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