Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

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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[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Directive 2001/82/EC of the European Parliament and of the Council[(3)] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[(4)] constituted the Union regulatory framework for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products.

(2) In the light of experience and following the assessment by the Commission on the functioning of the internal market for veterinary medicinal products, the regulatory 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 regulatory framework for veterinary medicinal products 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 entitled ‘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 medicinal products. In particular, the

drivers for investment in markets for medicinal products for human use and veterinary medicinal products 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 veterinary medicinal products 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 medicinal products 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 medicinal products for human use. 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 market for medicinal products for human use.

(5) This Regulation aims to reduce the administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.

(6) The identification of packs of veterinary medicinal products via identification codes is common practice in several Member States. Those Member States have developed integrated electronic systems at national level for the proper functioning of such codes, linked to national databases. The introduction of a harmonised Union-wide system has not been the subject of any assessment as to costs and administrative consequences. Instead, there should be a possibility 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.

(7) However, 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 development of a harmonised identification code for which the Commission should adopt uniform rules. The adoption by the Commission of rules concerning such an identification code would not prevent Member States from being able to choose whether or not to use such an identification code.

(8) In spite of 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 can 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 can 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 public and animal health, and for the development of the agriculture and aquaculture sectors.

(9) 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 of 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.

(10) This Regulation should not apply to veterinary medicinal products which have not undergone an industrial process such as, for example, non-processed blood.

(11) Antiparasitics include also substances with repelling activity that are presented for use as veterinary medicinal products.

(12) There is insufficient information to date on traditional herbal products used to treat animals in order to allow the setting up of a simplified system. Therefore, 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.

(13) This Regulation applies to veterinary medicinal products, including those products which Directive 2001/82/EC referred to as 'pre-mixes' and which in this Regulation are considered to be a pharmaceutical form of a veterinary medicinal product, until such time as those products are included in medicated feed or intermediate products, after which Regulation (EU) 2019/4 of the European Parliament and of the Council[(5)] applies to the exclusion of this Regulation.

(14) 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 the case of treatment of groups of animals, such administration should 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. In order to improve the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or 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 European Medicines Agency, established by Regulation (EC) No 726/2004 ('the Agency'), for example concerning measures to minimise over-dosage or under-dosage, unintended administration to non-target animals, the risk of cross-contamination and dissemination of those products in the environment.

(15) 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.

(16) 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, such as 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.

(17) The replacement or the addition of a new antigen or a new strain in the case of already authorised immunological veterinary medicinal products against, for example, avian influenza, bluetongue, foot and mouth disease or equine influenza should not be considered as adding a new active substance.

(18) 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 SMEs. It should be ensured that marketing authorisations granted in one Member State are recognised in other Member States.

(19) 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. That advice should be provided in addition to the operational guidance documents and other advice and assistance provided by the Agency.

(20) 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.

(21) 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 lays down new tasks for the coordination group, including the drawing up an annual list of reference veterinary medicinal products which are to be subject to harmonisation of the summary of product characteristics, the issuing of recommendations on pharmacovigilance and its involvement in the signal management process.

(22) Where a Member State, the Commission or the marketing authorisation holder considers that there are reasons to believe that a veterinary medicinal product could 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 relevant Member States, and taken on the basis of an overall benefit-risk assessment.

(23) 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.

(24) 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 of the European Parliament and of the Council[6] and any acts adopted on the basis thereof for the animal species for which the veterinary medicinal product is intended.

(25) There may be, however, 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 only in the interest of animal health or animal welfare. In the 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.

(26) Member States should be able to allow the 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.

(27) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that can affect public or animal health or the environment should require a scientific assessment.

(28) Directive 2010/63/EU of the European Parliament and of the Council[7] 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 the scope of that Directive. The design and performance of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such clinical trials should be designed to avoid causing pain, suffering or distress to animals and should take into account the principles laid down in 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').

(29) 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[8] 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 Agency should therefore give the widest possible access to the documents while carefully balancing the right for information with existing data

protection requirements. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001.

(30) 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, the grant of such marketing authorisations 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.

(31) For all new applications for a marketing authorisation, environmental risk assessments should be mandatory and should consist of two phases. In the first phase the extent of environmental exposure to 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.

(32) Where there is concern that a pharmaceutical substance could pose serious risk to the environment, it may be appropriate to examine that substance in the context of Union environmental legislation. In particular, under Directive 2000/60/EC of the European Parliament and of the Council[(9)], it may be appropriate to identify whether that substance is 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. Those measures could include measures to reduce emissions from manufacturing by following Best Available Techniques (BAT) under Directive 2010/75/EU of the European Parliament and of the Council[(10)], 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.

(33) 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 that 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, however, should be limited in time in order to allow for competition. Similar protection of investments should be applied to studies supporting a new pharmaceutical form, administration route or dosage that reduces the antimicrobial or antiparasitic resistance or improves the benefit-risk balance.

(34) 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.

(35) 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 an application for a marketing authorisation for a generic veterinary medicinal product has been submitted, is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to protect 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 Union assessment of the environmental properties of active substances for veterinary use by means of an active substance-based review ('monograph') system could be a potential alternative. The Commission should therefore submit a report to the European Parliament and the Council which examines the feasibility of such a monograph system and other potential alternatives for environmental risk assessment of veterinary medicinal products, accompanied, if appropriate, by a legislative proposal.

(36) 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 that 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.

(37) 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 a marketing authorisation for a generic biological veterinary medicinal product, the bioequivalence should therefore be demonstrated in order to ensure, based on the existing knowledge, that quality, safety and efficacy are similar.

(38) 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.

(39) 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, including societal, economical, ethical, environmental and welfare factors and the feasibility of controls, should also be taken into account.

(40) In certain circumstances where a significant public or animal 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 of 2 February 2000 on the precautionary principle. 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.

(41) Antimicrobial resistance to medicinal products for human use 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 importance for preventing or treating life-threatening infections in humans and encouraging and incentivising the development of new antimicrobials. It also needs to be ensured that appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use that is 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.

(42) It is necessary to mitigate the risk of development of antimicrobial resistance to medicinal products for human use and veterinary medicinal products. Therefore, an application for an antimicrobial veterinary medicinal product should contain information about the potential risks that use of that medicinal 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, antimicrobial veterinary medicinal products 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 veterinary medicinal product. Such conditions should include restrictions on the use of the veterinary medicinal product that is not in accordance with the terms of the marketing authorisation, in particular with the summary of product characteristics.

(43) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Such combined use should be taken into account, therefore, when assessing whether to authorise a veterinary medicinal product.

(44) 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 be maintained for as long as possible. The use of antimicrobials in medicinal products that are 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 other than in well-defined cases for the administration to 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 other than 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 the total use of antimicrobials in animals.

(45) In order to strengthen Member States' national policies on the 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. Member States should be allowed, therefore, following scientific recommendations, to define restrictive conditions for their use, for example conditioning their prescription to the realisation of antimicrobial susceptibility testing to ensure that there is no other antimicrobials available that are sufficiently effective or appropriate to treat diagnosed disease.

(46) 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. It should be possible, therefore, to decide that certain antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector. When making such decisions on antimicrobials, 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 Organization (WHO), the World Organisation for Animal Health (OIE), and the Codex Alimentarius.

(47) If an antimicrobial is administered or 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 the antimicrobial medicinal 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 medicinal products, while recognising their legitimate activity of retail in accordance with national law. In particular, veterinarians should not to be influenced, directly or indirectly, by economic incentives when prescribing those medicinal 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.

(48) The prudent use of antimicrobials is a cornerstone in addressing antimicrobial resistance. All the stakeholders concerned should together promote prudent use of antimicrobials. It is therefore important that guidance on the prudent use of antimicrobials in veterinary medicine be taken into account and further elaborated. The identification of risk factors and the development of criteria for the 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 the prudent use of antimicrobials, provided that those measures do not unduly restrict the functioning of the internal market.

(49) 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 OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials.

(50) 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. It is therefore important to continue the collection of such data and further develop it in line with a stepwise approach. That 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 data 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.

(51) 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 regard to dosage, uses and warnings of the veterinary medicinal products.

(52) 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 could 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 or animal health or environmental safety.

(53) In addition, Member States should be able 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.

(54) 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 veterinary medicinal product and data in support of the applications for the veterinary medicinal product should be identical. However, multiple applications for a specific veterinary medicinal 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 within the procedural framework for mutual recognition.

(55) Pharmacovigilance rules are necessary for the protection of public and animal health and of the environment. Collection of information on suspected adverse events should contribute to the good usage of veterinary medicinal products.

(56) Environmental incidents that are observed following the administration of a veterinary medicinal product to an animal should 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 in high concentrations of veterinary medicinal products in drinking water produced from surface water.

(57) 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 facilitate that veterinarians receive appropriate feedback on reporting made.

(58) In the light of experience, it has become clear that it is necessary to take measures to improve the operation of the pharmacovigilance system. That system should integrate and monitor data at Union level. It is in 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.

(59) 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 veterinary medicinal products, including those concerning use outside the terms of the granted marketing authorisation.

(60) It is necessary to increase the shared use of resources among 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.

(61) In specific cases, or from a public or animal health or environment perspective, it is necessary to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the veterinary medicinal product on the market. It should be possible, therefore, to impose the obligation to conduct post-authorisation studies on the marketing authorisation holder.

(62) 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. That database should include mechanisms for exchanging data with the existing national pharmacovigilance databases.

(63) The procedures that competent authorities and the Agency will adopt in order to evaluate the information on suspected adverse events that they receive should comply with the measures on good pharmacovigilance practice which should be 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 that 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 that purpose and proper attention should be given to it. That signal management process consists of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action.

(64) 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 veterinary medicinal products manufactured in the Union, or with requirements which are recognised to be at least equivalent thereto.

(65) The parallel trade in veterinary medicinal products concerns veterinary medicinal 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. The 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, and respecting the case law of the Court of Justice of the European Union ('the Court of Justice'). Any administrative procedures put in place in that context should not introduce an excessive burden. In particular, any approval of a licence for such parallel trade should be based on a simplified procedure.

(66) 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.

(67) 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 their final destination.

(68) The good manufacturing practice for the purpose of this Regulation should take into account the Union and international standards of animal welfare when active substances are prepared from animals. Measures to prevent or minimise discharge of active substances into the environment should be also taken into account. Any such measures should only be adopted following an evaluation of their impact.

(69) In order to ensure the uniform application of principles of good manufacturing practice and good distribution practice, 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.

(70) Although inactivated immunological veterinary medicinal products referred to in Article 2(3) should be manufactured in accordance with the principles of good manufacturing practice, detailed guidelines of good manufacturing practice should specifically be prepared for those products since they are manufactured in a way that is different from industrially prepared products. That would preserve their quality without hindering their manufacturing and availability.

(71) Companies should hold an authorisation to be able to distribute wholesale veterinary medicinal products and should comply with the principles of good distribution practice, so as to guarantee that such medicinal products 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 the case of parallel trade in veterinary medicinal products.

(72) In order to ensure transparency, a database should be established at Union level for the purpose 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.

(73) 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 in which 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 in which they are established should be allowed to sell veterinary medicinal products not subject to a veterinary prescription at a distance to buyers in other Member States. However, taking into account that in some Member States it is current practice to sell at a distance also those veterinary medicinal products which are subject to prescription, Member States should be allowed to continue such practice under certain conditions and within their territory only. In such cases, those Member States should take appropriate measures to avoid unintended consequences of such supply and establish rules on appropriate penalties.

(74) Veterinarians should always issue a veterinary prescription when supplying a veterinary medicinal product subject to a veterinary prescription only and not administering it themselves. Whenever the veterinarians administer 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.

(75) 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 that 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 can impose conditions for supplying medicinal products to the public within the limits of the Treaty on the Functioning of the European Union (TFEU).

(76) When examining the compatibility with Union law of the conditions for the supply of medicinal products, the Court of Justice has recognised, in the context of 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 TFEU 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 are to be allowed some discretion as regards the conditions for the supply on their territory of medicinal products to the public. Member States should be able, therefore, 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 or animal health. Such conditions should not unduly restrict the functioning of the internal market. In that context, 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 or animal health or of environment, provided that those conditions are proportionate to the risk and do not unduly restrict the functioning of the internal market.

(77) 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, recognisable throughout the Union, while allowing for the identification of the Member State in which the person offering veterinary medicinal products for sale at a distance is established. The Commission should develop the design for such a common 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 Agency, should give an explanation of the use of that common logo. All those websites should be linked in order to provide comprehensive information to the public.

(78) 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 human and animal health or the environment.

(79) Advertising, even of medicinal products not subject to a veterinary prescription, could affect public and animal health and distort competition. Therefore, advertising of veterinary medicinal products should meet certain criteria. Persons qualified to prescribe or supply veterinary medicinal products 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 assess the risk associated with their use may lead to medicinal product 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 under restricted conditions to allow advertising of immunological veterinary medicinal products also to professional animal keepers.

(80) 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, because that distinction is often misrepresented in advertising.

(81) The rules of advertisement in this Regulation are to be seen as specific rules that complement the general rules in Directive 2006/114/EC of the European Parliament and of the Council[(11)].

(82) 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 medicinal product stated in the prescription.

(83) The implementation of the principle of recognition of veterinary 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 medicinal 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.

(84) Information on veterinary medicinal products is essential in order to enable health professionals, authorities and companies make informed decisions. A key aspect is the creation of a Union database that should collate information on marketing authorisations granted in the Union. That database should enhance overall transparency, streamline and facilitate the flow of information between authorities, and prevent multiple reporting requirements.

(85) The verification of compliance with the legal requirements through controls is of fundamental importance to ensure that the objectives of this 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, the competent authorities should have the possibility to perform unannounced inspections.

(86) 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. That approach should allow those competent 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.

(87) 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 controls throughout the Union, the Commission should be able to carry out audits in the Member States to verify the functioning of national control systems. Those audits should be carried out so as to avoid any unnecessary administrative burden and, as far as possible, be coordinated with Member States and with any other Commission audits to be carried out under Regulation (EU) 2017/625 of the European Parliament and of the Council[(12)].

(88) 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 with this Regulation, as non-compliance can result in damage to public and animal health and the environment.

(89) 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-making 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 as to 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.

(90) Having regard to the special characteristics of homeopathic veterinary medicinal products, especially the constituents of those products, it is desirable to establish a special, simplified registration procedure and to provide specific provisions for package leaflets for certain homeopathic veterinary medicinal products which are placed on the market without indications. The quality aspect of homeopathic medicinal products is independent of their use, so no specific provisions should apply to such products 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, it does not regulate the use of registered homeopathic veterinary medicinal products. The use of such registered homeopathic veterinary medicinal 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 of the European Parliament and of the Council[13].

(91) In order to protect public and animal health and the environment, the activities, services and tasks attributed to the Agency in this Regulation should be adequately funded. Those activities, services and tasks should be funded through fees charged by the Agency to undertakings. Those fees, however, should not affect the right of Member States to charge fees for activities and tasks carried out at national level.

(92) 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 to Directive 2001/82/EC as last amended by Commission Directive 2009/9/EC[14] work sufficiently well in practice. There is no urgent need, therefore, 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, the Organisation for Economic Cooperation and Development (OECD) standards, and 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 their structure.

(93) In order to, inter alia, adapt this Regulation to the scientific developments of the sector, to exercise the supervisory powers of the Commission effectively, and to introduce harmonised standards within the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans; establishing the requirements for collection of data as

regards the antimicrobial medicinal products, rules on the methods of collection and quality assurance; establishing the rules to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed; providing details on content and format of the information as regards equine species in the single lifetime identification document; amending the rules on withdrawal period in the light of new scientific evidence; providing the necessary detailed rules on the application, by operators in third countries, of the provisions on the prohibition of the use of antimicrobial medicinal products in animals for the purpose of promoting growth or increase yield and the prohibition of the use of designated antimicrobials; laying down the procedure for the imposition of fines or periodic penalty payments as well as the conditions and methods for their collection; and amending Annex II in order to (i) adapt the requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products to technical and scientific progress and (ii) achieve a sufficient level of detail that ensures legal certainty and harmonisation as well as any necessary updating. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[(15)]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(94) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[(16)].

(95) 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 of the European Parliament and of the Council[(17)] and Directive 2006/123/EC of the European Parliament and of the Council[(18)].

(96) 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.

(97) 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:

(**1**) OJ C 242, 23.7.2015, p. 54.

(**2**) Position of the European Parliament of 25 October 2018 (not yet published in the Official Journal) and Decision of the Council of 26 November 2018.

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

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

(**5**) Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (see page 1 of this Official Journal).

(**6**) 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).

(**7**) 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).

(**8**) 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).

(**9**) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

(**10**) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

(**11**) Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21).

(**12**) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

(**13**) 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).

(**14**) Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (OJ L 44, 14.2.2009, p. 10).

(**15**) OJ L 123, 12.5.2016, p. 1.

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

(**17**) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

(**18**) Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ L 376, 27.12.2006, p. 36).

Status:
Point in time view as at 31/12/2020.

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