Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance)

REGULATION (EU) 2019/5 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use

(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 Article 114 and Article 168(4)(c) 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[(4)] of the European Parliament and of the Council constituted the Union regulatory framework for the manufacture, authorisation and distribution of veterinary medicinal products. In the light of experience and following the assessment by the Commission of the functioning of the internal market for veterinary medicinal products, the regulatory framework for veterinary medicinal products has been reviewed, and Regulation (EU) 2019/6 of the European Parliament and of the Council[(5)] on veterinary medicinal products has been adopted, with a view to harmonisation of the laws of the Member States.

(2) It is appropriate to maintain in Regulation (EC) No 726/2004 certain provisions relating to veterinary medicinal products, in particular those relating to the European Medicines

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Agency ('the Agency'), but as the procedures applicable to the centralised marketing authorisation of veterinary medicinal products are laid down in Regulation (EU) 2019/6, the parts of Regulation (EC) No 726/2004 that relate to procedures for such marketing authorisations and that are covered by Regulation (EU) 2019/6 should be repealed.

(3) The costs of the procedures and services associated with the operation of Regulation (EC) No 726/2004 need to be recovered from undertakings making medicinal products available on the market and from undertakings seeking authorisation. As Council Regulation (EC) No 297/95[(6)] and Regulation (EU) No 658/2014 of the European Parliament and of the Council[(7)] establish the fees payable to the Agency for the services it provides, it is not necessary to maintain any provisions on the structure and level of those fees in Regulation (EC) No 726/2004. However, in order to ensure that the entire current legal framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products remains unchanged until an agreement on changes thereto has been reached, it is appropriate to provide that Commission Regulation (EC) No 2049/2005[(8)] remain in force and continue to apply unless and until repealed. When reviewing the regulatory framework for fees payable to the Agency, the Commission should pay attention to potential risks related to the fluctuations in the fee revenue of the Agency.

(4) Before a medicinal product for human use is authorised for placing on the market of one or more Member States, it generally has to undergo extensive studies to ensure that it is safe, of high quality and effective for use in the target population. However, in the case of certain categories of medicinal products for human use, in order to meet unmet medical needs of patients and in the interest of public health, it may be necessary to grant marketing authorisations on the basis of less complete data than is normally the case. Such marketing authorisations should be granted subject to specific obligations. The categories of medicinal products for human use concerned should be the medicinal products, including orphan medicinal products, that aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats. Detailed rules on those marketing authorisations which are subject to specific obligations are specified in Commission Regulation (EC) No 507/2006[(9)]. Those rules should be maintained, but it is appropriate to consolidate them by moving their core elements into Regulation (EC) No 726/2004, while maintaining a delegation of powers that allows the Commission to supplement Regulation (EC) No 726/2004 by adjusting the procedures and provisions for granting and renewal of such marketing authorisations and by specifying the categories of medicinal products that fulfill the requirements of that Regulation for being granted a marketing authorisation subject to specific obligations.

(5) Marketing authorisations for medicinal products for human use are granted by a competent authority of a Member State pursuant to Directive 2001/83/EC of the European Parliament and of the Council[(10)] or by the Commission pursuant to Regulation (EC) No 726/2004. That Directive and that Regulation also provide the legal bases for the examination of applications for variations to the terms of marketing authorisations. Directive 2009/53/EC of the European Parliament and of the Council[(11)]

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has further harmonised the system for examination of applications for variations to cover also many medicinal products authorised under purely national procedures. That system, as laid down in Commission Regulation (EC) No 1234/2008[(12)], as amended following the adoption of Directive 2009/53/EC, should be maintained. It is appropriate, however, to consolidate that system by moving its core elements into Directive 2001/83/EC and Regulation (EC) No 726/2004, while maintaining in both acts a delegation of powers that allows the Commission to complement those core elements by laying down further necessary elements and to adapt the system for examination of applications for variations currently in force to technical and scientific progress. As the provisions on variations in Directive 2001/83/EC should remain aligned to those in Regulation (EC) No 726/2004, it is appropriate to make the same changes in both those acts.

(6) The Agency should provide advice for the regulatory acceptance of innovative development methods in the context of research and development of medicinal products for human use and veterinary medicinal products.

(7) Since 2015, the Agency, the European Food Safety Authority and the European Centre for Disease Prevention and Control have published Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Reports. It is appropriate that the Agency continue to contribute to periodic reporting on antimicrobial resistance at least every three years. Considering the seriousness of the threat from antimicrobial resistance, it is desirable to increase the reporting frequency within the limits set by feasibility and data reliability.

(8) In order to ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with Regulation (EC) No 726/2004, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties.

(9) Detailed rules concerning financial penalties for failure to comply with certain obligations laid down in Regulation (EC) No 726/2004 and in Regulation (EC) No 1901/2006 of the European Parliament and of the Council[(13)] are specified in Commission Regulation (EC) No 658/2007[(14)]. Those rules should be maintained, but it is appropriate to consolidate them by moving their core elements and the list specifying those obligations into Regulation (EC) No 726/2004, while maintaining a delegation of powers that allows the Commission to supplement Regulation (EC) No 726/2004 by laying down procedures for imposing such financial penalties. Regulation (EC) No 1901/2006 should be amended to take into account that the specification of obligations in that Regulation that are subject to financial penalties is laid down in Regulation (EC) No 726/2004 together with the powers that allow the Commission to lay down procedures for imposing such financial penalties.

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(10) As a consequence of the entry into force of the Treaty of Lisbon, the powers conferred on the Commission under Regulation (EC) No 726/2004 should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU). In order to supplement or amend certain non-essential elements of Regulation (EC) No 726/2004, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of determining the situations in which post-authorisation efficacy studies may be required, specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal, specifying the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations, establishing procedures for the examination of applications for the transfer of marketing authorisations, laying down the procedure and rules for the imposition of fines or periodic penalty payments for a failure to comply with the obligations under Regulation (EC) No 726/2004 as well as the conditions and methods for their collection. 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.

(11) In order to ensure uniform conditions for the implementation of Regulation (EC) No 726/2004 in relation to marketing authorisations for medicinal products for human use, 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)].

(12) It is appropriate, in order to provide for legal certainty, to clarify that Commission Regulation (EC) No 2141/96[(17)] remain in force and continue to apply unless and until repealed. For the same reason, it should be clarified that Regulations (EC) No 507/2006 and (EC) No 658/2007 remain in force and continue to apply unless and until repealed.

(13) Regulations (EC) No 726/2004 and (EC) No 1901/2006 as well as Directive 2001/83/EC should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 726/2004

Regulation (EC) No 726/2004 is amended as follows:

(1) the title is replaced by the following:

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Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency;

(2) the word 'Community' is replaced by the word 'Union' and any necessary grammatical changes are made;

(3) the words 'Community Register' in Article 13(1) and (2) are replaced by the words 'Union Register';

(4) the words 'Court of Justice of the European Communities' are replaced by the words 'Court of Justice of the European Union';

(5) the words 'Protocol on the Privileges and Immunities of the European Communities' are replaced by the words 'Protocol on the Privileges and Immunities of the European Union';

(6) in Article 1, the first paragraph is replaced by the following:

The purpose of this Regulation is to lay down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use and to establish a European Medicines Agency ("the Agency") which shall carry out the tasks relating to medicinal products for human use and veterinary medicinal products that are laid down in this Regulation and other relevant Union legislation.;

(7) in Article 2, the first paragraph is replaced by the following:

The definitions laid down in Article 1 of Directive 2001/83/EC shall apply for the purposes of this Regulation.

As a consequence, in this Regulation, the terms, "medicinal product" and "medicinal product for human use" mean a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC.

In addition, the following definitions shall apply for the purposes of this Regulation:

(1) "veterinary medicinal product" means a medicinal product as defined in point (1) of Article 4 of Regulation (EU) 2019/6 of the European Parliament and of the Council[(18)] ;

(2) "antimicrobial" means an antimicrobial as defined in point (12) of Article 4 of Regulation (EU) 2019/6.;

(8) Article 3 is amended as follows:

(a) paragraph 2 is replaced by the following:

2. Any medicinal product not appearing in Annex I may be granted a marketing authorisation by the Union in accordance with this Regulation, if:

a the medicinal product contains an active substance which, on 20 May 2004, was not authorised in the Union; or

b the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interest of patients' health at Union level.;