans.
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

## SECTION 8

### PROTECTION OF TECHNICAL DOCUMENTATION

#### *Article 33*

##### *Protection of technical documentation*

1. Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality, safety and efficacy originally submitted with a view to obtaining a marketing authorisation or a variation thereof shall not be used by other applicants for a marketing authorisation or a variation of the terms of a marketing authorisation for a veterinary medicinal product unless:
  - (a) the period of the protection of technical documentation as set out in Articles 34 and 35 has elapsed, or
  - (b) the applicants have obtained written agreement in the form of a letter of access with regard to that documentation.
2. The protection of the technical documentation as referred to in paragraph 1 ('the protection of technical documentation') shall also apply in Member States where the product is not authorised or is no longer authorised.
3. Any marketing authorisation or variation to the terms of a marketing authorisation differing from the previously granted marketing authorisation only with regard to strengths, pharmaceutical forms, administration routes or presentations shall be regarded as the same marketing authorisation as the one previously granted for the purpose of applying the rules of the protection of technical documentation.

#### *Article 34*

##### *Periods of the protection of technical documentation*

1. The period of the protection of technical documentation shall be:
  - (a) 10 years for the veterinary medicinal products for cattle, sheep, pigs, chickens, dogs and cats;
  - (b) 14 years for antimicrobial veterinary medicinal products for cattle, sheep, pigs, chickens, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;
  - (c) 18 years for veterinary medicinal products for bees;
  - (d) 14 years for veterinary medicinal products for animal species other than listed in paragraph 1(a) and (c).
2. The protection shall apply from the day when the marketing authorisation for the veterinary medicinal product was granted in accordance with Article 7.

### *Article 35*

#### *Prolongation of the periods of the protection of technical documentation*

1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by 1 year for each additional target species, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a).
2. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to a another species not listed in Article 34(1)(a), the period of the protection provided for in Article 34 shall be prolonged by 4 years.
3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed 18 years.
4. Where an applicant for a marketing authorisation for a veterinary medicinal product or for a variation to the terms of the marketing authorisation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of a maximum residue limit, together with clinical trials during the application procedure, other applicants shall not use those trials for a period of 5 years from the granting of the marketing authorisation for which they were carried out, unless the other applicant has obtained written agreement in the form of a letter of access with regard to those trials.

### *Article 36*

#### *Patent-related rights*

Conducting the necessary studies, tests and trials with a view to applying for a marketing authorisation in accordance with Article 16 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.

## **Chapter III**

### **Procedures for granting marketing authorisations**

#### **SECTION 1**

#### **MARKETING AUTHORISATIONS VALID THROUGHOUT THE UNION (‘CENTRALISED MARKETING AUTHORISATIONS’)**

### *Article 38*

#### *Scope of the centralised marketing authorisation procedure*

1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union.



2. Centralised marketing authorisation procedure shall apply in respect of the following veterinary medicinal products:
  - (a) veterinary medicinal products developed by means of one of the following biotechnological processes:
    - (i) recombinant DNA technology;
    - (ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;
    - (iii) hybridoma and monoclonal antibody methods;
  - (b) veterinary medicinal products intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals;
  - (c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;
  - (d) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;
  - (e) generic veterinary medicinal products of reference veterinary medicinal products authorised under the centralised authorisation procedure.
3. For veterinary medicinal products other than those listed in paragraph 2 a centralised marketing authorisation may be granted if no other marketing authorisation has been granted for the veterinary medicinal product within the Union.
4. The Commission, taking into account the state of animal and public health in the Union, shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend the list set out in paragraph 2.

#### *Article 39*

#### *Application for centralised marketing authorisation*

1. Applications for centralised marketing authorisations shall be submitted to the Agency. The application shall be accompanied by the fee payable to the Agency for the examination of the application.
2. The application for a centralised authorisation of veterinary medicinal product shall state a single name for the veterinary medicinal product to be used throughout the Union.
3. Translations of the labelling, package leaflet and the summary of the product characteristics shall be submitted in the languages determined by the Member States in accordance with Article 14.

*Article 40*  
*Procedure for centralised marketing authorisation*

1. Centralised marketing authorisations shall be granted by the Commission following an assessment by the Agency.
2. As an outcome of the assessment of an application for marketing authorisation for a veterinary medicinal product, the Agency shall draw up an opinion as referred to in Article 28.
3. The opinion shall be given within 210 days of receipt of a valid application. Exceptionally, where a particular expertise is required, the deadline may be extended by a maximum of 90 days.
4. When an application is submitted for a marketing authorisation in respect of veterinary medicinal products of major interest, particularly from the point of view of animal health and therapeutic innovation, the applicant may request an accelerated assessment procedure. The request shall be duly substantiated. If the Agency accepts the request, the time limit of 210 days shall be reduced to 150 days.
5. The opinion of the Agency shall be forwarded to the applicant. Within 15 days of receipt of the opinion the applicant may provide written notice to the Agency that he wishes to request a re-examination of the opinion. In such case, Article 41 shall apply.
6. After the completion of the procedure referred to in paragraph 5 the opinion shall be forwarded without delay to the Commission.
7. The Commission may request clarifications from the Agency as regards the content of the opinion, in which case the Agency shall provide a response to this request within 90 days.
8. Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include or make reference to the documents listed in Article 28. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences. The draft decision shall be forwarded to Member States and the applicant.
9. The Commission shall, by means of implementing acts, take a final decision on the granting of a centralised marketing authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
10. The Agency shall disseminate the documents referred to in Article 28 to the applicant.
11. The Agency shall make the opinion publicly available, after deleting any commercially confidential information.

*Article 41*  
*Re-examination of the opinion of the Agency*

1. Where the applicant requests a re-examination of the opinion in accordance with Article 40(5), he shall forward to the Agency detailed grounds for the request within 60 days after receipt of the opinion.
2. Within 60 days after receipt of the grounds for the request, the Agency shall re-examine its opinion. The reasons for the conclusions reached shall be annexed to the opinion.
3. Within 15 days after its adoption, the Agency shall forward its opinion to the Commission and the applicant.

**SECTION 2**  
**MARKETING AUTHORISATIONS VALID IN A SINGLE MEMBER STATE**  
**(‘NATIONAL MARKETING AUTHORISATION’)**

*Article 42*  
*Scope of national marketing authorisation*

National marketing authorisations shall be granted by the competent authorities in accordance with this Section and applicable national provisions. A national marketing authorisation shall be valid in the Member State which granted it.

National marketing authorisations shall only be granted in respect of veterinary medicinal products not falling within the scope of Article 38(2).

*Article 43*  
*Applications for national marketing authorisations*

Competent authorities shall verify whether an application for a national marketing authorisation has been submitted or granted for the same veterinary medicinal product in another Member State. Where that is the case, the competent authority of that Member State shall decline to assess the application and inform the applicant of the possibility to submit an application under the mutual recognition procedure or the decentralised authorisation procedure.

*Article 44*  
*Procedure for national marketing authorisation*

1. The procedure for granting a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the complete application.
2. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.

**SECTION 3**  
**MARKETING AUTHORISATIONS VALID IN SEVERAL MEMBER STATES**  
**(‘DECENTRALISED MARKETING AUTHORISATIONS’)**

*Article 45*

*Scope of decentralised marketing authorisation*

1. Decentralised marketing authorisations shall be granted by the competent authorities in accordance with this Section. They shall be valid in the Member States stated therein.
2. Decentralised marketing authorisations shall only be granted in respect of veterinary medicinal products for which no national marketing authorisation has been granted at the time of application for a decentralised marketing authorisation and which does not fall within the scope of Article 38(2).

*Article 46*

*Procedure for decentralised marketing authorisation*

1. Applications for decentralised marketing authorisation shall be submitted to the Member State chosen by the applicant (‘reference Member State’).
2. The application shall list Member States where the applicant seeks to obtain a marketing authorisation (‘Member States concerned’).
3. Within 120 days of receipt of a valid application, the reference Member State shall prepare an assessment report. The assessment report together with the approved summary of the product characteristics and text to appear in the labelling and package leaflet shall be forwarded to all Member States and the applicant, together with the list of the Member States concerned.
4. Within 90 days after receipt of the documents referred to in paragraph 3, Member States shall examine the assessment report, the summary of the product characteristics, the labelling and the package leaflet and inform the reference Member State of whether they have no objections to the assessment report, summary of product characteristics, labelling and package leaflet.
5. Where all Member States agree, the reference Member State shall record the agreement, close the procedure and inform the applicant and the Member States accordingly. Each Member State from the list referred to in paragraph 2 shall grant a marketing authorisation in conformity with the approved assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of the receipt of the information regarding the agreement from the reference Member State.
6. If at any stage of the procedure a Member State concerned invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product it shall no longer be considered as a Member State where the applicant seeks to obtain a marketing authorisation. However, a Member State having invoked those reasons

may subsequently recognise the marketing authorisation in accordance with Article 57.

7. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.

#### **SECTION 4**

### **MUTUAL RECOGNITION OF MARKETING AUTHORISATIONS GRANTED BY NATIONAL AUTHORITIES**

#### *Article 47*

#### *Scope of mutual recognition marketing authorisation*

A national marketing authorisation for a veterinary medicinal product shall be recognised by other Member States in accordance with the procedure laid down in Article 48.

#### *Article 48*

#### *Procedure for mutual recognition marketing authorisation*

1. Applications for mutual recognition of marketing authorisations shall be submitted to the Member State that granted the first national marketing authorisation ("reference Member State").
2. A minimum of 6 months shall elapse between the decision granting the first national marketing authorisation and the submission of the application for mutual recognition of the national marketing authorisation.
3. An application for mutual recognition of a marketing authorisation shall be accompanied by the following:
  - (a) an information about the Member States where the applicant seeks to obtain recognition of the marketing authorisation;
  - (b) copies of marketing authorisations granted for the veterinary medicinal product in other Member States;
  - (c) an information about the Member States in which an application for a marketing authorisation submitted by the applicant for the same veterinary medicinal product is under examination;
  - (d) a summary of the product characteristics proposed by the applicant;
  - (e) the text to appear in the labelling and package leaflet;
  - (f) information on refusals to grant a marketing authorisation in the Union or in a Member State or in a third country and the reasons for the refusal.
4. Within 90 days of receipt of a valid application, the reference Member State shall prepare an updated assessment report for the veterinary medicinal product. The

updated assessment report together with the approved summary of the product characteristics and the text to appear in the labelling and package leaflet shall be forwarded to all Member States and the applicant, together with the list of Member States where the applicant seeks to obtain recognition of the marketing authorisation ('concerned Member States').

5. Within 90 days after receipt of the documents referred to in paragraph 3, Member States shall examine the assessment report, the summary of the product characteristics, the labelling and the package leaflet and inform the reference Member State of whether it has no objections to the assessment report, summary of product characteristics, labelling and package leaflet.
6. Where all Member States agree, the reference Member State shall record the agreement, close the procedure and inform the applicant and the Member States accordingly. Each Member State referred to in paragraph 3 shall grant a marketing authorisation in conformity with the approved assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of the receipt of the information regarding the agreement from the reference Member State.
7. If at any stage of the procedure a concerned Member State invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product, it shall no longer be considered as a Member State where the applicant seeks to obtain a marketing authorisation. However, a Member State having invoked those reasons may subsequently recognise the marketing authorisation in accordance with Article 57.
8. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.

## **SECTION 5**

### **COORDINATION GROUP REVIEW AND SCIENTIFIC RE-EXAMINATION**

#### *Article 49*

##### *Coordination group review procedure*

1. If a Member State raises, within the time period referred to in Article 46(4) or Article 48(5) its objections to the assessment report, proposed summary of product characteristics or proposed labelling and package leaflet, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States and the applicant. The points of disagreement shall be referred without delay to the coordination group for mutual recognition and decentralised procedures set up by Article 142('the coordination group') by the reference Member State.
2. Within the coordination group, a rapporteur shall be appointed in order to prepare a second assessment report for the veterinary medicinal product.
3. The second assessment report shall be presented by the rapporteur to the coordination group within the period of 90 days. Upon presentation of the second assessment report, the coordination group shall adopt an opinion by a majority of the votes cast by the members of the coordination group represented at the meeting.

4. In the event of an opinion in favour of granting a marketing authorisation, the reference Member State shall record the agreement of Member States, close the procedure and inform Member States and the applicant accordingly.
5. Each Member State concerned shall grant a marketing authorisation in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the reference Member State.
6. In the event of an unfavourable opinion, the marketing authorisation shall be refused by each Member State concerned within 30 days of acknowledgement of the agreement. The scientific conclusions and grounds for revocation of the marketing authorisation shall be annexed to the unfavourable opinion.

*Article 50*  
*Request for scientific re-examination*

1. Within 15 days after receipt of the assessment report referred to in Article 46(3) or in Article 48(4) the applicant may provide written notice to the Agency requesting a re-examination of the assessment report. In that case the applicant shall forward to the Agency detailed grounds for the request within 60 days of receipt of the assessment report. The application shall be accompanied by proof of payment of the fee payable to the Agency for the re-examination.
2. Within 120 days of receipt of the grounds for the request, the Committee for Medicinal Products for Veterinary Use set up by Article 139 ('the Committee') shall re-examine the assessment report. The reasons for the conclusion reached shall be annexed to the opinion.
3. The re-examination procedure shall deal only with the points of the assessment report identified by the applicant in the written notice.
4. Within 15 days of its adoption, the Agency shall forward the opinion of the Committee to the coordination group, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions. Those documents shall be forwarded to the Commission, to Member States and to the applicant for information purposes.
5. Upon presentation of the Agency's opinion, the coordination group shall act by the majority of the votes cast by its members represented at the meeting. The reference Member State shall record the agreement, close the procedure and inform the applicant. Article 49 shall apply accordingly. Where the decision is not in accordance with the opinion of the Agency, the coordination group shall annex a detailed explanation of the reasons for the differences.

# Chapter IV

## Post marketing authorisation measures

### SECTION 1

#### UNION PRODUCT DATABASE

##### *Article 51*

##### *Union database on veterinary medicinal products*

1. A Union database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency.
2. The product database shall contain information on:
  - (a) veterinary medicinal products authorised within the Union by the Commission and by the competent authorities, together with their summaries of product characteristics, package leaflets and lists of sites where each product is manufactured;
  - (b) homeopathic veterinary medicinal products registered within the Union by the Commission and by the competent authorities, together with their package leaflet and lists of sites where each product is manufactured;
  - (c) veterinary medicinal products allowed to be used in a Member State in accordance with Articles 119 and 120.
3. Within 12 months from the date of the entry into force of this Regulation, the Agency shall make public a format for electronic submissions of information on marketing authorisations of veterinary medicinal products granted by the competent authorities.
4. The competent authorities shall submit information on marketing authorisations granted by them to the product database, using the format referred to in paragraph 3.
5. The Agency shall submit information on marketing authorisations granted by the Commission to the product database, using the format referred to in paragraph 3.
6. Within 12 months from the date of application of this Regulation, the competent authorities shall submit electronically information on all veterinary medicinal products authorised in their Member State before the date of application of this Regulation to the Agency, using the format referred to in paragraph 3.
7. The Agency shall, in collaboration with Member States and the Commission, draw up the functional specifications for the product database.
8. The Commission shall ensure that information reported to the product database is collected, collated and made accessible and that the information is shared.



*Article 52*  
*Access to the product database*

1. The competent authorities, the Agency and the Commission shall have full access to the information in the product database.
2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations.
3. The general public shall have access to information in the product database as regards the list of the authorised veterinary medicinal products, their summaries of product characteristics and package leaflets.

**SECTION 2**  
**PLACING ON THE MARKET**

*Article 53*  
*Placing on the market*

1. Marketing authorisation holders shall record in the product database the dates when their authorised veterinary medicinal products are placed on the market in a Member State.
2. Generic veterinary medicinal products shall not be placed on the market until the period of the protection of technical documentation for the reference veterinary medicinal product as set out in Articles 34 and 35 has elapsed.

*Article 54*  
*Collection of data on the sales and use of antimicrobial veterinary medicinal products*

1. Member States shall collect relevant and comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products.
2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall analyse the data and publish an annual report.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish detailed rules on the methods of gathering data on the use of antimicrobials and the method of transfer of these data to the Agency.
4. The Commission may, by means of implementing acts, set up the format and the requirements for the data to be collected in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

*Article 55*  
*Responsibilities of the marketing authorisation holders*

1. In respect of the manufacturing process and control methods stated in the application for a marketing authorisation for the veterinary medicinal product and in order to take account of scientific and technical progress, the marketing authorisation holders shall ensure that any changes that may be required to enable that veterinary medicinal product to be manufactured and verified by means of generally accepted scientific methods are introduced. The introduction of such changes shall be subject to the procedures laid down in Section 4 of this Chapter.
2. Competent authorities may require marketing authorisation holders to provide them with sufficient quantities of the veterinary medicinal products to enable controls to be made on the identification of the presence of residues of the veterinary medicinal products in question.
3. Upon request of a competent authority, the marketing authorisation holder shall provide technical expertise to facilitate the implementation of the analytical method for detecting residues of the veterinary medicinal products in the national reference laboratory designated under Council Directive 96/23/EC<sup>26</sup>.
4. In order to permit continuous assessment of the benefit-risk balance, a competent authority or the Agency may at any time ask the marketing authorisation holder to forward data demonstrating that the benefit-risk balance remains favourable.
5. The marketing authorisation holder shall without delay inform the competent authority or the Commission of any prohibition or restriction imposed by a competent authority and of any other new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned.
6. Upon request from a competent authority, the Commission or the Agency, the marketing authorisation holder shall provide the competent authority, the Commission or the Agency with all data in his possession relating to the volume of sales.

*Article 56*  
*National helpdesks for small and medium-sized enterprises*

1. In order to help small and medium-sized enterprises to comply with the requirements of this Regulation, Member States shall establish national helpdesks.
2. National helpdesks shall provide advice to applicants, marketing authorisation holders, manufacturers, importers and any other interested parties which are small or medium-sized enterprises on their responsibilities and obligations under this Regulation and on applications for the authorisation of veterinary medicinal products.

---

<sup>26</sup> Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

### **SECTION 3**

#### **SUBSEQUENT RECOGNITION IN THE MUTUAL RECOGNITION AND DECENTRALISED MARKETING AUTHORISATION PROCEDURES**

##### *Article 57*

##### *Subsequent recognition of marketing authorisations by other Member States*

1. After completion of a mutual recognition procedure laid down in Article 48 or a decentralised procedure laid down in Article 46, the marketing authorisation holder may submit an application for a marketing authorisation for a veterinary medicinal product to additional Member States. The application shall include the following:
  - (a) a list of all decisions granting marketing authorisations concerning this veterinary medicinal product;
  - (b) a list of variations introduced since the first marketing authorisation in the Union was granted;
  - (c) a summary report on pharmacovigilance data.
2. The additional Member State shall adopt a decision granting a marketing authorisation in conformity with the assessment report referred to in Articles 46(3) and 48(4) or, where appropriate, an updated assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of receipt of the documents listed in paragraph 1.
3. Paragraphs 1 and 2 shall not apply to veterinary medicinal products that have been authorised through a mutual recognition or decentralised procedure before the date of the application of this Regulation.
4. Recognition of marketing authorisations for those veterinary medicinal products shall be granted in accordance with the procedure laid down in Article 48.

### **SECTION 4**

#### **CHANGES TO MARKETING AUTHORISATIONS**

##### *Article 58*

##### *Variations to the terms of a marketing authorisation*

1. Variation to the terms of a marketing authorisation means a change to the terms of the marketing authorisation for a veterinary medicinal product as referred to in Article 31 ('variation').
2. The Commission shall, by means of implementing acts, establish a list of variations to the terms of a marketing authorisation for a veterinary medicinal product requiring assessment ('variations requiring assessment'). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3. The Commission shall take account of the following criteria when adopting those implementing acts:
  - (a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment;
  - (b) whether changes have an impact on the safety and efficacy of the veterinary medicinal product;
  - (c) whether changes imply a significant alteration to the summary of product characteristics.

#### *Article 59*

#### *Consequential changes to product information*

Where a variation entails consequential changes to the summary of the product characteristics, the labelling or the package leaflet, those changes shall be considered as part of that variation for the purposes of the examination of the application for a variation.

#### *Article 60*

#### *Variations to the terms of a marketing authorisation that do not require assessment*

1. Where a variation does not appear in the list established in accordance with Article 58(2), the marketing authorisation holder shall record the change in the product database within 12 months following the implementation of the variation.
2. If necessary, competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission shall amend the decision granting a marketing authorisation in accordance with the change.

#### *Article 61*

#### *Application for variations requiring assessment*

1. Marketing authorisation holder shall submit an application for a variation requiring assessment to a competent authority or to the Agency.
2. The application referred to in paragraph 1 shall contain:
  - (a) a description of the variation;
  - (b) reference to marketing authorisations affected by the application;
  - (c) where the variation leads to other variations to the terms of the same marketing authorisation, a description of those other variations;
  - (d) where the variation concerns marketing authorisations granted under the mutual recognition or decentralised procedures, a list of Member States which granted those marketing authorisations.

*Article 62*  
*Groups of variations*

When applying for several variations to the terms of the same marketing authorisation, a marketing authorisation holder may submit one application for all variations.

*Article 63*  
*Worksharing procedure*

1. When applying for variations to the terms of several marketing authorisations held by the same marketing authorisation holder and granted by different competent authorities and/or the Commission, the marketing authorisation holder shall submit an application to all competent authorities concerned and the Agency.
2. Where one of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation, the Agency shall assess the application in accordance with the procedure laid down in Article 64.
3. Where none of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation, the coordination group shall assign a competent authority among those having granted the marketing authorisations to assess the application in accordance with the procedure laid down in Article 64.

*Article 64*  
*Procedure for variations requiring assessment*

1. If a variation application fulfils the requirements laid down in Article 61, the competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall acknowledge receipt of a complete application.
2. If the application is incomplete, the competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall require the applicant to complete the application within a reasonable deadline.
3. The competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall assess the application and prepare an opinion on the variation within 60 days following the receipt of a valid application. However, where it is necessary having regard to the urgency of the matter, the opinion shall be adopted without delay.
4. Within the period referred to in paragraph 3, the competent authority or the Agency may require the applicant to provide supplementary information within a set time limit. The procedure shall be suspended until the supplementary information has been provided.
5. The opinion shall be forwarded to the applicant.
6. Where the opinion is prepared by the Agency, the opinion shall be forwarded to the Commission. Where the Agency assesses the application in accordance with Article

63(2), the opinion shall be forwarded to the Commission and all competent authorities concerned.

7. Where the opinion is prepared by a competent authority assigned in accordance with Article 63(3), the opinion shall be forwarded to all competent authorities concerned.
8. Within 15 days of receipt of the opinion, the applicant may submit a written request to the Agency or the competent authority for a re-examination of the opinion. Detailed grounds for requesting a re-examination shall be stated in the request or be forwarded to the Agency or to the competent authority within 60 days of receipt of the opinion.
9. Within 60 days of receipt of the grounds for the request, the Agency or the competent authority shall re-examine the points of the opinion identified in the request for re-examination by the applicant and adopt a re-examined opinion. The reasons for the conclusions reached shall be annexed to the opinion.

#### *Article 65*

##### *Measures to close the procedures for variations requiring assessment*

1. Within 30 days of the completion of the procedure laid down in Article 64(6) and (7) a competent authority or the Commission shall amend the marketing authorisation or reject the variation and inform the applicant of the grounds for the rejection. In case of centralised marketing authorisation, the Commission shall, by means of implementing acts, take a final decision amending the marketing authorisation or rejecting the variation. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
2. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for not following the opinion of the Agency.
3. The competent authority or the Agency shall notify the marketing authorisation holder of the amended marketing authorisation without delay.
4. The product database shall be updated accordingly.

#### *Article 66*

##### *Coordination group review*

Where the opinion is prepared by a competent authority assigned in accordance with Article 63(3), each competent authority concerned shall amend the marketing authorisation granted by it or reject the variation in line with the opinion prepared by the competent authority assigned in accordance with Article 63(3).

However, if a competent authority does not agree with the opinion, the coordination group review procedure laid down in Article 49 shall apply.

*Article 67*  
*Implementation of variations requiring assessment*

1. A marketing authorisation holder may implement a variation requiring assessment only after a competent authority or the Commission has amended the decision granting the marketing authorisation in accordance with that variation and the holder has been notified thereof.
2. Where requested by a competent authority or the Agency, a marketing authorisation holder shall supply without delay any information related to a variation to the terms of a marketing authorisation.

**SECTION 5**  
**HARMONISATION OF THE SUMMARIES OF THE PRODUCT CHARACTERISTICS FOR  
NATIONALLY AUTHORISED PRODUCTS**

*Article 68*  
*Preparatory phase of the harmonisation exercise*

1. A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 for veterinary medicinal products, other than homeopathic veterinary medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which national marketing authorisations have been granted in different Member States before 1 January 2004 ('similar products').
2. For the purposes of determining qualitative and quantitative composition of the active substances, different salts, esters, ethers, isomers, mixtures of isomers, complexes and derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy.

*Article 69*  
*Procedure for harmonisation of summaries of products characteristics*

1. By [12 months after the date of application of this Regulation for OP to insert the actual date] competent authorities shall provide the coordination group with lists of all products for which national marketing authorisations have been granted before 1 January 2004.
2. The coordination group shall establish groups of similar products. For each of the groups of similar products, the coordination group shall appoint one member to act as a rapporteur.
3. Within 120 days of his appointment, the rapporteur shall present the coordination group a report regarding possible harmonisation of summaries of product characteristics for the similar veterinary medicinal products in the group and propose a harmonised summary of products characteristics.

4. Harmonised summaries of product characteristics for veterinary medicinal products shall contain all of the following information:
  - (a) all species mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;
  - (b) all therapeutic indications mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;
  - (c) the shortest withdrawal period of those stated in the summaries of the product characteristics.
5. Upon presentation of a report, the coordination group shall act by a majority of the votes cast by the members of the coordination group represented at the meeting. The rapporteur shall record the agreement, close the procedure and inform Member States and the marketing authorisation holders accordingly.
6. In the event of an opinion in favour of adopting a harmonised summary of the product characteristics, each Member State shall vary a marketing authorisation in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur.
7. In the event of an unfavourable opinion, the procedure referred to in Article 49 shall apply.

#### *Article 70*

##### *Harmonisation of summary of products characteristics following reassessment*

1. By way of derogation from Article 69, the Committee may recommend to the Commission groups of similar veterinary medicinal products for which a scientific reassessment is necessary before a harmonised summary of the product characteristics is prepared.
2. The Commission shall, by means of implementing acts, adopt decisions on groups of product for which a reassessment is necessary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
3. By way of derogation from Article 69, veterinary medicinal products authorised before 20 July 2000 as well as veterinary medicinal products authorised after that date but which were identified as potentially harmful to the environment in the course of the environmental risk assessment shall be reassessed before a harmonised summary of the product characteristics is prepared.
4. For the purposes of paragraphs 1 and 3, the procedure for a Union interest referral in accordance with Articles 84 to 87 shall apply accordingly.



*Article 71*  
*Position of marketing authorisation holder*

Upon request from the coordination group or the Agency, holders of the marketing authorisations for products included in a group of similar products identified for a harmonisation of the summaries of the product characteristics shall submit information concerning their products.

**SECTION 6**  
**PHARMACOVIGILANCE**

*Article 72*  
*Pharmacovigilance system of the marketing authorisation holder*

1. Marketing authorisation holders shall elaborate and maintain a system for collecting information on the risks of veterinary medicinal products as regards animal health, public health and the environment enabling them to fulfil their pharmacovigilance responsibilities listed in Articles 73, 76 and 77 ('pharmacovigilance system').
2. Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders.

*Article 73*  
*Union pharmacovigilance system*

1. Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a system to monitor the safety of authorised veterinary medicinal products, enabling them to fulfil their responsibilities as listed in Articles 77 and 79 ('Union pharmacovigilance system').
2. Competent authorities, the Agency and marketing authorisation holders shall make available to healthcare professionals and animal holders different means of reporting to them the following events whether or not the event is considered to be product-related ('adverse events'):
  - (a) any response in an animal to a veterinary or human medicinal product, that is noxious and unintended;
  - (b) any observation of a lack of efficacy of a veterinary medicinal product following administration to an animal in accordance with the summary of product characteristics;
  - (c) any environmental incidents observed following administration of a veterinary medicinal product to an animal;
  - (d) any infringements of withdrawal period following administration to an animal of a veterinary or human medicinal product;
  - (e) any noxious response in humans to a veterinary medicinal product;

- (f) any finding of an active substance in a produce of a food-producing animal exceeding the levels of residues established in accordance with Regulation (EC) No 470/2009.

#### *Article 74*

##### *Union pharmacovigilance database*

1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the "pharmacovigilance database").
2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database.
3. The Agency shall ensure that information reported to the pharmacovigilance database is uploaded and made accessible in accordance with Article 75.

#### *Article 75*

##### *Access to the pharmacovigilance database*

1. The competent authorities shall have full access to the pharmacovigilance database.
2. Marketing authorisation holders shall have access to the pharmacovigilance database to the extent necessary for them to comply with their pharmacovigilance responsibilities as specified in Article 77.
3. The general public shall have access to the pharmacovigilance database only as regards the following information:
  - (a) the number of adverse events reported each year, broken down by product, animal species and type of adverse event;
  - (b) information on the process and outcome of the signal management referred to in Article 81 for veterinary medicinal products and groups of products.

#### *Article 76*

##### *Adverse events reporting*

1. Competent authorities shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred in the territory of their Member State, within 30 days following the receipt of the adverse event report.
2. Marketing authorisation holders shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred within the Union or in a third country with regard to their authorised veterinary medicinal products, within 30 days following the receipt of the adverse event report.
3. Competent authorities may, on their own initiative or on request from the Agency, request the marketing authorisation holder to collect specific pharmacovigilance

data, in particular regarding the use of a veterinary medicinal product in specified animal species, in the context of public and animal health, safety of the persons administering the product, and the protection of the environment. The authority shall state in detail the reasons for the request and inform other competent authorities and the Agency thereof.

4. Within 15 days after receipt of the request referred to in paragraph 3, the marketing authorisation holder may give written notice to the competent authority that he wishes a re-examination of the request to collect additional specific pharmacovigilance data.
5. Within 60 days following the receipt of the written notice, the competent authority shall re-examine the request and provide the marketing authorisation holder with its decision.

#### *Article 77*

##### *Pharmacovigilance responsibilities of the marketing authorisation holder*

1. The marketing authorisation holder shall be responsible for the pharmacovigilance of the products for which he holds a marketing authorisation.
2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in details in the pharmacovigilance system master file.
3. The marketing authorisation holder shall permanently have at his disposal one or more appropriately qualified persons responsible for pharmacovigilance. Those persons shall reside and operate in the Union. Only one qualified person shall be designated by the marketing authorisation holder per pharmacovigilance system master file.
4. Where the tasks of the qualified person responsible for pharmacovigilance listed in Article 78 have been contracted out to a third party, those arrangements shall be detailed in the contract.
5. The marketing authorisation holder shall, based on pharmacovigilance data and where necessary, submit changes to the terms of a marketing authorisation in accordance with Article 61.
6. The marketing authorisation holder shall not communicate information regarding adverse events to the general public in relation to the veterinary medicinal product without giving prior notification of his intention to the competent authority or authorities having granted the marketing authorisation or to the Agency where the marketing authorisation was granted in accordance with the centralised authorisation procedure.

Where the marketing authorisation holder communicates such information to the general public, he shall ensure that it is presented objectively and is not misleading.

*Article 78*  
*Qualified person responsible for pharmacovigilance*

Qualified persons responsible for pharmacovigilance as referred to in Article 77(3) shall carry out the following tasks:

- (a) elaborating and maintaining a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to the veterinary medicinal product for which the authorisation has been granted ('pharmacovigilance system master file') for all products under their responsibility;
- (b) allocating reference numbers to the pharmacovigilance system master file and communicating the reference number of the pharmacovigilance master file of each product to the product database;
- (c) notifying the competent authorities and the Agency of the place where the qualified person operates and where the pharmacovigilance system master file is accessible in the Union;
- (d) establishing and maintaining a system which ensures that all adverse events which are brought to the attention of the marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;
- (e) preparing the adverse event reports referred to in Article 76;
- (f) ensuring that collected adverse event reports are recorded in the pharmacovigilance database;
- (g) ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly, including providing information about the volume of sales or prescriptions of the veterinary medicinal product concerned;
- (h) providing competent authorities or the Agency with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;
- (i) evaluating by means of the pharmacovigilance system all information, considering options for risk minimisation and prevention and taking appropriate measures if necessary;
- (j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate corrective action plan is prepared and implemented;
- (k) ensuring that all personnel involved in the performance of pharmacovigilance activities receives continued training;

- (l) communicating any regulatory measure that is taken in a third country and is based on pharmacovigilance data to the competent authorities and the Agency within 15 days of receipt of such information.

#### *Article 79*

##### *Pharmacovigilance responsibilities of the competent authorities and the Agency*

1. Competent authorities shall evaluate all adverse events reported to them by healthcare professionals and animal holders, manage risks and take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.
2. Competent authorities shall take all appropriate measures to encourage the reporting of adverse events by healthcare professionals and animal holders.
3. Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of adverse events. The Agency and the competent authorities may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.
4. Competent authorities and the Agency shall provide the general public, veterinarians and other healthcare professionals with all important information on adverse events relating to the use of a veterinary medicinal product in a timely manner electronically or through other publicly available means of communication.
5. Competent authorities shall verify by means of inspections referred to in Article 125 that marketing authorisation holders comply with the requirements relating to pharmacovigilance laid down in this Section.
6. The Agency shall evaluate the adverse events to the centrally authorised veterinary medicinal products, manage risks and recommend measures to the Commission. The Commission shall take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.

#### *Article 80*

##### *Delegation of tasks by competent authority*

1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent authority in another Member State subject to the written agreement of the latter.
2. The delegating competent authority shall inform the Commission, the Agency and other Member States of the delegation in writing. The delegating competent authority and the Agency shall make that information public.

*Article 81*  
*Signal management process*

1. Competent authorities and the Agency shall cooperate in monitoring the data in the pharmacovigilance database to determine whether there is any change to the benefit-risk balance of veterinary medicinal products with a view to detecting risks to animal health, public health and protection of the environment ('signal management process').
2. Competent authorities and the Agency shall establish groups of veterinary medicinal products for which signal management process can be combined with a view of detecting risks to animal health, public health and protection of the environment.
3. The Agency and the coordination group shall agree on sharing of the monitoring of data on groups of veterinary medicinal products recorded in the pharmacovigilance database. For each group of veterinary medicinal products a competent authority or the Agency shall be appointed as responsible for the monitoring thereof ('lead authority').
4. The results of the signal management process shall be agreed upon by the competent authorities and, where appropriate, the Agency. The lead authority shall record the results in the pharmacovigilance database.
5. Where necessary, based on the results of the signal management process referred to in paragraph 4 the competent authorities or the Commission shall take appropriate measures as referred to in Articles 130 to 135.

**SECTION 7**  
**RE-EXAMINATION OF A MARKETING AUTHORISATION FOR A LIMITED MARKET**  
**AND IN EXCEPTIONAL CIRCUMSTANCES**

*Article 82*  
*Procedure for re-examination of a marketing authorisation for a limited market*

1. Before the expiry of the period of validity of 3 years, marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined on application from the marketing authorisation holder. After the initial re-examination, it shall be re-examined every 5 years.
2. The application for a re-examination shall be submitted to the competent authority that granted the authorisation or to the Agency at least 6 months before the expiry of the limited market marketing authorisation and shall demonstrate that the veterinary medicinal product remains for use in a limited market and that the marketing authorisation holder complies, if applicable, with the conditions referred to in Article 21(1).
3. When an application for re-examination has been submitted, the limited market marketing authorisation shall remain valid until a decision on the application has been adopted by the competent authority or the Commission.

4. The competent authority or the Agency shall assess the application for a re-examination in order to ascertain whether the benefit-risk balance is positive.
5. The competent authority or the Commission may at any time grant a marketing authorisation valid for an unlimited period of time in respect of a veterinary medicinal product authorised for a limited market, provided that the holder of the marketing authorisation for a limited market submits the missing comprehensive quality and efficacy data referred to in Article 21(1).

#### *Article 83*

##### *Procedure for re-examination of a marketing authorisation in exceptional circumstances*

1. Before the expiry of the period of validity of 1 year, marketing authorisations granted in accordance with Article 22 shall be re-examined on application from the marketing authorisation holder.
2. The application for re-examination shall be submitted to the competent authority that granted the authorisation or the Agency at least 3 months before the expiry of the marketing authorisation.
3. When an application for re-examination has been submitted, the marketing authorisation shall remain valid until a decision on the application has been adopted by the competent authority or the Commission.
4. The competent authority or the Commission may at any time grant a marketing authorisation valid for an unlimited period of time, provided that the marketing authorisation holder submits the missing comprehensive safety and efficacy data referred to in Article 22(1).

## **SECTION 8**

### **UNION INTEREST REFERRAL**

#### *Article 84*

##### *Scope of the Union interest referral*

1. Where the interests of the Union are involved, and in particular the interests of public or animal health or of the environment related to the quality, safety or efficacy of veterinary medicinal products or the free movement of products within the Union, any Member State or the Commission may refer its concern to the Agency for the application of the procedure laid down in Article 85. The matter of concern shall be clearly identified.
2. Upon request from the Agency, Member States and marketing authorisation holders shall forward to the Agency all available information relating to the Union interest referral.
3. Where the referral provided for in paragraph 1 concerns more than one veterinary medicinal product or a therapeutic class, the Agency may limit the procedure to specific parts of the terms of the marketing authorisation.

*Article 85*  
*Referral procedure*

1. The Agency shall publish information about referrals made in accordance with Article 84 on its website. Interested parties shall be invited to provide comments.
2. The Committee shall consider the referred matter and shall issue a reasoned opinion within 90 days of the date on which the matter was referred to it. That period may be extended by the Committee for a further period of up to 60 days, taking into account the views of the marketing authorisation holders concerned.
3. Before issuing its opinion, the Committee shall provide the marketing authorisation holder with the opportunity to present explanations within a specified time limit. The Committee may suspend the time limit referred to in paragraph 2 to allow the marketing authorisation holder to prepare the explanations.
4. In order to consider the matter, the Committee shall appoint one of its members to act as a rapporteur. The Committee may appoint independent experts to give advice on specific questions. When appointing such experts, the Committee shall define their tasks and specify the time limit for the completion of these tasks.
5. If it considers it appropriate, the Committee may invite any other person to provide information relating to the matter before it.
6. Within 15 days after its adoption, the Agency shall forward the final opinion of the Committee to Member States, the Commission and the marketing authorisation holder, together with an assessment report of the veterinary medicinal product and the reasons for its conclusions.

*Article 86*  
*Decision following the Union interest referral*

1. Within 15 days after receipt of the opinion referred to in Article 85(6), the Commission shall prepare a draft decision. If the draft decision is not in accordance with the opinion of the Agency, the Commission shall also set out a detailed explanation of the reasons for the differences in an annex to the draft decision.
2. The draft decision shall be forwarded to Member States.

*Article 87*  
*Commission decision following the referral*

1. The Commission shall, by means of implementing acts, take a final decision on the Union interest referral. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). Unless otherwise stated in the referral notification in accordance with Article 84, the decision shall apply to all veterinary medicinal products subject to the marketing authorisation that contain the active substance concerned by the referral.



2. Where the veterinary medicinal product has been authorised in accordance with the national, mutual recognition or decentralised procedures, the decision referred to in paragraph 1 shall be addressed to all Member States and communicated to the marketing authorisation holder for information.
3. Member States shall take any necessary action with regard to the marketing authorisations for all veterinary medicinal products concerned to comply with the decision within 30 days of its notification, unless a different period is foreseen in the decision.
4. In case of centrally authorised veterinary medicinal products a decision as referred to in paragraph 1 shall be addressed to the marketing authorisation holder.

## **Chapter V**

### **Homeopathic veterinary medicinal products**

#### *Article 88*

##### *Homeopathic veterinary medicinal products*

1. By way of derogation from Article 5, homeopathic veterinary medicinal products that satisfy the requirements set out in Article 89 and are not immunological homeopathic veterinary medicinal products shall be registered in accordance with Article 90.
2. The competent authorities shall record homeopathic veterinary medicinal products registered by them in the database referred to in Article 51.

#### *Article 89*

##### *Registration of homeopathic veterinary medicinal products*

1. Homeopathic veterinary medicinal products that satisfy all of the following conditions shall be subject to a registration procedure:
  - (a) the medicinal product is administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member States;
  - (b) there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture;
  - (c) no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to adapt paragraph 1(b) and (c) in the light of new scientific evidence.

*Article 90*

*Requirements and procedure for registration of homeopathic veterinary medicinal products*

1. The following documents shall be included in the application for a registration of a homeopathic veterinary medicinal product:
  - (a) scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;
  - (b) a dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens;
  - (c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation;
  - (d) the manufacturing authorisation for the veterinary medicinal products concerned;
  - (e) copies of any registrations or authorisations obtained for the same veterinary medicinal products in other Member States;
  - (f) the text to appear on the outer packaging and immediate packaging of the veterinary medicinal products to be registered;
  - (g) data concerning the stability of the medicinal product;
  - (h) in the case of veterinary medicinal products intended for food-producing species, proposed withdrawal period together with all requisite justification;
  - (i) in the case of veterinary medicinal products intended for food-producing species and containing pharmacologically active substances that have not been included in Regulation (EU) No 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009.
2. An application for registration may cover a series of medicinal products derived from the same homeopathic stock or stocks.
3. In a decision concerning registration the competent authority shall determine the conditions under which the homeopathic veterinary medicinal product may be made available to end users in accordance with Article 29.
4. The procedure of registering a homeopathic veterinary medicinal product shall be completed within 210 days after the submission of a valid application.

## **Chapter VI**

### **Manufacturing, import and export**

#### *Article 91*

##### *Manufacturing authorisations*

1. A manufacturing authorisation shall be required in order to carry out any of the following activities ('manufacturing'):
  - (a) to produce or import veterinary medicinal products; or
  - (b) to engage in any part of the process of producing a veterinary medicinal product or of bringing a veterinary medicinal product to its final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing it or any constituent of it for supply as part of that process.
2. Notwithstanding paragraph 1, a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out solely for retail in accordance with Articles 107 and 108.
3. The competent authorities shall record the manufacturing authorisations granted by them in the database on manufacturing, import and wholesale distribution set up in accordance with Article 94.
4. Manufacturing authorisations shall be valid throughout the Union.

#### *Article 92*

##### *Requirements for obtaining a manufacturing authorisation*

1. Applications for manufacturing authorisations shall be submitted to a competent authority in the Member State where 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) pharmaceutical forms which are to be manufactured or imported;
  - (c) details about the manufacturing site where the veterinary medicinal products are to be manufactured or tested;
  - (d) statement to the effect that the applicant fulfils the requirements laid down in Article 98.

*Article 93*  
*Granting of manufacturing authorisations*

1. Before granting a manufacturing authorisation, the competent authority shall carry out an inspection in accordance with Article 125 of the manufacturing site where the veterinary medicinal products are to be manufactured or tested.
2. An authorisation shall apply only to the manufacturing site, the veterinary medicinal products, and the pharmaceutical forms specified in the application.
3. Member States shall lay down procedures for granting manufacturing authorisations. The procedures for granting a manufacturing authorisation shall not exceed 90 days from the day on which the competent authority receives the application.
4. The competent authority may require the applicant to submit further information in addition to that supplied in the application pursuant to Article 92. Where the competent authority exercises this right, the time limit referred to in paragraph 3 of this Article shall be suspended until the additional data required has been submitted.
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. The manufacturing authorisation may be suspended if these requirements are not complied with.

*Article 94*  
*Database on manufacturing authorisations*

1. A Union database on manufacturing, import and wholesale distribution shall be set up and maintained by the Agency ('manufacturing and wholesale distribution database').
2. The database shall include information on any manufacturing and wholesale distribution authorisations granted by competent authorities within the Union.
3. The Agency shall make public a format for electronic submissions of data to the database.
4. Competent authorities shall record in the manufacturing and wholesale distribution database information on authorisations and certificates granted in accordance with Articles 93, 103 and 105 together with information on the veterinary medicinal products covered by the authorisations, using the format referred to in paragraph 3.
5. The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications for the manufacturing and wholesale distribution database.
6. The Agency shall ensure that information reported to the database is collated and made accessible and that the information is shared.

#### *Article 95*

##### *Access to the database on manufacturing authorisations*

1. The competent authorities shall have full access to the database set up in accordance with Article 94.
2. Manufacturers and wholesalers shall have access to the database to the extent necessary for them to comply with their obligations.
3. The general public shall have access to information in the database specifying the companies that have been granted manufacturing or wholesale distribution authorisations and the manufacturing sites and products concerned by these authorisations.

#### *Article 96*

##### *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 exceptional cases, this period of time may be extended by the competent authority to 90 days.
2. The application shall contain description of the requested change and the authorised products affected by this change.
3. Within the period referred to in paragraph 1, the competent authority may request the holder to provide supplementary information within a set time limit. The procedure shall be suspended until such time as the supplementary information has been provided.
4. The competent authority shall inform the holder of the outcome of the assessment and where appropriate, amend the manufacturing authorisation, and update, where appropriate, the manufacturing and wholesale distribution database.

#### *Article 97*

##### *Manufacturing authorisation for import and export*

1. The manufacturing authorisation shall also be required for imports from and exports to third countries.
2. The requirement referred to in paragraph 1 shall not apply to holders of a wholesale distribution authorisation referred to in Article 104.

#### *Article 98*

##### *Obligations of the manufacturing authorisation holders*

The holder of a manufacturing authorisation shall:

- (a) have at his disposal suitable and sufficient premises, technical equipment and testing facilities for the manufacture, export or import of the veterinary medicinal products stated in the manufacturing authorisation;
- (b) have at his disposal the services of at least one qualified person within the meaning of Article 100;
- (c) enable the qualified person referred to in Article 100 to carry out his duties, particularly by placing at his disposal all the necessary technical equipment and testing facilities;
- (d) inform the competent authority if the qualified person referred to in Article 100 is replaced;
- (e) have at his disposal the services of staff complying with the legal requirements existing in the Member State concerned as regards both manufacture and controls;
- (f) allow the representatives of the competent authority access to his premises at any time;
- (g) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with Article 99.

*Article 99*  
*Record keeping*

1. The following information shall be recorded in respect of all veterinary medicinal products supplied by the holder of a manufacturing authorisation:
  - (a) date of the transaction,
  - (b) name of the veterinary medicinal product,
  - (c) quantity supplied,
  - (d) name and address of the recipient,
  - (e) batch number.
2. The records mentioned in paragraph 1 shall be available for inspection by competent authorities for a period of 3 years.

*Article 100*  
*Qualified person for manufacturing*

1. The holder of a manufacturing authorisation shall have permanently and continuously at his 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 Article 101.

2. The qualified person shall be in possession of a diploma, certificate or other evidence of appropriate qualification and shall have acquired sufficient experience in the field of manufacturing. The holder of the authorisation may himself assume the responsibility referred to in paragraph 1, if he personally fulfils those conditions as specified above.

#### *Article 101*

##### *Batch release of veterinary medicinal products*

1. Where veterinary medicinal products have been manufactured by the holder of a manufacturing authorisation, the qualified person for manufacturing shall ensure that each batch of the veterinary medicinal products has been manufactured and tested in compliance with the terms of the marketing authorisation. The qualified person for manufacturing shall prepare a report to this effect.
2. Where veterinary medicinal products have been imported from third countries, the qualified person for manufacturing shall ensure that each imported production batch has undergone in the Union a 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.
3. The reports signed by the qualified person as referred to in paragraph 1 shall be valid throughout the Union.
4. The qualified person for manufacturing shall keep records in respect of each released production batch. These records shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for a period of 5 years.
5. Where veterinary medicinal products manufactured in the Union are imported into the Union from a third country, paragraph 1 shall apply.
6. 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 Commission Directive 91/412/EEC<sup>27</sup> and it is demonstrated that the tests referred to in paragraph 1 have been carried out in the exporting country, the competent authority in the Member State of importation may relieve the qualified person of the of responsibility for carrying out the tests referred to in paragraph 2.

#### *Article 102*

##### *Competent authorities' measures*

1. The competent authority shall ensure that the obligations of qualified persons referred to in Article 100 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.

---

<sup>27</sup> Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17/08/1991, p. 70).

2. The competent authority may temporarily suspend such persons upon the commencement of administrative or disciplinary proceedings against them for failure to fulfil their obligations.

### *Article 103*

#### *Certificates of manufacturing authorisations*

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

- (a) holds a manufacturing authorisation for the product in question, or
- (b) possesses a certificate of good manufacturing practice as referred to in Article 127.

When issuing such certificates, the competent authority shall attach the approved summary of the product characteristics or, in the absence thereof, an equivalent document, in case of veterinary medicinal products intended for export which are already authorised in their territory.

## **Chapter VII Supply and use**

### **SECTION 1**

#### **WHOLESALE DISTRIBUTION**

### *Article 104*

#### *Wholesale distribution of veterinary medicinal products*

1. The wholesale distribution of veterinary medicinal products shall be subject to the holding of a wholesale distribution authorisation. Member States shall lay down procedures for granting a wholesale distribution authorisation.
2. Wholesale distribution authorisations shall be valid throughout the Union.
3. Supplies of small quantities of veterinary medicinal products from one retailer to another shall not be regarded as wholesale distribution.
4. The wholesale distributor shall have an emergency plan guaranteeing the effective implementation of any withdrawal ordered by the competent authorities or the Commission or undertaken in cooperation with the manufacturer of the veterinary medicinal product in question or marketing authorisation holder.
5. A wholesale distributor shall supply veterinary medicinal products only to persons permitted to carry out retail activities in the Member State in accordance with Article 107(1), other wholesale distributors and exporters of veterinary medicinal products.



*Article 105*  
*Procedure for granting wholesale distribution authorisations*

1. An application for a wholesale distribution authorisation shall be submitted to the competent authority of the Member State in which the wholesale distributor is established.
2. The procedure for granting a wholesale distribution authorisation shall not exceed 90 days from the date on which the competent authority receives an application.
3. An applicant shall demonstrate in the application that he fulfils the following requirements:
  - (a) has at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of veterinary medicinal products;
  - (b) has an emergency plan guaranteeing effective implementation of any withdrawal ordered by the competent authorities or the Commission or undertaken in cooperation with the manufacturer of the veterinary medicinal product in question or marketing authorisation holder;
  - (c) has an appropriate record keeping system ensuring compliance with the requirements referred to in Article 106.
4. The competent authority shall inform the applicant of the outcome of the evaluation, grant or refuse the wholesale distribution authorisation, and upload the relevant information of the authorisation in the manufacturing and wholesale distribution database.

*Article 106*  
*Record keeping requirements for wholesale distributors*

1. The wholesale distributor shall keep detailed records. The following minimum information shall be recorded in respect of each purchase and sale transaction:
  - (a) date of the transaction;
  - (b) name of the veterinary medicinal product;
  - (c) batch number,
  - (d) expiry date of the veterinary medicinal product;
  - (e) quantity received or supplied;
  - (f) name and address of the supplier in the event of purchase or of the recipient in the event of sale.
2. At least once a year the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing medicinal

products with products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of three years.

## **SECTION 2**

### **RETAIL**

#### *Article 107*

##### *Retail of veterinary medicinal products and record keeping*

1. The retail of veterinary medicinal products shall be conducted only by persons who are permitted to carry out such operations under national law.
2. Persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their care, and only in the amount required for the treatment concerned.
3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each purchase and sale of veterinary medicinal products:
  - (a) date of the transaction;
  - (b) name of the veterinary medicinal product;
  - (c) batch number;
  - (d) quantity received or supplied;
  - (e) name and address of the supplier in the event of purchase, or of the recipient in the event of sale;
  - (f) name and address of the prescribing veterinarian and a copy of the prescription in case of veterinary medicinal products requiring a prescription in accordance with Article 29.
4. At least once a year a retailer shall carry out a detailed audit of the stock and compare the incoming and outgoing veterinary medicinal products recorded with products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities in accordance with Article 125 for a period of three years.

#### *Article 108*

##### *Retail of veterinary medicinal products at a distance*

1. Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products by means of information society services in the meaning of Directive 98/34/EC of the European Parliament and of the

Council<sup>28</sup> to natural or legal persons established in the Union under the condition that those medicinal products comply with the legislation of the destination Member State.

2. In addition to the information requirements set out in Article 6 of the Directive 2000/31/EC of the European Parliament and of the Council<sup>29</sup>, websites offering veterinary medicinal products shall contain at least:
  - (a) the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;
  - (b) a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 5;
  - (c) the common logo established in accordance with paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of veterinary medicinal products and containing a hyperlink to the entry of the retailer in the list of authorised retailers referred to in point (c) of paragraph 5.
3. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance to the public is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.
4. The Commission shall adopt the design of the common logo by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
5. Each Member State shall set up a website regarding sale of veterinary medicinal products at a distance, providing at least the following information:
  - (a) information on its national legislation applicable to the offering of veterinary medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;
  - (b) information on the common logo;
  - (c) a list of retailers established in the Member State authorised to offer veterinary medicinal products for sale at a distance to the public by means of information society services in accordance with paragraph 1 as well as the website addresses of those retailers.

---

<sup>28</sup> Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

<sup>29</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

The websites set up by Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 6.

6. The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons authorised to offer veterinary medicinal products for sale at a distance to the public by means of information society services in the Member State concerned.
7. Member States may impose conditions, justified on grounds of public health protection, for the retail on their territory of medicinal products offered for sale at a distance to the public by means of information society services.

#### *Article 109*

##### *Retail of anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic veterinary medicinal products*

1. Only manufacturers, wholesale distributors and retailers authorised specifically to do so in accordance with applicable national law shall be allowed to supply and purchase veterinary medicinal products which have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties or substances which may be used as veterinary medicinal products having those properties.
2. The competent authorities shall maintain a register of manufacturers, wholesale distributors and retailers authorised in accordance with paragraph 1.
3. Those manufacturers and suppliers shall keep detailed records of the following information in respect of each purchase and sale transaction:
  - (a) date of transaction;
  - (b) name and marketing authorisation number of the veterinary medicinal product;
  - (c) quantity received or supplied;
  - (d) name and address of the supplier in the event of purchase, or of the recipient in the event of sale.

These records shall be available for inspection by the competent authorities in accordance with Article 125 for a period of 3 years.

#### *Article 110*

##### *Veterinary prescriptions*

1. A veterinary prescription shall contain at least the following elements ('minimum requirements'):
  - (a) identification of the animal under treatment;
  - (b) full name and contact details of the animal owner or keeper;

- (c) issue date;
  - (d) full name and contact details, qualifications and professional membership number of the person writing the prescription;
  - (e) signature or an equivalent electronic form of identification of the person writing the prescription;
  - (f) name of the prescribed product;
  - (g) pharmaceutical form (tablet, solution, etc.);
  - (h) quantity;
  - (i) strength;
  - (j) dosage regimen;
  - (k) withdrawal period if relevant;
  - (l) any necessary warnings;
  - (m) if a product is prescribed for a condition not mentioned in the marketing authorisation for that product, a statement to that effect.
2. A veterinary prescription shall only be issued by a person qualified to do so in accordance with applicable national law.
  3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned.
  4. Veterinary prescriptions shall be recognised throughout the Union. A veterinary medicinal product prescribed shall be supplied in accordance with applicable national law.

### **SECTION 3**

#### **USE**

#### *Article 111*

##### *Use of veterinary medicinal products*

1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.
2. Member States shall lay down procedures for placing on the market of the medicinal products allowed to be used in their territory in accordance with Articles 115, 116, 119, 120 and 121.

*Article 112*  
*Record keeping by owners and keepers of food-producing animals*

1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the veterinary medicinal products they use and, if applicable, a copy of the veterinary prescription.
2. The following information shall be recorded:
  - (a) date of administering the veterinary medicinal product to the animal;
  - (b) name of the veterinary medicinal product;
  - (c) quantity of the veterinary medicinal product administered;
  - (d) name and address of the supplier;
  - (e) identification of the animals treated;
  - (f) name and address of the prescribing veterinarian and, if applicable, a copy of the prescription.
3. The information contained in these records shall be available for inspections by the competent authorities in accordance with Article 125 for a period of at least 3 years.

*Article 113*  
*Use of immunologicals*

1. The competent authorities may, in accordance with their national legislation, prohibit the manufacture, import, sale, supply and/or use of immunological veterinary medicinal products on the whole of their territory or in a part of it if at least one of the following conditions is fulfilled:
  - (a) the administration of the product to animals may interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease;
  - (b) the administration of the product to animals may cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals;
  - (c) the disease to which the product is intended to confer immunity is largely absent from the territory concerned.
2. The competent authorities shall inform the Commission of all instances in which the provisions of paragraph 1 are applied.

#### *Article 114*

##### *Veterinarians providing services in other Member States*

1. A veterinarian providing services in a Member State other than the one where he is established (the 'host Member State') may administer veterinary medicinal products authorised in the host Member State to animals in another Member State which are under his care in the amount required for the treatment of those animals where the following conditions are fulfilled:
  - (a) the authorisation to place the veterinary medicinal product on the market provided for in Article 5 has been issued by the competent authorities of the host Member State or by the Commission;
  - (b) the veterinary medicinal products are transported by the veterinarian in the original packaging;
  - (c) where intended for administration to food-producing animals, the veterinary medicinal products have the same qualitative and quantitative composition of active substances as the veterinary medicinal products authorised in the host Member State;
  - (d) the veterinarian follows the good veterinary practices applied in that Member State and ensures that the withdrawal period specified on the labelling of the veterinary medicinal product is observed;
  - (e) the veterinarian does not retail any veterinary medicinal product to an owner or keeper of animals treated in the host Member State unless this is permissible under the rules of the host Member State, the medicinal product is intended for animals under his care, and only the minimum quantities of veterinary medicinal product necessary to complete the treatment of those animals are retailed;
  - (f) the veterinarian keeps detailed records of the animals treated, their diagnosis, the veterinary medicinal products administered, the dose administered, the duration of treatment and the withdrawal period applied, for inspection by the competent authorities of the host Member State for a period of 3 years.
2. Paragraph 1 shall not apply to immunological veterinary medicinal products which are not authorised for use in the host Member State.

#### *Article 115*

##### *Use of medicinal products for species or indications outside the terms of the marketing authorisation in non food-producing species*

1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a non-food producing animal, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with the following:
  - (a) a medicinal product:

- (i) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another animal species, or for another condition in the same species;
  - (ii) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another species, for the same condition or for another condition;
  - (iii) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC of the European Parliament and of the Council<sup>30</sup> or Regulation (EC) No 726/2004;
    - (b) if there is no product as referred to in point (a), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.
2. The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.
  3. Paragraph 1 of this Article shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with Regulation (EC) No 504/2008, as not being intended for slaughter for human consumption.

#### *Article 116*

#### *Use of medicinal products for species or indications outside the terms of the marketing authorisation in food-producing species*

1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing animal of a non-aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with any of the following:
  - (a) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another food-producing animal species, or for another condition in the same species;
  - (b) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another food-producing species for the same condition or for another condition;
  - (c) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004, or
  - (d) if there is no product as referred to in point (a), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.

---

<sup>30</sup> 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).



2. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned with any of the following medicinal products:
  - (a) veterinary medicinal products authorised under this Regulation in the Member State concerned for use with another food-producing aquatic species, or for another condition in the same aquatic species;
  - (b) veterinary medicinal products authorised under this Regulation in another Member State for use in the same aquatic species or in another food-producing aquatic species for the condition in question or for another condition.
3. By way of derogation from paragraph 2, and until an implementing act referred to in paragraph 4 is established, if there is no product as referred to in subparagraphs (a) and (b) of paragraph 2, a veterinarian may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing animals of an aquatic species on a particular holding with:
  - (a) a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use with a food-producing non-aquatic species;
  - (b) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004.
4. The Commission may, by means of implementing acts, establish a list of veterinary medicinal products authorised in the Union for use in terrestrial animals which can be used for treatment of food-producing animals of an aquatic species in accordance with paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

The Commission shall take account of the following criteria when adopting those implementing acts:

- (a) risks to the environment if aquatic animals are treated with these medicinal products;
- (b) impact on animal health and public health if the aquatic animal affected by the condition cannot receive treatment with the potential listed antimicrobial medicinal product;
- (c) impact on the competitiveness of certain sectors in aquaculture in the Union if the animal affected by the condition cannot receive treatment with the antimicrobial medicinal product concerned;
- (d) availability or lack of availability of other medicines, treatments or measures for prevention or treatment of diseases or certain conditions in aquatic animals.

5. For the purpose of treatment in accordance with paragraphs 1 to 3, the veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.
6. Pharmacologically active substances included in the medicinal product used in accordance with paragraph 1 shall be listed in Table 1 of the Annex to Regulation (EU) No 37/2010. The veterinarian shall specify an appropriate withdrawal period in accordance with Article 117.
7. By way of derogation from paragraph 1 and from Article 16(1) of Regulation (EC) No 470/2009 and in case there is no medicinal product available as referred to in paragraph 1, a veterinarian may treat bees, during the period when no honey or other foodstuffs is produced, with a veterinary medicinal product authorised for bees in a third country which is a member or an observer of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.
8. The veterinarian shall keep records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products prescribed, the doses administered, the duration of the treatment and the withdrawal periods recommended, and shall make those records available for inspection by the competent authorities for a period of at least 5 years.

#### *Article 117*

#### *Withdrawal period for products used outside the terms of the marketing authorisation in food-producing species*

1. For the purpose of Article 116, unless a product used has a withdrawal period provided in its summary of the product characteristics for the species in question, a withdrawal period shall be set by the veterinarian in accordance with the following criteria:
  - (a) for meat and offal of food producing mammals and birds not less than:
    - (i) the longest withdrawal period provided in its summary of the product characteristics for any animal species multiplied by factor 1,5;
    - (ii) if the product is not authorised for food producing species, 28 days;
  - (b) for animal species producing milk for human consumption not less than:
    - (i) the longest withdrawal period provided in the summary of the product characteristics for any milk producing species multiplied by factor 1.5;
    - (ii) if the product is not authorised for any milk producing species, 7 days;
  - (c) for animal species producing eggs for human consumption not less than:
    - (i) the longest withdrawal period provided in the summary of the product characteristics for eggs multiplied by factor 1.5;

(ii) if the product is not authorised for any eggs producing species, 7 days;

(d) for aquatic animal species for human consumption and aquatic animal species producing eggs for human consumption not less than:

(i) the longest withdrawal period for any of the aquatic species indicated in the summary of the product characteristics multiplied by factor of 50 and expressed as number of days multiplied by the average water temperature ('degree-days'). The withdrawal period shall not be less than 50 degree-days;

(ii) if the product is not authorised for food producing aquatic animal species, 500 degree-days.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend the rules laid down in paragraph 1 in the light of new scientific evidence.

3. For bees, the veterinarian shall determine the appropriate withdrawal period by assessing the specific situation of the particular beehive(s) on a case-by-case basis.

4. With regard to homeopathic veterinary medicinal products the withdrawal period shall be established at zero days.

5. By way of derogation from paragraph 1, the Commission shall establish a list of substances:

(a) which are essential for the treatment of equidae, or which bring added clinical benefit compared to other treatment options available for equidae;

(b) for which the withdrawal period for equidae shall not be less than six months subject to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

#### *Article 118*

##### *Use of antimicrobial veterinary medicinal products for species or indications outside the terms of the marketing authorisation*

1. Antimicrobial medicinal products shall only be used in accordance with Articles 115 and 116 to treat conditions for which there is no other treatment available, and the use of which would not present a risk to public or animal health.

2. The Commission may, by means of implementing acts in accordance with the examination procedure referred to in Article 145(2), and taking into consideration scientific advice of the Agency, establish a list of antimicrobial medicinal products that cannot be used in accordance with paragraph 1, or which can only be used for treatment in accordance with paragraph 1 subject to certain conditions.

When adopting those implementing acts, the Commission shall take account of the following criteria:

- (a) risks to public health if the antimicrobial product is used in accordance with paragraph 1;
- (b) risk for human health in case of development of antimicrobial resistance;
- (c) availability of other treatments for animals,
- (d) availability of other antimicrobial treatments for humans;
- (e) impact on aquaculture and farming if the animal affected by the condition receives no treatment.

#### *Article 119*

##### *Health situation and listed diseases*

1. By way of derogation from Article 111, a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products is authorised in another Member State.
2. By way of derogation from Article 111, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EC) No.../.... of the European Parliament and the Council<sup>31</sup> [*Office of Publications, please insert number and, in a footnote, date, title and the OJ reference for the Regulation on animal health*] a competent authority may allow, for a limited period of time and under specific restrictions, the use of an immunological veterinary medicinal product authorised in another Member State.

#### *Article 120*

##### *Exemption for veterinary medicinal products for certain animals kept exclusively as pets*

Where veterinary medicinal products are intended solely for aquatic animals, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits kept exclusively as pets, Member States may permit exemptions, in their territory, from Article 5, provided that such products do not contain substances the use of which requires veterinary controls and that all possible measures are taken to prevent unauthorised use of the products for other animals.

#### *Article 121*

##### *Use of immunologicals from third countries*

If an animal is being imported from, or exported to, a third country and is thereby subject to specific binding health rules, a competent authority may permit the use, for the animal in question, of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the Member State in question but is authorised under the

---

<sup>31</sup> Regulation of the European Parliament and the Council of.... on animal health (OJ L.....).

legislation of the third country. A competent authority shall supervise the importation and the use of such immunological products.

*Article 122*  
*Disposal of veterinary medicinal products*

Member States shall ensure that appropriate collection systems are in place for veterinary medicinal products that are unused or expired.

**SECTION 4**  
**ADVERTISING**

*Article 123*  
*Advertising of veterinary medicinal products*

1. The advertising of a veterinary medicinal product shall make it clear that it aims at promoting the prescription, sale or use of the veterinary medicinal product.
2. The advertising shall be coherent with the summary of product characteristics and shall not include information in any form which could be misleading or lead to overconsumption of the veterinary medicinal product.

*Article 124*  
*Prohibition of advertising of certain veterinary medicinal products*

1. The advertising of the following veterinary medicinal products shall be prohibited :
  - (a) veterinary medicinal products which are available on veterinary prescription only;
  - (b) veterinary medicinal products which contain psychotropic drugs or narcotics, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the United Nations Convention on Psychotropic Substances of 1971.
2. The prohibition laid down in paragraph 1 shall not apply to advertising to persons permitted to prescribe or supply veterinary medicinal products.

## **Chapter VIII**

### **Inspections and controls**

#### *Article 125* *Controls*

1. Competent authorities shall perform controls of manufacturers, importers, marketing authorisation holders, wholesale distributors and suppliers of the veterinary medicinal products regularly, on a risk-basis, in order to verify that the requirements as set out in this Regulation are complied with.
2. The risk-based controls referred to in paragraph 1 shall be carried out by the competent authorities taking account of:
  - (a) the risk of non-compliance with the legal requirements associated with the activities of the undertakings and the location of the activities,
  - (b) the entity's past record as regards the results of inspections performed on them and their compliance with the requirements,
  - (c) any information that might indicate non-compliance with the legal requirements,
  - (d) the potential impact of non-compliance with the requirements on public health, animal health and the environment.
3. Inspections may also be carried out upon request of another competent authority, the Commission or the Agency.
4. The inspections shall be carried out by authorised representatives of the competent authority who shall be empowered to:
  - (a) inspect manufacturing or supply establishments and any laboratories entrusted by the manufacturing authorisation holder with the task of carrying out control tests;
  - (b) take samples of veterinary medicinal products and starting materials, including with a view to submit them for an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by a Member State;
  - (c) examine any documents relating to the object of the inspection;
  - (d) inspect the premises, records, documents and pharmacovigilance systems of marketing authorisation holders or any parties performing the activities as provided in Chapter IV on behalf of a marketing authorisation holder.

If necessary, the inspections may be carried out unannounced.

5. After each control, a competent authority shall draft a report on compliance with the requirements set out in this Regulation. Before adopting a report, the inspected entity shall have the opportunity to submit comments.
6. Inspection reports shall be uploaded to the appropriate database, with continuous access for all competent authorities.

*Article 126*  
*Audits by the Commission*

The Commission may carry out audits in Member States for the purpose of verifying the controls carried out by the competent authorities. After each audit, the Commission shall draft a report containing, where appropriate, recommendations to the Member State concerned. The audit report may be made public by the Commission.

*Article 127*  
*Certificates of good manufacturing practice*

1. Within 90 days after an inspection of a manufacturer, a certificate of good manufacturing practice shall be issued to the manufacturer if the inspection established that the manufacturer in question is complying with the requirements as set out in this Regulation and taking due account of the principles and guidelines on good manufacturing practice.
2. Competent authorities shall enter the certificates of good manufacturing practice into the database for manufacturing authorisations.
3. The conclusions reached following an inspection of a manufacturer shall be valid throughout the Union.
4. The competent authority may carry out inspections of starting material manufacturers at the manufacturer's own request. The competent authority shall verify that the manufacturing processes used in the manufacture of immunological veterinary medicinal products are validated and batch-to-batch consistency is ensured.
5. Without prejudice to any arrangements which may have been concluded between the Union and a third country, 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.
6. In order to verify whether the data submitted for obtaining a conformity certificate comply with the monographs of the European Pharmacopoeia, the standardisation body for nomenclatures and quality norms within the meaning of the Convention on the elaboration of a European Pharmacopoeia accepted by Council Decision 94/358/EC<sup>32</sup> (European Directorate for the Quality of Medicines & Healthcare) may ask the Commission or the Agency to request an inspection when the starting material concerned is subject to a European Pharmacopoeia monograph. In the event

---

<sup>32</sup> Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

of an inspection carried out upon request of the European Pharmacopoeia (European Directorate for the Quality of Medicines & Healthcare), a certificate of compliance with the monograph shall be issued.

#### *Article 128*

##### *Specific rules on pharmacovigilance inspections*

1. The pharmacovigilance inspections shall be coordinated by the Agency together with the competent authorities and shall ensure that all pharmacovigilance system master files in the Union, as identified in the product database, are regularly checked.
2. The competent authority in the Member State in which the qualified person responsible for pharmacovigilance operates shall carry out pharmacovigilance inspections. Any work-sharing initiatives and delegation of responsibilities between competent authorities shall ensure that there is no duplication of inspections of pharmacovigilance system master files.
3. The results of the pharmacovigilance inspections shall be collected in the pharmacovigilance database.

#### *Article 129*

##### *Proof of the product quality*

1. The marketing authorisation holder shall provide proof of the control tests carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in marketing authorisation.
2. For the purposes of application of paragraph 1, competent authorities may require the marketing authorisation holder for immunological veterinary medicinal products to submit to the competent authorities the copies of all the control reports signed by the qualified person in accordance with Article 101.
3. The marketing authorisation holder for immunological veterinary medicinal products shall ensure that an adequate number of representative samples of each batch of veterinary medical products is held in stock at least up to the expiry date, and provide samples promptly to the competent authorities upon request.
4. Where necessary for reasons of human or animal health, a competent authority may require the marketing authorisation holder for an immunological veterinary medicinal product to submit samples of batches of the bulk product and/or veterinary medicinal product for control by an Official Medicines Control Laboratory before the product is made available on the market.
5. Upon request by the competent authority, the marketing authorisation holder shall promptly supply the samples referred to in paragraph 4, together with the reports of the control referred to in this Chapter. The competent authority shall inform the competent authorities in other Member States in which the veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines & HealthCare of its intention to control batches or the batch in question.



In such cases, the competent authorities of another Member State shall not apply the provisions of paragraph 4.

6. On the basis of the control reports referred to in this Chapter, the laboratory responsible for the control shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished product, in accordance with the relevant provisions shown in the dossier for marketing authorisation.
7. The list of tests to be repeated by the laboratory responsible for the control shall be restricted to justified tests, provided that all competent authorities in the Member States concerned, and if appropriate the European Directorate for the Quality of Medicines & HealthCare, agree to this.

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

8. The competent authorities shall recognise the results of the tests.
9. Unless the Commission is informed that a longer period is necessary to conduct the tests, the competent authorities shall ensure that this control is completed within 60 days of receipt of the samples.
10. The competent authority shall notify the competent authorities of other Member States concerned, the European Directorate for the Quality of Medicines & HealthCare, the marketing authorisation holder and, if appropriate, the manufacturer, of the results of the tests within the same period of time.
11. If a competent authority concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take measures vis-a-vis the marketing authorisation holder and the manufacturer, and shall inform accordingly the competent authorities of other Member States in which the veterinary medicinal product is authorised.

## **Chapter IX**

### **Restrictions and penalties**

#### *Article 130*

#### *Temporary safety restrictions*

1. In the event of a risk to public or animal health or to the environment that requires urgent action, the competent authorities or, in the case of centralised marketing authorisations, the Commission may impose temporary safety restrictions on the marketing authorisation holder, including suspending the marketing authorisation and/or prohibiting the supply of a veterinary medicinal product. Other Member States and, where the temporary safety restriction is imposed by a competent authority, the Commission shall be informed of the temporary safety restriction imposed on the following working day at the latest.

2. Member States and the Commission may refer the issue to the Agency in accordance with Article 84.
3. Where applicable, the marketing authorisation holder shall submit an application for a variation to the terms of the marketing authorisation in accordance with Article 61.

#### *Article 131*

##### *Suspending, withdrawing or varying marketing authorisations*

1. The competent authority or the Commission shall suspend or withdraw the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is unfavourable.
2. The competent authority or the Commission shall suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation where the withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a public health hazard.
3. The competent authority or the Commission may suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation in case of any of the following:
  - (a) the marketing authorisation holder does not comply with the requirements set out in Article 55;
  - (b) the marketing authorisation holder does not comply with the requirements set out in Article 129;
  - (c) the pharmacovigilance system required in accordance with Article 72 is inadequate;
  - (d) the marketing authorisation holder does not fulfil his obligations laid down in Article 77;
  - (e) the maximum residue limit for the active substance established in accordance with Regulation (EC) No 470/2009 has been amended.
4. For the purpose of paragraphs 1 to 3, before taking action, the Commission shall request, where appropriate, the opinion of the Agency within time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons. Whenever practicable, the holder of the marketing authorisation for the veterinary medicinal product shall be invited to provide oral or written explanations.
5. Following an opinion by the Agency, the Commission shall adopt, where necessary, provisional measures, which shall be applied immediately. The Commission shall, by means of implementing acts, take a final decision. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
6. Member States shall lay down procedures for application of paragraphs 1 to 3.

*Article 132*  
*Suspending and withdrawing manufacturing authorisations*

In the event of non-compliance with the requirements laid down in Article 98, the competent authority shall take any of the following measures:

- (a) suspend manufacture of veterinary medicinal products;
- (b) suspend imports of veterinary medicinal products from third countries;
- (c) suspend the manufacturing authorisation for a category of preparations or for all preparations;
- (d) withdraw the manufacturing authorisation for a category of preparations or for all preparations.

*Article 133*  
*Prohibiting supply of veterinary medicinal products*

1. In duly justified cases, the competent authority or the Commission shall prohibit the supply of a veterinary medicinal product and require the marketing authorisation holder to withdraw the veterinary medicinal product from the market if any of the following apply:
  - (a) the benefit-risk balance of the veterinary medicinal product is unfavourable;
  - (b) the qualitative and quantitative composition of the veterinary medicinal product is not as stated in the summary of the product characteristics referred to in Article 30;
  - (c) the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a public health hazard;
  - (d) the control tests referred to in Article 129(1) have not been carried out.
2. The competent authorities or the Commission may confine the prohibition on supply and withdrawal from the market solely to the contested production batches.

*Article 134*  
*Penalties imposed by Member States*

1. Member States may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe their obligations in accordance with this Regulation.
2. Member States shall lay down rules concerning the initiation, duration, time-limits and conduct of the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection. The penalties provided for must be effective, dissuasive and proportionate to the nature,

duration and seriousness of the infringement as well as to the damage caused to public health, animal health and the environment.

3. Member States shall notify those provisions to the Commission by [*Publications Office: insert date counting 36 months from the date of entry into force of this Regulation*] and shall notify it without delay of any subsequent amendments affecting them.
4. Where the Member State imposes a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.

#### *Article 135*

#### *Penalties imposed by the Commission*

1. The Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe their obligations in accordance with this Regulation.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 laying down rules concerning the initiation, duration, time-limits and conduct of the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection.
3. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.
4. The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

## **Chapter X** **Regulatory network**

#### *Article 136*

#### *Competent authorities*

1. Member States shall designate the competent authorities to carry out tasks under this Regulation.
2. The competent authorities shall cooperate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall

communicate the appropriate information to each other, particularly regarding compliance with the requirements for the manufacturing and wholesale distribution authorisations, for the certificates of good manufacturing practice or for marketing authorisations.

3. Upon reasoned request, the competent authorities shall forthwith communicate the reports referred to in Article 125 and Article 129 to the competent authorities of other Member States.
4. Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic veterinary medicinal products manufactured and marketed within the Union.

#### *Article 137*

##### *Information to the Agency and international organisations from the competent authorities*

1. Each competent authority shall immediately inform the Agency of all decisions granting marketing authorisation and of all decisions refusing or withdrawing marketing authorisation, repealing a decision refusing or withdrawing marketing authorisation, prohibiting supply or withdrawing a product from the market, together with the reasons on which such decisions are based.
2. The competent authorities shall forthwith bring to the attention of the relevant international organisations, with a copy to the Agency, all appropriate information about actions taken pursuant to paragraph 1 which may affect the protection of health in third countries.

#### *Article 138*

##### *Scientific opinion for international organisations for animal health*

1. The Agency may give scientific opinions, in the context of cooperation with international organisations for animal health, for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union. For this purpose, an application shall be submitted to the Agency in accordance with the provisions of Article 7. The Agency may, after consulting the relevant organisation, draw up a scientific opinion.
2. The Committee shall establish specific procedural rules for the application of paragraph 1.

#### *Article 139*

##### *Committee for Medicinal Products for Veterinary Use*

1. A Committee for Medicinal Products for Veterinary Use ('the Committee') is hereby set up within the Agency.
2. The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all meetings of the Committee, working

parties and scientific advisory groups and all other meetings convened by the Agency or its committees.

3. The Committee may establish standing and temporary working parties. The Committee may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the Committee may delegate certain tasks associated with drawing up the scientific opinions referred to in Article 141(1)(b).
4. The Committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings. The Executive Director, in close consultation with the Committee shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n) of Regulation (EC) No 726/2004, particularly regarding the development of new therapies.
5. The Committee shall establish its own rules of procedure. Those rules shall, in particular, lay down:
  - (a) procedures for appointing and replacing the Chairman;
  - (b) the appointment of members of any working parties or scientific advisory groups on the basis of the lists of experts referred to in the second subparagraph of Article 62(2) of Regulation (EC) No 726/2004 and procedures for consultation of working parties and scientific advisory groups;
  - (c) a procedure for urgent adoption of opinions, particularly in relation to the provisions of this Regulation on market surveillance and pharmacovigilance.

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

6. The Secretariat of the Agency shall provide technical, scientific and administrative support for the Committee, and shall ensure consistency and quality of opinions of the Committee and appropriate coordination between this Committee, other committees of the Agency and the coordination group.
7. The opinions of the Committee shall be publicly accessible.

#### *Article 140*

##### *Members of the Committee for Medicinal Products for Veterinary Use*

1. Each Member State shall be entitled to appoint a Member and an alternate Member of the Committee. The alternates shall represent and vote for the Members in their absence and may act as rapporteurs.
2. Members and alternate Members of the Committee shall be appointed on the basis of their relevant expertise and experience in the scientific evaluation of medicinal products for veterinary use, in order to guarantee the highest level of qualifications and a broad spectrum of relevant expertise.

3. Member States shall submit relevant information to the Management Board of the Agency on expertise and experience in relation to the scientific profile established by the Committee of experts that the Member States consider for appointment for a position in the Committee.
4. The Management Board shall evaluate information on the expert or experts submitted by the Member State and shall communicate its conclusions to the Member State and the Committee.
5. Taking into account the conclusions referred to in paragraph 4, each Member State shall appoint one Member and one alternate to the Committee for a three-year term which may be renewed.
6. A Member State may delegate its tasks within the Committee to another Member State. Each Member State may represent no more than one other Member State.
7. The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.
8. With a view to the co-opting of such members, the Committee shall identify the specific complementary scientific competence of the additional member(s). Co-opted members shall be chosen among experts nominated by Member States or the Agency.
9. The members of the Committee may be accompanied by experts in specific scientific or technical fields.
10. Members of the Committee and experts responsible for evaluating veterinary medicinal products shall rely on the scientific evaluation and resources available to competent authorities. Each authority shall monitor and ensure the scientific level and independence of the evaluation carried out and the provision of appropriate contribution to the tasks of the Committee, and facilitate the activities of appointed Committee members and experts. To this end, Member States shall provide adequate scientific and technical resources to the members and experts they have nominated.
11. Member States shall refrain from giving Committee members and experts instructions incompatible with their own individual tasks, or with the tasks of the Committee and responsibilities of the Agency.

#### *Article 141*

#### *Tasks of the Committee for Medicinal Products for Veterinary Use*

1. The Committee shall have the following tasks:
  - (a) carry out the tasks conferred on the Committee under this Regulation and Regulation (EC) No 726/2004;
  - (b) prepare opinions of the Agency on questions relating to the evaluation and use of veterinary medicinal products;

- (c) upon request from the Executive Director of the Agency or the Commission draw up opinions on scientific matters concerning the evaluation and use of veterinary medicinal products;
  - (d) draw up opinions of the Agency on questions concerning the admissibility of files submitted in accordance with the centralised procedure, and on granting, varying, suspending or withdrawing a marketing authorisations for centrally authorised veterinary medicinal products;
  - (e) take due account of any request from Member States for opinions;
  - (f) formulate opinions whenever there is a request for a scientific re-examination in the course of mutual recognition or decentralised procedures;
  - (g) provide guidance on important questions and issues of general scientific or ethical nature
  - (h) give a scientific opinion, in the context of cooperation with international organisations for animal health, concerning the evaluation of certain veterinary medicinal products or active substances intended exclusively for markets outside the Union.
2. The members of the Committee shall ensure that there is appropriate coordination between the tasks of the Agency and the work of competent authorities.
  3. When preparing opinions the Committee shall use its best endeavours to reach a scientific consensus. If such consensus cannot be reached, the opinion shall consist of the position of the majority of members and divergent positions, with the grounds on which they are based.
  4. If there is a request for re-examination of an opinion where this possibility is provided for in the Union law, the Committee shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the opinion. The re-examination procedure may deal only with the points of the opinion initially identified by the applicant and may be based only on the scientific data available when the Committee adopted the opinion. The applicant may request that the Committee consults a scientific advisory group in connection with the re-examination.

#### *Article 142*

#### *Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*

1. The coordination group for mutual recognition and decentralised procedures for veterinary medicinal products ("the coordination group") is hereby set up.
2. The Agency shall provide a secretariat for the coordination group, which shall ensure effective and efficient operation of the procedures of the coordination group and appropriate liaison between this group, the Agency and national competent authorities.



3. The coordination group shall draw up its rules of procedure, which shall enter into force after receiving a favourable opinion from the Commission. These rules of procedure shall be made public.
4. The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all meetings of the coordination group.
5. The coordination group shall ensure that there is appropriate cooperation and coordination between the group, the competent authorities and the Agency.

#### *Article 143*

#### *Members of the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*

1. The coordination group shall be composed of one representative per Member State appointed for a renewable period of 3 years. Members of the group may arrange to be accompanied by experts.
2. Members of the coordination group and their experts shall rely on the scientific and regulatory resources available to their competent authorities on relevant scientific assessments and on the recommendations of the Committee for the fulfilment of their tasks. Each national competent authority shall monitor the quality of the evaluations carried out by their representative and facilitate their activities.
3. Members of the coordination group shall use their best endeavours to reach consensus on matters under discussion. If such consensus cannot be reached, the position of the simple majority of the members of the coordination group shall prevail.

#### *Article 144*

#### *Tasks of the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*

The coordination group shall have the following tasks:

- (a) examine questions concerning mutual recognition and decentralised procedures;
- (b) examine questions concerning pharmacovigilance of veterinary medicinal products authorised in Member States;
- (c) examine questions concerning variations to the terms of marketing authorisations granted by Member States;
- (d) provide recommendations to Member States whether a substance or a combination of substances is to be considered a veterinary medicinal product within the scope of this Regulation.

## **Chapter XI**

### **Final provisions**

#### *Article 145*

##### *Standing Committee on Veterinary Medicinal Products*

1. The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products ('the Standing Committee'). The Standing Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

#### *Article 146*

##### *Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 7(7), 16(6), 32(3), 38(4), 54(3), 89(2), 117(2) and 135(2) shall be conferred on the Commission for an indeterminate period of time from the date of the entry into force of this Regulation.
3. The delegation of power referred to in Articles 7(7), 16(6), 32(3), 38(4), 54(3), 89(2), 117(2) and 135(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 7(7), 16(6), 32(3), 38(4), 54(3), 89(2), 117(2) and 135(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### *Article 147*

##### *Data protection*

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.

*Article 148*  
*Repeal*

Directive 2001/82/EC is repealed.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IV.

*Article 149*  
*Transitional provisions*

1. Applications for marketing authorisations for veterinary medicinal products submitted in accordance with Regulation (EC) No 726/2004 before the date of application of this Regulation shall be examined in accordance with Regulation (EC) No 726/2004.
2. Applications for marketing authorisations for veterinary medicinal products submitted in accordance with the requirements of Directive 2001/82/EC before the date of application of this Regulation shall be examined in accordance with Directive 2001/82/EC.
3. Procedures initiated on the basis of Articles 33, 34, 35, 39, 40 and 78 of Directive 2001/82/EC before the date of application of this Regulation shall be completed in accordance with Directive 2001/82/EC.

*Article 150*  
*Entry into force*

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

It shall apply from [*Office of Publications please insert date counting 24 months from the entry into force*] except for Article 15, Article 54(4), Article 58(2), Article 108(4) and Article 116(4) which shall apply from the date of entry into force of this Regulation.

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*





## LEGISLATIVE FINANCIAL STATEMENT

### **1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management mode(s) planned

### **2. MANAGEMENT MEASURES**

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

### **3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
  - 3.2.1. *Summary of estimated impact on expenditure*
  - 3.2.2. *Estimated impact on operational appropriations*
  - 3.2.3. *Estimated impact on appropriations of an administrative nature*
  - 3.2.4. *Compatibility with the current multiannual financial framework*
  - 3.2.5. *Third-party contributions*
- 3.3. Estimated impact on revenue

## LEGISLATIVE FINANCIAL STATEMENT

### 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

#### 1.1. Title of the proposal/initiative

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS
--

#### 1.2. Policy area(s) concerned in the ABM/ABB structure<sup>33</sup>

HEADING 3: SECURITY AND CITIZENSHIP
-------------------------------------

PUBLIC HEALTH, ANIMAL HEALTH AND FOOD SAFETY.
---

#### 1.3. Nature of the proposal/initiative

The proposal/initiative relates to **a new action**

The proposal/initiative relates to **a new action following a pilot project/preparatory action**<sup>34</sup>

The proposal/initiative relates to **the extension of an existing action**

The proposal/initiative relates to **an action redirected towards a new action**

#### 1.4. Objective(s)

1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

Smart and inclusive growth (competitiveness for growth and jobs) and security and citizenship (public health and consumer protection)
---

1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

##### Specific objective

The general objective of this proposal is to ensure a high level of public health protection, high standards of quality and safety of veterinary medicinal products and the optimal functioning of the internal market. Specific objectives are to expand the market beyond the top four animal species, to simplify procedures for obtaining a marketing authorisation in multiple national markets, review data requirements in marketing authorisation procedures, simplify post authorisation requirements and review incentives for breakthrough medicines.

##### ABM/ABB activity(ies) concerned

To expand the market beyond the top four animal species, to simplify procedures for obtaining a marketing authorisation in multiple national markets, review data

<sup>33</sup> ABM: activity-based management; ABB: activity-based budgeting.

<sup>34</sup> As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

requirements in marketing authorisation procedures, simplify post authorisation requirements and review incentives for breakthrough medicines.



### 1.4.3. *Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

The main effects of the proposal are a simplified regulatory environment and reduced administrative burden whilst maintaining safeguards to ensure public and animal health, and safety to the environment and allowing more accessible use of medicines, stimulating the development of new medicines and facilitating the circulation of veterinary medicinal products across the EU.

The proposal also tackles the issue of antimicrobial resistance and introduces provisions to minimise risks to public health arising from the use of antimicrobials in veterinary medicine.

Effects on the pharmaceutical industry, wholesalers and importers: reduction of administrative burdens regarding authorisation of veterinary medicinal products and keeping them on the market; support to innovation.

Effects on veterinarians, farmers and companion animal owners: increased availability of veterinary medicinal products and greater accessibility of medicines.

### 1.4.4. *Indicators of results and impact*

*Specify the indicators for monitoring implementation of the proposal/initiative.*

Number of new veterinary medicinal products authorised

Number of applications submitted by SMEs

Numbers of variations submitted

Ratio of number of marketing authorisations for generics and innovative products

Number of extensions of existing marketing authorisation to new animal species

Sales of antimicrobials used in veterinary medicinal products

Number of referrals on veterinary antimicrobials

## **1.5. Grounds for the proposal/initiative**

### 1.5.1. *Requirement(s) to be met in the short or long term*

The legislation on veterinary medicinal products has been criticised by the pharmaceutical industry, veterinary surgeons, farmers and general public organisations as not adequate to the needs of the veterinary sector. These stakeholders have indicated that the current legislation is disproportionate and burdensome, and not conducive to innovation. This causes an overall problem regarding availability of veterinary medicinal products in the Union, for minor species, for rare or emerging diseases and for the treatment and prevention of some diseases in major species. This lack of authorised veterinary medicinal products

poses significant problems, e.g. poorer animal health and welfare, increased risk for human health, and economic and competitive disadvantage for EU farming.

The requirement is to review the legislation to modernise it and make it tailor-made to the needs of the sector.

#### 1.5.2. *Added value of EU involvement*

The current EU legislation on veterinary medicinal products provides the legal environment on authorisation, production, marketing, distribution and use of veterinary medicinal products. It brought some harmonisation to the procedures and rules required to place veterinary medicinal products on the EU market but there is evidence that the existing provisions do not deliver a functioning internal market. Diverging or incomplete transposition of the rules and the existence of numerous national requirements imply that companies are confronted with different rules and interpretation in countries and have also led to different levels of public and animal health protection. It is critically important to have a single market for veterinary medicinal products as the veterinary pharmaceutical sector is driven by commercial returns obtained through the sales of veterinary medicinal products on the resources spent. The current confined and fragmented markets do not allow the pharmaceutical sector to have a positive return on investments for developing new products for certain animal species. The ambition to improve the availability of medicines in the Union and the functioning of the internal market and market competition can only be carried out at EU level. Ultimately, this would benefit animal and human health across the Union.

#### 1.5.3. *Lessons learned from similar experiences in the past*

Some elements of the present initiative build on the experiences gained throughout the years in the area of the authorisation of veterinary medicinal products. The proposal is based on a study assessing the impact of the revision of the veterinary pharmaceutical legislation (available at [ec.europa.eu/health/files/veterinary/11-07-2011\\_final\\_report.pdf](http://ec.europa.eu/health/files/veterinary/11-07-2011_final_report.pdf)) and feedback from public consultation that took place from April to July 2010.

#### 1.5.4. *Compatibility and possible synergy with other appropriate instruments*

Synergy is expected with the revision of the legislation on medicated feed, the proposal for a regulation on official controls to ensure the application of food and feed law, rules on animal welfare, plant reproductive material, plant protection products, proposal for a regulation on animal health, the Regulation (EC) No 470/2009 for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency (EMA) and Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and the supervision of medicinal products for human and veterinary use.

## 1.6. Duration and financial impact

Proposal/initiative of **limited duration**

- Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
- Financial impact from YYYY to YYYY

X Proposal/initiative of **unlimited duration**

- Implementation with a start-up period of 24 months (the start-up period is the time between date of entry into force of the Regulation, 20 days after its publication, and the date of application of the Regulation). During this time all implementation measures have to be taken by the Commission in order to ensure that the Regulation can function on the day of application of the Regulation). The start-up period is followed by full-scale operation.

## 1.7. Management mode(s) planned<sup>35</sup>

### From the 2014 budget

X **Direct management** by the Commission

- by its departments, including by its staff in the Union delegations;
- by the executive agencies

**Shared management** with the Member States

X **Indirect management** by entrusting budget implementation tasks to:

- third countries or the bodies they have designated;
- international organisations and their agencies (to be specified);
- the EIB and the European Investment Fund;
- bodies referred to in Articles 208 and 209 of the Financial Regulation;
- public law bodies;
- bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;
- X bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;
- persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

---

<sup>35</sup> Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: [http://www.cc.cec/budg/man/budgmanag/budgmanag\\_en.html](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

- *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

## 2. MANAGEMENT MEASURES

### 2.1. Monitoring and reporting rules

*Specify frequency and conditions.*

The Commission has established mechanisms for working with the Member States to monitor implementation of the EU *acquis* in the area of veterinary medicinal products regulation. The Agency will provide the Commission and the Management Board yearly information relating to veterinary activities. 'Veterinary Pharmaceutical Committee' and the co-ordination group of Member States (CMDv) will be the main forum for the monitoring and assessment of the application of the new Regulation. In order to evaluate the implementation and effects of the new rules, the indicators as set out in 1.4.4 will be gathered and monitored at regular intervals.

### 2.2. Management and control system

#### 2.2.1. Risk(s) identified

The Agency may have insufficient fee income given the difficulty to predict the exact frequency, scope and costs of all the veterinary activities at the Agency. Moreover, the required resources for the European Medicines Agency are foreseen by a review of the fees charged for veterinary medicinal products. It is necessary that the new fee structure would be in place on time.

The updated EU databases for veterinary medicinal products and pharmacovigilance may not meet the requirements of the users (authorities and marketing authorisation holders). Thus, the revision of the rules would not provide the reduction in burden it intends to achieve.

#### 2.2.2. Information concerning the internal control system set up

The competent authority of a Member State has the responsibility to ensure, by means of inspections, that the legal requirements relating to veterinary medicinal products are complied with in the Member State. The Commission will audit the control systems of the Member States.

Moreover, monitoring will take place to ensure that the fee resources correspond with the additional tasks of the Agency and on an annual basis the required staff levels and resources will be reviewed.

Close and regular contacts with the developers of the IT tools should ensure that databases meet the requirements of users.

#### 2.2.3. Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error

Costs of audits of the Commission will be limited as these will be integrated in the audits of the Commission's Food and Veterinary Office (FVO) on the monitoring of residues in live animals and animal products in Member States. The objective of the

audit will be the implementation by the competent authority of the responsibility to ensure, by means of inspections, that the legal requirements relating to veterinary medicinal products are complied with in the Member State. The audits will assess the performance of the competent authority and other officially authorised entities involved in controls as well as the legal and administrative measures put in place to give effect to the EU requirements.

The expected level of risk of error is low because in the current legislation Member States already have the same responsibility. Audits of the Commission will lead to further improvement and harmonisation of control systems in Member States.

### **2.3. Measures to prevent fraud and irregularities**

*Specify existing or envisaged prevention and protection measures.*

[In addition to the application of all regulatory control mechanisms, DG SANCO will devise an anti-fraud strategy in line with the Commission's anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure *inter alia* that its internal anti-fraud related controls are fully aligned with the CASF and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the financing implementing activities of the Veterinary Medicinal Products Regulation will be set up. In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the financing implementing activities of the Regulation will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;
- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);
- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;
- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

#### 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading.....]	Diff./Non-diff. <sup>36</sup>	from EFTA countries <sup>37</sup>	from candidate countries <sup>38</sup>	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
3	17.0312 - EMA	Diff./Non-diff.	YES	NO	NO	NO

The annual subsidy to the EMA is paid under this budget line. However, all activities under this proposal are considered to be fee-financed. Consequently, no additional impact is foreseen of this proposal on the budget of the EU.

- New budget lines requested - NOT APPLICABLE

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading.....]	Diff./Non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
	[XX.YY.YY.YY]		YES/NO	YES/NO	YES/NO	YES/NO

<sup>36</sup> Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

<sup>37</sup> EFTA: European Free Trade Association.

<sup>38</sup> Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

### 3.2. Estimated impact on expenditure

[This section should be filled in using the **spreadsheet on budget data of an administrative nature** (second document in annex to this financial statement) and uploaded to CISNET for interservice consultation purposes.]

#### 3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

<b>Heading of multiannual financial framework</b>	Number	[Heading.....]
---	--------	----------------

DG: <.....>			Year N <sup>39</sup>	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			<b>TOTAL</b>
• Operational appropriations										
Number of budget line	Commitments	(1)								
	Payments	(2)								
Number of budget line	Commitments	(1a)								
	Payments	(2a)								
Appropriations of an administrative nature financed from the envelope of specific programmes <sup>40</sup>										
Number of budget line		(3)								
<b>TOTAL appropriations for DG &lt;.....&gt;</b>	Commitments	=1+1a +3								
	Payments	=2+2a								

<sup>39</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>40</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.



		+3								
--	--	----	--	--	--	--	--	--	--	--

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADING &lt;....&gt; of the multiannual financial framework</b>	Commitments	=4+ 6								
	Payments	=5+ 6								

**If more than one heading is affected by the proposal / initiative:**

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)</b>	Commitments	=4+ 6								
	Payments	=5+ 6								

<b>Heading of multiannual financial framework</b>	<b>5</b>	‘Administrative expenditure’
---	----------	------------------------------

EUR million (to three decimal places)

	Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
DG: <.....>								
• Human resources								
• Other administrative expenditure								
<b>TOTAL DG &lt;.....&gt;</b>	Appropriations							

<b>TOTAL appropriations under HEADING 5 of the multiannual financial framework</b>	(Total commitments = Total payments)								
--	--------------------------------------	--	--	--	--	--	--	--	--

EUR million (to three decimal places)

	Year N <sup>41</sup>	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework</b>	Commitments							
	Payments							

<sup>41</sup> Year N is the year in which implementation of the proposal/initiative starts.

3.2.2. *Estimated impact on operational appropriations*

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs  ↓			Year N		Year N+1		Year N+2		Year N+3		Enter as many years as necessary to show the duration of the impact (see point 1.6)						TOTAL	
	OUTPUTS																	
	Type <sup>42</sup>	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1 <sup>43</sup> ...																		
- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
<b>TOTAL COST</b>																		

<sup>42</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

<sup>43</sup> As described in point 1.4.2. ‘Specific objective(s)...’

### 3.2.3. Estimated impact on appropriations of an administrative nature

#### 3.2.3.1. Summary

- The proposal/initiative does not require the use of appropriations of an administrative nature
- The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year N <sup>44</sup>	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)	TOTAL
--	-------------------------	-------------	-------------	-------------	--	-------

<b>HEADING 5 of the multiannual financial framework</b>							
Human resources							
Other administrative expenditure							
<b>Subtotal HEADING 5 of the multiannual financial framework</b>							

<b>Outside HEADING 5<sup>45</sup> of the multiannual financial framework</b>							
Human resources							
Other expenditure of an administrative nature							
<b>Subtotal outside HEADING 5 of the multiannual financial framework</b>							

<b>TOTAL</b>							
--------------	--	--	--	--	--	--	--

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

<sup>44</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>45</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

### 3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources.
- The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full time equivalent units*

	Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
<b>• Establishment plan posts (officials and temporary staff)</b>							
XX 01 01 01 (Headquarters and Commission's Representation Offices)							
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
<b>• External staff (in Full Time Equivalent unit: FTE)<sup>46</sup></b>							
XX 01 02 01 (AC, END, INT from the 'global envelope')							
XX 01 02 02 (AC, AL, END, INT and JED in the delegations)							
XX 01 04 yy <sup>47</sup>	- at Headquarters						
	- in Delegations						
XX 01 05 02 (AC, END, INT - Indirect research)							
10 01 05 02 (AC, END, INT - Direct research)							
Other budget lines (specify)							
<b>TOTAL</b>							

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	
-------------------------------	--

<sup>46</sup> AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JED= Junior Experts in Delegations.

<sup>47</sup> Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

External staff	
----------------	--

3.2.4. *Compatibility with the current multiannual financial framework*

- The proposal/initiative is compatible the current multiannual financial framework.
- The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

The Commission Communication "Programming of human and financial resources for decentralised agencies 2014-2020" (COM (2013)519 final) lays down the Commission's resource plans for decentralised agencies, including EMA, for the period 2014-2020. The human resources requested in the present Legislative Financial Statement will be included in the financial programming already envisaged in the Communication. EMA will be invited to cover the additional activities required under this legal proposal on veterinary medicinal products by internal redeployment.

- The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties.
- The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to three decimal places)

	Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

### 3.3. Estimated impact on revenue

- The proposal/initiative has no financial impact on revenue.
- The proposal/initiative has the following financial impact:
  - on own resources
  - on miscellaneous revenue

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative <sup>48</sup>						
		Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article .....								

For miscellaneous ‘assigned’ revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

### **Annex: Estimate of costs and income of European Medicines Agency**

It is foreseen that the entire cost relating to veterinary medicinal products activities in the European Medicines Agency related to the revision is recouped through fees. Cost estimations and calculations in this Annex are based on this principle and, therefore, the proposal is not expected to have any financial impact on the budget of the EU. The proposal empowers the Commission to adopt delegated acts to amend fees. This would allow the Commission to adapt the fee structure in-time to the agreement of European Parliament and Council on this proposal.

The costs are based on a qualitative analysis of the expected change in seven areas of activity after implementation of the regulation: pre-authorisation activities (e.g. scientific advice), evaluation activities (marketing authorisation applications) post-authorisation activities (variations), arbitration and referral, monitoring activities (pharmacovigilance), other specialised areas and activities (advice to the Commission, international cooperation, surveillance of the use of veterinary antimicrobials, transparency) and inspections and compliance. The table below provides the estimate of the incremental costs and income of the implementation of the current legislative proposal.

The cost estimations comprise salary cost, evaluation cost, scientific meetings direct costs, translation costs and IT one-off costs and IT maintenance costs, and is the balance of the anticipated change in costs and loss of fee income to EMA after implementation of the revised regulation.

<sup>48</sup> As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % for collection costs.



Salary costs do not take into account inflation, exchange rates and additional pension costs (applicable from 2016 for the Agency). Evaluation cost concern the services provided by the National Competent Authorities (costs of rapporteurs' assessment activities). The direct costs for scientific meetings include the costs of travel and subsistence for delegates. Translation costs are the direct costs to the Agency for translation of opinions and other product-related documents.

For the income the revised implementing rules to the Fee Regulation as of 1 April 2013 has been used. The estimations do not take into account fee reductions that may be applied to stimulate the development of medicines for minor use and minor species or for SMEs.

<b><u>Estimate of costs and income for the EMA of implementing the revised rules</u></b>					
<b><u>Workload overview</u></b>					
					<i>in FTE</i>
<b>Workload (additional need for human resources)</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>
FTE workload for AD function or equivalent	0,95	3,92	7,76	8,72	8,82
FTE workload for AST function or equivalent	0,56	1,57	3,31	4,07	4,07
<b>Workload (savings on human resources)</b>					
FTE workload for AD function or equivalent	0,95	0,95	0,95	0,95	0,95
FTE workload for AST function or equivalent	3,9	3,9	3,9	3,9	3,9
<b>Workload (net effect on human resources, needs less savings)</b>					
FTE workload for AD function or equivalent	<b>0</b>	<b>2,97</b>	<b>6,81</b>	<b>7,77</b>	<b>7,87</b>
FTE workload for AST function or equivalent	<b>-3,34</b>	<b>-2,33</b>	<b>-0,59</b>	<b>0,17</b>	<b>0,17</b>

<b><u>EMA Income and cost estimates due to the revision of the Veterinary medicinal products</u></b>					
					<i>in EUR</i>
<b>Costs (EUR)</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>
Salary cost for AD function or equivalent (89.685 EUR/y)	-	266.364	610.755	696.852	705.821
Salary cost for AST function or equivalent (55.988 EUR/y)	- 187.000	- 130.452	- 33.033	9.518	9.518
Evaluation cost	186.950	344.650	754.900	1.062.300	1.062.300
Testing and sampling	-	-	-	-	-
Scientific meetings direct cost	173.547	201.638	238.365	238.365	238.365
Translations cost	14.268	252.854	519.976	548.512	548.512
IT one-off costs	700.000	-	-	-	-
IT maintenance costs (including running costs for ESVAC)	467.534	769.664	744.764	744.764	744.764
<b>Total cost</b>	<b>1.355.299</b>	<b>1.704.718</b>	<b>2.835.727</b>	<b>3.300.311</b>	<b>3.309.280</b>
<b>Income</b>					
Estimated income from fees payable to the EMA	<b>1.355.299</b>	<b>1.704.718</b>	<b>2.835.727</b>	<b>3.300.311</b>	<b>3.309.280</b>