

**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 ,

Having regard to the opinion of the Committee of the Regions ,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) 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 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 **while continuing to ensure a high level of protection of animal health, animal welfare and environment and safeguarding public health.**
- (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 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".

- (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.
- (5a) Identification of packs of veterinary medicinal products via identification codes is common practice in several Member States. These Member States have developed integrated electronic systems at national level for the proper functioning of such codes, linked to national databases. However, the introduction of a harmonised EU-wide system has not been the subject of any assessment as to costs and administrative consequences. Instead, the possibility should be given for Member States to decide at national level on whether or not to adopt a system for identification codes to be added to the information on the outer packaging of the veterinary medicinal products.**

- (5b) **The existing systems for identification codes currently used at national level vary and there is no standard format. The possibility should be provided for the future development of an EU-wide harmonised identification code through an empowerment for the Commission to adopt uniform rules on such a code. The adoption by the Commission of such rules would not prevent Member States from choosing whether or not to use such a identification code.**
- (6) **Despite the measures that farmers and other operators are obliged to take on the basis of rules adopted at Union level regarding health of kept animals, good animal husbandry, good hygiene, feed, management and biosecurity,** animals may suffer from a broad range of diseases which **need to** be prevented or treated **by veterinary medicinal products for both animal health and welfare reasons.** 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 **and the environment.** 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.
- (7a) **This Regulation should not apply to veterinary medicinal products which have not undergone an industrial process as, for example non-processed blood.**

- (7aa) Antiparasitics include also substances with repelling activity that are presented for use as veterinary medicinal products.**
- (7b) Since there is to date insufficient information on traditional herbal products used to treat animals in order to allow the setting up of a simplified system, the possibility of introducing such a simplified system should be examined by the Commission based on the information provided by the Member States on the use of such products on their territory.**
- (7c) This Regulation applies to veterinary medicinal products, including for the purpose of what in Directive 2001/82/EC was referred to as 'pre-mixes' and which are considered in this Regulation as one of the pharmaceutical forms of a veterinary medicinal product for the time up until these products are included in medicated feed or intermediate products, after which the medicated feed Regulation (XX)<sup>1</sup> applies to the exclusion of this Regulation.**
- (7d) To ensure the proper administration and appropriate dosing of certain veterinary medicinal products which are to be administered orally in feed or drinking water to animals, especially in case of treatment of groups of animals, it shall be properly described in the product information. Additional instructions for cleaning the equipment used for administration of those products should be set out to avoid cross-contamination and reduce antimicrobial resistance.**

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<sup>1</sup> **Regulation (EU) of the European** Parliament and the Council of... on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC (OJL...).

**In order to improve the effective and safe use of veterinary medicinal products authorized and prescribed for oral administration via other routes than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food producing animals, the Commission should, where necessary, adopt delegated acts. The Commission should take into account scientific recommendations of the Agency, for example concerning measures to minimize over-dosage or under-dosage, unintended administration to non-target animals, the risk of cross-contamination and dissemination in the environment of these products.**

- (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, **including novel therapy veterinary medicinal products with the exclusion of blood components, like plasma, platelet concentrates or red cells.** At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the **access of small and medium-sized enterprises (SMEs) to the** centralised authorisation procedure should be **facilitated by all appropriate means, and its use should be** extended to allow for applications for authorisations under that procedure to be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products.

- (9a) **The replacement or the addition of a new antigen or a new strain in case of already authorised immunological veterinary medicinal products against e. g. avian influenza, bluetongue, foot and mouth disease or equine influenza should not be considered as adding a new active substance.**
- (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 [...]. 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 **for mutual recognition and decentralised procedures for veterinary medicinal products ("the coordination group")** [...] without undue delay. **This Regulation also sets new tasks to the coordination group, including drawing up an annual list of reference veterinary medicinal products which are to be subject to harmonisation of the summary of product characteristics, issuing recommendations on pharmacovigilance and the involvement in the signal management process.**

- (14) Where a Member State, [...] the Commission **or the marketing authorisation holder** 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 [...] 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 **Regulation (EC) No 470/2009 and any acts adopted on the basis thereof [...]**<sup>2</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 appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain, **and particular care should therefore be taken when administering antimicrobials.**

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<sup>2</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).

- (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 **or emerging 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>3</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 [...] **optimised in order** to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be the [...] **designed to avoid causing pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU, including the use of alternative test methods wherever possible, and the guidelines of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ('VICH')**.
- (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.

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<sup>3</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).

- (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. **The general public should therefore have access to information in the product database, the pharmacovigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority.** Regulation (EC) No 1049/2001 of the European Parliament and of the Council<sup>4</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.

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<sup>4</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.

**(24a) Where there is concern that a pharmaceutical substance could pose serious risk to the environment, it may be appropriate to consider that substance in the context of Union environmental legislation. In particular, under the Water Framework Directive, it may be appropriate to identify the substance as a substance for inclusion in the surface water watch list, in order to gather monitoring data on it. It may be appropriate to include it in the list of priority substances and to set an environmental quality standard for it, as well as to identify measures to reduce its emissions to the environment. These could include measures to reduce emissions from manufacturing by following Best Available Techniques (BAT) under the Industrial Emissions Directive, particularly if the emission of active pharmaceutical ingredients have been identified as a key environmental issue during the drafting or revision of relevant Best Available Technique Reference Documents (BREFs) and their accompanying BAT Conclusions.**

(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 [...] **pharmacologically** active substances **of** [...] the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, **in particular on veterinary medicinal products for minor species and antimicrobials**, 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. **Similar protection of investments should be applied to studies supporting a new pharmaceutical form, administration route or dosage reducing the antimicrobial or antiparasitic resistance or improving the benefit-risk balance.**

- (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. **The establishment of a single European assessment of the environmental properties of active substances for veterinary use by means of a monograph system could be a potential alternative. The Commission should therefore submit a report to the European Parliament and the Council examining the feasibility of active substance based review system ('monographs') and other potential alternatives for environmental risk assessment of veterinary medicinal products, accompanied if appropriate by a legislative proposal.**
- (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 [...]. 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 **also** 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>5</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.

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<sup>5</sup> Communication from the Commission on the precautionary principle, COM (2000) 1 (final).

- (33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. [...] **Due to the complexity of the problem, its cross-border dimension and the high economic burden, its impact goes beyond its severe consequences for human and animal health and has become a global public health concern that affects the whole of society and requires urgent and coordinated intersectoral action in accordance with the "One Health" approach.** Such action includes strengthening of the prudent use of antimicrobials, avoiding their routine prophylactic and metaphylactic use, actions to restrict the use in animals of antimicrobials that are of critical for preventing or treating life-threatening infections in humans and encouraging and incentivizing the development of new antibiotics. It **also** 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 [...], **which should be taken into account when assessing whether to authorise a veterinary medicinal product.**
- (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 [...] medicinal products **used in animals** may accelerate the emergence and spread of resistant micro-organisms and may compromise the effective use of the already limited number of existing antimicrobials to treat human infections. Therefore, the misuse of antimicrobials should not be allowed. **Antimicrobial medicinal products should not be used for prophylaxis unless in well-defined cases for the treatment of an individual animal or restricted number of animals when the risk for infection is very high or its consequences are likely to be severe. Antibiotic medicinal products should not be used for prophylaxis unless in exceptional cases only for the administration to an individual animal. Antimicrobial medicinal products should be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in a group of animals is high and where no appropriate alternatives are available. Such restrictions should allow the decrease of prophylactic and metaphylactic use in animals towards representing a smaller proportion of total antimicrobial use in animals.**

**(36a) In order to strengthen Member States' national policies on prudent use of antimicrobials, especially those antimicrobials which are important for the treatment of infections in humans, but which are also necessary for the use in the veterinary medicine, it may be necessary to restrict or prohibit their use. Therefore the Member States should be permitted following scientific recommendations, to define restrictive conditions for their use, e.g. conditioning their prescription to the realisation of antimicrobial susceptibility testing to ensure that there is no other antimicrobials available sufficiently effective or appropriate to treat diagnosed disease.**

(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. **When deciding, the Commission should also take into account available recommendations on the matter provided for by the European Food Safety Authority (EFSA) and other relevant Union Agencies, which in turn also take into account any relevant recommendations from international organisations, such as the World Health Organisation, the World Animal Health Organisation and the Codex Alimentarius.**

(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. [...] **Veterinarians** have a key role in ensuring prudent use of antimicrobials and consequently they should [...] **prescribe such products based on their knowledge of antimicrobial resistance, their epidemiological and clinical knowledge and their understanding of the risk factors for the individual animal or group of animals. In addition, the veterinarians should respect their professional code of conduct. Veterinarians should ensure that they are not in a situation of conflict of interest when prescribing medicines, while recognizing their legitimate activity of retail in accordance with national law, in particular not to be influenced, directly or indirectly, by economic incentives when prescribing those products. Furthermore, the supply of veterinary medicinal products by veterinarians should be restricted to the amount required for treatment of the animals under their care.**

**All concerned stakeholders should together promote prudent use of antimicrobials.**

(38a) **Prudent use of antimicrobials is a cornerstone in addressing antimicrobial resistance. It is therefore important that guidance on prudent use of antimicrobials in veterinary medicine is taken into account and further elaborated. The identification of risk factors and the development of criteria for initiation of administration of antimicrobials, as well as the identification of alternative measures, could help in avoiding the unnecessary use of antimicrobial medicinal products, including through metaphylaxis.**

**In addition, Member States should be allowed to take further restrictive measures to implement national policy on prudent use of antimicrobials, provided that those measures do not unduly restrict the functioning of the internal market.**

(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. [...]Antimicrobial resistant organisms can spread to humans and animals in the Union **and third countries** through consumption of products of animal origin **from the Union or** [...] from third countries, from direct contact with animals or humans [...] 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. [...]**For those reasons it should also be ensured, in a non-discriminatory and proportionate manner, that operators in third countries respect certain basic conditions relating to antimicrobial resistance for animals and products of animal origin exported to the Union. Any such action should respect Union obligations under relevant international agreements. This should contribute to the international fight against antimicrobial resistance, [...]in particular in line with the WHO Global Action Plan and the World Organisation for Animal Health Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials.**

- (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 **continue the collection of such data [...] and further develop it in line with a stepwise approach. This data, when available, should be analysed with** 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 **technical** rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data **on the sales and use of antimicrobials used in animals** under the coordination of the Agency. **It should be possible to make further adjustments to the obligations on data collection when the procedures in the Member States for the collection of data on sales and use of antimicrobials are sufficiently reliable.**
- (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 **at least in regards to dosage, uses and warnings of the veterinary medicinal products[...].**

- (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, [...] pictograms and abbreviations **might be developed and used as an alternative to such textual information**. 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 [...] **summary of product characteristics, labelling and package leaflet** of veterinary medicinal products authorised in their territory. [...]
- (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 **suspected** adverse events should contribute to the good usage of veterinary medicinal products.

- (45aa) Environmental incidents observed following the administration of a veterinary medicinal product to an animal shall also be reported as suspected adverse events. Such incidents may consist for example in a significant increase of soil contamination by a substance to levels considered harmful for the environment or high concentrations of veterinary medicinal products in drinking water produced from surface water.**
- (45a) The competent authorities, the Agency and marketing authorisation holders should encourage and facilitate the reporting of suspected adverse events in particular by veterinarians and other health care professionals where such events occur during the conduct of their duties, as well as facilitating that veterinarians can receive appropriate feed back on reporting made.**
- (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 **in order to ensure the continuous evaluation of the benefit-risk balance** of the veterinary medicinal products they place on the market. They should collect reports on **suspected** 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 competent authorities should use those data to ensure the continuous **assessment of the benefit-risk balance** [...] of the veterinary medicinal products that are on the market.
- (49) [...] **In specific cases, it is necessary** or from a public health, [...] animal health **and environment** 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 [...] **may** be imposed on the marketing authorisation holder.
- (50) A pharmacovigilance database at Union level should be established to record and integrate information of **suspected** adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of **suspected** adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities. **The pharmacovigilance database should take into account mechanisms for exchanging data with the existing national pharmacovigilance databases.**
- (50a) **The procedures that competent authorities and the Agency will adopt in order to evaluate the suspected adverse events that they receive should comply with the implementing act on measures on good pharmacovigilance practice adopted by the Commission and, as appropriate, be based on a common standard derived from the current Commission guidelines on pharmacovigilance for veterinary medicinal products.**

**The evaluation performed by the competent authority or the Agency in this way may be one of the means by which it is determined whether there is any change to the benefit-risk balance of those veterinary medicinal products. It is however emphasised that the ‘signal management process’ is the ‘gold standard’ for this purpose and proper attention should be given to it.**

**The signal management process consists of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action.**

- (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.

- (51a) Parallel trade in veterinary medicinal products authorised under national, decentralised, mutual recognition or subsequent recognition procedure should be regulated to ensure that the principles of the free movement of goods are restricted only for the purpose of safeguarding public and animal health in a harmonised manner, respecting the case law of the Court. Any administrative procedures put in place should not introduce an excessive burden, in particular, any approval of a licence for the parallel trade should be based on a simplified procedure. Such parallel trade concerns products traded from one Member State to another and is distinct from imports in that the latter are products coming from third countries into the Union.**

- (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.
- (53a) The good manufacturing practices referred to in this Regulation should take into account the Union and international standards of animal welfare when active substances are prepared from animals. Measures for the prevention or minimisation of discharge of active substances into the environment should be also be taken into account. Any such measures should only be adopted following an evaluation of their impact.**
- (53b) In order to ensure the uniform application of principles of good manufacturing practices and good distribution practices, the compilation of Union procedures for inspections and exchange of information should serve as a basis for competent authorities when performing controls on manufacturers and wholesale distributors.**
- (53c) Although inactivated immunological veterinary medicinal products referred to in Article 2(2a) should be manufactured in accordance with the principles of good manufacturing practice, detailed guidelines of good manufacturing practice should specifically be prepared for these products as the way they are manufactured is different from industrially prepared products. This would preserve their quality without hindering their manufacturing and availability.**

- (54) Companies should be in possession of an authorisation to be able to wholesale [...] veterinary medicinal products **and comply with the principles of good distribution practices**, 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 **and should also be required in case of parallel trade of veterinary medicinal products**.
- (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 [...] non-prescription veterinary medicinal products [...] **at a distance** to buyers in other Member States. **However, taking into account that in some Member States, it is current practice to sell veterinary medicinal products subject to prescription at a distance, Member States should, subject to certain conditions, be allowed to continue such practice within their territory. In such a case, Member States should take appropriate measures to avoid unintended consequences of such supply and establish rules on appropriate penalties.**

- (56a) Veterinarians should always issue a veterinary prescription when supplying a prescription only veterinary medicinal product and not administering it themselves. Whenever the veterinarians administers such medicinal products themselves it should be left up to national provisions to specify whether a veterinary prescription needs to be issued. However, veterinarians should always keep records of the medicinal products that they have administered.**
- (57) The illegal sale of veterinary medicinal products to the public [...] **at a distance** 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.

- (58a) Member States should be able to subject the supply of veterinary medicinal products offered for retail to stricter conditions justified by the protection of public health, animal health or environment, provided that these conditions are proportionate to the risk and do 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 [...] **disposal of waste** 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. **However, in order to preserve the animal health status in their territory, Member States should be able to allow under restricted conditions advertising of immunological veterinary medicinal products also to professional animal keepers.**

- (61a) With regard to the advertising of veterinary medicinal products, Member States' experience has shown that it is necessary to put emphasis on the distinction between feed and biocidal products on the one hand and veterinary medicinal products on the other hand, because that distinction is often misrepresented in advertising.**
- (61b) The rules of advertisement in this Regulation are to be seen as specific rules that comprise the general rules in Directive 2006/114/EC .**
- (62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a **veterinarian** [...] 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 **veterinarians** [...] 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 **model format** [...] **for veterinary** 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 **veterinary** prescriptions, as long as this does not prevent **veterinary** 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. **These audits should be carried out so as to avoid unnecessary administrative burden and, as far as possible, coordinated with Member States and with any other Commission audits foreseen under the 'Official Controls Regulation'.**
- (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 **to this Regulation**, as non-compliance can result in damage to animal and public health and the environment.

*N.B.: According to the memorandum of understanding between the institutions, a unique recital should preferably list all provisions containing implementing and delegated powers. It should be drafted at a later stage by lawyer linguists and relevant recitals of the Commission proposal consequently deleted.*

- (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 **for centrally authorised product** , 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 [...] **package leaflet** for certain homeopathic veterinary medicinal products which are placed on the market without [...] indications [...]. 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. **Moreover, while the use of homeopathic veterinary medicinal products authorised under this Regulation is regulated in the same way as other authorised veterinary medicinal products, the use of registered homeopathic veterinary medicinal products is not regulated in this Act. The use of such registered products is therefore subject to national law which is also the case as regards homeopathic medicinal products registered in accordance with Directive 2001/83/EC.**

~~(72)~~ [...]

- (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 **the requirements regarding the technical documentation on the quality, safety and efficacy** [...] 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.
- (74a) It is generally accepted that the existing requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products presented when applying for a marketing authorisation in Annex I of Directive 2001/82/EC as last amended in 2009 work sufficiently well in practice. Therefore, there is no urgent need to substantially change those requirements. However, there is a need to adjust those requirements in order to respond to the identified discrepancies with the international scientific progress or latest developments, including guidance from VICH, WHO, OECD standards, taking into account also the need to develop specific requirements for novel therapy veterinary medicinal products while avoiding major overhaul of the current provisions, in particular not altering its structure.**
- (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)~~ [...]

(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.

**(80a) When providing services in another Member State veterinarians should follow any national rules present in the host Member State pursuant to Directive 2005/36 EC on Recognition of Professional qualifications and Directive 2006/123 EC on Services in the Internal Market.**

- (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,

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, [...] manufacturing, import, export, supply, **distribution**, 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, [...] **Articles 98a and 98b** shall also apply to active substances [...] used as starting materials in veterinary medicinal products.

- 2a. In addition to the products referred to in paragraph 1, Articles 98a, 110, 112, 122, 124, 125 and 133 shall also apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of animals in a unit having confirmed epidemiological link.
- 2b. By way of derogation from paragraphs 1 and 2, only Articles 98a, 51, 52, 122, 123, 125, 133 and section 6 of Chapter IV shall apply to veterinary medicinal products authorised in accordance with Article 5(6).
- 2c. By way of derogation from paragraph 1, Articles 5 to 12a, 15 to 28, 30 to 50, 54 to 70, 82 to 86, 98b, 103, 111, 111a, 113, 115 to 119, 129a, 131 and 135 of this Regulation shall not apply to homeopathic veterinary medicinal products which are registered in accordance with Article 89.
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, narcotic or psychotropic properties and that may be used in animals;
  - (b) veterinary medicinal products prepared in a pharmacy **or by a person permitted to do so under national law**, 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'). **Such official formula shall be subject to a veterinary prescription when intended for food producing animals.**

4. This Regulation shall not apply to:
- [...]
- (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 ;
  - (e) veterinary medicinal products intended for research and development.
  - (f) **medicated feed and intermediate products as defined in Regulation (EU) No [XX].**

**5. This Regulation shall, except as regards the centralised marketing authorisation procedure, be without prejudice to national provisions on fees.**

**5a. Nothing in this Regulation shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate regarding narcotic and psychotropic substances.**

### *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 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. [...] **For the purpose of paragraph 1, 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[...];
  - (ba) its purpose is to be used in animals with a view 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;
- (2a) ‘active substance’ means any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product that, when used in its production, becomes an active ingredient of that product;**
- (2b) ‘excipient’ means any constituent of a veterinary medicinal product other than active substance(s) and packaging material;**
- (3) ‘immunological veterinary medicinal product’ means a veterinary medicinal product [...] 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 where an active substance [...] 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 **veterinary** medicinal product, and with regard to which [...] bioequivalence with the reference veterinary medicinal product **has been demonstrated**;
- (6a) 'reference veterinary medicinal product' means a veterinary medicinal product authorised within the meaning of the provisions referred to in Article 5(1), based on an application in accordance with the provisions of Article 7;**
- (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 micro-organisms 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;
- (8a) 'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections including antibiotics, antivirals, antifungals and anti-protozoals;**
- (8aa) 'antiparasitic' means a substance that kills or interrupts the development of parasites, used for the purpose of treating or preventing an infection, infestation or disease caused or transmitted by parasites, including substances with a repelling activity.**
- (8b) 'antibiotic' means any substance with a direct action on bacteria used for treatment or prevention of infections;**
- (8c) 'metaphylaxis' means the administration of a medicinal product to a group of animals after the diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk which may already be subclinically infected;**

- (8e) **'prophylaxis' means the administration of a medicinal product to an animal or group of animals before clinical signs of a disease, in order to prevent the occurrence of disease or infection;**
- (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 [...] resistance;
- (12) 'common name' means the international non-proprietary name recommended by the World Health Organisation for a **substance** [...] or, if one does not exist, the name generally used;
- (12a) 'name of the veterinary medicinal product' means either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder;**
- (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 [...] **the applicant in relation to** 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 **for meat production**, pigs, chickens, dogs and cats;
- (21) 'pharmacovigilance' means the [...] **science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events or any other problem related to a medicinal product;**
- (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 [...] for the verification of compliance with this Regulation;
- (24) 'veterinary prescription' means **a document issued by a veterinarian** [...] for a veterinary medicinal product or a medicinal product for human use [...] for **its** use in animal(s);
- (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)~~ [...]

- (27) **'placing on the market'** means the first making available of a veterinary medicinal product on the whole of the Union market or in one or more Member States, as applicable;
- (28) **'wholesale distribution'** means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products whether for profit or not, apart from retail supply of veterinary medicinal products to the public;
- (29) **'aquatic species'** means species as defined in Article 4(3) of Regulation (EU) 2016/429;
- (30) **'Agency'** means the European Medicines Agency as established by Regulation (EC) No 726/2004;
- (31) **'food producing animals'** means food producing animals as defined in Article 2 (b) of Regulation (EC) No 470/2009;
- (32) **'variation'** means a change to the terms of the marketing authorisation for a veterinary medicinal product as referred to in Article 31;
- (33) **'advertising of veterinary medicinal products'** means the making of a representation in any form in connection with veterinary medicinal products in order to promote the supply, distribution, sale, prescription or use of veterinary medicinal products comprising also the supply of samples and sponsorships;
- (34) **'signal management process'** means a process for performing active surveillance of pharmacovigilance data for veterinary medicinal products [...] in order to assess the pharmacovigilance data and determine whether there is any change to the benefit-risk balance of those veterinary medicinal products, with a view to detecting risks to animal health, public health and protection of the environment;
- (35) **'potential serious risk to human or animal health or for the environment'** means a situation where there is a significantly high probability that a serious hazard resulting from the use of a veterinary medicinal product will affect human or animal health or the environment;
- (36) **'novel therapy veterinary medicinal product'** means a veterinary medicinal product specifically designed for gene therapy, regenerative medicine, tissue engineering, blood product therapy, phage therapy, a veterinary medicinal product issued from nanotechnologies, or any other therapy which is considered as nascent field in veterinary medicine;
- (37) **'epidemiological unit'** means an epidemiological unit as defined in Article 4(39) of Regulation (EU) 2016/429.

## 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 [...] by a competent authority **or by the Commission, as applicable**, in accordance with Articles **40**, 44, 46, [...] 48, **48a** or **49** [...].
2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.
3. Decisions to grant, refuse, suspend, [...] **revoke** or [...] **amend by way of a variation** a marketing authorisation shall be made public.
4. [...] **A marketing authorisation for a veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to marketing authorisation holders.**
5. **A marketing authorisation for a veterinary medicinal product intended for one or more food producing animals may only be granted if the pharmacologically active substance(s) is allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof for the animal species concerned.**

6. [...] **In the case of veterinary medicinal products** [...] intended [...] for **aquarium or pond animals, ornamental fish**, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits **which are exclusively** kept [...] as pets [...], Member States may permit exemptions [...] from **this Article** [...], provided that such products [...] **are not subject to a veterinary prescription** and that all [...] **necessary** measures are [...] **in place in the Member State** to prevent unauthorised use of the **veterinary medicinal** products for other animals.

#### *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[...] 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;
  - (d) **the subsequent recognition procedure laid down in Article 48a.**
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 Agency [...].
3. Applications shall be submitted electronically [...] **and** the formats made available by the Agency shall be used.
4. The applicant shall be responsible for the accuracy of the **information and documentation** [...] submitted.

5. Within 15 days of receipt of the application, the competent authority or the Agency, **as applicable**, shall notify the applicant of whether all [...] **information and documentation** required in accordance with Article 7 have been [...] **submitted and the application is valid**.
6. Where the competent authority or the Agency, **as applicable**, considers that the application is incomplete, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information **and documentation**. **If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn**.
7. **If the applicant fails to provide a complete translation of the required documentation within a period of six months from having received the information referred to in Article 46(5), 48(5b) and Article 48a(2), the application shall be considered to have been withdrawn**.

*Article 6a*  
*Languages*

1. The language or languages of **the summary of the product characteristics and the information on the labelling and on the package leaflet** shall, **unless the Member State [...]** determines[...] **otherwise, be the official language or languages of the [...]** Member State where the veterinary medicinal product is made available on the market.
- ~~2.~~ [...]
3. Veterinary medicinal products may be labelled in several languages.

## Section 2

### Dossier requirements

#### Article 7

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

1. An application for a marketing authorisation shall contain the following [...]:
  - (a) the [...] information set out in Annex I;
  - (b) technical documentation **necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in accordance with** the requirements set out in Annex II;
  - ~~(e)~~—[...]
  - (ca) a summary of the pharmacovigilance system master file.**
  
2. Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information **and technical documentation** listed in paragraph 1:
  - (a) documentation on [...] the direct or indirect risks, to public or animal health **or to the environment** 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 [...] **animals** and containing pharmacologically active substances that are not [...] **allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof** for the animal species [...] **concerned**, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with **that** Regulation [...] 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 human consumption in [...] **the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429 and any acts adopted on the basis thereof** and the active substances contained in those veterinary medicinal products are not [...] **allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.**
  
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>6</sup> the application shall in addition to the documents listed in paragraph 1 **of this Article** 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 [...] and 44, the applicant shall, in addition to the information listed in paragraph 1 **of this Article**, submit a declaration stating that he has not submitted an application for a marketing authorisation **and, if applicable, a marketing authorisation has not been granted** for the **same** veterinary medicinal product in another Member State **or in the Union.**
  
7. [...].

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<sup>6</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).

### Section 3

#### Clinical trials

##### Article 8

##### [...]Clinical trials

1. An application for the approval of a clinical trial shall be submitted **in accordance with national law** 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 [...] food chain unless **a suitable withdrawal period has been set by the competent authority**. [...]
3. The competent authority shall issue a decision **to approve or refuse** [...] a clinical trial within 60 days **of** [...] the receipt of a **valid** application. [...]
4. The clinical trials referred to in paragraph 1 shall be carried out taking due account of [...] the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.
5. **Data stemming from** [...] 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 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 [...] the following information **and shall, subject to Article 10(3), contain no other 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;
  - ~~(h)~~
  - (i) route of administration;**
  - (j) if applicable, the withdrawal period, even if it is zero.**
  
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or [...] **in abbreviations or pictograms common throughout the Union as listed in accordance with Article 15(1).**
  
3. **Notwithstanding paragraph 1, a Member State may decide that, on the immediate packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1.**

## Article 10

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

1. The outer packaging of a veterinary medicinal product shall contain [...] the following information **and shall contain no other 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) **without prejudice to Article 12(4)**, recommendation to read the package leaflet;
  - (f) [...]
  - (g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product";
  - (h) **in case of veterinary medicinal products not subject to a veterinary prescription, the indication(s)**;
  - (i) **the marketing authorisation number**.
- 1a. **Notwithstanding paragraph 1, a Member State may decide that, on the outer packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1. Such a code may be used to replace the marketing authorisation number referred to in paragraph (1)(i).**
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or [...] **in** abbreviations or pictograms common throughout the Union, **as listed in accordance with Article 15(1)**.
3. Where there is no outer packaging, all the particulars listed in paragraphs 1 **and 1a** shall appear on the immediate packaging.

## *Article 11*

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

1. By way of derogation from Article 9, [...] immediate packaging units **which are too small to contain in a readable form the information referred to in that Article** shall contain [...] the following information **and shall contain no other 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."
  
2. **The packaging units referred to in paragraph 1 shall have an outer-packaging fulfilling the requirements set out in Article 10(1), (1a) and (2).**

## *Article 11a*

**By way of derogation from Articles 9(1), 10(1) and 11(1), Member States may, within their territory, on request of the applicant, allow him to include on the immediate package or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics, to the exclusion of any advertising of a veterinary medicinal product.**

Article 12

*Package leaflet of veterinary medicinal products*

1. The package leaflet shall be **made readily available by the marketing authorisation holder** [...] 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 **followed by its strength and pharmaceutical form** [...];
  - (ba) qualitative and quantitative composition of the active substance(s);**
  - ~~(e)~~ [...]
  - (d) the target species, the dosage for each species, the method and route of administration and, **if necessary**, advice on correct administration [...];
  - (e) the [...]indications **for use**;
  - (f) the contra-indications and adverse events [...];
  - (g) **if applicable**, the withdrawal period, even if this is [...] **zero**;
  - (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) [...] **information on the collection systems referred to in Article 122 applicable to the veterinary medicinal product in question**;
  - (k) the marketing authorisation number;
  - ~~(l)~~ [...]
  - ~~(m)~~ [...]
  - (l) contact details to report suspected adverse events to the marketing authorisation holder or to its representative, as appropriate;**
  - (m) classification of the veterinary medicinal product as referred to in Article 29.**

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. **That** 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 **readable**, clear and understandable, in terms that are comprehensible to the general public. **Member States may decide that it shall be made available on paper, or electronically, or both.**
4. **By derogation from paragraph 1, the information required in accordance with this Article may, alternatively, be provided on the packaging of the veterinary medicinal product.**

#### *Article 12a*

**The information listed in Articles 9 to 12 shall comply with the summary of the product characteristics as set out in Article 30.**

#### *Article 13*

##### *Package leaflet of **registered** 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 [...] shall contain [...], **at least**, 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 **registration** [...] holder and, where appropriate, of the manufacturer;
- (c) method of administration and, if necessary, route;
- ~~(d)~~—[...]

- (e) pharmaceutical form;
- (f) special storage precautions, if any;
- (g) the target species and, where appropriate, dosage for each such species;**
- (h) a special warning if necessary for the **homeopathic veterinary** medicinal product;
- ~~(i)~~—[...]
- (j) registration number;
- (k) withdrawal period, if applicable.
- (l) the statement "homeopathic veterinary medicinal product".

*Article 14*

*Languages*

[...]

*Article 15*

*[...] Implementing powers with respect to section 4*

- 0. The Commission shall, when appropriate, by means of implementing acts, provide uniform rules on the identification code referred to in Articles 9(3) and 10(1a). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
1. 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).
- 2. The Commission shall, by means of implementing acts, provide uniform rules on the size of packaging units referred to in Article 11. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**

## Section 5

### Specific 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), **it shall not be required that** an application for a marketing authorisation for a generic veterinary medicinal product [...] contains the documentation on safety and efficacy if all the following conditions are fulfilled:
  - (aa) **bioavailability studies have demonstrated its bioequivalence with the reference veterinary medicinal product or a justification is provided as to why such studies were not performed;**
    - (a) the application satisfies the requirements set out in Annex II[...];
    - (b) the applicant [...] demonstrates that the application concerns a generic veterinary medicinal product of a **reference** veterinary medicinal product [...] **for which** the period of protection of the technical documentation [...] laid down in Articles 34 and 35 has elapsed or is due to elapse in less than 2 years [...];
    - (c) — [...]
2. [...] **Where the active substance of a generic veterinary medicinal product** 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.

- 2a. Where several immediate-release oral pharmaceutical forms of a generic veterinary medicinal product are presented, they shall be considered to be the same pharmaceutical form.**
3. Where the reference veterinary medicinal product [...] **is** 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 [...] **is** 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, **as applicable**, may request information on the reference veterinary medicinal product from the competent authority of the Member State where it [...] **is** 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 [...] **essentially similar** 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, **as applicable**, 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 [...] **1 October 2005** [...].
7. — [...]

## *Article 16a*

### *Hybrid veterinary medicinal products*

1. By way of derogation from Article 16(1), the results of appropriate pre-clinical studies and **/or** 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), [...]indications **for use**, 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 for a hybrid veterinary medicinal product** may be conducted with batches of the reference product [...] **authorised** in the Union or in third countries.

[...]The applicant shall demonstrate [...] that the [...] reference product **in third countries has been authorised in accordance with requirements equivalent to those established for the reference veterinary medicinal product and** are so highly similar that they can substitute [...] each other in the clinical trials.

*Article 17*

*Combination veterinary medicinal products*

By way of derogation from Article 7(1)(b) **in the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products it shall not be required to provide safety and efficacy data relating to each individual active substance.**

[...]

*Article 18*

*Hybrid veterinary medicinal products*

[...]

*Article 19*

*Application based on informed consent*

By way of derogation from Article [...] **7(1)(b)**, an applicant for a marketing authorisation for a [...] veterinary medicinal product shall not be required to provide the **technical** documentation on **quality**, safety and efficacy if he demonstrates in the form of a letter of access that he is allowed to use [...] **that** documentation [...] **submitted in respect of** the [...] **authorised** 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 [...] **on safety and efficacy** 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 II[...].

## Section 6

### **Marketing authorisations for [...] limited markets and in exceptional circumstances**

#### *Article 21*

##### *[...] Applications for limited markets*

1. By way of derogation from Article 7(1)(b), **the applicant shall not be required to provide** [...] **a comprehensive safety** and/or efficacy documentation required in accordance with Annex II[...] if all the following conditions are met:
  - (a) the benefit of the [...] 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. [...]
3. Where a **veterinary** medicinal product has been granted a marketing authorisation in accordance with **the terms of** this Article, the summary of product characteristics shall clearly state that only a limited assessment of [...] **safety** and/or efficacy has been conducted due to the lack of comprehensive [...] **safety and/or efficacy** data.

### *Article 21a*

#### *Validity [...] of a marketing authorisation for a limited market and procedure for its re-examination*

0. **By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be valid for a period of 5 years.**
1. Before the expiry of the period of validity [...] **referred to in paragraph 0**, marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined **on the basis of an** application from the marketing authorisation holder **including an updated benefit-risk assessment**[...].
2. The application for a re-examination shall be submitted to the competent authority that granted the authorisation or to the Agency, **as applicable**, at least 6 months before the expiry of the **period of validity referred to in paragraph 0**, [...] and shall **be limited to** demonstrating[...] that the **conditions referred to in Article 21(1) continue to be fulfilled** [...].
3. When an application for re-examination has been submitted, the [...] marketing authorisation **for a limited market** shall remain valid until a decision [...] has been adopted by the competent authority or the Commission, **as applicable**.
4. The competent authority or the Agency, **as applicable**, shall assess [...] applications for a re-examination **and extend the validity of the marketing authorisation by additional periods of five years if** the benefit-risk balance [...] **remains** positive.
5. The competent authority or the Commission, **as applicable**, 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 [...] **data on [...] safety and/or efficacy** [...] referred to in Article 21(1).

## *Article 22*

### *[...] Applications in exceptional circumstances*

[...]By way of derogation from Article 7(1)(b), in exceptional circumstances related to animal or public health, [...]an [...] applicant **may submit an application which does not meet all requirements of that provision, for which the benefit of the immediate availability on the market of the concerned veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided. In such case, the applicant shall be required to demonstrate**[...] that for objective **and** verifiable reasons [...] the quality, safety and/or efficacy documentation required in accordance with [...] Annex II **cannot be provided.**

## *Article 22a*

### *Terms of the marketing authorisation in exceptional circumstances*

1. **In exceptional circumstances referred to in Article 22, a marketing authorisation may be granted** [...] subject to [...] **one or more** of the following **requirements for the marketing authorisation holder**:
  - (a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;
  - (b) a requirement to notify **to** the competent authorities **or the Agency, as applicable**, of any [...] **adverse event** relating to the use of the veterinary medicinal product;
  - (c) a requirement to conduct post-authorisation studies.
2. [...]
3. Where a **veterinary** medicinal product has been granted a marketing authorisation in accordance with **the terms of** 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.

## *Article 22b*

### *Validity of a marketing authorisation in exceptional circumstances and procedure for its re-examination*

- 0. By way of derogation from Article 5(2), a marketing authorisation in exceptional circumstances shall be valid for a period of 1 year.**
1. Before the expiry of the period of validity [...] **referred to in paragraph 0**, marketing authorisations granted in accordance with Article 22 **and 22a** shall be re-examined on application from the marketing authorisation holder **including an updated benefit-risk assessment**.
2. **The** [...] application for re-examination shall be submitted to the competent authority that granted the authorisation or the Agency, **as applicable**, at least 3 months before the expiry of the [...] **period of validity referred to in paragraph 0**, and shall demonstrate that the **exceptional circumstances related to animal health or public health remain**.
3. When an application for re-examination has been submitted, the marketing authorisation shall remain valid until a decision [...] has been adopted by the competent authority or the Commission, **as applicable**.
- 3a. The competent authority or the Agency, as applicable, shall assess the application and extend the validity of the marketing authorisation for one year if the benefit-risk balance remains positive.**
4. The competent authority or the Commission, **as applicable**, may at any time grant a marketing authorisation valid for an unlimited period of time **in respect of a veterinary medicinal product authorised in accordance with Article 22 and 22a**, provided that the marketing authorisation holder submits the missing [...] data **on quality, safety and/or efficacy** referred to in Article 22[...].

## Section 7

### Examination of applications and basis for granting marketing authorisations

#### Article 23

##### *Examination of applications*

1. The competent authority or the Agency, **as applicable**, to which the application has been submitted in accordance with Article 6 shall:
  - (a) verify that the **data** [...] submitted complies with the requirements laid down in Article 7[...];
  - (b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.
  - (c) **draw up a conclusion on the benefit-risk balance for the veterinary medicinal product.**
  
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, **as applicable**, examining the application may require an applicant to provide [...] to the Union reference laboratory, an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose, **samples which are necessary** 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 [...] that, **in case of veterinary medicinal products intended for food producing animals**, the analytical detection method proposed by the applicant for the purposes of [...] residue **depletion** 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 for official controls of animals and products of animal origin in accordance with Regulation (EU) No 2017/625** [...].
2. The time limits laid down in Articles 40, 44, 46, [...] 48 **and 48a** shall be suspended until the samples requested in accordance with paragraph 1 **of this Article** have been provided.

#### *Article 25*

##### *Information on manufacturers **in third countries***

The competent authority [...] **or the Agency, as applicable, to which the application has been submitted in accordance with Article 6, shall ascertain, through the procedure in Articles 91 to 93, 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). **A competent authority or the Agency, as applicable, may request the relevant competent authority to present information ascertaining that the manufacturers of veterinary medicinal products are able to carry out the activities referred to in this Article.**

*Article 26*

***Additional information [...] from the applicant***

The competent authority or the Agency, **as applicable**, 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, **as applicable**, shall request the applicant to provide [...] **additional information** [...] within a given deadline. In such case the time limits laid down in Articles 40, 44, 46, [...] 48 **and 48a** shall be suspended until the [...] **additional information has been provided.**

*Article 27*

***Withdrawal of applications***

1. An applicant may withdraw his application for marketing authorisation submitted to a competent authority or the Agency, **as applicable**, at any time before the decision referred to in Article [...] **40, 44, 46, 48 or 48a** has been taken.
2. If an applicant withdraws his application for a marketing authorisation submitted to a competent authority or the Agency, **as applicable**, before the [...] **examination** 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, **as applicable**, to which the application was submitted in accordance with Article 6.
3. [...] **The competent authorities or the Agency, as applicable, shall make publicly available the information that the application has been withdrawn together with** [...] the opinion, [...] **already** drawn up, [...] after deletion of any commercially confidential information.

*Article 28*

*Outcome of the assessment*

1. **The competent authority or the Agency, as applicable, examining the application in accordance with Article 23, shall prepare, respectively, an assessment report or an opinion. In case of a favourable assessment [...], that assessment report or opinion shall include the following [...]:**
  - (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 **safe and effective** use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with Article 29;
  - ~~(c)~~ [...]
  - (d) the [...] text of the labelling and package leaflet **referred to in Articles 9 to 12.**
  
- 1a. **In case of an unfavourable assessment, the assessment report or the opinion, referred to in paragraph 1, shall contain the justification for arriving at the outcome.**
  
- ~~2.~~ [...]
  
- ~~3.~~ [...]

Article 29

[...] *Classification of veterinary medicinal products*

1. **The competent authority or the Commission, as applicable, granting a marketing authorisation as referred to in Article 5(1)** shall classify the following veterinary medicinal products as subject to veterinary prescription:
  - (a) veterinary medicinal products which contain [...] narcotic drugs **or psychotropic substances, or substances frequently used in the illicit manufacture of these drugs or substances** 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 **and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 or by Union legislation on drug precursors;**
  - (b) veterinary medicinal products for food-producing animals;
  - (c) antimicrobial veterinary medicinal products;
  - (d) veterinary medicinal 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;
  - (dd) veterinary medicinal products used for euthanasia of animals;**
  - ~~(e)~~—[...]
  - (f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the Union;
  - (g) **immunological veterinary medicinal products;**
  - (h) **without prejudice to Council Directive 96/22/EC, veterinary medicinal products containing an active substances having a hormonal or thyrostatic action and beta-agonists.**

2. **The** [...] competent authority or the Commission, **as applicable**, may classify a veterinary medicinal product as subject to veterinary prescription **if it is classified as a narcotic drug in accordance with national legislation or** where special precautions are contained in the summary of product characteristics referred to in Article 30. [...]
  
3. By the way of derogation from paragraph 1, [...] **the** competent authority or the [...] **Commission, as applicable**, may, **except as regards veterinary medicinal products referred to in paragraphs 1(a), 1(c), 1(dd) and 1(h)**, [...] classify a veterinary medicinal product as **not** 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 **or to other animals**, 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 **adverse events** [...] 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) [...]
  - (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 [...] 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, **in the order indicated below**, the following information:
  - (a) name of the veterinary medicinal product followed by its strength and pharmaceutical form **and, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States;**
  - (b) qualitative and quantitative composition of the active substance(s) [...] **and qualitative composition of excipients and other constituents stating their common name or their chemical description and, if that knowledge is essential for proper administration of the veterinary medicinal product, their quantitative composition;**
  - (c) clinical information:
    - (i) **target species;**
    - (ii) indications for use **for each target species,**
    - (iii) contra-indications,
    - (iv) special warnings [...],
    - (v) special precautions for use, including **in particular special precautions for safe use in the target species,** special precautions to be taken by the person administering the **veterinary** medicinal product to the animals **and special precautions for the protection of the environment;**
    - (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 **dosage** [...],
    - (x) [...] symptoms **of overdose** and, **where applicable,** emergency procedures and antidotes in the event of overdose, [...],
    - (xi) [...] special [...] restrictions for use,

~~(xii)~~[...],

(xiii) special conditions for use, including restrictions on the use of antimicrobial **and antiparasitic veterinary medicinal products** in order to limit the risk of development of [...] resistance,

[...] **(xiii)** **if applicable**, withdrawal periods[...] **including when it is zero** [...],

(e) pharmacological information:

**(oi) Anatomical Therapeutic Chemical Veterinary Code (ATC Vet Code);**

(i) pharmacodynamics,

(ii) pharmacokinetics,

**In case of an immunological veterinary medicinal product, instead of points (0i), (i) and (ii), immunological information;**

**(eb)**[...] pharmaceutical particulars:

(i[...]) major incompatibilities,

([...]**ii**) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time,

([...]**iii**) special precautions for storage,

**(iv)**[...] nature and composition of immediate packaging,

**(v** [...]) 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) [...] date of the first **marketing** authorisation;

(i) [...] date of the last revision of the summary of the product characteristics;

(j) if applicable, for products [...] **referred to in** Article 21 or Article 22a, the statement 'marketing authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised requirements for documentation'.

- (k) information on the collection systems referred to in Article 122 applicable to the veterinary medicinal product in question;**
- (l) classification of the veterinary medicinal product as referred to in Article 29 per Member State in which it is authorised.**

- 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 referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 28(1) and shall set out [...] any 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. [...]
- 2a. **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 given the potential development of antimicrobial resistance.**

*Article 32*

*Decisions refusing marketing authorisations*

- 0. Decisions refusing marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 28(1a) and shall be duly justified and include the reasons for refusal.**
1. A marketing authorisation shall be refused **on any of the following grounds:**
- (aa) the application does not comply with the relevant provisions of this Chapter;**
  - (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)~~ [...]
  - (d) the **veterinary medicinal** 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 **proposed** withdrawal period is not long enough to ensure food safety **or is insufficiently substantiated;**
  - ~~(f)~~ [...]
  - (g) **the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance** outweighs the benefits of the product to animal health;
  - (h) [...] the applicant has not provided sufficient proof of [...] **efficacy** as regards the target species;
  - (i) the qualitative or quantitative composition of the product is not as stated in the application[...];
  - (j) **risks to public health, animal health or for the environment are not sufficiently addressed; or,**
  - (k) **the active substance within the product meets the criteria for being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative and the product is intended to be used in food producing animals, unless it is shown by evidence that the active substance is essential to prevent or control a serious risk to animal health.**

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 **as provided for in paragraph 4.**
3. The Commission shall [...] adopt delegated acts in accordance with Article 146 **supplementing the rules of this Regulation concerning the establishment of criteria** [...] 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 [...] **those antimicrobials.**
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).
5. **The Commission shall take into account of the scientific advice of the Agency, the European Food Safety Authority (EFSA) and other relevant Union agencies, when adopting the acts referred to in paragraphs 3 and 4.**

## **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 [...] **referred to** 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 **is due to elapse in less than 2 years**,
  - (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 **veterinary medicinal** product is not authorised or is no longer authorised.
3. [...] **Marketing authorisation or a variation to the terms of a marketing authorisation differing from the previously granted marketing authorisation only with regard to target species, strengths, pharmaceutical forms, administration routes or presentations shall be regarded as the same marketing authorisation as the one previously granted to the same marketing authorisation holder** 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 **for meat production**, pigs, chickens, dogs and cats;
  - (b) 14 years for antimicrobial veterinary medicinal products for cattle, sheep **for meat production**, 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 **the provisions referred to in Article [...]** **5(1)**.

## Article 35

### *Prolongation [...]and additional periods of the protection of technical documentation*

1. Where **the first marketing authorisation is granted for more than one species listed in Article 34(1)(a) or (b), or** a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a) **or (b)**, the period of the protection provided for in that Article shall be prolonged by 1 year for each additional target species, provided that, **in case of a [...] variation, the application** has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a) **or (b)**.
2. Where **the first marketing authorisation is granted for more than one species listed in Article 34(1)(d) or** a variation is approved in accordance with Article 65 extending the marketing authorisation to [...] -another species not [...] **referred to** in Article 34(1)(a), the period of the protection provided for in Article 34 shall be prolonged by 4 years, **provided that, in case of a variation, the application has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(d)**.
3. The period of the protection **provided for in Article 34** 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 [...] 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 [...] **a** marketing authorisation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of a maximum residue limit, together with **safety and residues tests and pre-clinical and** clinical trials during the application procedure, other applicants shall not [...] **refer to results of those tests and** trials for a period of 5 years from the granting of the marketing authorisation for which they were carried out [...]. **The prohibition on using those results shall not apply, insofar as the** other applicants have obtained [...] a letter of access with regard to those **tests and** trials.

**5. If a variation to the terms of the marketing authorisation approved in accordance with Article 65 involves a change to the pharmaceutical form, administration route or dosage, which is considered by the Agency or the competent authorities referred to in Article 64 to have demonstrated:**

- (a) a reduction in the antimicrobial or antiparasitic resistance, or,**
- (b) an improvement of the benefit-risk balance of the veterinary medicinal product, the results of the concerned pre-clinical studies or clinical trials shall benefit from 4 years protection. The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those tests and 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 [...] requirements **set out there in** shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products **as defined in Article 1(a) of Regulation (EC) No 469/2009<sup>7</sup>**.

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<sup>7</sup> Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

## Chapter III

### Procedures for [...] 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 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;
  - (da) novel therapy veterinary medicinal products;**
  - (e) [...]

- 2a. **Points (d) and (da) of paragraph 2 shall not apply to veterinary medicinal products consisting exclusively of blood components.**
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. [...]

#### *Article 39*

##### *Application for centralised marketing authorisation*

1. **An application** 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 **marketing** authorisation of **a** veterinary medicinal product shall state a single name for the veterinary medicinal product to be used throughout the Union.
3. [...]

#### *Article 40*

##### *Procedure for centralised marketing authorization*

1. [...]
2. **The Agency shall assess the application referred to in Article 39.** As an outcome of the assessment [...] the Agency shall [...] **prepare an opinion containing the information** [...] 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. [...] **In case the applicant has not provided written notice in accordance with** paragraph 5, [...] **the Agency** [...] shall, **without undue delay**, forward **its opinion** 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.
- 7a. **The applicant shall submit to the Agency the necessary translations of the summary of product characteristics, package leaflet and labelling in accordance with Article 6a, within the time limit set by the Agency, but at the latest on the date the draft decision is forwarded to the competent authorities in accordance with paragraph 8.**
8. Within 15 days of receipt of the opinion, the Commission shall prepare a draft [...] decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include [...] **the opinion prepared in accordance with paragraph 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 the differences. The draft decision shall be forwarded to **the competent authorities of Member States and to** the applicant.

9. The Commission shall, by means of implementing acts, take a [...] decision on the granting **or refusal** of a centralised marketing authorisation **in accordance with this Section on the basis of the opinion prepared by** the Agency. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
- ~~10.~~ [...]
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 **90** [...] days after receipt of the **detailed** grounds for the request, the Agency shall re-examine its opinion. The [...] conclusions reached **and the reasons for the conclusions** shall be annexed to the opinion **and shall form an integral part thereof**.
3. Within 15 days after [...] **the re-examination of its opinion**, the Agency shall forward its opinion to the Commission and the applicant.
4. **Subsequent to the procedure set out in paragraph 3 of this Article, paragraphs (7) to (11) of Article 40 shall apply.**

## Section 2

### Marketing authorisations valid in a single Member State ('national marketing authorisation')

#### Article 42

##### *Scope of national marketing authorization*

1. 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 **only** in the Member State **of the competent authority** which granted it.
2. National marketing authorisations shall **not** [...] be granted in respect of veterinary medicinal products [...] falling within the scope of Article 38(2) **or for which a national marketing authorisation has been granted or an application in accordance with this Section is pending in another Member State or in the Union.**

#### ~~Article 43~~

##### ~~*Applications for national marketing authorisations*~~

[...]

#### Article 44

##### *Procedure for national marketing authorisation*

1. The procedure for granting **or refusing** a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the **valid** [...] application.
  - 1a. **The competent authority shall prepare an assessment report containing the information referred to in Article 28.**
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 authorization*

1. Decentralised marketing authorisations shall be granted by the competent authorities in **the Member States where the applicant seeks to obtain a marketing authorisation ('concerned Member States')** in accordance with this Section. They shall be valid in those Member States [...].
2. Decentralised marketing authorisations shall **not** [...] be granted in respect of veterinary medicinal products for which a [...] national marketing authorisation has been granted **or for which an application for a marketing authorisation is pending** at the time of **the** application for a decentralised marketing authorisation [...] **or** which [...] fall within the scope of Article 38(2).

##### Article 46

###### *Procedure for decentralised marketing authorisation*

1. An application[...] for decentralised marketing authorisation shall be submitted to the **competent authority in the** Member State chosen by the applicant **to prepare an assessment report and to act in accordance with the provisions in this Section** ('reference Member State') **and to the competent authorities in the other concerned Member States.**
2. The application shall list **the concerned** Member States [...].

- 2a. If the applicant indicates that one or more of the concerned Member States shall no longer be considered as such, the competent authorities in those Member States shall provide to the competent authority in the reference Member State and to the competent authorities in the other concerned Member States any information they consider relevant relating to the withdrawal of the application.**
3. Within 120 days of receipt of a valid application, the **competent authority in the** reference Member State shall prepare an assessment report **containing the information referred to in Article 28 and shall forward it to the competent authorities in the other concerned** Member States and **to** the applicant [...].
4. Within 90 days after receipt of the **assessment report** [...] referred to in paragraph 3, **the competent authorities in the other concerned** Member States [...] shall examine **it** [...] and inform the **competent authority in the** reference Member State of whether they have [...] **any objection to [...] it on the ground that it would pose a potential serious risk to human or animal health or for the environment. The assessment report resulting from this examination shall be forwarded by the competent authority in the reference Member State to the competent authorities in the other concerned Member States and to the applicant.**
- 4a. **If requested by the competent authorities in the reference Member State or in another concerned Member State, the coordination group shall be convened to examine the assessment report within the period referred to in paragraph 4.**

5. Where [...] **the assessment report is favourable and where no competent authority has informed the competent authority in the reference Member State of an objection thereto, as set out in paragraph 4, the latter shall record [...] that there is an agreement, close the procedure and inform the applicant and the competent authorities in all Member States accordingly, without undue delay. [...] The competent authorities in the concerned Member States shall grant a marketing authorisation in conformity with the assessment report within 30 days of the receipt of both the information on the agreement from the competent authority in the reference Member State and also the complete translations of the summary of product characteristics, labelling and package leaflet from the applicant, whichever is submitted the latest.**
- 5a. **Where the assessment report is unfavourable and where none of the concerned competent authorities has informed the competent authority in the reference Member State of an objection thereto, as set out in paragraph 4, the competent authority in the reference Member State shall record that there is a refusal to grant the marketing authorisation, close the procedure and inform the applicant and the competent authorities in all Member States accordingly, without undue delay.**
- 5b. **Where a competent authority informs the competent authority in the reference Member State of an objection in accordance with paragraph 4, the procedure set out in Article 49 shall apply.**
6. If at any stage of the procedure **the competent authority in a concerned Member State [...]** invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product, **that Member State [...]** shall no longer be considered as a **concerned Member State. [...]**
7. **The competent authority in the reference Member State shall make the assessment report publicly available, after deleting any commercially confidential information.**

*Article 46a*

*Request by the applicant for re-examination of the assessment report*

- 1. Within 15 days after receipt of the assessment report referred to in Article 46(4) the applicant may provide written notice to the competent authority in the reference Member State requesting a re-examination of the assessment report. In that case, the applicant shall forward to the competent authority in the reference Member State detailed grounds for the request within 60 days after receipt of that assessment report. The competent authority in the reference Member State shall without delay forward this request and the detailed grounds to the coordination group.**
- 2. Within 60 days after receipt of the detailed grounds for the request for re-examination of the assessment report, the coordination group shall re-examine the assessment report. The conclusions reached and the reasons for the conclusions shall be annexed to the assessment report and shall form an integral part thereof.**
- 3. Within 15 days after the re-examination of the assessment report, the competent authority in the reference Member State shall forward the assessment report to the applicant.**
- 4. Subsequent to the procedure set out in paragraph 3 of this Article, paragraphs (5), (5a), (6) and (7) of Article 46 shall apply.**

## Section 4

### Mutual recognition of marketing authorisations granted by national authorities

#### *Article 47*

##### *Scope of mutual recognition of marketing authorisations*

A national marketing authorisation for a veterinary medicinal product, **granted in accordance with Article 44**, shall be recognised [...] **in** other Member States in accordance with the procedure laid down in Article 48 [...].

#### *Article 48*

##### *Procedure for mutual recognition of marketing authorisations*

1. **An application for mutual recognition of a marketing authorisation shall be submitted to the competent authority in the Member State that granted the [...] national marketing authorisation in accordance with Article 44 ('reference Member State') and to the competent authorities in the Member States where the applicant seeks to obtain a marketing authorisation ('concerned Member States').**
  - 1a. **The application shall list the concerned Member States.**
  2. A minimum of 6 months shall elapse between the decision granting the [...] national marketing authorisation and the submission of the application for mutual recognition of that national marketing authorisation.
  - 2a. **If the applicant indicates that one or more of the concerned Member States shall no longer be considered as such, the competent authorities in those Member States shall provide to the competent authority in the reference Member State and to the competent authorities in the other concerned Member States, any information they consider relevant relating to the withdrawal of the application.**

- ~~3.~~ [...]
4. Within 90 days of receipt of a valid application, the **competent authority in the** reference Member State shall prepare an updated assessment report **containing the information referred to in Article 28** for the veterinary medicinal product [...] **and shall forward it to the competent authorities in the concerned** Member States and **to the applicant** [...].
5. Within 90 days after receipt of the **updated assessment report** [...] referred to in paragraph [...] **4, the competent authorities in the concerned** Member States shall examine [...] **it** and inform the **competent authority in the** reference Member State of whether [...] **they have any objections to it on the ground that it would pose a potential serious risk to human or animal health or for the environment. The assessment report resulting from this examination shall be forwarded by the competent authority in the reference Member State to the competent authorities in the other concerned Member States and to the applicant.**
- 5a. **If requested by the competent authorities in the reference Member States or in another concerned Member State, the coordination group shall be convened to examine the updated assessment report within the period referred to in paragraph 5.**

- 5b. Where no competent authority of any concerned Member State has informed the competent authority in the reference Member State of an objection to the updated assessment report, as set out in paragraph 5, the latter shall record that there is an agreement, close the procedure and inform the applicant and the competent authorities in all Member States accordingly, without undue delay. The competent authorities in the concerned Member States shall grant a marketing authorisation in conformity with the updated assessment report within 30 days of the receipt of both the information on the agreement from the competent authority in the reference Member State and also the complete translations of the summary of product characteristics, labelling and package leaflet from the applicant, whichever is submitted the latest.**
- 5c. Where a competent authority of any concerned Member State informs the competent authority in the reference Member State of an objection in accordance with paragraph 5, the procedure set out in Article 49 shall apply.**

~~6- [...]~~

7. If at any stage of the procedure **the competent authority in** a concerned Member State invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product, [...] **that Member State** shall no longer be considered as a **concerned** Member State. [...]
8. **The [...]** competent authority [...] **in the reference Member State** shall make the assessment report publicly available, after deleting any commercially confidential information.

## Section 4a

### Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures

#### Article 48a

*Subsequent recognition of marketing authorisations by [...] additional concerned Member States*

1. After completion of a **decentralised procedure laid down in Article 46** or a mutual recognition procedure laid down in Article 48 **granting a marketing authorisation** [...], the marketing authorisation holder may submit an application for a marketing authorisation for [...] **the** veterinary medicinal product to **the competent authorities in additional concerned Member States and to the competent authority in the reference Member State referred to in Article 46 or 48, as applicable, in accordance with the procedure laid down in this Article**. The application shall include the following, **in addition to the data referred to in Article 7**:
  - (a) a list of all decisions granting, **suspending or revoking** marketing authorisations concerning this veterinary medicinal product;
  - (b) [...] **information on the** variations introduced since the marketing authorisation [...] **by decentralised procedure laid down in Article 46(5) or by mutual recognition procedure laid down in Article 48(5a)** was granted;
  - (c) a summary report on pharmacovigilance data.
- 1a. **The competent authority in the reference Member State referred to in Article 46 or 48, as applicable, shall within 60 days forward to the competent authorities in the additional concerned Member States the decision on granting marketing authorisation and any variations thereto and shall, within that period, prepare and forward an updated assessment report concerning that marketing authorisation and those variations as applicable, and inform the applicant accordingly.**

2. The **competent authority in each additional concerned Member State** shall [...] **grant** a marketing authorisation in conformity with the **updated** assessment report referred to in **paragraph 1a** [...] within **60** days of receipt of the **data referred to** in paragraph 1 **and the complete translations of the summary of product characteristics, labelling and package leaflet, whichever is submitted the latest.**
  
- 2a. **By derogation from paragraph 2, if the competent authority in an additional concerned Member State has reasons for refusing the marketing authorisation on the ground that it would pose a potential serious risk to human or animal health or for the environment, it shall, at the latest within a period of 60 days of receipt of both the data referred to in paragraph 1 and updated assessment report referred to in paragraph (1a) raise its objections and provide a detailed statement of the reasons to the competent authority in the reference Member State referred to in Article 46 or 48, as applicable, and to the competent authorities in the concerned Member States, referred to in those Articles, and to the applicant.**
  
- ~~3-4.~~ [...]
  
5. **In case of objections in accordance with paragraph 2a, the competent authority in the reference Member State shall take any appropriate initiatives, in order to seek an agreement as regards the objections made. The competent authorities shall use their best endeavours to reach an agreement on the action to be taken.**
  
6. **The competent authority in the reference Member State shall provide the applicant with the opportunity to make his point of view known orally or in writing.**

7. **In case, following the initiatives by the competent authority in the reference Member State, an agreement among the competent authorities in the Member States having already granted a marketing authorisation and the competent authorities in the additional concerned Member States has been found, the competent authorities in the additional concerned Member States shall grant a marketing authorisation in accordance with paragraph 2.**
  
8. **If the competent authority in the reference Member State has not been able to find an agreement at the latest within a period of 60 days from the objections referred to in paragraph 2a were raised, it shall refer the application together with the updated assessment report referred to in paragraph 1a and the objections of the competent authorities in the additional concerned Member State to the coordination group in accordance with the review procedure set out in Article 49.**

## **Section 5**

### **[...] Review procedure [...]**

#### *Article 49*

#### *[...]Review procedure*

1. **If the competent authority in a concerned Member State raises [...] according to Article 46(4) [...], Article 48(5), Article 48a(8) or Article 64(7aa) any objection as referred to in those provisions to, respectively, the assessment report or the updated assessment report, it shall provide without delay [...] a detailed statement of the reasons for any such objection [...] to the competent authority in the reference Member State, to the competent authorities in the [...] concerned Member States and to the applicant or the marketing authorisation holder. The points of disagreement shall be referred without delay by the competent authority [...] in the reference Member State to the coordination group.**

- 1a. The competent authority in the reference Member State shall take any appropriate initiatives in order to seek an agreement within the period of 90 days as regards the objection made.**
- 1b. The competent authority in the reference Member State shall provide the applicant or the marketing authorisation holder with the opportunity to make his point of view known orally or in writing.**

~~2-4.~~[...]

- 5. [...] In case an agreement among the competent authorities referred to in Articles 46(1), 48(1), 48a(1) or 64(1) has been reached, the competent authority in the reference Member State shall close the procedure and inform the applicant or the marketing authorisation holder. The competent authorities in the concerned Member States shall grant or vary a marketing authorisation [...].**
- 6 [...]When the competent authorities referred to in Articles 46(1), 48(1), 48a(1) and 64(1) reach an agreement by consensus to refuse the marketing authorisation or to reject the variation, the competent authority in the reference Member State close the procedure and inform the applicant or the marketing authorisation holder providing the grounds for the refusal or the rejection. The competent authorities in the concerned Member State shall refuse the marketing authorisation or reject the variation.**
- 6a. If an agreement between the competent authorities cannot be reached by consensus, the coordination group shall provide the Commission with the assessment report referred to in Articles 46(4), 48(5), 48a(2a) or 64(3), together with information on the points of disagreement at the latest within a period of 90 days from when the objection referred to in paragraph 1 was raised.**

- 7. Within 30 days of receipt of the documents referred to in paragraph 5b, the Commission shall prepare a draft decision to be taken in respect of the application. The draft decision shall be forwarded to the competent authorities in the Member States and to the applicant or the marketing authorisation holder.**
  
- 8. The Commission may request clarifications from the competent authorities and/or the Agency. The time limit laid down in paragraph 7 shall be suspended until the clarifications have been provided.**
  
- 8a. For the purpose of work-sharing procedure in respect of variations requiring assessment in accordance with Article 64, references in this Article to a competent authority in the reference Member State shall be understood as references to a competent authority agreed upon in accordance with Article 63(3), and references to concerned Member States as references to relevant Member States.**
  
- 9. The Commission shall, by means of implementing acts, take a decision on the granting, changing, or refusing or revoking of a marketing authorisation or rejecting the variation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**

*Article 50*

*Request for scientific re-examination*

[...]

## 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 **in collaboration with the Member States in accordance with the provisions in this Section.**
  
2. The product database shall contain [...] **at least the following** information [...]:
  - (a) **for** veterinary medicinal products authorised within the Union by the Commission and by the competent authorities: [...] **name of the veterinary medicinal product, its active substance(s) and its strength**, summary of product characteristics, package leaflet, **the assessment report**, [...] list of sites where [...] **the product is manufactured and the dates of its placing on the market in a Member State**;
  - (b) **for** [...] homeopathic veterinary medicinal products registered **in accordance with Chapter V** within the Union [...] by the competent authorities: **name of the registered homeopathic veterinary medicinal product**, [...] package leaflet and lists of sites where [...] **the product is manufactured**;
  - (c) veterinary medicinal products allowed to be used in a Member State in accordance with Article [...] **5(6)**;
  - (d) **the annual volume of sales and information on the availability for each veterinary medicinal product.**
  
3. [...]

- 3a. **The Commission shall, by means of implementing acts, adopt the necessary measures and practical arrangements laying down:**
- (a) **the technical specifications of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission;**
  - (b) **the practical arrangements for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information;**
  - (c) **detailed specifications of the information to be included, updated and shared and by whom;**
  - (d) **contingency arrangements to be applied in case of unavailability of any of the functionalities of the product database;**
  - (e) **where appropriate, data to be included in addition to the information of the product database as referred to in paragraph 2.**

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

4-8: [...]

#### *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, **without changing the information therein**, as regards the list of the [...] veterinary medicinal products, [...] the summary of product characteristics, [...] package leaflets [...] **and assessment reports after the deletion of any commercially confidential information by the competent authority.**

## Section 2

[...]

### Collection of data by Member States and responsibilities of marketing authorisation holders

#### *Article 53*

##### *Placing on the market*

[...]

#### *Article 54*

##### *Collection of data on [...] antimicrobial [...] medicinal products used in animals*

1. Member States shall collect relevant and comparable data on the volume of sales and the use of [...] antimicrobial medicinal products **used in animals, to enable in particular the direct or indirect evaluation of the use in food producing animals at farm level in accordance with this Article and within the time limits set in paragraph 4aa.**
2. Member States shall send **collated** data on the volume of sales and the use [...] **per animal species and per types of antimicrobial medicinal products used in animals** to the Agency **in accordance with paragraph 4aa and within the time limits set therein.** The Agency shall **cooperate with Member States and with other Union agencies to analyse [...] these data and publish an annual report. The Agency shall take into account these data when adopting any relevant guidelines and recommendations.**
3. The Commission shall [...] adopt delegated acts in accordance with Article 146 [...] **supplementing the provisions of this Article concerning the establishment of the requirements as regards:**

- (a) the types of antimicrobials medicinal products used in animals for which data shall be collected;**
- (b) the quality assurance that Member States and the Agency shall put in place to ensure quality and comparability of data; and,**
- (c) the [...]rules on the methods of gathering data on the use of the antimicrobial medicinal products used in animals and on the method of transfer of these data to the Agency.**

4. The Commission **shall** [...], by means of implementing acts, set up the format [...]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).

**4aa. Member States shall be allowed to apply a progressive stepwise approach, regarding the obligations set out in this Article, whereby:**

- (i) within two years from the date of application as referred to in Article 150, data shall be collected at least for the species and categories included in Commission Implementing Decision 2013/652/EU in its version of [date of adoption of this Regulation];**
- (ii) within five years from the date of application as referred to in Article 150, data shall be collected for all food producing animal species,**
- (iii) within eight years from the date of application as referred to in Article 150, data shall be collected for other animals which are bred or kept.**

**4a. Nothing in point (iii) in the second subparagraph of paragraph 4 shall be understood to include an obligation to collect data from natural persons keeping companion animals.**

*Article 55*

*Responsibilities of the marketing authorisation holders*

- 0a. The marketing authorisation holder shall be responsible for the marketing of his veterinary medicinal products. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.**
  
- 0b. The marketing authorisation holder shall, within the limits of his responsibilities, ensure appropriate and continued supplies of his veterinary medicinal products.**
  
- 1. After a marketing authorisation has been granted, the marketing authorisation holder shall, in respect of the **methods of** manufacture and control [...] stated in the application for a marketing authorisation, [...] take account of scientific and technical progress, **and introduce** [...] any changes that may be required to enable [...] **the** veterinary medicinal product to be manufactured and [...] **controlled** by means of generally accepted scientific methods [...].**  
The introduction of such changes shall be subject to the procedures laid down in Section 4 of this Chapter.
  
- 1aa. The marketing authorisation holder shall ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with the current scientific knowledge.**
  
- 1a. As regards generic veterinary medicinal products and hybrid veterinary medicinal products the marketing authorisation holder shall not place such products on the Union 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.**

- 1b. **The marketing authorisation holder shall record in the product database the dates when its authorised veterinary medicinal products are placed on the market and information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the concerned marketing authorisations.**
  
2. **Upon request of the** competent authorities, [...] **the** marketing authorisation holder[...] **shall** [...] provide them with sufficient quantities of [...] **samples** to enable controls to be made on [...] **its** veterinary medicinal products [...] **placed on the Union market.**
  
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 **European Union** [...] reference laboratory designated under **Regulation (EU) No 2017/625** [...].
  
4. [...] **The marketing authorisation holder shall upon request by** [...] **a** competent authority or the Agency, **within the time limit set, provide** [...] data demonstrating that the benefit-risk balance remains favourable.
  
5. The marketing authorisation holder shall without delay inform the competent authority **which has granted the marketing authorisation**, or the Commission, **as applicable**, of any prohibition or restriction imposed by a competent authority **or an authority of a third country** and of any other new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned, **including from the outcome of the signal management process carried out in accordance with Article 81.**

6. [...] **The marketing authorisation holder shall provide the competent authority, the Commission or the Agency, as applicable, within the time limit set, with all data in his possession relating to the volume of sales of the veterinary medicinal product concerned.**
- 6a. **The marketing authorisation holder shall record in the product database the annual volume of sales for each veterinary medicinal product.**
7. **The marketing authorisation holder shall without delay inform the competent authority which has granted the marketing authorisation, or the Commission, as applicable, of any action to be taken by him to cease the marketing of a veterinary medicinal product prior to taking such action, together with the reasons therefore.**

*Article 56*

*[...]Small and medium-sized enterprises*

1. **Member States shall, in accordance with their national law, take appropriate measures [...] to [...] advise small and medium-sized enterprises on compliance [...] with the requirements of this Regulation [...].**
- 2.——[...]

### ~~Section 3~~

#### ~~Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures~~

##### ~~Article 57~~

#### ~~Subsequent recognition in the mutual recognition and decentralized marketing authorization procedures~~

[...]

### Section 4

#### Changes to the terms of the marketing authorisations

##### Article 58

#### Variations [...]

1. [...]

2. The Commission shall, by means of implementing acts, establish a list of variations [...] **not** 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 **quality, safety or** [...] efficacy of the veterinary medicinal product;
  - (c) whether changes imply [...] **no more than a minor** alteration to the summary of product characteristics;
  - (d) **whether changes are of an administrative nature.**

*Article 59*

*Consequential changes to product information*

[...]

*Article 60*

*Variations [...] that do not require assessment*

1. Where a variation [...] appears in the list established in accordance with Article 58(2), the marketing authorisation holder shall record **within 30 days** the change, **including as applicable the summary of product characteristics, labelling or package leaflet in accordance with the languages referred to in Article 6a**, in the product database [...] following the implementation [...] of [...] **that** variation.
2. If necessary, competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission, **by means of implementing acts**, shall amend [...] **the** marketing authorisation in accordance with the change recorded **as referred to in paragraph 1**.
3. **The reference Member State or the Commission, where applicable, shall inform the marketing authorisation holder and the competent authorities in the relevant Member States as to whether the variation is approved or rejected by recording this information in the product database.**

*Article 61*

*Application for variations requiring assessment*

1. **Where a variation does not appear in the list established in accordance with Article 58(2), the [...]marketing authorisation holder shall submit an application for a variation requiring assessment to [...]the competent authority which has granted the marketing authorisation or to the Agency, as applicable. The applications shall be submitted electronically.**
  
2. The application referred to in paragraph 1 shall contain:
  - (a) a description of the variation;
  - (aa) data referred to in Article 7 relevant to the variation in question;**
  - (b) [...] **details of the** marketing authorisation(s) affected by the application;
  - (c) where the variation leads to other **consequential** 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 61a*

*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 62*

*Groups of variations*

When **the marketing authorisation holder** applies for several variations [...] **not appearing in the list established in accordance with Article 58(2) regarding** the same marketing authorisation **or for one variation not appearing in that list in respect of several different marketing authorisations, he** [...] may submit one application for all variations.

*Article 63*

*Worksharing procedure*

1. When **the marketing authorisation holder** applies for **one or more** variations **which are identical in all relevant Member States and which do not appear in the list established in accordance with Article 58(2), regarding** [...] several marketing authorisations **which are** held by the same marketing authorisation holder and **which have been** granted by different competent authorities and/or the Commission, [...] **he** shall submit an **identical** application to [...] competent authorities **in all relevant Member States** [...] and, **in case a variation to a centrally authorised veterinary medicinal product is included, to** the Agency.
2. Where [...] **any** 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 **agree upon** [...] a competent authority among those having granted the marketing authorisations to assess the application in accordance with the procedure laid down in Article 64.
4. **The Commission may, by means of implementing acts, adopt the necessary arrangements regarding the functioning of the worksharing procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**

## Article 64

### *Procedure for variations requiring assessment*

1. If an [...] application **for a variation** fulfils the requirements laid down in Article 61, the competent authority, [...] the Agency, [...] **the competent authority [...] agreed upon** in accordance with Article 63(3), **or the competent authority in the reference Member State, as applicable**, shall **within 15 days** acknowledge receipt of a **valid** [...] application.
2. If the application is incomplete, the competent authority, [...] the Agency [...], [...] **the competent authority [...] agreed upon** in accordance with Article 63(3), **or the competent authority in the reference Member State, as applicable**, shall require the [...] **marketing authorisation holder [...] to provide the missing information and documentation** within a reasonable deadline.
3. The competent authority, [...] the Agency, [...] **the competent authority [...] agreed upon** in accordance with Article 63(3), **or the competent authority in the reference Member State, as applicable**, shall assess the application and prepare, **respectively, an assessment report or an opinion, in accordance with Article 28**, on the variation. **That assessment report or opinion shall be prepared** within 60 days following the receipt of a valid [...] application. [...] **In case the assessment of a variation application requires more time due to its complexity, the competent authority or the Agency may extend this time limit to 90 days. In such a case the competent authority or the Agency, as applicable, shall inform the marketing authorisation holder accordingly.**
4. Within the period referred to in paragraph 3, the competent authority or the Agency, **as applicable**, may require the [...] **marketing authorisation holder** to provide supplementary information within a set time limit. The procedure shall be suspended until the supplementary information has been provided.

5.——[...]

6. Where the opinion **referred to in paragraph 3** is prepared by the Agency, [...] **the Agency shall [...] forward [...] it to the Commission. [...] and to the marketing authorisation holder.**
- 6a. **Where the opinion referred to in paragraph 3 is prepared by the Agency in accordance with Article 63(2), the Agency shall forward it to all competent authorities in the relevant Member States, to the Commission and to the marketing authorisation holder.**
7. Where the [...] **assessment report referred to in paragraph 3** is prepared by **the [...]** competent authority [...] **agreed upon** in accordance with Article 63(3), **or by the competent authority in the reference Member State, [...]** it shall be forwarded to [...] **the competent authorities in all relevant Member States and to the marketing authorisation holder.**
- 7aa. **If a competent authority does not agree with the assessment report referred to in paragraph 7, the review procedure laid down in Article 49 shall apply.**
- 7a. **Subject to the outcome of the procedure provided for in paragraph 7aa, if applicable, the opinion or the assessment report referred to in paragraph 3 shall be forwarded to the marketing authorisation holder without delay.**
8. Within 15 days of receipt of the opinion **or the assessment report**, the [...] **marketing authorisation holder** may submit a written request to the **competent authority, the Agency, [...]** the competent authority **agreed upon in accordance with Article 63(3), or the competent authority in the reference Member State, as applicable**, for a re-examination of the opinion **or the assessment report**. Detailed grounds for requesting a re-examination shall be [...] **submitted to the competent authority, the Agency, [...]** to the competent authority **agreed upon in accordance with Article 63(3) or the competent authority in the reference Member State, as applicable**, within 60 days of receipt of the opinion **or the assessment report**.

9. Within 60 days of receipt of the grounds for the request, [...] the competent authority, **the Agency, the competent authority agreed upon in accordance with Article 63(3) or the competent authority in the reference Member State, as applicable**, shall re-examine the points of the opinion **or the assessment report** identified in the request for re-examination by the [...] **marketing authorisation holder** and adopt a re-examined opinion **or assessment report**. The reasons for the conclusions reached shall be annexed to the opinion **or the assessment report**.

#### *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 [...] **and of receiving the complete translations of the summary of the product characteristics, labelling and package leaflet from the marketing authorisation holder**, the competent authority, [...] the Commission **or the competent authorities in the Member States listed in accordance with Article 61(2)(d), as applicable**, shall amend the marketing authorisation or reject the variation **in line with the opinion or the assessment report referred to in Article 64** and inform the [...] **marketing authorisation holder** of the grounds for the rejection.[...].
2. **In case of a centralised marketing authorisation, the Commission shall prepare a draft decision to be taken in respect of the variation.** Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall [...] **provide** a detailed explanation of the reasons for not following the opinion of the Agency. **The decision amending the marketing authorisation or rejecting the variation shall be adopted by the Commission by means of implementing acts. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**

3. The competent authority or the [...] **Commission, as applicable**, shall notify the marketing authorisation holder of the amended marketing authorisation without delay.
4. The product database shall be updated accordingly **by the competent authority, the Commission, the Agency, or the competent authorities in the Member States listed in accordance with Article 61(2)(d), as applicable.**

*Article 66*

*Coordination group review*

[...]

*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, **as applicable**, has amended the decision granting the marketing authorisation in accordance with that variation, **has set a deadline for the implementation** and **has notified the marketing authorisation** [...] thereof **in accordance with Article 65(3).**
2. Where requested by a competent authority or the [...] **Commission**, a marketing authorisation holder shall supply, without delay, any information related to **the implementation of a variation** [...].

## Section 5

### Harmonisation of the summaries of [...] product characteristics for nationally authorised products

#### Article 68

*[...] Scope of the harmonisation [...] of summary of product characteristics of veterinary medicinal product*

[...] A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 **and Article 69a** for:

- (a) **reference** veterinary medicinal products [...], which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which [...] marketing authorisations have been granted **in accordance with Article 44** in different Member States [...] **for the same marketing authorisation holder.**
- (b) **generic and hybrid veterinary medicinal products.**

[...]

#### Article 69

*Procedure for harmonisation of summaries of product[...] characteristics **for the reference veterinary medicinal products***

1. [...] **The** competent authorities [...] shall **submit annually to** the coordination group [...] **a** list [...]of **reference veterinary medicinal products and their summary of products characteristics** [...] for which [...] marketing authorisation[...] has been granted [...] **in accordance with Article 44 if, according to the competent authority, they should be subject to the procedure for harmonization of their summaries of product characteristics.**

- 1a. The marketing authorisation holder may apply for the procedure of harmonisation of summaries of product characteristics for a reference veterinary medicinal product by submitting to the coordination group the list of different names of this veterinary medicinal product and the different summaries of product characteristics for which marketing authorisation has been granted in accordance with Article 44 in different Member States.**
- 1aa. The coordination group shall, taking into account the lists provided by the Member States in accordance with paragraph 1 or any application received from a marketing authorisation holder in accordance with paragraph 1a, draw up annually and publish a list of reference veterinary medicinal products which shall be subject to harmonisation of their summaries of product characteristics and shall appoint a reference Member State for each concerned reference veterinary medicinal product.**
- 1aaa. When drawing up this list, the coordination group may decide on prioritising its work on harmonisation of summaries of product characteristics, taking into account the recommendations of the Agency on class or group of reference veterinary medicinal products that shall be harmonised in order to protect human or animal health or the environment, including mitigation measures to prevent the risk for the environment.**
- 1b. Upon request by the competent authority in the reference Member State referred to in paragraph 1aa, the marketing authorisation holder shall provide the coordination group with a summary detailing the differences between the summaries of product characteristics, his proposal for a harmonised summary of product characteristics, package leaflet and labelling in accordance with Article 6a, supported by the appropriate existing data submitted in accordance with Article 7 relevant to the proposal for harmonisation in question.**

2. **[...] Within 180 days of receipt of the information referred to in paragraph 1b the competent authority in the reference Member State shall examine in consultation with the marketing authorisation holder, the documents submitted in accordance with paragraph 1b, prepare a report and submit it to the coordination group and to the marketing authorisation holder.**
3. **[...] After receipt of the report, if the coordination group agrees by consensus on the harmonised summary of product characteristics, the competent authority in the reference Member State shall record that there is an agreement, close the procedure, inform the marketing authorisation holder accordingly and transmit to him the harmonised summary of product characteristics.**
- 3a. **The marketing authorisation holder shall submit to the competent authorities in each relevant Member State the necessary translations of the summary of product characteristics, package leaflet and labelling in accordance with Article 6a, within the time limit set by the coordination group.**
4. **[...] Following agreement in accordance with paragraph 3, the competent authorities in each relevant Member State shall vary the marketing authorisation in conformity with the agreement within 30 days of the receipt of the documents referred to in paragraph 3a.**
- 4a. **The competent authority in the reference Member State shall take any appropriate initiatives in order to seek an agreement within the coordination group before the initiation of the procedure set out in paragraph 5.**
5. **[...] In the event of lack of consensus, following the efforts referred to in paragraph 4a, in favour of a harmonised summary of product characteristics, the procedure for a Union interest referral in accordance with Articles 85 to 87 shall apply accordingly.**

6. [...] In order to maintain the level of harmonisation of the summary of product characteristics achieved, any future variation of the concerned marketing authorisations shall follow the mutual recognition procedure.

7. [...]

#### *Article 69a*

#### *Procedure for harmonisation of summaries of product characteristics for generic and hybrid veterinary medicinal products*

1. When the procedure referred to in Article 69 has been closed and a harmonised summary of product characteristics for a reference veterinary medicinal product has been agreed, the marketing authorisation holders of generic veterinary medicinal products shall apply within 60 days of the decision by the competent authorities in each Member State and in accordance with Article 61 for the harmonisation of the following sections of the summary of product characteristics for the concerned generic veterinary medicinal products, as applicable:
  - (a) target species;
  - (b) clinical information referred to in Article 30(1)(c);
  - (c) the withdrawal period.
2. By way of derogation from paragraph 1, in case of a marketing authorisation for a hybrid veterinary medicinal product supported by additional pre-clinical studies and/or clinical trials, the relevant sections of the summary of product characteristics referred to in paragraph 1 shall not be considered to be subject to harmonisation.
3. The marketing authorisation holders of generic and hybrid veterinary medicinal products shall ensure that the summaries of products characteristics shall be essentially similar to that in the reference veterinary medicinal products.

*Article 70*

~~Harmonisation of summary of products characteristics following reassessment~~

[...]

**The list referred to in Article 69(1) shall not contain any reference veterinary medicinal product authorised before 1 October 2005, and which is identified as potentially harmful to the environment and has not been subject to an environmental risk assessment.**

**In such a case, the competent authority shall request the marketing authorization holder to update the relevant environmental safety documentation referred to in Article 7(1) (b), taking into account the review referred to in Article 149e, and the environmental risk assessment of generic veterinary medicinal products of such reference medicinal products, if applicable.**

*Article 71*

~~*Position of marketing authorization holder*~~

[...]

## Section 6

### Pharmacovigilance

#### *Article 72*

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

[...]

#### *Article 73*

#### *Union pharmacovigilance system*

1. Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a **Union pharmacovigilance** system to **carry out pharmacovigilance tasks with respect to** [...] the safety **and efficacy** of authorised veterinary medicinal products **in order to ensure continuous assessment of the benefit-risk balance** [...].
2. Competent authorities, the Agency and marketing authorisation holders shall **take the necessary measures** to make available [...] means [...] **to report and encourage reporting** of the following **suspected adverse** events [...]:
  - (a) any **unfavourable and unintended reaction** [...] in any animal to a veterinary [...] medicinal product [...];
  - (b) any observation of a lack of efficacy of a veterinary medicinal product following **its** administration to an animal, **whether** in accordance with the summary of product characteristics **or not**;
  - (c) any environmental incidents observed following **the** administration of a veterinary medicinal product to an animal;
  - ~~(d)~~ [...]
  - (e) any noxious **reaction** [...] in humans **exposed** to a veterinary medicinal product;
  - (f) any finding of **a pharmacologically** [...] active substance **or marker residue** in a [...] **product of animal origin** [...] exceeding the **maximum** levels of residues established in accordance with Regulation (EC) No 470/2009 **after the set withdrawal period has been observed**;

- (g) **any suspected transmission of an infectious agent via a veterinary medicinal product;**
- (h) **any unfavourable and unintended reaction in an animal to a medicinal product for human use.**

*Article 74*

*Union pharmacovigilance database*

1. The Agency shall, **in collaboration with Member States**, establish and maintain a Union database on pharmacovigilance **for the reporting and recording of suspected adverse events referred to in paragraph 2 of Article 73** [...] (the "pharmacovigilance database"), [...] **which shall also include the information on qualified person responsible for pharmacovigilance, the reference number(s) of the pharmacovigilance system master file, the results and outcomes of the signal management process and results of pharmacovigilance inspections in accordance with provisions of Article 128.**
- 1a. **The pharmacovigilance database and the product database referred to in Article 51 shall be interconnected.**
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 **is uploaded in** [...] the pharmacovigilance database [...] and made accessible in accordance with Article 75.
4. **The system shall be set-up as a data-processing network allowing transmission of data between Member States, the Commission, the Agency and the marketing authorisation holders to ensure that in the event of an alert related to pharmacovigilance data, options for risk management and any appropriate measures can be considered as referred to in Articles 130, 131 and 133.**

## 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 **with respect to data related to the veterinary medicinal products for which they hold a marketing authorisation and to other non-confidential data related to veterinary medicinal products for which they do not hold a marketing authorisation** to the extent necessary for them to comply with their pharmacovigilance responsibilities as specified in Article 77, **78 and 81**.
3. The general public shall have access to the pharmacovigilance database [...], **without changing the information** therein as regards the following information:
  - (a) **the number and, at the latest within two years from the date of application, the incidence** [...] of **suspected** adverse events reported each year, broken down by product, animal species and type of **suspected** adverse event;
  - (b) [...] **the results and outcomes referred to in Article 81(0) that arise from** [...] the signal management **process performed by the marketing authorisation holder** [...] for veterinary medicinal products [...] **or** groups of **veterinary medicinal** products.

## Article 76

### *Reporting and recording of suspected adverse events [...]*

1. Competent authorities shall record in the pharmacovigilance database all **suspected** adverse events which were reported to them [...] and that occurred in the territory of their Member State, within 30 days [...] **of** receipt of the **suspected** adverse event report.

2. Marketing authorisation holders shall record in the pharmacovigilance database all **suspected** adverse events which were reported to them [...] and that occurred within the Union or in a third country **or that have been published in the scientific literature** with regard to their authorised veterinary medicinal products, [...] without delay and no later than within 30 days [...] **of [...]** receipt of the **suspected** adverse event report.
- 2a. **The Agency may request the marketing authorisation holder for centrally authorised products, or for nationally authorised products in case they fall within the scope of a Union interest referral, to collect specific pharmacovigilance data additional to the data listed in Article 73(2) and to carry out post marketing surveillance studies. The Agency shall state in detail the reasons for the request, give an appropriate deadline and inform competent authorities thereof.**
3. Competent authorities [...] **may** request the marketing authorisation holder **for nationally authorised veterinary medicinal products** to collect [...] specific pharmacovigilance data, [...] **additional to the data [...] listed in Article 73(2) [...] and to carry out post marketing surveillance studies.** The **competent** authority shall state in detail the reasons for the request, **give an appropriate deadline** and inform other competent authorities and the Agency thereof.
4. [...]
5. [...]

#### *Article 77*

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

0. **Marketing authorisation holders shall establish and maintain a system for collecting, collating and evaluating information on the suspected adverse events concerning their authorised veterinary medicinal products enabling them to fulfil their pharmacovigilance responsibilities ('pharmacovigilance system').**

- 00. The marketing authorisation holder shall have in place one or more pharmacovigilance system master files describing in details the pharmacovigilance system with respect to his authorised veterinary medicinal products. For each veterinary medicinal product the marketing authorisation holder shall not have more than one pharmacovigilance system master file.**
- 000. The marketing authorisation holder shall have a local or regional representative for the purpose of receiving reports of suspected adverse events, able to communicate in the languages of the relevant Member States.**
- 1. The marketing authorisation holder shall be responsible for the pharmacovigilance of the veterinary medicinal product [...] for which he holds a marketing authorisation and shall continuously evaluate by appropriate means the benefit-risk balance of this veterinary medicinal product and if necessary, take appropriate measures.**
- 1a. The marketing authorisation holder shall comply with good pharmacovigilance practices for veterinary medicinal products.**
- 1b. The Commission shall, by means of implementing acts, adopt necessary measures on good pharmacovigilance practices for veterinary medicinal products and also on the format and content of the pharmacovigilance system master file and its summary.**

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

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 **designate** [...] one or more [...] qualified persons **to carry out the tasks provided for in Article 78** [...]. The **qualified** person(s) shall reside and operate in the Union. **The qualified person(s) shall be appropriately qualified and be permanently at the disposal of the marketing authorisation holder.** Only one **such** qualified person shall be designated [...] **for each** pharmacovigilance system master file.
4. [...] **The tasks of the qualified person responsible for pharmacovigilance listed in Article 78 may be** [...] contracted out to a third party **on the conditions set out in paragraph (3). In such cases** those arrangements shall be detailed in the contract **and included in the pharmacovigilance system master file.**
5. The marketing authorisation holder shall, based on **the assessment of the** pharmacovigilance data, and where necessary, [...] submit **without undue delay** [...] **an application for a variation** [...] to the terms of a marketing authorisation in accordance with Article 61.
6. The marketing authorisation holder shall not **make a public announcement** [...] **on pharmacovigilance** information [...] in relation to [...] **his** [...] veterinary medicinal products without giving prior **or simultaneous** notification of his intention to the competent authority **having granted the marketing authorisation or to the Agency, as applicable** [...].  
[...] **The marketing authorisation holder shall ensure that such public announcement** [...] is presented objectively and is not misleading.

Article 78

*Qualified person responsible for pharmacovigilance*

1. **The qualified person** responsible for pharmacovigilance as referred to in Article 77(3) shall [...] **ensure that** the following tasks **are carried out**:
  - (a) elaborating and maintaining **the pharmacovigilance system master file** [...];
  - (b) allocating reference numbers to the pharmacovigilance system master file and communicating the reference number of the pharmacovigilance **system** master file [...] to the [...] **pharmacovigilance** database **for each product**;
  - (c) notifying the competent authorities **and** [...] the Agency, **as applicable**, of the place where [...] **he/she** operates [...];
  - (d) establishing and maintaining a system which ensures that all **suspected** 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) **compiling** [...] the **suspected** adverse event reports referred to in paragraph 2 of Article 76, **evaluating them, where necessary**,
  - (f) [...] **and** record[...]ing **them** 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 [...];
  - (h) providing competent authorities or the Agency, **as applicable**, 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) [...] **applying the signal management process referred to in Article 81 and ensuring that any arrangements for the fulfilment of responsibilities referred to in paragraph 1 of Article 77 are in place**;

- (j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate **preventive or corrective** action plan is prepared, [...] implemented **and, where necessary, ensuring changes to the pharmacovigilance system master file**;
- (k) ensuring that all personnel **of the marketing authorisation holder** involved in the performance of pharmacovigilance activities receives continued training;
- (l) communicating any regulatory measure that is taken in a third country **and is related with pharmacovigilance data** [...] to the competent authorities and **to the Agency** within **21** [...] days of receipt of such information.

**2. The qualified person responsible for pharmacovigilance referred to in Article 77(3) shall be the contact point for the marketing authorisation holder regarding pharmacovigilance inspections.**

*Article 79*

*Pharmacovigilance responsibilities of the competent authorities and the Agency*

1. Competent authorities shall **lay down the necessary procedures to** evaluate [...] **the results and outcomes of signal management process recorded in the pharmacovigilance database in accordance with paragraph 00 of Article 81 as well as suspected** adverse events reported to them, [...] **consider options for risk management** and take [...] **any appropriate** measures referred to in Articles 130 [...], **131 and 133** concerning marketing authorisations [...].

~~2.~~—[...]

3. Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of **suspected** adverse events. The Agency [...] 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 **make publicly available** [...] all important information on adverse events relating to the use of a veterinary medicinal product. **This shall be done** in a timely manner [...] **by any** publicly available means of communication **with a prior or simultaneous notification to the marketing authorisation holder**.
5. Competent authorities shall verify by means of **controls and** inspections referred to in Articles 125 **and 128** that marketing authorisation holders comply with the requirements relating to pharmacovigilance laid down in this Section.
6. The Agency shall **lay down the necessary procedures to** evaluate [...] **suspected** adverse events **reported to it regarding** [...] centrally authorised veterinary medicinal products, [...] and recommend **risk management** measures to the Commission. The Commission shall take [...] **any appropriate** [...] measures referred to in Articles 130, **131, and 133** [...] concerning marketing authorisations [...].
7. **The competent authority or the Agency, as applicable, may at any time request the marketing authorisation holder to submit a copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit the copy at the latest seven days after receipt of the request.**

#### *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 [...] **competent authorities and** make that information public. [...]

*Article 81*

*Signal management process*

- 0. Marketing authorisation holders shall carry out signal management process for their veterinary medicinal products, if necessary taking into account sales data and other relevant pharmacovigilance data of which they can reasonably be expected to be aware of and which may be useful for the signal management process. This data may include scientific information gathered from scientific literature reviews.**
  
- 00. Where the outcome of signal management process identifies a change to the benefit-risk balance or a new risk, marketing authorisation holders shall notify it without delay and no later than within 30 days to the competent authorities or to the Agency, as applicable, and take the necessary action in accordance with paragraph 5 of Article 77.**

**All results and outcomes of signal management process, including a conclusion on the benefit-risk balance, and, if applicable, references to relevant scientific literature shall be recorded by the marketing authorisation holder in the pharmacovigilance database at least annually.**

**In the case of veterinary medicinal products referred to in Article 38(2)(c), the marketing authorisation holder shall record in the pharmacovigilance database all results and outcomes of signal management process, including a conclusion on the benefit-risk balance, and, if applicable, references to relevant scientific literature according to the frequency specified in the marketing authorisation.**

- 1. Competent authorities and the Agency [...] may decide to perform targeted signal management process for a given veterinary medicinal product or a group of veterinary medicinal products.**

2.—[...]

3. **For the purpose of paragraph 1**, the Agency and the coordination group shall [...] **share the tasks related to the targeted signal management process and shall jointly select for each veterinary medicinal product or group of veterinary medicinal products, a competent authority or the Agency [...] as responsible for [...] such targeted signal management** ('lead authority').
- 3a. **When selecting a competent authority or the Agency responsible for the targeted signal management process in accordance with paragraph 3, the Agency and the coordination group shall take into account the fair allocation of tasks and shall avoid duplication of work.**
4. [...]
5. Where [...] the competent authorities or the Commission, **as applicable, consider that follow-up action is necessary, they** shall take appropriate measures as referred to in Articles 130, 131 and 133 [...].

#### **Section 7**

#### **~~Re-examination of a marketing authorisation for a limited market and in exceptional circumstances~~**

##### *Article 82*

*~~Procedure for re-examination the marketing authorisation for a limited market~~*

[...]

##### *Article 83*

*~~Procedure for re-examination the marketing authorisation for a limited market~~*

[...]

## 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 [...], [...] **the marketing authorisation holder, [...] one or more competent authority in one or more Member States** 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.
  - 1a. **The marketing authorisation holder, the concerned competent authority or the Commission shall inform the other concerned parties accordingly.**
2. Upon request from the Agency, **competent authorities in the Member States** and marketing authorisation holders shall forward to the Agency all available information relating to the Union interest referral.
3. [...] **The Agency may limit the [...] referral provided for in paragraph 1** to specific parts of the terms of the marketing authorisation.

*Article 85*  
*Referral procedure*

1. The Agency shall publish **on its website** information [...] **that a referral has been** made in accordance with Article 84 [...], **and shall invite** interested parties [...] to provide comments.
2. The **Agency shall request the** Committee **referred to in Article 139 to** [...] consider the referred matter. **The Committee** [...] shall issue a reasoned opinion within [...] **120** days of [...] the matter [...] **being** 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 holders **concerned** 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 holders **concerned** 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. [...]
6. Within 15 days after its adoption **by the Committee**, the Agency shall forward the [...] opinion [...] to Member States, the Commission and the marketing authorisation holders **concerned**, together with an assessment report of the veterinary medicinal product and the reasons for its conclusions.

7. **Within 15 days after receipt of the opinion, the marketing authorisation holder may notify the Agency in writing of his intention to request a re-examination of the opinion. In that case, he shall forward to the Agency the detailed reasons for the request of examination within 60 days after receipt of the opinion.**
8. **Within 60 days following receipt of a request as referred to in paragraph 7, the Committee shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the assessment report referred to in paragraph 6 of this Article.**

*Article 86*

*Decision following the Union interest referral*

1. Within 15 days after receipt of the opinion referred to in Article 85(6) **and subject to the procedures referred to in paragraphs 7 and 8 of Article 85**, 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*

- [...] **3.** The Commission shall, by means of implementing acts, take a [...] 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 [...] **the** veterinary medicinal products [...] concerned by the referral.

[...] **4.** Where the veterinary medicinal products **concerned by the referral** have [...] been authorised in accordance with the national, mutual recognition or decentralised procedures, the decision referred to in paragraph [...] **3** shall be addressed to all Member States and communicated to the marketing authorisation holders **concerned** for information.

[...] **5. Competent authorities and marketing authorisation holders concerned** [...] shall take any necessary action with regard to the marketing authorisations for [...] **the** veterinary medicinal products concerned to comply with the decision within 30 days of its notification, unless a different period is foreseen in the decision. **Such action shall include, where appropriate, a request to the marketing authorisation holder to submit an application for a variation referred to in Article 61(1).**

[...] **6.** In case of centrally authorised veterinary medicinal products **concerned by the referral**, a decision as referred to in paragraph [...] **3** shall be addressed to the marketing authorisation holder **and communicated also to the Member States.**

**7. Nationally authorised veterinary medicinal products which have been subject to a referral procedure shall henceforth be transferred to a mutual recognition procedure.**

## **Chapter V**

### **Homeopathic veterinary medicinal products**

#### *Article 88*

#### *Homeopathic veterinary medicinal products*

1. [...] **Homeopathic veterinary medicinal products** that satisfy the [...] **conditions** set out in Article 89 [...] shall be registered in accordance with Article 90.

**1a. Homeopathic veterinary medicinal products that do not meet the conditions set out in Article 89 shall be subject to Article 5.**

~~2.~~ [...]

## Article 89

### *Registration of homeopathic veterinary medicinal products*

1. **A homeopathic veterinary medicinal product** that satisfies all of the following conditions shall be subject to a registration procedure:
  - (a) [...] **it** 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) [...] **it has** a sufficient degree of dilution to guarantee **its** the safety [...]; **and** [...] shall not contain more than one part per 10 000 of the mother tincture;
  - (c) **it has** no [...] therapeutic indication appearing **on its** the labelling [...] or in any information relating thereto.
  
2. [...] **Member States may lay down procedures for the registration of homeopathic veterinary medicinal products in addition to those laid down in this Chapter.**

## Article 90

### *Application [...] 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 [...] route of administration, pharmaceutical form 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 [...] use, 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 **homeopathic** veterinary medicinal products concerned;
- (e) copies of any registrations [...] obtained for the same **homeopathic** veterinary medicinal products in other Member States;
- (f) the text to appear on the **package leaflet**, outer packaging and immediate packaging of the **homeopathic** veterinary medicinal products to be registered;
- (g) data concerning the stability of the **homeopathic veterinary** medicinal product;
- (h) in the case of **homeopathic** veterinary medicinal products intended for food-producing [...] species, [...] **the active substances shall be those pharmacologically active substances allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.**

⊕ [...] ]

2. An application for registration may cover a series of **homeopathic veterinary** medicinal products **of the same pharmaceutical form and** derived from the same homeopathic stock or stocks.
3. [...] **The competent authority [...] may** determine the conditions under which the **registered** homeopathic veterinary medicinal products may be made available [...].
4. The procedure of [...] **registration of** a homeopathic veterinary medicinal product shall be completed within **90** [...] days after the submission of a valid application.
5. **A registration holder of homeopathic veterinary medicinal products shall be subject to the same obligations as a marketing authorisation holder in so far as the provisions apply to registered homeopathic veterinary medicinal products in accordance with Article 2c.**
6. **A registration for a homeopathic veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to registration holders.**

**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 [...]:
  - (a) to **manufacture** [...] veterinary medicinal products [...] **even if intended only for export**;
  - (b) to engage in any part of the process of **manufacturing** [...] a veterinary medicinal product or of bringing a veterinary medicinal product to its final state, including engaging in the processing, assembling, packaging **and repackaging**, labelling **and relabelling**, storing [...], sterilising, testing or releasing it [...] or supply as part of that process[...]; **or**
  - (c) **to import veterinary medicinal products.**
  
2. Notwithstanding paragraph 1, **Member States may decide that** a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation **of veterinary medicinal products**, where these processes are carried out solely for retail **directly to the public** in accordance with Articles 107 and 108.
  
- 2a. **Where paragraph 2 is applied, the package leaflet shall be given with each divided part and the batch number and expiry date shall be clearly indicated.**
  
3. The competent authorities shall record the manufacturing authorisations granted by them in the database on manufacturing [...] and wholesale distribution set up in accordance with Article 94.
  
4. Manufacturing authorisations shall be valid throughout the Union.

*Article 92*

*[...] Application for [...] manufacturing authorization*

1. **An application for a manufacturing authorization**[...] 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;
  - (aa) name and address of the applicant;**
  - (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 **imported** [...];
  - (d) **a statement to the effect that the applicant fulfils the requirements laid down in Articles 98 and 100.**

*Article 93*

*Procedure for granting of manufacturing authorisations*

1. Before granting a manufacturing authorisation, the competent authority shall carry out an inspection [...] of the manufacturing site [...].
2. [...] **A manufacturing** authorisation shall apply only to the manufacturing site [...] and the pharmaceutical forms specified in the application **referred to in Article 92.**
3. Member States shall lay down procedures for granting **or refusing** manufacturing authorisations. [...] **Such procedures shall not exceed 90 days from receipt by the competent authority of a manufacturing authorisation 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 **or revoked** until the additional data required has been submitted.<sup>8</sup>
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 **conditionally granted** manufacturing authorisation [...] **shall** be suspended **or revoked** if these requirements are not complied with.

#### *Article 94*

##### *Database on manufacturing [...]and wholesale distribution*

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 **manufacturing and wholesale distribution** database shall include information **regarding the granting, suspension or revocation by competent authorities of [...]** any manufacturing **authorisations**, [...] wholesale distribution authorisations, **certificates of good manufacturing practice**, and **registrations of manufacturers, importers and distributors of active substances [...]**.
- 3.—[...]
4. Competent authorities shall record in the manufacturing and wholesale distribution database information on **manufacturing and wholesale distribution** authorisations and certificates granted in accordance with Articles 93, **98a** and [...] 105 [...] together with information on[...] **importers, manufacturers and distributors of active substances registered in accordance with Article 98b**.

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<sup>8</sup> Will be moved as paragraph 1a in the final text.

5. The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications, **including the format for electronic submissions of data**, for the manufacturing and wholesale distribution database.
6. The Agency shall ensure that information reported to the **manufacturing and wholesale distribution** database is collated and made accessible and that the information is shared.

*Article 95*

*Access to the database on manufacturing authorisations*

[...] **7** The competent authorities shall have full access to the **manufacturing and wholesale distribution** database [...].

[...]

[...] **8.** The general public shall have access to information in the **manufacturing and wholesale distribution** database, **without changing the information therein.** [...]

*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 [...] **justified** cases, **including when an inspection is necessary**, this period of time may be extended by the competent authority to 90 days.
2. The application shall contain a description of the requested 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 **and may decide to perform an inspection**. The procedure shall be suspended until such time as the supplementary information has been provided.
4. The competent authority shall **assess the application**, 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 authorization for export and import~~*

[...]

*Article 98*

*Obligations of the manufacturing authorisation holders*

1. The holder of a manufacturing authorisation shall:
  - (a) have at his disposal suitable and sufficient premises, technical equipment and testing facilities, for the **activities** [...] stated in [...] **his** manufacturing authorisation;
  - (b) have at his disposal the services of at least one qualified person within the meaning of Article 100 **and ensure that the qualified person operates in compliance with that Article**;
  - (c) enable the qualified person referred to in Article 100 to carry out his duties, particularly by **providing access to all the necessary documents and premises, and by** placing at his disposal all the necessary technical equipment and testing facilities;
  - (d) [...] **give at least a 30 days prior notice to the competent authority before the replacement of the qualified person referred to in Article 100, or, if prior notice is not possible because the replacement is unexpected, inform the competent authority immediately**;

- (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,[...] in accordance with Article 99, **and samples of each batch;**
- (h) **only supply veterinary medicinal products to wholesale distributors of veterinary medicinal products;**
- (i) **inform the competent authority and the marketing authorisation holder immediately if he obtains information that veterinary medicinal products which come under the scope of his manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those veterinary medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale by means of information society services;**
- (j) **comply with good manufacturing practices for veterinary medicinal products and use as starting materials only active substances which have been manufactured in accordance with good manufacturing practices and distributed in accordance with good distribution practices for active substances;**
- (k) **verify that each manufacturer, distributor or importer within the Union from whom he obtains active substances is registered with the competent authority of the Member State in which he is established, in accordance with Article 98b;**
- (l) **perform audits based on a risk assessment on the manufacturer, distributor and importers from whom he obtains active substances.**

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

## *Article 98a*

### *Certificates of good manufacturing practice*

1. Within 90 days after an inspection [...], the competent authority shall issue a certificate of good manufacturing practice of the manufacturer **for the manufacturing site concerned** if the inspection establishes [...] that the manufacturer in question is [...] **in compliance** with the requirements as set out in this Regulation and [...] **with the implementing act adopted in accordance with Article 98(2)**.
- 2a. **If the outcome of the inspection as referred to in paragraph 1 is that the manufacturer does not comply with good manufacturing practice, the information shall be entered into the database for manufacturing and wholesale distribution referred to in Article 94.**
3. The conclusions reached following an inspection of a manufacturer shall be valid throughout the Union.
4. [...]
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. **Importers of veterinary medicinal products, before those products are supplied to the Union, shall ensure that the manufacturer established in a third country is in possession of a certificate of good manufacturing practice issued by a competent authority or there is an equivalent confirmation in case the third country is party of an arrangement concluded between the Union and the third country.**

*Article 98b*

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

- 1. Importers, manufacturers and distributors of active substances, used as starting materials in veterinary medicinal products, who are established in the Union, shall register their activity with the competent authority of the Member State in which they are established and shall comply with good manufacturing practice or good distribution practice, as applicable.**
  
- 2. The registration form shall include, at least, the following information:**
  - (i) name or corporate name and permanent address;**
  - (ii) the active substances which are to be imported, manufactured or distributed;**
  - (iii) particulars regarding the premises and the technical equipment.**
  
- 3. The persons referred to in paragraph 1 shall submit the registration form to the competent authority at least 60 days prior to the intended start of their activity or in the case of importers, manufacturers and distributors of active substances in operation before the date of application of this Regulation, 60 days after the date of application.**
  
- 4. The competent authority may, based on a risk assessment, decide to carry out an inspection. If the competent authority notifies within 60 days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the competent authority has notified that the activity may start. If within 60 days of the receipt of the registration form the competent authority has not notified that an inspection will be carried out, the activity may start. In such a case, the competent authority shall carry out the inspection and communicate to the person(s) referred to in paragraph 1 the results of the inspection within 60 days of the notification of its intention to carry out the inspection.**

5. **The persons referred to in paragraph 1 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed must be notified immediately.**
6. **Competent authorities shall enter the information provided in accordance with paragraph 2 of this Article and Article 131(b) in the manufacturing and wholesale distribution database referred to in Article 94.**
7. **This Article shall be without prejudice to Article 98a.**
8. **The Commission shall, by means of implementing acts, adopt measures on good distribution practices for active substances used as starting materials in veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**

*Article 99*

*Record keeping*

1. **The holder of a manufacturing authorisation shall record the following information [...] in respect of all veterinary medicinal products supplied by him [...]:**
  - (a) date of the transaction,
  - (b) name of the veterinary medicinal product, **and marketing authorisation number if applicable, as well as pharmaceutical form and strength, as appropriate,**
  - (c) quantity supplied,
  - (d) name and address of the recipient,
  - (e) batch number,
  - (f) **date of expiry.**

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

#### *Article 100*

##### *Qualified person **responsible for manufacturing and batch release***

1. The holder of a manufacturing authorisation shall have permanently [...] 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 **this** Article [...].
2. The qualified person shall [...] **hold a university degree in one or more of the following scientific disciplines: pharmacy, human medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology.** [...]
3. **The qualified person** shall have acquired [...] **practical** experience **over at least two years, in one or more undertakings which are authorised manufacturers, in the activities of quality assurance of medicinal products, of qualitative analysis of medicinal products, of quantitative analysis of active substances and the checking necessary to ensure the quality of veterinary medicinal products.**

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

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

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

*Article 101*

*Batch release of veterinary medicinal products*

[...] 6. [...] The qualified person **responsible** for manufacturing shall ensure that each batch of the veterinary medicinal products [...] **is manufactured in compliance with good manufacturing practice**, and tested in compliance with the terms of the marketing authorisation. **The qualified person for manufacturing shall draw up a control report to this effect. Such control report shall be valid throughout the Union.** [...].

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

[...]

[...] 8. The qualified person **responsible** 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 [...] **one year after the date of expiry of the batch or at least five years, whichever is the longer.**

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

[...] **10.** Where veterinary medicinal products are imported from third countries with which the Union has made arrangements regarding application of standards of good manufacturing practice at least equivalent to those laid down **in accordance with Article 98(2)** [...] and it is demonstrated that the tests referred to in paragraph [...] **6** have been carried out in the exporting country, the [...] **qualified person may draw up the control report referred to in paragraph 6 without the necessary tests referred to in paragraph 7 being carried out [...], unless the competent authority of the Member State of importation decides otherwise.**

*Article 102*

*Competent authorities' measures*

[...]

*Article 103*

*Certificates of veterinary medicinal product [...]*

1. Upon request of [...] **a** manufacturer or **an** exporter of veterinary medicinal products, or of the authorities of an importing third country, the competent authority [...] **or the Agency** shall certify that [...]:
  - (a) **the manufacturer** [...] holds a manufacturing authorisation; **or** [...],
  - (b) **the manufacturer** possesses a certificate of good manufacturing practice as referred to in Article [...] **98a; or,**
  - (c) **the veterinary medicinal product in question has been granted a marketing authorisation in that Member State, or in the case of a request to the Agency, that it has been granted a centralised marketing authorisation.**
  
2. When issuing such certificates, the competent authority **or the Agency** shall [...] **take into account the relevant prevailing administrative arrangements with regard to the content and format of such certificates.**

## Chapter VII

### Supply and use

#### Section 1

#### Wholesale distribution

##### *Article 104*

##### *Wholesale distribution authorisations [...]*

1. The wholesale distribution of veterinary medicinal products shall be subject to the holding of a wholesale distribution authorisation. [...]

**1a. The holders of a wholesale distribution authorisation shall be established in the Union.**

2. Wholesale distribution authorisations shall be valid throughout the Union.

3. **Member States may decide that** supplies of small quantities of veterinary medicinal products from one retailer to another **in the same Member State**, shall not be **subject to the requirement of holding a [...]** wholesale distribution **authorisation**.

**3a. By derogation from paragraph 1, a holder of a manufacturing authorisation shall not be required to hold a wholesale distribution authorisation for the veterinary medicinal products covered by the manufacturing authorisation.**

[...]

4. **The Commission shall, by means of implementing acts, adopt measures on good distribution practices for veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**

*Article 105*

*Application and procedures for [...] wholesale distribution authorisations*

1. An application for a wholesale distribution authorisation shall be submitted to the competent authority [...] **in the Member State where the site(s) of [...] the wholesale distributor is/are located.**

[...] **1a.** An applicant shall demonstrate in the application that he fulfils the following requirements:

- (a) has at his disposal technically competent staff and **in particular at least one person designated as responsible person, meeting the conditions provided for in national law;**
- (aa) **has** [...] 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 [...] **a plan guaranteeing effective implementation of any withdrawal or recall ordered by the competent authorities or the Commission or undertaken in cooperation with the manufacturer [...] or marketing authorisation holder of the veterinary medicinal product in question;**
- (c) has an appropriate record keeping system ensuring compliance with the requirements referred to in Article 105a;
- (d) **has a statement to the effect that he fulfils the requirements laid down in Article 105a.**

- 1b. Member States shall lay down procedures for granting, refusing, suspending, revoking or changing a wholesale distribution authorisation.**

2. The procedure for granting, **refusing, suspending, revoking or changing** [...] wholesale distribution authorisation shall not exceed 90 days from the date on which the competent authority receives [...] application **in accordance to national law**.
3. The competent authority shall inform the applicant of the outcome of the evaluation, grant, [...] refuse **or change** the wholesale distribution authorisation, and upload the relevant information of the authorisation in the manufacturing and wholesale distribution database **referred to in Article 94**.

#### **Article 105a**

##### **Obligations of wholesale distributors**

1. **Wholesale distributors shall obtain veterinary medicinal products only from holders of a manufacturing authorisation or from other holders of a wholesale distribution authorisation.**
2. **A wholesale distributor shall supply veterinary medicinal products only to persons permitted to carry out retail activities in a Member State in accordance with Article 107(1), other wholesale distributors of veterinary medicinal products and to other persons or entities in accordance with the national law.**
3. **The holder of a wholesale distribution authorisation shall have permanently at his disposal the services of at least one responsible person for wholesale distribution.**
4. **Wholesale distributors of a veterinary medicinal product shall, within the limits of their responsibility, ensure appropriate and continued supply of such veterinary medicinal product to persons authorised to supply veterinary medicinal products in accordance with Article 107(1), so that the needs for animal health in the Member State in question are covered.**

**5. A wholesale distributor shall comply with the good distribution practices for veterinary medicinal products as referred to in Article 104(6).**

**5a. Wholesale distributors shall immediately inform the competent authority and, where applicable, the marketing authorisation holder, of veterinary medicinal products they receive or are offered which they identify as falsified or suspected to be falsified.**

*Article 106*

*Record-keeping requirements for wholesale distributors*

[...]6. The wholesale distributor shall keep detailed records **of at least** the following [...] information [...] in respect of each [...] transaction:

- (a) date of the transaction;
- (b) name of the veterinary medicinal product **including pharmaceutical form and strength, as appropriate;**
- (c) batch number[...];
- (d) expiry date of the veterinary medicinal product;
- (e) quantity received or supplied, **stating pack size and number of packs;**
- (f) name and address of the supplier in the event of purchase or of the recipient in the event of sale.

[...]7. 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 **veterinary** 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 [...] **five** years.

*Article 106a*

*Parallel trade in veterinary medicinal products*

- 1. For the purpose of parallel trade in veterinary medicinal products, the wholesale distributor shall ensure that the veterinary medicinal product he intends to source from a Member State ('source Member State') and distribute in another ('destination Member State') share a common origin with the veterinary medicinal product already authorised in the destination Member State. The veterinary medicinal products are is considered as sharing a common origin if they fulfill the following conditions:**
  - (a) they have the same qualitative and quantitative composition in terms of active substances and excipients, and;**
  - (aa) they have the same pharmaceutical form, and;**
  - (b) they have the same clinical information and, if applicable, withdrawal period; and,**
  - (bb) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation;**
- 1a. The veterinary medicinal product obtained from a source Member State shall comply with the labelling and language requirements of the destination Member State.**
- 2. Competent authorities shall lay down administrative procedures for the parallel trade in veterinary medicinal products and administrative procedure for the approval of the application for parallel trade in such products.**
- 3. Competent authorities of the destination Member State shall make public the list of veterinary medicinal products that are parallel traded in that Member State, in the product database as referred to in Article 51.**

- 4. A wholesale distributor who is not the marketing authorisation holder shall notify the marketing authorisation holder and the competent authority of the source Member State of his intention to parallel trade the veterinary medicinal product to a destination Member State.**
  
- 5. A wholesale distributor intending to parallel trade a veterinary medicinal product to a destination Member State shall comply with at least the following obligations:**
  - (a) submit a declaration to the competent authority in the destination Member State and take appropriate measures to ensure that the wholesale distributor in the source Member State will keep him informed of any pharmacovigilance issues;**
  - (b) notify the marketing authorisation holder in the destination Member State about the veterinary medicinal product to be procured from the source Member State and intended to be placed on the market in the destination Member State at least one month prior to submitting to the competent authority the application for parallel trade of that veterinary medicinal product;**
  - (c) submit a written declaration to the competent authority of the destination Member State that he has notified the marketing authorisation holder in the destination Member State in accordance with point (b) together with a copy of that notification;**
  - (d) not trade a veterinary medicinal product which has been recalled from the market of the source Member State or destination Member State for quality, safety or efficacy reasons.**
  - (e) collect suspected adverse events and report them to the marketing authorisation holder of the parallel traded veterinary medicinal product.**

6. **The following information shall be attached to the list referred to in paragraph 3 in respect of all veterinary medicinal products:**
- (a) **name of the veterinary medicinal product(s);**
  - (b) **active substance(s);**
  - (c) **pharmaceutical form(s);**
  - (d) **classification of the veterinary medicinal product(s) in the destination Member State;**
  - (e) **marketing authorisation number of the veterinary medicinal product(s) in the Member State from where it is sourced;**
  - (f) **marketing authorisation number of the veterinary medicinal product(s) in the Member State of destination;**
  - (g) **name and address of the wholesale distributor in the source Member State and of the wholesale distributor in the destination Member State.**
7. **This Article shall not apply to centrally authorised veterinary medicinal products.**

## **Section 2**

### **Retail**

#### *Article 107*

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

1. **The rules on [...] retail of veterinary medicinal products shall be determined [...] by [...] national law, unless otherwise provided in this Regulation.**
- 1b. **Without prejudice to Article 104(3), retailers of veterinary medicinal products shall obtain veterinary medicinal products only from holders of a wholesale distribution authorisation.**
- ~~2.~~ [...]

3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each **transaction** [...] of veterinary medicinal products **requiring a veterinary prescription under Article 29**:
  - (a) date of the transaction;
  - (b) name of the veterinary medicinal product **including pharmaceutical form and strength, as appropriate**;
  - (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 [...] **contact details** of the prescribing veterinarian and a copy of the **veterinary prescription, where appropriate** [...].
  - (g) **marketing authorisation number**.
- 3a. **Where Member States consider it necessary, they may require retailers to keep detailed records of any transaction of veterinary medicinal products not subject to veterinary prescription.**
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 **results of the detailed audit and the records referred to in paragraph 3** shall be available for inspection by the competent authorities in accordance with Article 125 for a period of [...] **five** years.
5. **Member States may impose conditions justified on grounds of protection of public health, animal health or of environment for the retail on their territory of veterinary medicinal products provided that such conditions comply with Union law, are proportionate and non-discriminatory.**

*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>9</sup> to natural or legal persons established in the Union [...] **provided that these veterinary medicinal products are not subject to a veterinary prescription pursuant to Article 29 and that they comply with this Regulation and applicable legislation of the Member State where the veterinary products are retailed. [...]**
- 1a. **By way of derogation from paragraph 1, a Member State may allow persons permitted to supply veterinary medicinal products in accordance with Article 107(1) to offer veterinary medicinal products subject to a veterinary prescription pursuant to Article 29 by means of information society services, provided that the Member State has provided a secure system for such supplies. Such permission shall only be granted to persons established in their territory and supply shall only occur within the territory of that Member State.**
- 1aa. **That Member State shall ensure that adapted measures are in place in order to guarantee that the requirements relating to a veterinary prescription are respected as regards supply by means of information society services and shall notify the Commission and other Member States if it makes use of the derogation referred to in paragraph 1a and shall, when necessary, cooperate with the Commission and other Member States to avoid any unintended consequences of such supply. The Member States shall establish rules on appropriate penalties to ensure that the national rules adopted are respected, including rules on the withdrawal of such permissions.**

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<sup>9</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). Delegations are invited to note that Directive 98/34 has been repealed and replaced by Directive 2015/1535.

- 1b. The persons and activities referred to in paragraph 1 and paragraph 1a shall be subject to the controls referred to in Article 125 by the competent authority of the Member State where the retailer is established.**
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>10</sup>, **retailers** [...] offering veterinary medicinal products **by means of information society services** shall **provide** [...] at least **the following information**:
- (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 [...] of veterinary medicinal products and containing a hyperlink to the entry of the retailer in the list of [...] **permitted** 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 [...] 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 **referred to in paragraph 3** by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

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<sup>10</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).

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 [...] by means of information society services, **in accordance with paragraphs 1 and 1a**, 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 [...] **permitted** to offer veterinary medicinal products for sale at a distance [...] by means of information society services in accordance with paragraphs 1 **and 1a** as well as the website addresses of those retailers.

[...]

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 [...] **permitted** to offer veterinary medicinal products for sale at a distance [...] 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 **veterinary** medicinal products offered for sale at a distance [...] by means of information society services.
8. **The websites set up by Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 6.**

*Article 109*

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

[...]

*Article 110*

*Veterinary prescriptions*

- 00. A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian.**
  
- 000. The veterinarian shall be able to provide justification for a veterinary prescription of antimicrobial medicinal products, in particular for metaphylaxis and for prophylaxis.**
  
- 0. A veterinary prescription shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.**
  
- 1a. By way of derogation from Article 4(24) and paragraph 0 of this Article, a Member State may allow that a veterinary prescription is issued by a professional person, other than a veterinarian, qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall exclude prescription of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary and shall be valid only in that Member State.**

**Paragraphs 1, 3, 5, 6 and 8 shall apply, mutatis mutandis, to such prescriptions.**

1. A veterinary prescription shall contain at least the following elements [...]:
  - (a) identification of the animal **or groups of animals to be treated** [...];
  - (b) full name and contact details of the animal owner or keeper;
  - (c) issue date;
  - (d) full name and contact details [...] of the [...] **veterinarian** [...] **including, if available, the professional number**;
  - (e) signature or an equivalent electronic form of identification of **the veterinarian** [...];
  - (f) name of the prescribed **medicinal** product, **including its active substance(s)**;
  - (g) pharmaceutical form **and strength** [...];
  - (h) quantity **prescribed, or the number of packs, including pack size**;
  - (i) [...]
  - (j) dosage regimen;
  - (k) **for food producing species**, withdrawal period **even if zero days** [...];
  - (l) any [...] warnings **necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials**;
  - (m) if a product is prescribed [...] **under the provisions of Articles 115, 116 and 116a**, a statement to that effect;
  - (n) **if a product is prescribed under the provisions of Article 111a paragraphs 2 and 3, a statement to that effect.**
2. [...]
3. [...]The quantity prescribed [...] shall be **limited** [...] to the amount required for the treatment or therapy concerned. **As regards antimicrobial medicinal products for metaphylaxis or prophylaxis such products shall be prescribed only for a limited duration to cover the period of risk.**
4. Veterinary prescriptions **issued in accordance with paragraph 0** shall be recognised throughout the Union [...].

- 5. The Commission may, by means of implementing acts, set a model format for the requirements set in paragraph 1, which model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
- 6. The medicinal product prescribed shall be supplied in accordance with applicable national law.**
- 7. A veterinary prescription for antimicrobial medicinal products shall be valid for 5 days from the date of issuing.**
- 8. In addition to the requirements set out in this Article, Member States may lay down rules on record keeping for veterinarians when issuing veterinary prescriptions.**
- 9. Notwithstanding Article 29, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered by a veterinarian himself without a veterinary prescription, unless otherwise provided for under applicable national law. The veterinarian shall keep records in accordance with applicable national law.**

### Section 3

#### Use

#### Article 111

#### *Use of [...] medicinal products*

1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.
- 1a. **The use of veterinary medicinal products in accordance with this Section shall be without prejudice to Articles 46 and 47 of Regulation (EU) 2016/429<sup>11</sup>.**
2. Member States [...] **may lay down [...] any procedures they deem necessary for the [...] implementation [...] of Articles 113, 114, 115, 116, 116a and 119 [...].**
3. **Member States may, if duly justified, decide that a veterinary medicinal product shall be administered by a veterinarian only.**
4. **Inactivated immunological veterinary medicinal products referred to in Article 2(2a) shall only be used in those animals in exceptional circumstances, in accordance with a veterinary prescription, and if no immunological veterinary medicinal product is authorised for the target animal species and the indication.**
5. **The Commission shall adopt delegated acts, in accordance with Article 146, supplementing the provisions of this Article, as necessary, concerning the establishment of rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via other routes than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food producing animals. The Commission shall take into account the scientific advice of the Agency, when adopting those delegated acts.**

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<sup>11</sup> Regulation (EU) No 429/2016 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L84, 31.3.2016, p.1).

*Article 111a*

*Use of antimicrobial medicinal products*

- 1. Antimicrobial medicinal products shall not be applied routinely nor used to compensate for poor hygiene, or inadequate animal husbandry or lack of care or to compensate for poor farm management.**
- 1a. Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth or increase yield.**
- 2. Antimicrobial medicinal products shall not be used for prophylaxis unless, in exceptional cases for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe. In such cases the use of antibiotic medicinal products for prophylaxis shall be limited to the administration to individual animal only, under the conditions laid down in the first sentence.**
- 3. Antimicrobial medicinal products shall be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available. Member States may provide guidance regarding the other appropriate alternatives referred to in this paragraph and shall actively support the development and application of guidelines which promote the understanding of risk factors associated with metaphylaxis and include criteria for its initiation.**
- 4. The designated antimicrobials referred to in Article 32(4) shall not be used in accordance with Articles 115, 116 and 116a.**

- 5. The Commission may, by means of implementing acts, and taking into consideration scientific advice of the Agency, establish a list of antimicrobials which:**
- (a) shall not be used in accordance with Articles 115, 116 and 116a, or**
  - (b) shall only be used in accordance with Articles 115, 116 and 116a subject to certain conditions.**

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

- (a) risks to animal or public health if the antimicrobials is used in accordance with Articles 115, 116 and 116a;**
- (b) risk for animal or public 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.**

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

- 6. A Member State may further restrict or prohibit the use of certain antimicrobials in animals on its territory if the administration of such products to animals is contrary to the implementation of a national policy on prudent use of antimicrobials.**
- 7. Measures adopted on the basis of paragraph (6) shall be proportionate and justified.**
- 8. The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph (6).**

## 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 [...] medicinal products they use and, if applicable, a copy of the veterinary prescription.
2. [...] **Records referred to in paragraph 1 shall include:**
  - (a) date of [...] **first administration** of the [...] medicinal product to the animals;
  - (b) name of the [...] medicinal product;
  - (c) quantity of the [...] medicinal product administered;
  - (d) name and address of the supplier;
  - (d0) evidence of acquisition;**
  - (e) identification of the animal[...] **or group of animals** treated;
  - (f) name and [...] **contact details** of the prescribing veterinarian, **if applicable** [...];
  - (g) withdrawal period even if zero days;**
  - (h) duration of treatment.**
- 2a. **If the information to be recorded in accordance with paragraph 2 is already available on the copy of veterinary prescription, in a record kept on the farm or for equine animals recorded in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429, it does not need to be recorded separately.**
- 2b. **Member States may lay down additional requirements for record-keeping by owners and keepers of food producing animals.**
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 [...] **five** years.

### *Article 112b*

#### *Record keeping obligations for equine animals*

1. **The Commission shall adopt delegated acts in accordance with Article 146 supplementing this Regulation concerning the content and format of the information necessary to apply Articles 115(3) and 117(5) to be contained in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429.**
2. **The Commission shall adopt implementing acts, laying down model forms to enter the information necessary to apply Articles 115(3) and 117(5) to be contained in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**

### *Article 113*

#### *Use of immunological[...] veterinary medicinal products*

1. [...] The competent authorities may, in accordance with **the applicable national law** [...], prohibit the manufacture, import, **distribution, possession**, sale, supply and/or use of immunological veterinary medicinal products on [...] 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 [...] **disease** in live animals or **contamination of** [...] foodstuffs or other products obtained from treated animals;
  - (c) the **strain(s) of disease agents** to which the product is intended to confer immunity is largely absent **in terms of geographic spread** from the territory concerned.

2. [...] **By way of derogation from Article 111(1), and in the absence of a product as referred to in Article 119, in the event of an outbreak of a listed diseases as referred to in Article 5 of Regulation (EU) No 429/2016 or an emerging disease as referred to in Article 6 of that Regulation, a competent authority may allow, the use of an immunological veterinary medicinal product not authorised within the Union.**
- 2a. **By way of derogation from Article 111(1), when immunological veterinary medicinal product has been authorised but is no longer available within the Union for a disease which is not referred to in Article 5 or Article 6 of Regulation (EU) No 429/2016 but which is already present in the Union, a competent authority may, in the interest of animal health, welfare and public health, allow the use of an immunological veterinary medicinal product not authorised within the Union on a case by case basis.**
3. **The competent authorities shall inform the Commission without delay when the provisions of paragraph 1, 2 and 2a are applied, together with information on the conditions imposed in the implementation of those provisions.**
4. **If an animal is being exported to a third country and is thereby subject to specific binding health rules in that third country, a competent authority may permit the use, solely 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 its use is allowed in the third country to where the animal is to be exported.**

*Article 114*

*[...]Use of veterinary medicinal products by veterinarians providing services in other  
Member States*

1. A veterinarian providing services in a 'host Member State' (a Member State other than the one where he is established) [...] **shall be allowed to [...] possess and [...] treat animals with** veterinary medicinal products **which are not** authorised in that[...] host Member State to animals **or groups of animals** [...] which are under his care in the [...] **necessary quantity not exceeding the amount** required for the treatment **prescribed by the veterinarian provided that the following conditions are fulfilled:**
  - (a) **a [...] marketing** authorisation [...] **for** the veterinary medicinal product **to be administered to the animals has been granted** [...] by the competent authorities of the [...] Member State **in which the veterinarian is established** or by the Commission;
  - (b) the **concerned** veterinary medicinal products are transported by the veterinarian in their original packaging;
  - ~~(c)~~—[...]
  - (d) the veterinarian follows the good veterinary practices applied in that **host** Member State [...];
  - (dd) the veterinarian sets the withdrawal period specified on the labelling or package leaflet of the veterinary medicinal product used;**
  - (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 [...].
  - ~~(f)~~ [...]
2. Paragraph 1 shall not apply to immunological veterinary medicinal products [...] **except in case of toxins and sera.**

*Article 115*

*Use of medicinal products [...] outside the terms of the marketing authorisation in non food-producing species [...]*

1. By way of derogation from Article 111(1), where there is no authorised veterinary medicinal product in a Member State for an **indication concerning** a non-food producing [...] **species**, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally-treat the animals concerned with the following:
  - (a) **a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use in the same species or another species for the same indication or for another indication;**  
[...]
  - (b) **if there is no product as referred to in point (a), a medicinal product for human use authorised in accordance with Directive 2001/83/EC of the European Parliament and of the Council<sup>12</sup> or Regulation (EC) No 726/2004;**
  - (c) **if there is no product as referred to in points (a) and (b), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.**
- 1a. **Except as regards immunological veterinary medicinal products, in case there is no medicinal product available as referred to in paragraph 1 the veterinarian responsible may under his/her direct responsibility and in particular to avoid causing unacceptable suffering exceptionally treat a non-food producing animal with a veterinary medicinal product authorised in a third country for the same animal species and same indication.**

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<sup>12</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. The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, **in accordance with the national provisions.**
3. [...] **This Article shall also apply to the treatment by a veterinarian of an animal belonging to the [...] equine species provided that it [...] is declared [...] as not being intended for slaughter for human consumption in the single lifetime identification document referred to in Article 114(1) of Regulation (EU) No 2016/429.**
4. **This Article shall apply also when an authorised veterinary medicinal product is not available in the Member State concerned.**

#### *Article 116*

*Use of medicinal products [...] outside the terms of the marketing authorisation in food-producing [...] terrestrial species*

1. By way of derogation from Article 111(1), where there is no authorised veterinary medicinal product in a Member State for an **indication [...] concerning a food-producing terrestrial [...] species**, the veterinarian responsible may, under his/**her** direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with [...] the following:
  - (a) a veterinary medicinal product authorised under this Regulation in the Member State concerned [...] **or in another Member State for use in the same or in another food-producing terrestrial species for the same indication, or for another indication;**
  - (b) [...] **if there is no product as referred to in point (a), a veterinary medicinal product authorised under this Regulation in the Member State concerned for use in a non-food producing species for the same indication;**

- (c) **if there is no product as referred to in points (a) or (b)[...],** a medicinal product for human use authorised [...] 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 points (a), (b), [...] or (c),** a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription [...].

[...]

**4a. Except as regards immunological veterinary medicinal products, in case there is no medicinal product available as referred to in paragraph 1, the veterinarian responsible may under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food producing terrestrial animals with a veterinary medicinal product authorised in a third country for the same species and same indication.**

**5. The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, in accordance with the national provisions.**

6. Pharmacologically active substances [...] included in the medicinal product used in accordance with paragraphs 0, 1 **and 4a** shall be [...] **allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.**

[...]

8. [...] **This Article shall apply also when an authorised veterinary medicinal product is not available in the Member State concerned.**

*Article 116a*

*Use of veterinary medicinal products for food producing aquatic species*

- 1. By way of derogation from Article 111(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning 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 the following:**
  - (a) veterinary medicinal products authorised under this Regulation in the same Member State or in another Member State for use in the same species or in another food-producing aquatic species and for the same indication or for another indication; or,**
  - (b) if there is no product as referred to in point (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 terrestrial species containing a substance present in the list established in accordance with paragraph 3; or,**
  - (c) if there is no product as referred to in points (a) and (b), a medicinal product for human use authorised in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004 and containing substances present in the list established in accordance with paragraph 3; or,**
  - (d) if there is no product as referred to in points (a), (b) or (c), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.**

- 2. By way of derogation from paragraphs 1 (b) and (c), until the list referred to in paragraph 3 is established, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing aquatic species of 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 terrestrial species;**
  - (b) if there is no product as referred to in point (a), a medicinal product for human use authorised in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004.**
- 3. The Commission shall, by means of implementing acts, at the latest within five years from the date referred to in the second paragraph of Article 150, establish a list of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial species or substances contained in a medicinal product for human use authorised in the Union in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004, which may be used in food-producing 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 the food-producing aquatic species are treated with these substances;**
  - (b) impact on animal and public health if the food-producing aquatic species affected cannot receive an antimicrobial listed in accordance with Article 111a(5);**
  - (c) availability or lack of availability of other medicines, treatments or measures for prevention or treatment of diseases or certain indications in food-producing aquatic species.**

4. **Except as regards immunological veterinary medicinal products, in case there is no medicinal product available as referred to in paragraph 1 and 2, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food producing aquatic species with a veterinary medicinal product authorised in a third country for the same species and same indication.**
- 4a. **The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, in accordance with the national provisions.**
5. **Pharmacologically active substances included in the medicinal product used in accordance with paragraphs 0, 1, 2 and 4 shall be allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.**
6. **This Article shall apply also when an authorised veterinary medicinal product is not available in the Member State concerned.**

*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 **and 116a**, unless a product used has a withdrawal period provided in its summary of the product characteristics for the **animal** species in question, a withdrawal period shall be set by the veterinarian in accordance with the following criteria:

- (a) for meat and offal **from** [...] food producing mammals and **poultry and farmed game** birds not less than:
  - (i) the longest withdrawal period provided in its summary of the product characteristics for [...] **meat and offal** multiplied by factor 1,5;
  - (ii) if the product is not authorised for food producing [...] **animals**, 28 days;
  - (iii) one day, if the product has a zero days withdrawal period and it is used in a different animal family than the one authorised.**
- (b) for **milk from** animals [...] producing milk for human consumption not less than:
  - (i) the longest withdrawal period **for milk** provided in the summary of the product characteristics for any **animal** [...] multiplied by factor 1.5;
  - (ii) if the product is not authorised for [...] **animals producing milk for human consumption**, 7 days;
  - (iii) one day, if the product has a zero days withdrawal period.**
- (c) for **eggs from** animals [...] producing eggs for human consumption not less than:
  - (i) the longest withdrawal period **for eggs** provided in the summary of the product characteristics for **any animal** [...] multiplied by factor 1.5;
  - (ii) if the product is not authorised for [...] **animals producing eggs for human consumption** [...] **10** days;
- (d) for aquatic **species** [...] **producing meat** 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 **1.5** [...] and expressed as [...] ('degree-days'). [...]
  - ~~(ii)~~ [...]
  - (iii) if the product is authorised for food producing terrestrial animals, the longest withdrawal period for any of the food producing animals indicated in the summary of product characteristics multiplied by a factor of 50 and expressed as degree days, but not exceeding 500 degree-days;**
  - (iv) if the product is not authorised for food producing species, 500 degree-days;**
  - (v) 25 degree days if the highest withdrawal period for any animal species is zero days.**

- 1a. **If, on calculation of the withdrawal period according to paragraph 1 subparagraphs (a)(i), (b)(i), (c)(i),d(i) and (d)(iii) result in a fraction of days, the withdrawal period shall be rounded up to the nearest number of days.**
2. The Commission **is** [...] empowered to adopt delegated acts in accordance with Article 146 in order to amend the rules laid down in paragraph 1 **and 3** 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 **and in particular risk of residue in honey or in any other foodstuffs harvested from beehive(s) intended for human consumption.**
4. [...]
5. By way of derogation from paragraph 1 **and paragraph 6 of Article 116**, the Commission shall, **by means of implementing acts**, establish a list of substances [...];  
[...] which are essential for the treatment of **equine species** [...], or which bring added clinical benefit compared to other treatment options available for **equine species** [...];  
[...]for which [...] the withdrawal period [...] for **equine species** [...] shall [...] be [...] six months [...].

*Article 118*

~~*Use of antimicrobial veterinary medicinal products for species or indications outside the terms of the marketing authorization*~~

[...]

*Article 119*

*Health situation [...]*

[...] By way of derogation from Article 111(1), 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.

[...]

*Article 120*

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

[...]

*Article 121*

*Use of immunologicals for third countries*

[...]

*Article 122*

*Collection and disposal of [...] waste of veterinary medicinal products*

Member States shall ensure that appropriate [...] systems are in place for **the collection and disposal of waste of** veterinary medicinal products [...].

## *Article 122a*

### *Animals or products of animal origin imported into the Union*

1. **The provisions of Article 111a(1a) shall apply, mutatis mutandis, to operators in third countries and they shall not use the designated antimicrobials referred to in Article 32(4), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.**
2. **The Commission shall adopt delegated acts in accordance with Article 146 supplementing this Article in order to provide the necessary detailed rules on the application of paragraph 1.**

## **Section 4**

### **Advertising**

#### *Article 123*

##### *Advertising of veterinary medicinal products*

0. **Only veterinary medicinal products that are authorised or registered in a Member State may be advertised in that Member State, unless otherwise decided by the competent authority in accordance with the applicable national law.**
1. The advertising of a veterinary medicinal product shall make it clear that it aims at promoting the [...] **supply, sale, prescription, distribution** or use of the veterinary medicinal product.
  - 1a. **The advertising shall not be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide.**
2. The advertising shall [...] **comply with the summary of the product characteristics of the advertised veterinary medicinal product** [...].

- 2a. [...] **The advertising** shall not include information in any form which could be misleading or lead to [...] **incorrect use** of the veterinary medicinal product.
- 2b. **The advertising shall encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties.**
3. **The suspension of a marketing authorisation shall preclude the advertising of the veterinary medicinal product in the Member State where it is suspended during the period of suspension.**
4. **Veterinary medicinal products shall not be distributed for promotional purposes except for small quantities of samples.**
5. **Antimicrobial veterinary medicinal products shall not be distributed for promotional purposes as samples or in any other presentation.**
6. **The samples referred to in paragraph 5 shall be appropriately labelled indicating that they are samples and given directly to veterinarians or other persons allowed to supply during sponsored events or by sales representatives during their visits.**

*Article 124*

*[...] Advertising of veterinary medicinal products subject to veterinary prescription*

1. The advertising of [...] veterinary medicinal products [...] **that are subject to veterinary prescription in accordance with Article 29 shall be allowed only when made exclusively to the following persons:**
  - (a) [...] veterinarians;
  - (b) [...] persons permitted to supply veterinary medicinal products in accordance with the national legislation.
  
2. [...] **By way of derogation from paragraph 1, advertising of veterinary medicinal products subject to veterinary prescription in accordance with Article 29 to professional keepers of animals may be permitted by the Member State provided the following conditions are fulfilled:**
  - (a) the advertising is limited to immunological veterinary medicinal products;
  - (b) the advertising includes an express invitation to the professional keepers of animal to consult the veterinarian about the immunological veterinary medicinal product.
  
3. **Notwithstanding the provisions of paragraphs 1 and 2 the advertising of inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of animals in a unit having a confirmed epidemiological link shall be prohibited to all persons.**

*Article 124a*

*Promotion of medicinal products used in animals*

- 1. Where medicinal products are being promoted to persons qualified to prescribe or supply them in accordance with this Regulation, no gifts, pecuniary advantages or benefit in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of prescription or supply of medicinal products.**
- 2. Persons qualified to prescribe or supply medicinal products as referred to in paragraph 1 shall not solicit or accept any inducement prohibited under that paragraph.**
- 3. Paragraph 1 shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality shall always be strictly limited to those main objectives of the event.**
- 4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3.**

*Article 124b*

*Implementation of advertising provisions*

**Member States may lay down any procedures they deem necessary for the implementation of Articles 123, 124 and 124a.**

**Chapter VIII**  
**Inspections and controls**

*Article 125*

*Controls*

1. Competent authorities shall [...] **carry out** controls of **the following persons**:
  - manufacturers **and** importers of **veterinary medicinal products and active substances**;
  - **distributors of active substances**;
  - marketing authorisation holders;
  - **holders of a wholesale [...] distribution authorisation**;
  - **retailers [...]**;
  - **owners and keepers of food-producing animals**;
  - **veterinarians**;
  - **holders of a registration for homeopathic veterinary medicinal products**;
  - **holders of veterinary medicinal products authorised in accordance with Article 5(6)**; and,
  - **any other persons having obligations under this Regulation.**
  
- 1a. **The controls referred to in paragraph 1 shall be carried out** regularly, on a risk-basis, in order to verify that **the persons referred to in paragraph 1 comply with the provisions of [...]** this Regulation [...].

2. The risk-based controls referred to in paragraph 1a shall be carried out by the competent authorities taking account of **at least**:
  - (a) the **intrinsic risks** [...] associated with the activities of the [...] **persons referred to in paragraph 1** and the location of their activities,
  - (b) the [...] **past record of the persons referred to paragraph 1** [...] as regards the results of [...] **controls** performed on them and their **previous** compliance [...],
  - (c) any information that might indicate non-compliance [...],
  - (d) the potential impact of non-compliance [...] on public health, animal health, **animal welfare** and the environment.
  
3. [...] **Controls** may also be carried out upon request of [...] **a competent authority of another Member State**, the Commission or the Agency.
  
4. [...] **Controls** shall be carried out by [...] representatives of the competent authority. [...]
  
- 4a. **Inspections may be carried out as part of the controls. Such inspection may be made unannounced. During these inspections the representatives of a competent authority shall at least be empowered to:**
  - (a) inspect [...] **the premises, equipment, means of transport, records, documents and systems, related to the objective of the inspection;**
  - (b) **inspect and** take samples [...] with a view to 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) [...] **document any evidence deemed necessary by the representatives;**
  - (d) **carry out the same controls on any parties performing the tasks required under this Regulation with, for or on behalf of the persons referred to in paragraph 1 [...].**

5. [...] **The representatives of the competent authorities shall keep records of every control that they carry out and where necessary shall draw up a report. The person referred to in paragraph 1 shall be promptly informed in writing by the competent authority of any case of non-compliance identified through the controls and shall have the opportunity to submit comments within a time set by the competent authority.**
- 6a. **The competent authorities shall have procedures or arrangements in place to ensure that staff performing controls are free of any conflict of interest.**
6. [...]

*Article 126*

*Audits by the Commission*

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

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

*Article 127*

*Certificates of good manufacturing practice*

[...]

*Article 127a*  
*Certificate of suitability*

[...] In order to verify whether the data submitted for obtaining a [...] certificate **of suitability** complies with the monographs of the European Pharmacopoeia the standardisation body for nomenclatures and quality norms within the meaning of the Convention on the elaboration of a European Pharmacopoeia accepted by Council Decision 94/358/EC<sup>13</sup> (European Directorate for the Quality of Medicines & Healthcare) may ask the Commission or the Agency to request an inspection **by a competent authority** when the starting material concerned is subject to a European Pharmacopoeia monograph[...].

*Article 128*  
*Specific rules on pharmacovigilance inspections*

1. The **competent authorities and** the [...] Agency [...] shall ensure that all pharmacovigilance system master files in the Union [...] are regularly checked **and that the pharmacovigilance systems are being correctly applied.**
- 1a. **Inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 40 shall be coordinated by the Agency and carried out by the competent authorities.**
- 1b. **Inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 44, Article 46 and Article 48 and 48a shall be carried out by the competent authorities.**

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<sup>13</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).

2. **Inspections of the pharmacovigilance systems master files shall be carried out by [...]** the competent authorities [...] of the Member States in which the **pharmacovigilance system master files are located.** [...]
- 2a. **Notwithstanding paragraph 2 and pursuant to Article 80, a competent authority may enter into** any work-sharing initiatives and delegation of responsibilities [...] **with other** competent authorities [...] **to avoid the** duplication of inspections of pharmacovigilance systems.[...].
3. The results of the pharmacovigilance inspections shall be **recorded** [...] in the pharmacovigilance database **as referred to in Article 74.**

*Article 129*

*Proof of the product quality for veterinary medicinal products*

1. The marketing authorisation holder shall **have at his disposal the results** of the control tests carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in marketing authorisation.
2. **If a competent authority concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take measures 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, and also the Agency in the case the veterinary medicinal product is authorised under the centralised procedure.**

## *Article 129a*

### *Proof of the product quality specific for immunological veterinary medicinal products*

- [...] **1.** For the purposes of application of paragraph 1 of **Article 129**, 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 100** [...].
- [...] **2.** 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.
- [...] **3.** 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 **immunological** veterinary medicinal product for control by an Official Medicines Control Laboratory before the product is [...] **placed** on the market.
- [...] **4.** Upon request by [...] a competent authority, the marketing authorisation holder shall promptly supply the samples referred to in paragraph [...] **2**, together with the reports of the control referred to in [...] **paragraph 1, for control testing**. The competent authority shall inform the competent authorities in other Member States in which the **immunological** veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines & HealthCare **and the Agency in the case that immunological veterinary medicinal products is authorised under the centralised procedure**, of its intention to control batches **of the immunological veterinary medicinal products**. [...]

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

[...] **6.** The list of tests to be repeated by the laboratory responsible for the control shall be restricted to justified tests, provided that all competent authorities in the 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.

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

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

[...] **9.** The competent authority shall notify the competent authorities of other 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.

[...]

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

## 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, [...] temporary safety restrictions **may be imposed** on the marketing authorisation holder **and other persons having obligations under this Regulation by the competent authority and, in the case of centrally authorised veterinary medicinal product, also by the Commission. The temporary safety restrictions may include:** [...]
  - (a) **restriction of supply of the veterinary medicinal product at the request of the competent authority and, in the case of centrally authorised veterinary medicinal product, also at the request of the Commission to the competent authority;**
  - (b) **restriction of the use of the veterinary medicinal product at the request of the competent authority and, in the case of centrally authorised veterinary medicinal product, also at the request of the Commission to the competent authority;**
  - (c) **suspension of a marketing authorisation by the competent authority having granted that marketing authorisation and, in the case of centrally authorised veterinary medicinal product, by the Commission.**
- 1a. **The competent authority concerned shall inform the other competent authorities and the Commission of any temporary safety restriction imposed at the latest on the following working day. In the case of centralised marketing authorisations, the Commission shall inform within the same time the competent authorities of any temporary safety restriction imposed.**
2. [...] **Competent authorities** and the Commission may, **at the same time as imposing the restriction in accordance with paragraph 1**, 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, [...] revoking or varying **the terms of marketing authorisations***

1. The competent authority or, **in the case of centralised marketing authorisations**, the Commission, shall suspend or [...] **revoke or request the marketing authorisation holder to submit an application for a variation to the terms of** the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is **no longer** [...]favourable **or is** [...] **insufficient to ensure food safety.**
  
- 2a. **The competent authority or, in the case of centralised marketing authorisations, the Commission, shall revoke the marketing authorisation if the marketing authorisation holder no longer fulfils the requirement on establishment in the Union, set out in Article 5(4).**
  
3. The competent authority or, **in the case of centralised marketing authorisations**, the Commission may suspend **or** [...] **revoke** the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation, **as applicable**, in case of **one or more** [...] 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 **established** [...] in accordance with **paragraph 0 of Article 77**[...] is inadequate;
  - (d) the marketing authorisation holder does not fulfil his obligations laid down in Article 77;
  - (e) [...] **the qualified person responsible for pharmacovigilance does not fulfill his tasks as laid down in Article 78.**

4. For the purpose of paragraphs 1 to 3, **in case of centralised marketing authorisations**, 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. [...] The holder of the marketing authorisation for the veterinary medicinal product shall be invited to provide oral or written explanations **within a given deadline**.

[...] 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).

[...]5. Member States shall lay down procedures for application of paragraphs 1 to 3.

#### *Article 131a*

##### *Suspending and revoking a wholesale distribution authorization*

1. **In the event of non-compliance with the requirements laid down in paragraph 3 of Article 105a the competent authority shall suspend or revoke the wholesale distribution authorisation of veterinary medicinal products.**
2. **In the event of non-compliance with the requirements laid down in Article 105a, other than paragraph 3 thereof, the competent authority may, without prejudice to any other appropriate measures according to national law, take one or more of the following measures:**
  - (a) **suspend the wholesale distribution authorisation;**
  - (b) **suspend the wholesale distribution authorisation for one or more categories of veterinary medicinal products;**
  - (c) **revoke the wholesale distribution authorisation for one or more category of veterinary medicinal products.**

*Article 131b*

*Removal of importers, manufacturers and distributors of active substance from the manufacturing and wholesale distribution data base*

**In the event of non-compliance of importers, manufacturers and distributors of active substance with the requirements laid down in Article 98b, the competent authority shall, temporarily or definitively, remove them from the manufacturing and wholesale distribution data base.**

*Article 132*

*Suspending and [...] **revoking** manufacturing authorisations*

In the event of non-compliance with the requirements laid down in Article 98 [...], the competent authority shall, without prejudice to any other appropriate measures according to **national law**, take **one or more** [...] of the following measures:

- (a) suspend **the** manufacture of veterinary medicinal products;
- (b) suspend imports of veterinary medicinal products from third countries;
- (c) suspend **or revoke** the manufacturing authorisation for [...] **one or more pharmaceutical forms** [...];
- (ca) **suspend or revoke one or more activities in one or more manufacturing sites.**
- (~~d~~) [...]

*Article 133*

*Prohibiting **the** supply of veterinary medicinal products*

1. [...] **In the event of a risk to public or animal health or to the environment**, the competent authority or, **in the case of centrally authorised products** the Commission, shall prohibit the supply of a veterinary medicinal product and require the marketing authorisation holder **and/or suppliers to cease the supply and/or [...] recall** the veterinary medicinal product from the market if any of the following apply:
  - (a) the benefit-risk balance of the veterinary medicinal product is **no longer** [...]favourable;
  - (b) the qualitative and/ **or** 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 **insufficient to ensure food safety** [...];
  - (d) the control tests referred to in Article 129(1) have not been carried out; **or**
  - (e) **the incorrect labelling leading to a serious risk for animal or public health**
  
2. The competent authorities or the Commission may confine the prohibition on supply and [...] **recall** from the market solely to the contested production batches **of the concerned veterinary medicinal product**.

*Article 134*

*Penalties imposed by Member States*

1. **Member States shall lay down rules on penalties applicable to infringements of this Regulation and take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, dissuasive and proportionate.**
  
- ~~2.~~ [...]

~~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.

[...] **1a. The competent authorities shall ensure the publication of information on the type and number of cases where financial penalties were imposed, having regard to the legitimate interest of the concerned parties in the protection of their business secrets.**

**2. Member States shall inform the Commission immediately of any litigation against marketing authorisation holders of centrally authorised veterinary medicinal products instituted for infringement of this Regulation.**

#### *Article 135*

#### *Financial penalties imposed by the Commission on marketing authorisation holders of centrally authorised veterinary medicinal products*

**1. The Commission may impose financial penalties on the [...] marketing authorisation holders of centrally authorised veterinary medicinal products granted under this Regulation if they fail to observe any of their obligations [...] laid down in Annex III in connection with those marketing authorisations.**

**1aa. The Commission may, insofar as specifically provided for in the delegated acts referred to in paragraph 2(bb), impose the financial penalties referred to in paragraph 1 also on a different legal entity or entities provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:**

- (i) exerted a decisive influence over the marketing authorisation holder, or**
- (ii) were involved in, or could have addressed, the infringement by the marketing authorisation holder.**

- 1a. Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to observe any of the obligations referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.**
- 1b. In determining whether to impose a financial penalty and in determining the appropriate financial penalty, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the infringement.**
- 1c. For the purposes of paragraph 1, the Commission shall also take into account:
  - (a) any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts, and,**
  - (b) any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.****
- 1d. Where the Commission finds that the marketing authorisation holder has committed, intentionally or negligently, an infringement as referred to in paragraph 1, it may adopt a decision imposing a fine not exceeding 5 % of the holder's Union turnover in the business year preceding the date of the decision.**

**Where the marketing authorisation holder has not terminated the infringement, the Commission may, in the decision referred to in paragraph 1, impose periodic penalty payments per day not exceeding 2,5 % of the holder's average daily Union turnover in the business year preceding the date of the decision.**

**Periodic penalty payments may be imposed for a period running from the date of notification of that decision until the infringement has been brought to an end.**

2. The Commission [...] is empowered to adopt delegated acts in accordance with Article 146 **supplementing this Regulation by** laying down: [...]
  - (a) **procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of defence, access to file, legal representation and confidentiality;**
  - (bb) **further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;**
  - (b) **rules on duration of procedure and limitation periods;**
  - (c) **elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments as well as the conditions and methods for their collection.**
  
- 2a. **For the conduct of the investigation, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency.**
  
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.
- 1a. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to carry out the activities required by 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 [...].
3. Upon reasoned request, the competent authorities shall forthwith communicate the [...] **written records** referred to in Article 125 and **control reports referred to in** Article 129 to the competent authorities of other Member States.
4. [...].

*Article 137*

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

[...]

### *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 **Agency** [...] shall establish specific procedural rules for the **implementation** [...] of paragraph 1.

### *Article 139*

#### *Committee for **Veterinary Medicinal Products** [...]*

1. A Committee for **Veterinary Medicinal Products** [...] ('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 [...].
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 **veterinary** medicinal products [...], 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 [...] **novel** therapy [...] **veterinary medicinal products**.

**4a. The Committee shall establish a standing working party for pharmacovigilance with a remit including evaluating potential signals in pharmacovigilance arising from the Union pharmacovigilance system, proposing the options for risk management referred to in Article 79 to the Committee and to the coordination group, and coordinating the communication about pharmacovigilance between the competent authorities and the Agency.**

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 **accredited** 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, **and** other committees of the Agency referred to in **Article 56 of Regulation (EC) No 726/2004** and the coordination group.

7. The opinions of the Committee shall be publicly accessible.

*Article 140*

*Members of the Committee [...]*

1. Each Member State shall, **after consultation of the Management Board of the Agency, [...]** appoint **for a three-year term which may be renewed, one [...]** 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 alternates of the Committee shall be appointed on the basis of their relevant expertise and experience in the scientific [...] **assessment of veterinary** medicinal products [...], in order to guarantee the highest level of qualifications and a broad spectrum of relevant expertise.

[...]

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.
- 8a. **The Committee may appoint for the purpose of performing its tasks listed under Article 141, one of its members to act as rapporteur. The Committee may also appoint a second member to act as co-rapporteur.**

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 [...] **assessing** veterinary medicinal products shall rely on the scientific evaluation and resources available to competent authorities. Each **competent** authority shall monitor and ensure the scientific level and independence of the evaluation carried out and [...] **provide** 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 [...]*

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 **scientific** 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 [...] **prepare** opinions on scientific matters concerning the evaluation and use of veterinary medicinal products;

- (d) **prepare** [...] opinions of the Agency on questions concerning the admissibility of **applications** [...] submitted in accordance with the centralised procedure, and on granting, varying, suspending or [...] **revoking** a marketing authorisations for centrally authorised veterinary medicinal products;
- (e) take due account of any request from Member States for scientific opinions;
- (f) [...]
- (g) provide guidance on important questions and issues of general scientific [...] nature;
- (h) give a scientific opinion, in the context of cooperation with **the World** [...] Organisations for [...] **Animal** [...] **Health**, concerning the evaluation of certain veterinary medicinal products [...] intended exclusively for markets outside the Union.
- (i) **advise on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009;**
- (j) **provide scientific advice on the use of antimicrobials and antiparasitics in animals in order to minimise the occurrence of resistance in the Union; this advice shall be updated when needed;**
- (k) **provide objective scientific opinions to the Member States on the questions which are referred to them.**

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 [...] **to assist in the operations** of the procedures of the coordination group and **to ensure an** appropriate liaison between this group, the Agency and [...] 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 [...] **cooperate closely with** the competent authorities and the Agency.

### *Article 143*

#### *Members of the coordination group [...]*

1. The coordination group shall be composed of one representative per Member State appointed for a renewable period of 3 years. **Member States may appoint an alternate representative.** Members of the **coordination** 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 [...] 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 [...].

### *Article 144*

#### *Tasks of the coordination group [...]*

The coordination group shall have the following tasks:

- (a) examine questions concerning mutual recognition and decentralised procedures;
- (b) examine [...] **advice from the pharmacovigilance working party of the Committee concerning risk management measures in pharmacovigilance related to [...] veterinary medicinal products authorised in Member States and issue recommendations to the Member States and to the marketing authorisation holders as necessary;**
- (c) examine questions concerning variations to the terms of marketing authorisations granted by Member States;
- (d) provide recommendations to Member States whether a **specific product or a group of products** [...] is to be considered a veterinary medicinal product within the scope of this Regulation.

- (e) **coordinate the selection of the lead authority responsible for the assessment of the results of the signal management process referred to in Article 81(3);**
- (ea) **draw up and publish an annual list of reference veterinary medicinal products which shall be subject to harmonisation of the summaries of product characteristics in accordance with Article 69(1aaa).**

## **Chapter XI**

### **[...] Common and procedural 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 145a*

#### *Amendments to Annex II*

1. **The Commission is empowered to adopt delegated acts in accordance with Article 146(2) amending Annex II to adapt the requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products to technical and scientific progress.**
2. **The Commission shall adopt delegated acts in accordance with Article 146(2a) amending Annex II to achieve a sufficient level of detail to ensure legal certainty and harmonisation as well as any necessary updating, while avoiding unnecessary disruption with the current Annex II, including as regards the introduction of specific requirements for novel therapy veterinary medicinal products. When adopting those delegated acts, the Commission shall have due regard to animal health, public health and environmental considerations.**

*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 [...] 32(3), [...] 54(3), [...] **112b(1), 117(2), 122a(2), [...] 135(2), and 145a(1)** shall be conferred on the Commission for [...] period of [...] **five years** from the date of the entry into force of this Regulation. **The Commission shall draw up a report in respect of the delegation of power by not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for the periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**
- 2a. **The power to adopt delegated acts referred to in Article 145a (2) shall be conferred on the Commission for a period from the entry into force of this Regulation until the date of application referred to in Article 150.**
3. The delegation of power referred to in **paragraph 2 and 2a**[...] 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.
- 3a. **Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law Making.**

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 **provisions listed in paragraph 2 and 2a** [...] 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 **Regulation (EU) No 2016/679**<sup>14</sup> [...] 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.

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<sup>14</sup> **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ( OJ, L119, 4.5.2016, p.1)**

## Chapter XII

### Transitional and final provisions

#### *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 148a*

##### *Relation with other Union acts*

1. **Nothing in this Regulation shall be understood to affect the provisions laid down in Council Directive 96/22/EC.**
2. **The provisions of Commission Regulation No 1234/2008 shall not apply to veterinary medicinal products covered by the provisions of this Regulation.**
3. **The provisions of Commission Regulation No 658/2007 shall not apply to veterinary medicinal products covered by the provisions of this Regulation.**

#### *Article 149*

##### *Prior applications [...]*

1. Applications for marketing authorisations for veterinary medicinal products **or variations thereof [...]** **validated** in accordance with Regulation (EC) No 726/2004 before the date of application of this Regulation shall be [...] **completed** in accordance with Regulation (EC) No 726/2004.

2. Applications for marketing authorisations for veterinary medicinal products [...] **validated** in accordance with the requirements of Directive 2001/82/EC before the date of application of this Regulation shall be [...] **completed** 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 149a*

##### *Existing veterinary medicinal products, marketing authorisations and registrations*

1. **Marketing authorisations of veterinary medicinal products and registrations of homeopathic veterinary medicinal products granted in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 before the date of application of this Regulation shall be deemed to have been issued in accordance with this Regulation, and are, as such, subject to the relevant provisions under this Regulation.**  
**The first subparagraph shall not apply to marketing authorisations for antimicrobial veterinary medicinal products which have been reserved for treatment in humans in accordance with implementing acts adopted on the basis of Article 32(4).**
2. **Veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may continue to be made available until five years after the date of application of this Regulation, even if they are not in compliance with Articles 9 to 13 or with other provisions of this Regulation.**
3. **By derogation from paragraph 1 of this Article, the periods of protection provided for in Article 34 shall not apply to reference veterinary medicinal products for which an authorisation has been granted before the date of application referred to in Article 150 and, instead, the corresponding provisions in the repealed acts referred to shall continue to apply in that respect.**

*Article 149b*

*Transitional measures regarding delegated and implementing acts*

- 1. The delegated acts referred to in Article 122a(2) and the implementing acts referred to in Articles 32(4), 54(4), 77(1b), 98b(9), 104(6) and 108(4) shall be adopted before and shall apply from the date of application in accordance with Article 150.**
- 1a. Without prejudice to the date of application referred to in Article 150, the Commission shall adopt the delegated acts referred to in Article 32(3) at the latest 4 months before the date of application referred to in Article 150. Such act shall apply from the date of application in accordance with Article 150.**
- 2. Without prejudice to the date of application referred to in Article 150, the Commission shall adopt the delegated acts referred to in Articles 54(3) and 145a(2) and the implementing acts referred to in Articles 51(3a) and 58(2) at the latest on 12 months before the date of application referred to in Article 150. Such acts shall apply from the date of application in accordance with Article 150.**
- 3. Without prejudice to the date of application referred to in Article 150, the delegated acts referred to in Article 112b(1) and the implementing acts referred to in Articles 15(1), 15(2), 98(2), 112b(2) and 117(5) shall be adopted at the latest by 36 months from the date of application in accordance with Article 150 and shall start to apply at the earliest on the date of application referred to in Article 150.**

**4. Without prejudice to the date of application referred to in Article 150, the Commission is empowered to adopt delegated and implementing acts provided for in this Regulation as from [the date of entry into force of this Regulation]. Such acts, unless otherwise provided in this Regulation, shall apply from the date of application in accordance with Article 150.**

**When adopting the delegated and implementing acts referred to in this Article, the Commission shall allow sufficient time between their adoption and their start of application.**

*Article 149c*

*Establishment of the pharmacovigilance database and setting up of the manufacturing and wholesale distribution database*

**Without prejudice to the date of application referred to in Article 150, the Agency, in collaboration with the Member States and the Commission, shall, in accordance with Articles 74 and 94 respectively, ensure the establishment of the pharmacovigilance database and the setting up of the manufacturing and wholesale distribution database at the latest by the date of application of this Regulation.**

*Article 149d*

*Initial input to the product database by competent authorities*

**At the latest by the date of application of this Regulation, the competent authorities shall submit, electronically, information on all veterinary medicinal products authorised in their Member State at that time to the Agency, using the format referred to in Article 51(3a)(a).**

*Article 149e*

*Review of rules for environmental risk assessment*

**By the date of application of this Regulation, the Commission shall present a report to the European Parliament and to the Council on a feasibility study of an active substance based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products, to be accompanied, if appropriate, by a legislative proposal.**

*Article 149f*

*Commission report on traditional herbal products used to treat animals*

**The Commission shall report to the European Parliament and to the Council within five years after the date of application of this Regulation, on traditional herbal products used to treat animals in the Union. If appropriate, the Commission shall make a legislative proposal in order to introduce a simplified system for registering traditional herbal products used to treat animals.**

**The Member States shall provide information to the Commission on such traditional herbal products within its territory.**

*Article 149g*

*Review of measures regarding animals of the equine species*

**No later than three years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and to the Council on its assessment of the situation as regards the treatment with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries, to be accompanied by any appropriate action by the Commission taking into account in particular public health, animal welfare, the risks for fraud and the level playing field with third countries.**

*Article 149h*

*Transitional measures regarding certain certificates of good manufacturing practice*

**Without prejudice to the date of application referred to in Article 150, the obligations regarding certificates of good manufacturing practices for inactivated immunological veterinary medicinal products which are manufactured from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of animals in a unit having a confirmed epidemiological link shall only start to apply at the start of application of the implementing acts laying down specific measures on good manufacturing practices for those products referred to in Article 98(2).**

*Article 150*

*Entry into force and application*

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

It shall apply from [*Office of Publications please insert date counting 36 [...] months from the entry into force*].[...]

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

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## ANNEX I

### Administrative information referred to in Article 7(1)(a)

#### **0. Legal basis for the application for the marketing authorisation.**

##### **1. Applicant**

- 1.1. Name [...] and address or registered place of business of the **applicant** [...];
- 1.2. Name and address of manufacturer (s) or **importer(s) of the finished product and name and address of the manufacturer of the active substance(s)**
- 1.3. Name and address of the sites involved in the different stages of the manufacturing, **importing, control and batch release.**  
[...]

##### **2. Identification of the veterinary medicinal product**

- 2.1. [...] Name of the veterinary medicinal product **and Anatomical Therapeutic Chemical Veterinary code (ATCVet Code)**
- 2.2. Active substance(s) **and, if applicable, diluent(s)**
- 2.3. Strength **or, in case of immunological veterinary medicinal product, biological activity, potency or titre**
- 2.4. Pharmaceutical form
- 2.5. Route of administration
- 2.6. [...]

2.7. Target species

### **3. Manufacturing and pharmacovigilance information**

3.1. Proof of a manufacturing authorisation **or certificate of good manufacturing practice**

3.2. [...] **Reference number of pharmacovigilance system master file.**

### **4. Product information**

4.1. [...] **Proposed** summary of the product characteristics drawn up in accordance with Article 30

4.2. Description of the final presentation of the product, including packaging and labelling

4.3. [...] **Proposed** text of the information to be provided **on** the immediate packaging, outer packaging and the package leaflet in accordance with Articles 9-[...] **13** of this Regulation.

### **5. Other information**

5.1. List of countries in which a marketing authorisation has been granted **or revoked** for the veterinary medicinal product

5.2. Copies of all the summaries of product characteristics as included in the terms of marketing authorisations granted by Member States, [...]

5.3. List of countries in which an application has been submitted or refused

5.4. List of **Member States** [...] where the veterinary medicinal product is to be placed on the market, [...]

5.5. Critical expert reports on quality, safety and efficacy **of the veterinary medicinal product.**

## **ANNEX II**

### **Technical requirements referred to in Article 7(1)(b)**

Annexes II and III of the above mentioned proposal are merged into one single annex (Annex II), the content of which is replaced by the content of current Annex I of Directive 2001/82/EC at last amended by Commission Directive 2009/9/EC of February 2009.

## **ANNEX III**

### **List of the obligations referred to in Article 135(1):**

- (0) the obligation, as an applicant, to provide accurate information and documentation as referred to in Article 6(4);**
- (00) the obligation to provide, in an application submitted in accordance with Article 61, the data referred to in Article 61(2)(aa);**
- (1) the obligation to comply with the conditions referred to in Articles 21 and 22;**
- (2) the obligation to comply with conditions included in the marketing authorisation of the veterinary medicinal product, as referred to in Article 31(1);**
- (3) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the veterinary medicinal products to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 55(1);**
- (4) the obligation to keep up to date the summary of product characteristics, package leaflet and labelling with the current scientific knowledge, as provided for in Article 55(1aa);**
- (5) the obligation to record in the product database the dates when its authorised veterinary medicinal products are placed on the market and information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the concerned marketing authorisations as well as data relating to the volume of sales of the product, as provided in Article 55(1b) and Article 55(6), respectively;**

- (6) the obligation to provide within the time limit set, at the request of a competent authority or the Agency, any data demonstrating that the risk-benefit balance remains favourable, as provided for in Articles 55(4);**
  - (7) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the product, as provided for in Article 55(5);**
  - (8) the obligation to place the veterinary medicinal product on the market in accordance with the content of the summary of the product characteristics and the labelling and package leaflet as contained in the marketing authorisation;**
  - (9) the obligation to record and report suspected adverse events for their veterinary medicinal products, in accordance with Article 76(2);**
  - (10) the obligation to collect specific pharmacovigilance data additional to the data listed in Article 73(2) and to carry out post marketing surveillance studies in accordance to Article 76(2a);**
  - (11) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Article 77(6);**
  - (12) the obligation to operate a pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including, maintenance of a pharmacovigilance system master file in accordance with Article 77;**
  - (13) the obligation to submit, at the request of the Agency, a copy of its pharmacovigilance system master file(s), as provided for in Article 79(7);**
  - (14) the obligation to carry out signal management process and to record the results and outcomes of that process in accordance with Article 81(0) and (00).**
  - (15) the obligation to provide to the Agency all available information relating to an Union interest referral, as referred to in Article 84(2).**
-