



**EUROPEAN UNION**

**THE EUROPEAN PARLIAMENT**

**THE COUNCIL**

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**LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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

**REGULATION (EU) 2018/...**  
**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of ...**

**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<sup>1</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

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<sup>1</sup> OJ C 242, 23.7.2015, p. 39.

<sup>2</sup> Position of the European Parliament of 25 October 2018 (not yet published in the Official Journal) and decision of the Council of ....

Whereas:

- (1) Directive 2001/82/EC of the European Parliament and of the Council<sup>1</sup> and Regulation (EC) No 726/2004 of the European Parliament and of the Council<sup>2</sup> 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) 2018/... of the European Parliament and of the Council<sup>3+</sup> on veterinary medicinal products has been adopted, with a view to harmonisation of the laws of the Member States.

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

<sup>2</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

<sup>3</sup> Regulation (EU) 2018/... of the European Parliament and of the Council of ... on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L...).

<sup>+</sup> OJ: Please insert in the text the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)) and insert the number, date and OJ reference of that Regulation in the footnote.

- (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 Agency ('the Agency'), but as the procedures applicable to the centralised marketing authorisation of veterinary medicinal products are laid down in Regulation (EU) 2018/...<sup>+</sup>, the parts of Regulation (EC) No 726/2004 that relate to procedures for such marketing authorisations and that are covered by Regulation (EU) 2018/...<sup>+</sup> should be repealed.

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<sup>+</sup> OJ: Please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

- (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<sup>1</sup> and Regulation (EU) No 658/2014 of the European Parliament and of the Council<sup>2</sup> 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<sup>3</sup> 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.

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<sup>1</sup> Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

<sup>2</sup> Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (OJ L 189, 27.6.2014, p. 112).

<sup>3</sup> Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).

- (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<sup>1</sup>. 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.

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<sup>1</sup> Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6).

(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<sup>1</sup> 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<sup>2</sup> 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<sup>3</sup>, 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.

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<sup>1</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

<sup>2</sup> Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (OJ L 168, 30.6.2009, p. 33).

<sup>3</sup> Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).



- (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<sup>1</sup> are specified in Commission Regulation (EC) No 658/2007<sup>2</sup>. 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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<sup>1</sup> Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

<sup>2</sup> Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10).

(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<sup>1</sup>. 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.

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<sup>1</sup> OJ L 123, 12.5.2016, p. 1.

- (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<sup>1</sup>.
- (12) It is appropriate, in order to provide for legal certainty, to clarify that Commission Regulation (EC) No 2141/96<sup>2</sup> 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) Regulation (EC) No 726/2004, Regulation (EC) No 1901/2006 and Directive 2001/83/EC should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

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<sup>1</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

<sup>2</sup> Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).

*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:  
  
‘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) 2018/... of the European Parliament and of the Council\*+;

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+ OJ: please insert in the text the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)) and insert the number, date and OJ reference of that Regulation in the footnote.

- (2) ‘antimicrobial’ means an antimicrobial as defined in point (12) of Article 4 of Regulation (EU) 2018/...<sup>+</sup>.

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\* Regulation (EU) 2018/... of the European Parliament and of the Council of ... on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L ...).’;

- (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.’;

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<sup>+</sup> OJ: please insert in the text the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)) and insert the number, date and OJ reference of that Regulation in the footnote.

(b) in paragraph 3, the introductory wording and point (a) are replaced by the following:

‘A generic medicinal product of a reference medicinal product authorised by the Union may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC under the following conditions:

(a) the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC;’;

(c) paragraph 4 is deleted;

(9) in Article 4, paragraph 3 is deleted;

(10) in Article 9(1), point (d) is replaced by the following:

‘(d) the authorisation needs to be granted subject to the conditions provided for in Article 14(8) and Article 14-a.’;

(11) Article 10 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. The Commission shall, by means of implementing acts, take a final decision within 15 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).’;



(b) paragraph 5 is replaced by the following:

‘5. The Commission shall, by means of implementing acts, adopt detailed rules for the implementation of paragraph 4 which specify the applicable time limits and procedures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).’;

(12) in Article 10b, paragraph 1 is replaced by the following:

‘1. The Commission is empowered to adopt delegated acts in accordance with Article 87b, in order to supplement this Regulation by determining the situations in which post-authorisation efficacy studies may be required under point (cc) of Article 9(4) and point (b) of Article 10a(1).’;

(13) Article 14 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Without prejudice to paragraphs 4 and 5 of this Article and to Article 14-a, a marketing authorisation shall be valid for five years.’;

(b) paragraph 7 is deleted.

(14) the following Article is inserted before Article 14a:

*“Article 14-a*

1. In duly justified cases, to meet unmet medical needs of patients, a marketing authorisation may, for medicinal products intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, be granted prior to the submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. In emergency situations, a marketing authorisation for such medicinal products may be granted also where comprehensive pre-clinical or pharmaceutical data have not been supplied.
2. For the purposes of this Article, ‘unmet medical needs’ means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the Union or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected.
3. Marketing authorisations may be granted pursuant to this Article only if the risk-benefit balance of the medicinal product is favourable and the applicant is likely to be able to provide comprehensive data.

4. Marketing authorisations granted pursuant to this Article shall be subject to specific obligations. Those specific obligations and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency.
5. As part of the specific obligations referred to in paragraph 4, the holder of a marketing authorisation granted pursuant to this Article shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is favourable.
6. The summary of product characteristics and the package leaflet shall clearly mention that the marketing authorisation for the medicinal product has been granted subject to specific obligations as referred to in paragraph 4.
7. By way of derogation from Article 14(1), a marketing authorisation granted pursuant to this Article shall be valid for one year, on a renewable basis.
8. When the specific obligations referred to in paragraph 4 of this Article have been fulfilled, the Commission may, following an application by the marketing authorisation holder, and after receiving a favourable opinion from the Agency, grant a marketing authorisation valid for five years and renewable pursuant to Article 14(2) and (3).

9. The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by specifying:
- (a) the categories of medicinal products to which paragraph 1 of this Article applies; and
  - (b) the procedures and requirements for granting a marketing authorisation pursuant to this Article and for its renewal.”;

(15) in Article 16, paragraph 4 is deleted;

(16) the following Articles are inserted:

*‘Article 16a*

1. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to the terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon.
2. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the Agency.

3. The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by:
  - (a) specifying the categories in which variations shall be classified; and
  - (b) establishing procedures for the examination of applications for variations to the terms of marketing authorisations.

#### *Article 16b*

A marketing authorisation may be transferred to a new marketing authorisation holder. Such a transfer shall not be considered to be a variation. The transfer shall be subject to prior approval by the Commission, following the submission of an application for the transfer to the Agency.

The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by establishing procedures for the examination of applications to the Agency for the transfer of marketing authorisations.’;

(17) Article 20 is amended as follows:

(a) paragraph 3 is replaced by the following:

- ‘3. At any stage of the procedure laid down in this Article, following appropriate consultation of the Agency, the Commission may take temporary measures. Those temporary measures shall be applied immediately.

Without undue delay, the Commission shall, by means of implementing acts, adopt a final decision concerning the measures to be taken in respect of the medicinal product concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2) of this Regulation.

The Commission may also, pursuant to Article 127a of Directive 2001/83/EC, adopt a decision addressed to the Member States.’;

(b) paragraph 6 is replaced by the following:

‘6. The suspensive measures referred to in paragraph 4 may be maintained in force until such time as a final decision has been adopted in accordance with paragraph 3.’;

(18) the following Article is inserted before Chapter 3:

*‘Article 20a*

Where the Agency concludes that a holder of a marketing authorisation granted pursuant to Article 14-a failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly. The Commission shall adopt a decision to vary, suspend or revoke that marketing authorisation in accordance with the procedure set out in Article 10.’;

(19) Articles 30 to 54 are deleted;

(20) Article 55 is replaced by the following:

*‘Article 55*

A European Medicines Agency is hereby established.

The Agency shall be responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products.’;

(21) Article 56 is amended as follows:

(a) in paragraph 1, point (b) is replaced by the following:

‘(b) the Committee for Veterinary Medicinal Products set up pursuant to Article 139(1) of Regulation (EU) 2018/...+.’;

(b) in paragraph 2, the first subparagraph is replaced by the following:

‘2. The committees referred to in points (a), (aa), (c), (d), (da) and (e) of paragraph 1 of this Article may each establish standing and temporary working parties. The committee referred to in point (a) of paragraph 1 of this Article may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which it may delegate certain tasks associated with drawing up the scientific opinions referred to in Article 5.’;

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<sup>+</sup> OJ: please insert the number of Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

(c) paragraph 3 is replaced by the following:

‘3. The Executive Director, in consultation with the Committee for Medicinal Products for Human Use and the Committee for Veterinary Medicinal Products, shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in point (n) of Article 57(1), including advice on the use of novel methodologies and tools in research and development, particularly regarding the development of new therapies.

Those committees shall each establish a standing working party with the sole remit of providing scientific advice to undertakings.’;

(d) in paragraph 4, the words ‘the Committee for Medicinal Products for Veterinary use’ are replaced by the words ‘the Committee for Veterinary Medicinal Products’;



(22) Article 57 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) the introductory wording and points (a) to (f) are replaced by the following:

‘1. The Agency shall provide the Member States and the institutions of the Union with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use or veterinary medicinal products which is referred to it in accordance with the Union legislation relating to medicinal products for human use or veterinary medicinal products.

To that end, the Agency, acting particularly through its committees, shall carry out the following tasks:

- (a) coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products for human use and of veterinary medicinal products which are subject to Union marketing authorisation procedures;
- (b) transmitting on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets for the medicinal products for human use;

- (c) coordinating the monitoring of medicinal products for human use and of veterinary medicinal products which have been authorised in the Union and providing advice on the measures necessary to ensure the safe and effective use of those products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;
- (d) ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products for human use and to veterinary medicinal products authorised in the Union by means of databases that are permanently accessible to all Member States;
- (e) assisting Member States with the rapid communication of information on pharmacovigilance concerns relating to medicinal products for human use to healthcare professionals and coordinating the safety announcements of the national competent authorities;
- (f) distributing appropriate information on pharmacovigilance concerns relating to medicinal products for human use to the general public, in particular by setting up and maintaining a European medicines web-portal;’;

- (ii) points (g) and (h) are deleted;
- (iii) points (i) to (t) are replaced by the following:
  - ‘(i) coordinating, as regards medicinal products for human use and veterinary medicinal products, the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice and, as regards medicinal products for human use, the verification of compliance with pharmacovigilance obligations;
  - (j) upon request, providing technical and scientific support in order to improve cooperation between the Union, its Member States, international organisations and third countries on scientific and technical issues relating to the evaluation of medicinal products for human use and of veterinary medicinal products, in particular in the context of discussions organised in the framework of international conferences on harmonisation;
  - (k) recording the status of marketing authorisations for medicinal products for human use and for veterinary medicinal products granted in accordance with Union marketing authorisation procedures;

- (l) creating a database on medicinal products for human use, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database is to facilitate the search for information already authorised for package leaflets; it is to include a section on medicinal products for human use authorised for the treatment of children; the information provided to the general public is to be worded in an appropriate and comprehensible manner;
- (m) assisting the Union and its Member States in the provision of information to health-care professionals and the general public about medicinal products for human use and about veterinary medicinal products evaluated by the Agency;
- (n) advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products for human use and of veterinary medicinal products;
- (o) checking that the conditions laid down in Union legislation on medicinal products for human use and on veterinary medicinal products and in the marketing authorisations are met in the case of parallel distribution of medicinal products for human use and on veterinary medicinal products authorised in accordance with this Regulation or, as applicable, Regulation (EU) 2018/...<sup>+</sup>;

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<sup>+</sup> OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

- (p) drawing up, at the Commission's request, any other scientific opinion concerning the evaluation of medicinal products for human use and of veterinary medicinal products or the starting materials used in the manufacture of medicinal products for human use and of veterinary medicinal products;
- (q) with a view to the protection of public health, compiling scientific information concerning pathogenic agents which might be used in biological warfare, including the existence of vaccines and other medicinal products for human use and other veterinary medicinal products available to prevent or treat the effects of such agents;
- (r) coordinating the supervision of the quality of medicinal products for human use and of veterinary medicinal products placed on the market by requesting testing of compliance with their authorised specifications by an Official Medicines Control Laboratory or by a laboratory that a Member State has designated for that purpose;
- (s) forwarding annually to the budgetary authority any information relevant to the outcome of the evaluation procedures for medicinal products for human use and veterinary medicinal products;

- (t) taking decisions as referred to in Article 7(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council\*;

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\* Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).’;

- (iv) the following point is added:

‘(u) contributing to the joint reporting with the European Food Safety Authority and European Centre for Disease Prevention and Control on the sales and use of antimicrobials in human and veterinary medicine as well as on the situation as regards antimicrobial resistance in the Union based on contributions received by Member States, taking into account the reporting requirements and periodicity in Article 57 of Regulation (EU) 2018/...<sup>+</sup>. Such joint reporting shall be carried out at least every three years.’;

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<sup>+</sup> OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

(b) in paragraph 2, the first subparagraph is replaced by the following:

‘2. The database provided for in point (l) of paragraph 1 of this Article shall include the summaries of product characteristics, the package leaflet and the information shown on the labelling. That database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC. The database shall subsequently be extended to include any medicinal product for human use authorised in the Union.’;

(23) in Article 59, paragraph 4 is replaced by the following:

‘4. Unless otherwise provided for in this Regulation, Regulation (EU) 2018/...<sup>+</sup> or Directive 2001/83/EC, where there is a fundamental conflict over scientific points and the body concerned is a body in a Member State, the Agency and the national body concerned shall work together either to resolve the conflict or to prepare a joint document clarifying the scientific points of conflict. Such joint document shall be published immediately after its adoption.’;

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<sup>+</sup> OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

(24) Article 61 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

‘1. Each Member State shall, after consultation of the Management Board, appoint, for a three-year term which may be renewed, one member and one alternate to the Committee for Medicinal Products for Human Use.

The alternates shall represent and vote for the members in their absence and may also be appointed to act as rapporteurs in accordance with Article 62.

Members and alternates shall be chosen for their role and experience in the evaluation of medicinal products for human use as appropriate and shall represent the national competent authorities.

2. The Committee for Medicinal Products for Human Use may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. Those members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

With a view to the co-opting of such members, the Committee for Medicinal Products for Human Use shall identify the specific complementary scientific competence of the additional member or members. Co-opted members shall be chosen among experts nominated by Member States or the Agency.’;

(b) in paragraphs 3, 5 and 8, the words ‘each committee’ are replaced by the words ‘the Committee for Medicinal Products for Human Use’;



(c) paragraph 4 is replaced by the following:

‘4. The Executive Director of the Agency or his or her representative and representatives of the Commission shall be entitled to attend all meetings of the committees referred to in Article 56(1), working parties and scientific advisory groups and all other meetings convened by the Agency or its committees.’;

(d) paragraphs 6 and 7 are replaced by the following:

‘6. Members of the Committee for Medicinal Products for Human Use and experts responsible for evaluating medicinal products shall rely on the scientific evaluation and resources available to national marketing authorisation bodies. Each competent national authority shall monitor the scientific level and independence of the evaluation carried out and facilitate the activities of nominated members of that Committee and experts. Member States shall refrain from giving those members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.

7. When preparing the opinion, the committees referred to in Article 56(1) shall use their best endeavours to reach a scientific consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members and divergent positions, with the grounds on which they are based.’;

(25) Article 62 is amended as follows:

(a) in paragraph 1, the third and fourth subparagraphs are replaced by the following:

‘When consulting the scientific advisory groups referred to in Article 56(2), the Committee shall forward to them the draft assessment report or reports drawn up by the rapporteur or the co-rapporteur. The opinion issued by the scientific advisory group shall be forwarded to the chairman of the relevant committee in such a way as to ensure that the deadlines laid down in Article 6(3) are met.

The substance of the opinion shall be included in the assessment report published pursuant to Article 13(3).’;

(b) paragraph 2 is replaced by the following:

‘2. Member States shall transmit to the Agency the names of national experts with proven experience in the evaluation of medicinal products for human use and veterinary medicinal products who, taking into account Article 63(2), would be available to serve on working parties or scientific advisory groups of any of the committees referred to in Article 56(1), together with an indication of their qualifications and specific areas of expertise.

The Agency shall establish and maintain a list of accredited experts. That list shall include the national experts referred to in the first subparagraph and any other experts appointed by the Agency or the Commission, and shall be updated.’;

(26) Article 64 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Executive Director shall be appointed by the Management Board, on a proposal from the Commission, for a period of five years on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the *Official Journal of the European Union* and, as appropriate, by other means. Before appointment, the candidate nominated by the Management Board shall be immediately invited to make a statement to the European Parliament and to answer any questions put by its Members. The mandate of the Executive Director may be renewed once by the Management Board, upon a proposal from the Commission. The Management Board may, upon a proposal from the Commission, remove the Executive Director from his or her post.’;

(b) in paragraph 3, the second subparagraph is replaced by the following:

‘The draft report covering the activities of the Agency in the previous year shall include information about the number of applications evaluated by the Agency, the time taken for completion of the evaluation, and the medicinal products for human use and veterinary medicinal products authorised, rejected or withdrawn.’;

(27) Article 66 is amended as follows:

(a) point (a) is replaced by the following:

‘(a) adopt an opinion on the rules of procedures of the Committee for Medicinal Products for Human Use (Article 61 of this Regulation) and the Committee for Veterinary Medicinal Products (Article 139 of Regulation (EU) 2018/...+);’;

(b) point (j) is deleted;

(c) point (k) is replaced by following:

‘(k) adopt rules to ensure the availability to the public of information concerning the authorisation or supervision of medicinal products for human use and of veterinary medicinal products (Article 80).’;

(28) in Article 67, paragraph 3 is replaced by the following:

“3. The Agency’s revenue shall consist of:

(a) a contribution from the Union;

(b) a contribution from third countries participating in the work of the Agency with which the Union has concluded international agreements for this purpose;

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<sup>+</sup> OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

- (c) fees paid by undertakings:
  - (i) for obtaining and maintaining Union marketing authorisations for medicinal products for human use and for veterinary medicinal products and for other services provided by the Agency, as provided for in this Regulation and in Regulation (EU) 2018/...<sup>+</sup>; and
  - (ii) for services provided by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC;
- (d) charges for other services provided by the Agency;
- (e) Union funding in the form of grants for participation in research and assistance projects, in accordance with the Agency's financial rules referred to in Article 68(11) and with the provisions of the relevant instruments supporting the policies of the Union.

The European Parliament and the Council ('the budgetary authority') shall re-examine, when necessary, the level of the Union contribution, referred to in point (a) of the first subparagraph, on the basis of an evaluation of needs and by taking account of the level of fees referred to in point (c) of the first subparagraph.”;

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<sup>+</sup> OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

(29) Article 68 is replaced by the following:

*“Article 68*

1. The Executive Director shall implement the budget of the Agency in accordance with Regulation (EU) 2018/1046 of the European Parliament and of the Council\* (‘the Financial Regulation’).
2. By 1 March of financial year n+1, the Agency’s accounting officer shall send the provisional accounts for year n to the Commission’s accounting officer and to the Court of Auditors.
3. By 31 March of financial year n+1, the Executive Director shall send the report on the budgetary and financial management for year n to the European Parliament, to the Council, to the Commission and to the Court of Auditors.
4. By 31 March of financial year n+1, the Commission’s accounting officer shall send the Agency’s provisional accounts for year n, consolidated with the Commission’s provisional accounts, to the Court of Auditors.

On receipt of the Court of Auditors’ observations on the Agency’s provisional accounts pursuant to Article 246 of the Financial Regulation, the Agency’s accounting officer shall draw up the Agency’s final accounts and the Executive Director shall submit them to the Management Board for an opinion.

5. The Management Board shall deliver an opinion on the Agency's final accounts for year n.
6. The Agency's accounting officer shall, by 1 July of financial year n+1, send the final accounts, together with the Management Board's opinion, to the European Parliament, to the Council, to the Court of Auditors and to the Commission's accounting officer.
7. The final accounts for year n shall be published in the *Official Journal of the European Union* by 15 November of financial year n+1.
8. The Executive Director shall send to the Court of Auditors a reply to its observations by 30 September of financial year n+1. The Executive Director shall also send that reply to the Management Board.
9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year concerned, as laid down in Article 261(3) of the Financial Regulation.
10. The European Parliament, upon a recommendation from the Council, shall, before 15 May of financial year n+2, give a discharge to the Executive Director in respect of the implementation of the budget for year n.

11. The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They shall not depart from Commission Delegated Regulation (EU) No 1271/2013\*\* unless specifically required for the Agency's operation and with the Commission's prior consent.

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\* Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

\*\* Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 328, 7.12.2013, p. 42).”;

(30) Article 70 is deleted;

(31) in Article 75, the first paragraph is replaced by the following:

‘The staff of the Agency shall be subject to the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union. In respect of its staff, the Agency shall exercise the powers which have been devolved to the appointing authority.’;



(32) Article 77 is replaced by the following:

*‘Article 77*

The Commission may, in agreement with the Management Board and the relevant committee, invite representatives of international organisations with an interest in the harmonisation of technical requirements applicable to medicinal products for human use and to veterinary medicinal products to participate as observers in the work of the Agency. The conditions for participation shall be determined in advance by the Commission.’;

(33) in Article 78, paragraph 2 is replaced by following:

‘2. The committees referred to in Article 56(1) of this Regulation and any working parties and scientific advisory groups established in accordance with that Article or Article 139(3) of Regulation (EU) 2018/...<sup>+</sup> shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use and of veterinary medicinal products, in particular patient organisations and healthcare professionals’ associations. Rapporteurs appointed by those committees may, on an advisory basis, establish contacts with representatives of patient organisations and healthcare professionals’ associations relevant to the indication of the medicinal product for human use or veterinary medicinal product concerned.’;

(34) Article 79 is deleted;

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<sup>+</sup> OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).

(35) in Article 80, the first paragraph is replaced by the following:

‘To ensure an appropriate level of transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products for human use and of veterinary medicinal products which is not of a confidential nature.’;

(36) in Article 82, paragraph 3 is replaced by the following:

‘3. Without prejudice to the unique Union nature of the content of the documents referred to in points (a) to (d) of Article 9(4), this Regulation shall not prohibit the use of two or more commercial designs for a given medicinal product for human use covered by a single marketing authorisation.’;

(37) In Article 84, paragraph 3 is deleted;

(38) the following Article is inserted:

*Article 84a*

1. The Commission may impose financial penalties in the form of fines or periodic penalty payments on the holders of marketing authorisations granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.

2. The Commission may, insofar as specifically provided for in the delegated acts referred to in point (b) of paragraph 10, impose the financial penalties referred to in paragraph 1 also on a legal entity or legal entities other than the marketing authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:
  - (a) exerted a decisive influence over the marketing authorisation holder; or
  - (b) were involved in, or could have addressed, such failure to comply with the obligation by the marketing authorisation holder.
3. Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to comply with any of the obligations, as referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.
4. In determining whether to impose a financial penalty and in determining its appropriate amount, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the failure to comply with the obligations.

5. For the purposes of paragraph 1, the Commission shall also take into account:
  - (a) any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts; and
  - (b) any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.
6. Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.

Where the marketing authorisation holder continues to fail to comply with its obligations referred to in paragraph 1, the Commission may adopt a decision imposing periodic penalty payments per day not exceeding 2,5 % of the marketing authorisation holder's average daily Union turnover in the business year preceding the date of that decision.

Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Commission's decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in paragraph 1, has been brought to an end.

7. When conducting the investigation on a failure to comply with any of the obligations referred to in paragraph 1, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency.
8. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders for the protection of their business secrets.
9. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. The Court of Justice of the European Union may cancel, reduce or increase the fine or periodic penalty payment imposed by the Commission.
10. The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by laying down:
  - (a) procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of the defence, access to file, legal representation and confidentiality;
  - (b) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;

- (c) rules on duration of procedure and limitation periods;
- (d) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments, as well as the conditions and methods for their collection.’;

(39) Article 86 is replaced by the following:

*‘Article 86*

At least every ten years, the Commission shall publish a general report on the experience acquired as a result of the operation of the procedures laid down in this Regulation and in Chapter 4 of Title III of Directive [2001/83/EC](#).’;

(40) the following Article is inserted:

*‘Article 86a*

By 2019, the Commission shall review the regulatory framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products. The Commission shall put forward, as appropriate, legislative proposals with a view to update that framework. When reviewing the regulatory framework for fees payable to the Agency, the Commission shall pay attention to potential risks related to the fluctuations in the fee revenue of the Agency.’;

(41) Article 87 is replaced by the following:

*Article 87*

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use established by Article 121 of Directive 2001/83/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council\*.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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\* 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).';

(42) Article 87b is replaced by the following:

*Article 87b*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 10b(1), 14-a(9), 16a(3), the second paragraph of Article 16b, and Article 84a(10) shall be conferred on the Commission for a period of five years from... [one day after the date of the entry into force of this amending Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Articles 10b(1), 14-a(9), 16a(3), the second paragraph of Article 16b, and Article 84a(10) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making\*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.



6. A delegated act adopted pursuant to Articles 10b(1), 14-a(9), 16a(3), the second paragraph of Article 16b, and Article 84a(10) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.?’;

- (43) Articles 87c and 87d are deleted;
- (44) the Annex becomes Annex I;
- (45) point 2 of Annex I is deleted;
- (46) the text set out in the Annex to this Regulation is added as Annex II.

*Article 2*  
*Amendments to Directive 2001/83/EC*

Directive 2001/83/EC is amended as follows:

(1) in Article 1, the following point is inserted:

‘26a. Variation or variation to the terms of a marketing authorisation:

An amendment to the contents of the particulars and documents referred to in:

- (a) Article 8(3) and Articles 9 to 11 of this Directive and Annex I thereto, Article 6(2) of Regulation (EC) No 726/2004 and in Article 7 of Regulation (EC) No 1394/2007; and
- (b) the terms of the decision granting the marketing authorisation for a medicinal product for human use, including the summary of the product characteristics and any conditions, obligations, or restrictions affecting the marketing authorisation, or changes to the labelling or the package leaflet related to changes to the summary of the product characteristics.’;

(2) Article 23b is amended as follows:

(a) paragraphs 1 to 4 are replaced by the following:

- ‘1. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon.
2. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority.
- 2a. The Commission is empowered to adopt delegated acts in accordance with Article 121a in order to supplement this Directive by:
  - (a) specifying the categories in which variations shall be classified; and
  - (b) establishing procedures for the examination of applications for variations to the terms of marketing authorisations.

3. When adopting the delegated acts referred to in this Article, the Commission shall endeavour to make possible the submission of a single application for one or more identical changes made to the terms of different marketing authorisations.
4. A Member State may continue to apply national provisions on variations applicable at the time of entry into force of Commission Regulation (EC) No 1234/2008\* to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. Where a medicinal product subject to national provisions in accordance with this Article is subsequently granted a marketing authorisation in another Member State, Regulation (EC) No 1234/2008 shall apply to that medicinal product from that date.

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\* Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).’;

- (b) in paragraph 5, the words ‘the implementing regulation’ are replaced by the words ‘Regulation (EC) No 1234/2008’;

(3) Articles 121a, 121b and 121c are replaced by the following:

‘*Article 121a*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 22b, 23b(2a), 47, 52b and 54a shall be conferred on the Commission for a period of five years from... [one day after the date of the entry into force of this amending Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Articles 22b, 23b(2a), 47, 52b and 54a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making\*.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 22b, 23b(2a), 47, 52b and 54a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.’.

### *Article 3*

#### *Amendment to Regulation (EC) No 1901/2006*

In Article 49 of Regulation (EC) No 1901/2006, paragraph 3 is replaced by the following:

- ‘3. The Commission may, in relation to medicinal products authorised in accordance with Regulation (EC) No 726/2004, impose, in accordance with the procedure laid down in Article 84a of that Regulation, financial penalties in the form of fines or periodic penalty payments for the failure to comply with the obligations set out in this Regulation that are listed in Annex II to Regulation (EC) No 726/2004.’.

#### *Article 4*

##### *Transitional provisions*

1. Regulations (EC) No 2141/96, (EC) No 2049/2005, (EC) No 507/2006 and (EC) No 658/2007 shall remain in force and continue to apply unless and until repealed.
2. Regulation (EC) No 1234/2008 shall continue to apply unless and until repealed as regards medicinal products for human use that are covered by Regulation (EC) No 726/2004 and Directive 2001/83/EC and that are not excluded from the scope of Regulation (EC) No 1234/2008 pursuant to Article 23b(4) and (5) of Directive 2001/83/EC.

#### *Article 5<sup>+</sup>*

##### *Entry into force and application*

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

Points (2) to (5), (10), (12) to (16), (18), (26), (28), (29), (31), (37), (38), (40), (42) to (44) and (46) of Article 1, and Articles 2, 3 and 4 shall apply from ... [one day after the date of the entry into force of this Regulation].

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<sup>+</sup> OJ: please ensure that this Regulation enters into force at the same time as Regulations contained in documents PE-CONS 43/18 (2014/0255(COD)) and PE-CONS 45/18 (2014/0257(COD)).

Points (1), (6) to (9), (11), (17), (19) to (25), (27), (30), (32) to (36), (39), (41) and (45) of Article 1 shall apply from ... [three years after the date of the entry into force of the VMP Regulation - PE-CONS 45/18 - 2014/0257(COD)].

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

Done at ...,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

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## ANNEX

### ‘ANNEX II

#### List of the obligations referred to in Article 84a

- (1) the obligation to submit complete and accurate particulars and documents in an application for marketing authorisation submitted to the Agency or in response to obligations laid down in this Regulation and in Regulation (EC) No 1901/2006 to the extent that the failure to comply with the obligation concerns a material particular;
- (2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal product for human use, as referred to in point (b) of Article 9(4) and in the second subparagraph of Article 10(1);
- (3) the obligation to comply with conditions or restrictions included in the marketing authorisation with regard to the safe and effective use of the medicinal product for human use as referred to in points (aa), (c), (ca), (cb) and (cc) of Article 9(4) and in Article 10(1);
- (4) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the medicinal products for human use to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 16(1);

- (5) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the medicinal product for human use is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the product, as provided for in Article 16(2);
- (6) the obligation to keep product information up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made public on the European medicines web-portal, as provided for in Article 16(3);
- (7) the obligation to provide, at the request of the Agency, any data demonstrating that the risk-benefit balance remains favourable, as provided for in Article 16(3a);
- (8) the obligation to place the medicinal product for human use on the market in accordance with the content of the summary of the product characteristics and the labelling and package leaflet as contained in the marketing authorisation;
- (9) the obligation to comply with the conditions referred to in Article 14(8) and Article 14-a;
- (10) the obligation to notify the Agency of the dates of actual marketing and of the date when the medicinal product for human use ceases to be on the market, and to provide to the Agency data relating to the volume of sales and the volume of prescriptions of the medicinal product for human use, as provided in Article 13(4);

- (11) the obligation to operate a comprehensive pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including the operation of a quality system, maintenance of a pharmacovigilance system master file and performance of regular audits, in accordance with Article 21 of this Regulation in conjunction with Article 104 of Directive 2001/83/EC;
- (12) the obligation to submit, at the request of the Agency, a copy of the pharmacovigilance system master file, as provided for in Article 16(3a);
- (13) the obligation to operate a risk management system as provided for in Article 14a and Article 21(2) of this Regulation in conjunction with Article 104(3) of Directive 2001/83/EC and Article 34(2) of Regulation (EC) No 1901/2006;
- (14) the obligation to record and report suspected adverse reactions for medicinal products for human use, in accordance with Article 28(1) of this Regulation in conjunction with Article 107 of Directive 2001/83/EC;
- (15) the obligation to submit periodic safety update reports, in accordance with Article 28(2) of this Regulation in conjunction with Article 107b of Directive 2001/83/EC;
- (16) the obligation to conduct post-marketing studies, including post-authorisation safety studies and post-authorisation efficacy studies, and to submit them for review, as provided for in Article 10a of this Regulation and Article 34(2) of Regulation (EC) No 1901/2006;

- (17) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Article 22 of this Regulation and Article 106a(1) of Directive 2001/83/EC;
  - (18) the obligation to comply with the time limits for initiating or completing measures specified in the Agency's decision on deferral following the initial marketing authorisation of the medicinal product for human use concerned and in accordance with the definitive opinion referred to in Article 25(5) of Regulation (EC) No 1901/2006;
  - (19) the obligation to place the medicinal product for human use on the market within two years of the date on which the paediatric indication is authorised, as provided for in Article 33 of Regulation (EC) No 1901/2006;
  - (20) the obligation to transfer the marketing authorisation or to allow a third party to use documentation contained in the file of the medicinal product, as provided for in the first paragraph of Article 35 of Regulation (EC) No 1901/2006;
  - (21) the obligation to submit paediatric studies to the Agency, including the obligation to enter information on third country clinical trials into the European database, as provided for in Articles 41(1) and (2), 45(1) and 46(1) of Regulation (EC) No 1901/2006;
  - (22) the obligation to submit an annual report to the Agency as provided for in Article 34(4) of Regulation (EC) No 1901/2006 and to inform the Agency in accordance with the second paragraph of Article 35 of that Regulation.'
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