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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. prev. doc.:	14352/17 PHARM 51 VETER 107 SAN 419 MI 824 AGRILEG 224 CODEC 1813
No. Cion doc.:	13240/14 PHARM 69 VETER 86 MI 666 AGRILEG 186 CODEC 1839
Subject:	Proposal for a Regulation amending Regulation (EC) No 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

I. INTRODUCTION

1. On 10 September 2014, the Commission transmitted to the European Parliament and to the Council the Proposal[1] for a Regulation amending Regulation (EC) No 726/2004[2]. This proposal was adopted together with a Proposal[3] for a Regulation on Veterinary Medicinal Products ("the VMP Regulation") and a Proposal[4] for a Regulation on medicated feed. These Proposals together constitute the "Animal medicines package".

2. The legal basis for the is Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union ("TFEU"). The ordinary legislative procedure is applicable.

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1 13240/14 PHARM 69 VETER 86 MI 666 AGRILEG 186 CODEC 1839. Being part of the "Animal medicines package" it was not accompanied by a separate Impact Assessment.
2 OJ L 136, 30.4.2004, p. 1-33.
3 13289/14 AGRILEG 185 VETER 87 PHARM 70 MI 665 CODEC 1838
4 13196/14 AGRILEG 179 VETER 84 CODEC 1813

3. The Commission proposal aims at making Regulation (EC) No 726/2004 compatible with the VMP Regulation; at creating a legal basis for laying down fees payable to the European Medicines Agency ("EMA") in an implementing act that would replace the legislative acts now in force; and at adapting the provisions on powers conferred on the Commission to the TFEU ("Lisbonisation").

4. Member States' national parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity. None of the national parliaments objected to the proposals[5].

5. The European Economic and Social Committee was consulted and issued its opinion on the Proposal on 21 January 2015[6]. The Committee of the Regions on 19 November 2014 informed the Council that it had decided not to deliver any opinion given the low impact of the measures proposed on the local or regional authorities.

6. On 10 March 2016, the European Parliament voted to adopt 35 amendments[7] to the Proposal. The vote on the legislative resolution was postponed to a later session, in order not to close the first reading. Informal contacts between the Council and the European Parliament indicate that the Parliament is willing to engage in negotiations aiming at reaching an agreement at first reading on the Proposal.

II. STATE OF PLAY

7. On 1 December 2017, the Working Party on Pharmaceuticals and Medical Devices concluded[8] its examination[9] of the Regulation amending Regulation (EC) No 726/2004. Based on interventions at that meeting the Presidency has made a few changes that are included in Annex A.

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5 http://www.ipex.eu/

6 Opinion available in document INT/762-EESC-2014-06070-00-01-AC-TRA of 21 January 2015.

7 Council document 6874/16.

8 The Danish and United Kingdom delegations maintain parliamentary scrutiny reservations.

9 Text set out in document 14352/17. Changes compared to that text are underlined in Annex A.

8. All delegations agree to the provisions that ensure compatibility of Regulation (EC) No 726/2004 with the VMP Regulation. All delegations further agree that fees payable to the EMA should be regulated in a legislative act rather than in an implementing act as proposed by the Commission. All delegations also agree to the Presidency suggestions for rewording the provisions aiming at the Lisbonisation of Regulation (EC) No 726/2004[10].

9. The provisions on variations to marketing authorisations in Directive 2001/83/EC[11] and the provisions on financial penalties for infringements of obligations in connection to marketing authorisations in Regulation (EC) No 1901/2006[12] are currently subject to Lisbonisation through the "Omnibus proposal"[13].

10. A Presidency mandate for entering into negotiations with the European Parliament on the Proposal should therefore also include the possibility for the Presidency to explore the procedural steps to ensure that at the end of those negotiations any provisions on variations agreed as part of the Lisbonisation of Directive 2001/83/EC and any provisions on financial penalties agreed as part of the Lisbonisation of Regulation (EC) No 1901/2006 are compatible with the corresponding provisions in Regulation (EC) No 726/2004. The Presidency has for this purpose developed proposals that are set out in Annex B and Annex C and that are supported by all delegations.

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10 A few delegations maintain scrutiny reservation (see footnotes on Articles 14aa and 84a(1a)).
11 OJ L 311, 28.11.2001, p. 67–128.
12 OJ L 378, 27.12.2006, p.1.
13 The provisions proposed by the Commission are set out in document 5623/17 ADD 1 REV 1.

III. CONCLUSION

In the light of the above, the Permanent Representatives Committee is invited to:

(a) mandate the Presidency to enter into negotiations aiming to reach an agreement at first reading on the Proposal for a Regulation amending Regulation (EC) No 726/2004 using the text set out in Annex A as the Council starting point; and to

(b) mandate the Presidency to explore the procedural steps necessary to ensure that at the end of those negotiations any changes to Directive 2001/83/EC and Regulation (EC) No 1901/2006 made as part of their Lisbonisation are compatible with the provisions on variations and financial penalties laid down in Regulation (EC) No 726/2004, thereby building on the texts set out in Annex B and in Annex C; and to

(c) instruct the Working Party on Pharmaceuticals and Medical devices to assist the Presidency as necessary, in particular in examining the amendments voted by the European Parliament.

ANNEX A

Proposal for a[14]

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

(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[15],

Having regard to the opinion of the Committee of the Regions[16],

Acting in accordance with the ordinary legislative procedure,

Whereas:

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[14] Explanations regarding the text formatting in the Annexes
Proposed additions and deletions of text in the Commission proposal are, respectively, indicated in ***bold italics*** or in ~~strikethrough~~.
Changes that are presented for the first time are indicated in ***bold italics and underlined*** or in ~~***bold italics strikethrough and underlined***~~.

[15] OJ C , , p. .

[16] OJ C , , p. .

(1) Directive 2001/82/EC of the European Parliament and of the Council[17] and Regulation (EC) ***No*** 726/2004 of the European Parliament and of the Council[18] constituted the Union regulatory framework for the manufacture, authorisation and distribution of veterinary medicinal products. In the light of the experience acquired 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) No~~ [~~…~~***reference to the VMP Regulation***] of the European Parliament and of the Council[19] laying down procedures for the authorisation and supervision of veterinary medicinal products has been adopted.

(2) ***It is appropriate to maintain certain provisions relating to veterinary medicinal products, in particular those relating to the European Medicines Agency, in*** Regulation (EU) No ***726/2004,*** ~~[…]~~ ~~also provides for~~ ***but as the procedures applicable to*** centralised marketing authorisations for veterinary medicinal products~~.~~ ***are laid down in Regulation [reference to the VMP Regulation], the*** ~~The~~ parts of Regulation (EC) ***No*** 726/2004 ***that relate*** ~~relating~~ to procedures for those marketing authorisation ***and that are covered by Regulation [reference to the VMP Regulation]*** should ~~therefore~~ be repealed.

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17 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).

18 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).

19 Regulation … of the European Parliament and of the Council of … … … on veterinary medicinal products (OJ L …, … … …, p. …).

(3) The costs of the procedures and services associated with the operation of this Regulation need to be recovered from those making medicinal products available on the market and from those seeking authorisation. ***As Council Regulation (EC) No 297/95[20] and Regulation (EU) No 658/2014 of the European Parliament and of the Council[21] establish the fees payable to the European Medicines Agency (hereinafter referred to as '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. 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 of changes thereto has been reached, it is however appropriate to provide that Commission Regulation (EC) No 2049/2005[22] remain in force and continue to apply unless and until repealed.*** ~~It is appropriate to establish certain principles applicable to fees payable to the Agency, including the need to take into account, as appropriate, the specific needs for SMEs. The provisions regulating fees should be brought into line with the Treaty of Lisbon.~~

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[20] ***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).***

[21] ***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.***

[22] ***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. 4-7.)***

(3a) 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. In the case of certain categories of medicinal products, however, in order to meet unmet medical needs of patients and in the interests of public health, it may be necessary to grant marketing authorisations on the basis of less complete data than is normally the case. Those marketing authorisations should be granted subject to specific obligations. The categories concerned should be 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 marketing authorisationssubject to specific obligations are specified in Commission Regulation (EC) No 507/2006[23]. Those rules should be maintained, but it is appropriate to consolidate them by moving the core provisions into the basic act, while maintaing 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 Regulation (EC) No 726/2004 for being granted a marketing authorisation subject to specific obligations.

[23] *OJ L 92, 30.3.2006, p. 6.*

(3b) Marketing authorisations for medicinal products for human use are granted by a competent authority of a Member State pursuant to Direcive 2001/83/EC[24] or by the Commission pursuant to Regulation (EC) No 726/2004. Those basic acts also provide the legal bases for the examination of applications for variations to the terms of marketing authorisations. Directive 2009/53/EC[25] of the European Parliament and of the Council 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[26] should be maintained. It is however appropriate to consolidate it by moving its core elements into the basic acts, while maintaing a delegation of powers that allows the Commission to complement the core elements by laying down further necessary elements and to adapt the system 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) 726/2004 it is appropriate to make the same changes in both legal acts.

(3c) In order to ensure the enforcement of certain obligations connected with the marketing authorisation for medicinal products granted in accordance with this Regulation, the Commission may impose financial penalties. When assessing the responsibility for failures to observe those obligations and imposing such penalties, it is important to provide means to address the fact that marketing authorisation holders may be part of a wider economic entity. Otherwise, there is a clear and identified risk that the responsibility for infringements could be evaded, which might impact the ability to impose effective, proportional and dissuasive penalties.

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24 *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. 67–128).*

25 *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, 30.06.2009, p. 33).*

26 *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).*

(4) 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*** ~~of the Treaty~~ should be delegated to the Commission in respect of ~~amending the Annex to technical and scientific progress,~~ determining the situations in which post-authorisation efficacy studies may be required, ~~laying down provisions and requirements~~ ~~for granting marketing authorisations subject to certain~~ ~~specific obligations~~ establishing procedures ~~for the examination of applications for variations to the terms of marketing authorisations and~~ for the examination of applications for the transfer of marketing authorisations and laying down the procedure for investigating the infringements and the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation~~, the maximum amounts of these penalties~~ as well as the conditions and methods for their collection.

(5) It is of particular importance that the Commission ~~carries~~ ***carry*** out appropriate consultations during its ~~preparation of delegated acts~~ ***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***[27]***. 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*** ~~The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council~~.

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27 OJ L 123, 12.5.2016, p. 1.

(6) In order to ensure uniform conditions for the implementation of Regulation (EC) No 726/2004, implementing powers should be conferred on the Commission to adopt implementing acts in relation to marketing authorisations for medicinal products for human use. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[28].

(7) Regulation (EC) No 726/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

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';

(1a) the word 'Community' shall be replaced by 'Union' and any necessary grammatical changes shall be made, [except in the second sub-paragraph of Article 13(1), in Article 13(2) ~~and in point (g) of Article 57(1)~~[29];

[28] 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).

[29] As this point is deleted, because the issue is entirely regulated in the VMP Regulation it should not be maintained here.

(2) 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 (hereinafter referred to as 'the Agency') ***that shall undertake the tasks relating to medicinal products for human use and veterinary medicinal products that are laid down in this Regulation and other Union legislation***.'

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

'***For the purposes of this Regulation, the following definitions shall apply:***

(1) "medicinal product" and "medicinal product for human use" means a medicinal product as defined in point (2) of Article 1 in Directive 2001/83/EC;

(2) "veterinary medicinal product" means a medicinal product as defined in point (1) of Article 4 in Regulation [reference to the VMP Regulation].

~~The~~ ***In addition, the*** definitions ***in points (3) to (33)*** of Article 1 of Directive 2001/83/EC shall apply for the purposes of this Regulation.';

(4) Article 3 is amended as follows:

(a) ~~in~~ paragraph 2~~, point (b)~~ 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 the provisions of 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 interests of patients health at Union level.',

(b) in paragraph 3, the introductory phrase 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.*** ~~replaced by the following:~~
~~'The Commission shall be empowered to adopt delegated acts in accordance with Article 87b in order to amend the Annex to technical and scientific progress without extending the scope of the centralised procedure.'~~;

(5) Article 4(3) is deleted;

(5a) 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 in Article 14aa.';

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

(7) Article 10b(1) is replaced by the following:

'The Commission ~~shall be~~ ***is*** empowered to adopt ~~measures, by means of~~ delegated acts in accordance with Article 87b, to ***supplement this Regulation,*** ~~determine~~ ***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).';

(7a) Article 14(1) is replaced by the following:

'1. Without prejudice to paragraphs 4 and 5 of this Article and Article 14aa a marketing authorisation shall be valid for five years.';

(7b) Article 14(7) is deleted.

(8) ***The following*** Article 14***aa*** ~~(7)~~ is ~~replaced by the following~~ ***added before Article 14a***:

'***Article 14aa***[30] [31]

~~7~~***1***. In ~~the interests of public health~~ ***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.***

[30] PT: Add a requirement that "emergency situations" must either be recognised as such by the World Health Organisation or through Decision No 1082/2013/EU.

[31] IT: Maintain an explicit reference to Orphan medicinal products.

1b. ***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 positive and the applicant is likely to be able to provide comprehensive data.***

4. ***Marketing authorisations granted pursuant to this Article shall be*** subject to certain specific obligations, to be reviewed annually by the Agency.

5. ***As part of the specific obligations, 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 positive.***

6. Those obligations and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation. 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 those obligations.

7. By way of derogation from paragraph 1 ***of Article 14***, such authorisation shall be valid for one year, on a renewable basis.

8. ***When the specific obligations 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 paragraphs 2 and 3 of Article 14.***

9. The Commission ~~shall be~~ ***is*** empowered to adopt delegated acts in accordance with Article 87b ~~in order~~ to ***supplement this Regulation by:***

(a) specifying the categories of medicinal products that fall under paragraph 1; and

(b) ~~lay down~~ ~~provisions and~~ ***specifying the procedures and*** requirements for granting ***a*** ~~such~~ marketing authorisation ***pursuant to this Article*** and for its renewal.';

(9) Article 16(4) is ***deleted.*** ~~replaced by the following:~~

(9a) The following Article 16a is added:

'***Article 16a***[32]

1. For the purposes of this Article and of Articles 5, 14 and 16, 'variation' and 'variation to the terms of a marketing authorisation' mean any amendment to any of the following:

(a) the information referred to in Article 8(3) and Articles 9 to 11 of Directive 2001/83/EC and Annex I thereto, in Article 6(2) of this Regulation, 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 connected with changes to the summary of the product characteristics.

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[32] *The Presidency stresses the need to keep the alignment between the provisions on variations in Regulation (EC) No 726/2004 with those in Article 23b of Directive 2001/83/EC (currently subject to Lisbonisation through the "Omnibus proposal" (5623/17). (See also Annex C.)*

2. 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 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.

3. 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[33] notification by the marketing authorisation holder to the Agency.

4. The Commission ~~shall be~~ ***is*** empowered to adopt delegated acts in accordance with Article 87b ***to supplement this Regulation by:***

(a) specifying the categories in which variations shall be classified,

and

(b) ~~***further specifying the***~~ establishing procedures for the examination of applications for variations to the terms of marketing authorisations ~~and for the examination of applications for the transfer of marketing authorisations~~.';

[33] *Added following agreement at the meeting of the Working party on Pharmaceuticals and Medical devices on 1 December 2017.*

(9b) The following Article 16b is added:

'Article 16b

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

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

(10) 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.

~~The~~ ***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).

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

(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 ~~reached~~ ***adopted*** in accordance with paragraph 3.';

(10a) The following Article 20a is inserted immediately after Article 20:

'Article 20a

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

(10b) 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.';

(10c) Point (b) of Article 56(1) is replaced by the following:

'(b) the Committee for Veterinary Medicinal Products established pursuant to Article 139(1) of Regulation [reference to the VMP Regulation];';

(10d) The first subparagraph of Article 56(2) is replaced by the following:

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

(10e) In Articles56(3) and 56(4) 'the Committee for Medicinal Products for Veterinary use' is replaced by 'the Committee for Veterinary Medicinal Products;';

(10f) Article 57(1) is 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 or veterinary use which is referred to it in accordance with the provisions of Union legislation relating to medicinal products.

To this end, the Agency, acting particularly through its committees, shall undertake the following tasks:

(a) coordination of 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 these medicinal products for human use;

(c) coordinating the monitoring of medicinal products for human use and of veterinary medicinal products which have been authorised within the Union and providing advice on the measures necessary to ensure the safe and effective use of those medicinal 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 data bases 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[34] 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[35] to the general public, in particular by setting up and maintaining a European medicines web-portal;

(i)[36] 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 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 shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children; the information provided to the public shall be worded in an appropriate and comprehensible manner;

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34 *Added following a comment by Cion at the meeting of the Working party on Pharmaceuticals and Medical devices on 1 December 2017.*

35 *Added following a comment by Cion at the meeting of the Working party on Pharmaceuticals and Medical devices on 1 December 2017.*

36 *The additions of text in this point are analogous to those in points (e) and (f).*

(m) assisting the Union and 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 observed in the case of parallel distribution of medicinal products for human use and on veterinary medicinal products authorised in accordance with this Regulation or Regulation [reference to the VMP Regulation], as applicable;

(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, compilation of 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 to treat, the effects of such agents;

(r) coordination of 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;

(t) taking decisions as referred to in Article 7(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use[37].';

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[37] *OJ L 378, 27.12.2006, p.1.*

(11) The first subparagraph of Article 57(2) is replaced by the following:

‘2. The database provided for in paragraph 1(l) shall include the summaries of product characteristics, the ~~patient or user~~ package leaflet and the information shown on the labelling. The 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.’;

(12) Article 59(4) is replaced by the following:

‘4. Save as otherwise provided in this Regulation, in Regulation (EU) No [~~…~~ ***reference to the VMP Regulation***] or in 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. This document shall be published immediately after its adoption.’;

(13) Article 61~~(1)~~ ***is amended as follows:***

(a) paragraph 1 is 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 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 competent national authorities.’;

(b) in paragraphs 2 and 6 'the committees' is replaced by 'the Committee for Medicinal Products for Human Use';

(c) in paragraphs 3, 5 and 8 'each committee' is replaced by 'the Committee for Medicinal Products for Human Use';

(d) in paragraph 4 'the committees' is replaced by 'the committees referred to in Article 56(1)';

(e) in paragraph 7 'each committee' is replaced by 'the committees referred to in Article 56(1)';

(13a) The third and fourth paragraph of Article 62(1) 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(s) 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).';

(13b) The first subparagraph of Article 62(2) is replaced by the following: '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. ';

~~(14) in Article 62(3), the second subparagraph is deleted~~;

(14a) The last sentence of Article 64(3) 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 within 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.';

(14b) 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) and the Committee for Veterinary Medicinal Products (Article 139 (5) in Regulation [reference to the VMP Regulation]);';

(b) 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).';

(15) the first subparagraph of Article 67(3) is replaced by the following:
'The Agency's revenue shall consist of a contribution from the Union, fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, or 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 and charges for other services provided by the Agency.';

(16) Article 70 is ***deleted.*** ~~replaced by the following:~~

~~'Article 70~~

~~1. The Commission shall, on the basis of the principles set out in paragraph 2, adopt implementing acts in accordance with the procedure laid down in Article 87(2) specifying:~~

~~(a) the structure and the level of the fees and charges referred to in Article 67(3);~~

~~(b) the services for which charges may be collected;~~

~~(c) the conditions under which small and medium-sized enterprises may pay reduced fees, defer payment of fees or receive administrative assistance;~~

~~(d) the rules defining the remuneration for work carried out by the member of the relevant committee or the coordination group who acts as a rapporteur; and~~

~~(e) the conditions for payment and remuneration.~~

~~The fees shall be set at such a level as to avoid a deficit or a significant accumulation of surplus in the budget of the Agency and be revised when this is not the case.~~

~~2. When adopting the implementing acts referred to in paragraph 1, the Commission shall take the following into account:~~

~~(a) fees shall be set at such a level as to ensure that the revenue derived from them is, in principle, sufficient to cover the costs of the services delivered and shall not exceed what is necessary to cover the costs;~~

~~(b) the level of the fees shall take into account the results of a transparent and objective evaluation of the costs of the Agency and the costs of the tasks carried out by the national competent authorities;~~

~~(c) the specific needs of SMEs shall be taken into account, as appropriate, including the possibility of splitting payments into several instalments and phases;~~

~~(d) on public health grounds the fee may be totally or partially waived for a particular category of medicinal products;~~

~~(e) the structure and amount of fees shall take into account whether information has been submitted jointly or separately;~~

~~(f) under exceptional and duly justified circumstances and upon acceptance by the Agency, the whole fee or part of it may be waived;~~

~~(g) the remuneration for the work of the rapporteur shall be paid in principle to the national competent authority employing the rapporteur or, where the rapporteur is not employed by the national competent authority, the Member State that nominated him;~~

~~(h) the time of payment for the fees and charges shall be fixed taking due account of the time limits under the provisions of this Regulation and Regulation (EU) No [...]';~~

(16a) Article 77 is replaced by 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 regulations 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 beforehand by the Commission.';

(16b) Article 78(2) is replaced by following:

'2. The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article or Article 139(3) of Regulation [reference to the VMP Regulation] 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 health-care professionals' associations. Rapporteurs appointed by these committees may, on an advisory basis, establish contacts with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product for human use or veterinary medicinal product concerned.';

(16c) The first subparagraph of Article 80 is replaced by following:

'To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director and in agreement with the Commission, shall 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.';

(16d) Article 82(3) is replaced by 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.';

(17) Article 84(3) is ***deleted.*** ~~replaced by the following:~~

(17a) The following Article 84a is inserted after Article 84:

'***Article 84a***[38]

~~3~~ ***1***. The Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe ***any of the*** obligations laid down ***in Annex II***[39] in connection with the marketing authorisations ~~granted in accordance with this Regulation~~.

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[38] *The Presidency stresses the need to keep the alignment between the provisions on financial penalties in Regulation (EC) No 726/2004 with those in Article 49(3) of Regulation (EC) No 1901/2006 on paediatric medicinal products (currently subject to "Lisbonisation" through the "Omnibus proposal" (5623/17). (See also Annex C.)*

[39] *Annex II replaces Article 1 (scope) of Commission Regulation (EC) No 658/2007 (Financial penalties for infringements in connection with marketing authorisations granted under Reg. 726/2004). It lists obligations stemming from Regulations 726/2004 and 1901/2006 (Paediatric medicines).*

1a.[40] ***The Commission may, insofar as specifically provided for in the delegated acts referred to in paragraph 9, point (aa), impose the financial penalties referred to in paragraph 1 also on a different legal entity or entities provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:***

(i) exerted a decisive influence over the marketing authorisation holder, or

(ii) were involved in, or could have addressed, the infringement by the marketing authorisation holder.

2. ***Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to observe any of the obligations referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.***

3. ***In determining whether to impose a financial penalty and in determining the appropriate financial penalty, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the infringement.***

4. ***For the purposes of paragraph 1, the Commission shall also take into account***

- ***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***
- ***any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.***

[40] PL: Scrutiny reservation.

5. Where the Commission finds that the marketing authorisation holder has committed, intentionally or negligently, an infringement as referred to in paragraph 3, it may adopt a decision imposing a fine not exceeding 5 % of the holder's Union turnover in the business year preceding the date of the decision.

Where the marketing authorisation holder has not terminated the infringement, the Commission may, in the decision referred to in paragraph 3, impose periodic penalty payments per day not exceeding 2,5 % of the holder's average daily Union turnover in the business year preceding the date of the decision.

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

~~The Commission shall be empowered to adopt delegated acts in accordance with Article 87b laying down:~~

~~(a) a list of obligations under this regulation, the infringement of which may be subject to financial penalties;~~

~~(b) procedures for the exercise of powers to impose 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;~~

~~(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 fees and periodic penalty payments, their maximum amounts as well as the conditions and methods for their collection.~~

6. For the conduct of the investigation, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency.

7. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.

8. The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

9. The Commission is empowered to adopt delegated acts in accordance with Article 87b 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;

(aa) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;

(b) rules on duration of procedure and limitation periods;

(c) elements to be taken into account by the Commission when setting the level of and imposing fees and periodic penalty payments, as well as the conditions and methods for their collection. ***';***

(18) 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.';

(19) 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. The Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.’

(20) 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 ~~delegation of~~ power ***to adopt delegated acts*** referred to in Articles ~~3(4),~~ 10b(1), ~~14(7),~~ ***14aa(9),*** ~~16(4)~~ ***16a(4), 16b*** and ~~84(3)~~ ***84a(9)*** shall be conferred on the Commission for ~~an indeterminate period of time~~ ***a period of 5 years*** from ***[…]***[41] ~~the date of entry into force of this 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 5-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 ~~3(4),~~ 10b(1), ~~14(7),~~ ***14aa(9),*** ~~16(4)~~ ***16a(4), 16b*** and ~~84(3)~~ ***84a(9)*** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

3a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[42]

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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41 *Date to be decided based on current reporting obligations.*

42 IT: Reservation against addition of this paragraph.

5. A delegated act adopted pursuant to Articles ~~3(4),~~ 10b(1), ~~14(7),~~ ***14aa(9),*** ~~16(4)~~ ***16a(4), 16b*** and ~~84(3)~~ ***84a(9)*** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of ~~two~~ ***three*** months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by ~~two~~ ***three*** months at the initiative of the European Parliament or of the Council.';

(21) Articles 30 to 54, Articles 79, 87c and 87d and point 2 of the Annex are deleted***;***

(22) The Annex becomes Annex I;

(23) The Annex set out in the Annex to this Regulation is added as Annex II.[43]

Article 1a

1. Commission Regulation (EC) No 2049/2005[44], Commission Regulation (EC) No 2141/96[45] and Commission Delegated Regulation (EU) No 357/2014[46] shall remain in force and continue to apply unless and until repealed.

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[43] *In this document this is the Annex set out in the Annex to ANNEX A.*

[44] ***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. 4-7.)***

[45] ***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.***

[46] ***Commission Delegated Regulation (EU) No 357/2014 of 3 February 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council as regards situations in which post-authorisation efficacy studies may be required. (OJ L 107, 10.4.2014, p. 1).***

2. ***Commission Regulation (EC) No 507/2006[47] shall, with the exception of Articles […][48] that are repealed, continue to apply unless and until repealed.***

3. ***Commission Regulation (EC) No 658/2007[49] shall, with the exception of Articles […][50] that are repealed, continue to apply unless and until repealed.***

4. ***Commission Regulation (EC) No 1234/2008[51] 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 exempted from the provisions in that Commission Regulation by virtue of paragraphs 4 and 5 of Article 23b of Directive 2001/83/EC. Articles […][52] of Regulation (EC) No 1234/2008 shall however be repealed.***

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47 ***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).***

48 *As part of concluding the negotiations with the European Parliament it will be examined at technical level exactly what parts of Commission Regulation (EC) No 507/2006 must be deleted in order to avoid duplication of provisions in Regulation (EC) No 726/2004.*

49 ***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).***

50 *As part of concluding the negotiations with the European Parliament it will be examined at technical level exactly what parts of Commission Regulation (EC) No 658/2007 must be deleted in order to avoid duplication of provisions in Regulation (EC) No 726/2004.*

51 ***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).***

52 *As part of concluding the negotiations with the European Parliament it will be examined at technical level exactly what parts of Commission Regulation (EC) No 1234/2008 must be deleted in order to avoid duplication of provisions in Regulation (EC) No 726/2004 and Directive 2001/83/EC.*

Article 2

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

[the entry into force and ***the*** *application* ***of the provisions that adapts Regulation (EC) No 726/2004 to the VMP Regulation*** *should be on the same dates as of the new Regulation on veterinary medicinal products* ***but the date of application for the Lisbonisation provisions could be earlier****]*

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

'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 infringement 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, as referred to in Article 9(4)(b) 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 as referred to in Article 9(4)(aa), (c), (ca), (cb) and (cc) and 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 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 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 Articles 16(3a);

(8) the obligation to place the medicinal product on the market in accordance with the content of the summary of the product characteristics and the labelling and package leaflet as contained in the marketing authorisation;

(9) the obligation to comply with the conditions referred to in Article 14(8) and 14aa;

(10) the obligation to notify the Agency of the dates of actual marketing and of the date when the product 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 product, 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 read together 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) read together 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) read together Article 107 of Directive 2001/83/EC;

(15) the obligation to submit periodic safety update reports, in accordance with Article 28(2) read together 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 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 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 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 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 marketing authorisation dossier, as provided for in the first subparagraph 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 into the European database on third country clinical trials, as provided for in Article 41(1) and (2), Article 45(1) and Article 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 subparagraph of Article 35 of that Regulation.

ANNEX B

Changes to Article 23b of Directive 2001/83/EC that result from the proposed replacement of Article 16(4) by Article 16a in Regulation (EC) No 726/2004

This Annex sets out changes to the Lisbonisation of Article 23b that is proposed by the Commission in document 5623/17 ADD 1 REV 1.

(2) in Article 23b, paragraph***s 1 and*** 2 ***are*** ~~is~~ replaced by the following:

"***1. For the purposes of this Article and of Articles 6, 24, 27, 31, 35, 107c, 107g, 107k and 107q and of Point (3)(c) of Section 1.1 in Part III of Annex I and of Point (c) of Section 1.2 in Part III of annex I, 'variation' and 'variation to the term of a marketing information' means any amendment to any of the following:***

(a) the information referred to in Article 8(3) and Articles 9 to 11 of this Directive and its Annex I, 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 connected with changes to the summary of the product characteristics.

2. 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 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.

2a. 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[53] notification by the marketing authorisation holder to the competent authority.

2***b***. The Commission is empowered to adopt delegated acts in accordance with Article 121a ***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*** ~~the arrangements referred to in in paragraph 1~~.";

(2a) in Article 23b, paragraph 3 is replaced by the following:

3. When adopting the delegated acts referred to in this Article, the Commission shall make efforts to make it possible to submit a single application for one or more identical changes made to the terms of a number of marketing authorisations.

(2b) In Article 23b(4), the words "the implementing regulation" are replaced by "Commission Regulation No 1234/2008".

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[53] *Added following agreement at the meeting of the Working party on Pharmaceuticals and Medical devices on 1 December 2017.*

ANNEX C

Changes to Article 49(3) of Regulation (EC) No 1901/2006 that result from the proposed replacement of Article 84(3) by Article 84a in Regulation (EC) No 726/2004

This Annex sets out changes to the Lisbonisation of Article 49(3) that is proposed by the Commission in document 5623/17 ADD 1 REV 1.

(2) in Article 49, paragraph 3 is replaced by the following:

"3. The Commission may***, in relation to medicinal products authorised through the procedure laid down in Regulation (EC) No 726/2004, pursuant to Article 84a of that Regulation*** impose financial penalties in the form of fines or periodic penalty payments for the infringement of the ***obligations based on*** ~~provisions of~~ this Regulation ~~or the implementing measures adopted pursuant to it~~ ***that are listed in Annex II to*** ~~in relation to medicinal products authorised through the procedure laid down in~~ Regulation (EC) No 726/2004.

~~The Commission is empowered to adopt delegated acts in accordance with Article 50a laying down:~~

~~(a) a list of obligations under this Regulation, the infringement of which may be subject to financial penalties;~~

~~(b) procedures for the exercise of powers to impose fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of defence, access to file, legal representation and confidentiality;~~

~~(c) rules on duration of procedure and limitation periods;~~

~~(d) elements to be taken into account by the Commission when setting the level of fines and periodic penalty payments, their maximum amounts, as well as the conditions and method for their collection.~~

~~For the conduct of the investigation the Commission may cooperate with national competent authorities and shall rely on resources provided by the Agency.~~

~~The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payments imposed.~~";