Council of the European Union

Brussels, 23 February 2018
(OR. en)

6462/18
ADD 1

LIMITE

PHARM 10
VETER 16
SAN 65
MI 102
AGRILEG 31
CODEC 227

Interinstitutional File:
2014/0256 (COD)

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. prev. doc.:	5923/18 PHARM 7 VETER 9 SAN 52 MI 69 AGRILEG 19 CODEC 158
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 *- Analysis of the final compromise text with a view to agreement*

I. INTRODUCTION

This "four-columns table" is intended to facilitate comparison of the text of the Commission Proposal, the amendments voted by the European Parliament on 10 March 2016, the mandate[1] agreed by the Permanent Representatives Committee on 20 December 2017 and the compromise tentatively agreed at the second informal trilogue on 21 February.

[1] This mandate was updated at the meeting of the Permanent Representatives Committee on 14 February 2018. (Doc. 5923/18 + ADD 1.)

II. ANNEXES IN THIS DOCUMENT

This document contains the following Annexes:

Annex AA lists the items in the "four-columns table" according to subject;

Annex A contains explanations of the tables used in this document;

Annex B contains the changes to the Recitals proposed by the co-legislators,

Annex C contains the changes proposed by the co-legislators for Articles 1 to 59;

Annex D contains the changes proposed by the co-legislators for Articles 61 to 87d, a new Article on changes to Directive 2001/83/EC, a new Article on changes to Regulation (EC) No 1901/2006, a new Article on Commission acts based on Regulation (EC) No 726/2004 and a new Annex;

Annex E contains consequential changes to Entry 140 (Directive 2001/83/EC) in the Lisbonisation omnibus proposal[2]; and

Annex F contains consequential changes to Entry 157 (Regulation (EC) No 1901/2006) in the Lisbonisation omnibus proposal.

The changes to the Lisbonisation omnibus proposal set out in Annexes E and F are included to give a complete picture of the provisions necessary to achieve alignment between Regulation (EC) No 726/2004, Directive 2001/83/EC and Regulation (EC) No 1901/2006 as regards "variations" and "financial penalties".

---

[2] Doc. 5623/17 + ADD 1 REV 1.

Items organised by subject

1. **Alignment to the Proposal for a Regulation on VMP and technical adjustments**

   Council text and EP AMs 1, 3, 10, 11, 14, 15, 19, 20, 21 (1st part), 22 (items 2, 3, 10, 20, 21, 23, 25, 36, 57-58, 60-64, 68, 70-76, 82-85, 109-112, 134)

2. **Conditional marketing authorisations**

   Council text - Recital 3a, Article 14aa, Article 20a (items 5, 31, 37,38, 39-48, 59, 131)

3. **Variations and Transfer of marketing authorisations**

   Council text - Recital 3b, Article 16a+16b (items 6, 49-54, 55, 133, (158-164))

4. **Financial penalties**

   Council text - Recital 3c, Article 84a + Annex II (items 7, 113-122, 128, 129, 132, 135-157, (129j, 165))

5. **Alignment to other legislative acts on medicinal products**

   Council text **(**items 129a-129i,129j,158-164, 165)

6. **Transitional provisions on Commission acts "Article 1a"**

   Council text (items 130-133)

7. **Agency fees**

   i) **Deletion of Article 70 + EP AM31** - (items 78, 107, 130)

   ii) **EP AM 32 on Article 70a & Council text of Recital 3**- (items 4, 108, 123a)

8. **Lisbonisation**

   i) **Council text on Article 3(4)** (item 27)

   ii) **Period of delegation of power 5 years & scrutiny period 3+3 months** - Article 87b + Recitals 4, 5 -Council text and EP AMs 2+35 (items 8, 9, 125+ 126)

9. **Agency tasks**

   Council text Article 57(1) (items 65, 65a)

10. **Antimicrobial Resistance**

    EP AM18 (items 6a, 65a, 67)

11. **"Alternative testing"**

    EP AM 4, 5, 12 - recitals 6b, 6c and Article 6(4a) (items 11, 12, 29, 30)

12. **Comparative efficacy**

    EP AM 6, 7, 8, 9, 13, 16, 17 - (items 13, 14, 15, 22, 32, 64, 66)

13. List of accredited experts

EP AM 21(2nd part) - (item 77)

14. Executive Director appointment

EP AM 23 Article 64(1) (item 81)

15. Agency revenues and Reserve fund

EP AM 25 and AM 26 Article 67(3) - (items 86-92)

16. Financing of Agency staff

EP AM 27, 28, 29 - (items 93, 94, 95)

17. Alignment of Article 68 to the Financial Regulation

EP AM 30 - (items 96-106)

18. Review report

EP AM 34 - (item 123)

19. Items where there are no changes to the Commission proposal

(items 1, 16, 17, 18, 19, 24, 26, 28, 33, 34, 35, 56, 69, 124, 127**)**

20. Issues addressed in other items

(items 79, 80 - in item 75, item 67 in item 65a and 6a)

Explanation of the table layout

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
1 item is unchanged compared to the previous document	Entry 157 Point (2) [Art. 49(3)]	Plain text in this column is text from the Commission proposal.	Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain.	Plain text in this column is text from the Commission proposal that Coreper wishes to maintain.	*This column contains the text tentatively agreed between the Institutions. With exception of Items 6a, 11, 63, 65a and 123a it is the same as that of the Coreper mandate of 14 February 2018 (see document 5923/18).*
1* item numbering followed by asterisk means that the contents of the item has been changed compared to that in document 5923/18.		***Text in bold italics in this column is text from the Commission proposal that the EP proposes to delete.*** Plain text in this column preceded by: **No corresponding proposal by the Commission** is taken from the consolidated version of the present Regulation (EC) No 726/2004. It is included to make changes proposed by the EP or the Council clearer.	***Text in bold italics in this column is text that the EP proposes to add to the Commission proposal.***	***Text in bold italics*** in this column is text that Coreper has <u>agreed to add</u>. Text in ~~strikethrough~~ in this column is text that Coreper has agreed to delete. <u>Underlining</u> is used to draw the attention to certain words, but has no other significance. In the cases where the compromise text from the trilogue on 21 February differs from that of the Coreper mandate of 14 February, the text of the Coreper mandate of 14 February is set out **HERE** and preceded by the text: **Presidency compromise proposal approved by Coreper on 14 February 2018:**	In the cases where the compromise text from the trilogue on 21 February differs from that of the Coreper mandate of 14 February, the text of the Coreper mandate of 14 February is for comparison set out in the neighbour column.

Citations and Recitals

This Annex contains the Citations and Recitals in the Proposal for a Regulation amending Regulation (EC) No 726/2004. For explanations of layout and fonts see Annex A.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
1	Citations	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, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:	**No EP amendment**	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, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:	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, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
2	Recital (1)	(1) Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) 726/2004 of the European Parliament and of the Council constituted the Union regulatory framework for the manufacture, authorisation and distribution of veterinary medicinal products. In the light of 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 […] of the European Parliament and of the Council[7] laying down procedures for the authorisation and supervision of veterinary medicinal products has been adopted.	**Amendment 1** (1) Directive 2001/82/EC of the European Parliament and of the Council[5] and Regulation (EC) ***No*** 726/2004 of the European Parliament and of the Council[6] 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 […] of the European Parliament and of the Council[7] laying down procedures for the authorisation and supervision of veterinary medicinal products has been adopted***, with a view to harmonisation of the laws of the Member States***.	(1) Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) ***No*** 726/2004 of the European Parliament and of the Council 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 laying down procedures for the authorisation and supervision of veterinary medicinal products has been adopted.	(1) Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) ***No*** 726/2004 of the European Parliament and of the Council 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 laying down procedures for the authorisation and supervision of veterinary medicinal products has been adopted.***, with a view to harmonisation of the laws of the Member States***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
3	Recital (2)	(2) Regulation (EU) No […] also provides for centralised marketing authorisations for veterinary medicinal products. The parts of Regulation (EC) 726/2004 relating to procedures for those marketing authorisation should therefore be repealed.	**No EP Amendment**	(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~~ ***Certain*** 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.	(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~~ ***Certain*** 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.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
4	Recital (3)	(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.	**No EP Amendment**	(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 and Regulation (EU) No 658/2014 of the European Parliament and of the Council 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 remain in force and continue to apply unless and until repealed.***	(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 and Regulation (EU) No 658/2014 of the European Parliament and of the Council 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 remain in force and continue to apply unless and until repealed.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
4 continued	Recital (3)	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.		~~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.~~	~~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.~~ ***When reviewing the legal 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.***
5	Recital (3a) (new)			***(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.***	***(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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
5 continued	Recital (3a) (new)			***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. 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.***	***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. 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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
6	Recital (3b) (new)			***(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 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 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 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.***	***(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 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 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 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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
6 continued	Recital (3b) (new)			***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.***	***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.***
6a*	Recital (3ba) (new)			*No corresponding item in the text of 20 December* **Presidency compromise proposal approved by Coreper on 14 February 2018:** ***(3ba) In 2015, the EMA, EFSA and ECDC published a Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report. It is appropriate to provide that the EMA should continue to contribute to periodic reporting on this issue that should be carried out at least every three years. Considering the seriousness of the threat from AMR, it is desirable to increase the reporting frequency within the limits set by feasibility and data reliability.***	***(3ba) Since 2015, the EMA, EFSA and ECDC have published Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Reports. It is appropriate to provide that the EMA should continue to contribute to periodic reporting on this issue that should be carried out at least every [three*] years. Considering the seriousness of the threat from AMR, it is desirable to increase the reporting frequency within the limits set by feasibility and data reliability.*** **** to be verified that this reporting frequency is not incompatible with what is agreed for the VMP Regulation.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
7	Recital (3c) (new)			***(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.***	***(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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
8	Recital (4)	(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. 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 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	**Amendment 2** **(**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. 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 of the Treaty should be delegated to the Commission in respect of amending the Annex ***with regard*** to technical and scientific progress ***so as to facilitate the placing on the market of new medicinal products***, 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	(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	(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

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
8 continued	Recital (4)	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.	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.	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.	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.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
9	Recital (5)	(5) It is of particular importance that the Commission carries out appropriate consultations during its preparation of delegated acts, including at expert level. 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.	**No EP Amendment**	(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. 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~~.	(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. 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~~.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
10	Recital (6)	(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	**Amendment 3** (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 ***and veterinary*** use. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.	(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	(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
11*	Recital (6a) (new)(EP)		**Amendment 4** ***(6a) Advances in alternative testing require the creation of a regulatory framework capable of adapting to new developments in this field, including for example the recognition and evaluation of modelling and simulation technologies.***	*No corresponding item in the text of 20 December* **Presidency compromise proposal approved by Coreper on 14 February 2018:** ***(6a) The Agency should provide advice for the regulatory acceptance of innovative development methods in the context of research and development of new therapies.***	***(6a) 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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
12	Recital (6b) (new)(EP)		**Amendment 5** ***(6b) Animal testing currently plays a key regulatory and scientific role in the development of medicines, and in relation to the replacement, reduction or refinement of animal testing is subject to Directive 2010/63/EU.***	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*
13	Recital (6c) (new) (EP)		**Amendment 6** ***(6c) In the interest of public health, authorisation decisions adopted under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy.***	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*
14	Recital (6d) (new) (EP)		**Amendment 7** ***(6d) Provision should be made for the quality, safety and efficacy criteria laid down in Directives 2001/83/EC and 2001/82/EC to apply to medicinal products authorised by the Union and it should be possible to assess the risk-benefit balance of all medicinal products when they are placed on the market, at the time of the renewal of the authorisation and at any other time the competent authority deems appropriate.***	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
15	Recital (6e) (new)(EP)		**Amendment 8** ***(6e) Member States have developed an evaluation of the comparative efficacy of medicinal products aimed at positioning a new medicinal product with respect to those that already exist in the same therapeutic class. Similarly, the Council, in its conclusions on medicinal products and public health, adopted on 29 June 2000, emphasised the importance of identifying medicinal products that presented an added therapeutic value. That evaluation should be conducted in the context of the marketing authorisation.***	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*
16	Recital (7)	(7) Regulation (EC) No 726/2004 should therefore be amended accordingly,	**No EP Amendment**	(7) Regulation (EC) No 726/2004 should therefore be amended accordingly,	(7) Regulation (EC) No 726/2004 should therefore be amended accordingly,
17		HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:

Article 1, Points (1) to (12)

This Annex contains the first Points in Article 1 of the Proposal for a Regulation amending Regulation (EC) No 726/2004. These Points set out changes to the Title and to some of the Articles in Regulation (EC) No 726/2004, starting with Article 1 and ending with article 59. For explanations of layout and fonts see Annex A.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
18	Article 1 Introductory part	*Article 1* Regulation (EC) No 726/2004 is amended as follows:	**No EP amendment**	*Article 1* Regulation (EC) No 726/2004 is amended as follows:	*Article 1* Regulation (EC) No 726/2004 is amended as follows:
19	Article 1 Point (1) [Title]	(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';		(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';	(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';
20	Article 1 Point (1a) (new) [General]			***(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) and in Article 13(2);***	***(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) and in Article 13(2);***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
21	Article 1 Point (2) [Art. 1, first para]	(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').	**No EP Amendment**	(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***.'	(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***.'

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
22	Article 1 Point (2a) (new) (EP) [Art. 1, second para]	**No corresponding proposal by the Commission** The provisions of this Regulation shall not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions**.** In particular, Member States shall be free to choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies.	**Amendment 9** ***(2a) In Article 1, the second paragraph is replaced by the following:*** "The provisions of this Regulation shall not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions***, provided that Member States take into due consideration the reference comparative evaluation of human medicinal product as referred to in Article 9(4).*** In particular, Member States shall be free to choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies."	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
23	Article 1 Point (3) [Art. 2, first para]	(3) in Article 2, the first paragraph is replaced by the following: The definitions of Article 1 of Directive 2001/83/EC shall apply for the purposes of this Regulation.';	**Amendment 10** The definitions laid down in Article 1 of Directive 2001/83/EC ***and***, ***as appropriate, in Article 4 of Regulation (EU) .../... of the European Parliament and of the Council [reference to the VMP Regulation]*** shall apply for the purposes of this Regulation.	(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.';	(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 other*** definitions of Article 1 of Directive 2001/83/EC shall apply for the purposes of this Regulation.';

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
24	Article 1 Point (4) [Art. 3]	(4) Article 3 is amended as follows:		(4) Article 3 is amended as follows:	(4) Article 3 is amended as follows:
25	Article 1 Point (4)(a) [Art. 3(2)]	(a) ***in*** paragraph 2***, point (b)*** is replaced by the following: '(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.',	**Amendment 11** (a) paragraph 2 is replaced by the following: "2. Any medicinal product not appearing in the Annex may be granted a marketing authorisation by the ***Union*** in accordance with this Regulation, if: (a) the medicinal product contains a new active substance which, on the date of entry into force of this Regulation, 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."	(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 <u>Union</u> 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.',	(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 <u>Union</u> 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.',

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
26	Article 1 Point (4)(b) [Art. 3(3)]	(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;',	**No EP Amendment**	(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;',	(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;',
27	Article 1 Point (4)(c) [Art. 3(4)]	(c) paragraph 4 is 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.';	**No EP Amendment**	(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.'~~;	(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.'~~;
28	Article 1 Point (5) [Art. 4(3)]	(5) Article 4(3) is deleted;	**No EP Amendment**	(5) Article 4(3) is deleted;	(5) Article 4(3) is deleted;

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
29	Article 1 Point (5a) (new) (EP) [Art. 6(4a) (new)]	**No corresponding proposal by the Commission**	**Amendment 12 (first part)** ***(5a) In Article 6, the following paragraphs are added:*** ***"4a. The Agency shall verify that applicants for marketing authorisations have acted in accordance with Article 13(1) of Directive 2010/63/EU.***	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text*
30	Article 1 Point (5a) (new) (EP) [Art. 6(4b) (new)]	**No corresponding proposal by the Commission**	**Amendment 12 (second part)** ***4b. The Agency shall develop a framework for the regulatory acceptance of alternative models and shall take into consideration the opportunities presented by these new concepts which aim at providing for more predictive medicines. These concepts may be based on human-relevant computer or cellular models, pathways of toxicity, or adverse outcome pathways."***	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text*
31	Article 1 Point (5a) (new) [Art. 9(1)(d)]			***(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.';***	***(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.';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
32	Article 1 Point (5b) (new) (EP) [Art. 9(4)(da) (new)]	**No corresponding proposal by the Commission**	**Amendment 13** ***(5b) In Article 9(4), the following point is inserted: "(da) the comparative evaluation of the human medicinal product;"***	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text*
33	Article 1 Point (6) [Art. 10]	(6) Article 10 is amended as follows:		(6) Article 10 is amended as follows:	(6) Article 10 is amended as follows:
34	Article 1 Point (6) [Art. 10(2)]	(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).’,	**No EP Amendment**	(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).’,	(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).’,

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
35	Article 1 Point (6) [Art. 10(5)]	(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).';	**No EP Amendment**	(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).';	(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).';
36	Article 1 Point (7) [Art. 10b(1)]	(7) Article 10b(1) is replaced by the following: 'The Commission shall be empowered to adopt measures, by means of delegated acts in accordance with Article 87b, to determine 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).';	**No EP Amendment**	(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).';	(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).';

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
37	Article 1 Point (7a) (new) [Art. 14(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.';***	***(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.';***
38	Article 1 Point (7b) (new) [Art. 14(7)]			***(7b) Article 14(7) is deleted.***	***(7b) Article 14(7) is deleted.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
39	Article 1 Point (8) [Art. 14aa (new)]	(8) Article 14 (7) is replaced by the following:		(8) ***The following*** Article 14***aa*** ~~(7)~~ is ~~replaced by the following~~ ***added before Article 14a***: ‘***Article 14aa***	(8) ***The following*** Article 14***aa*** ~~(7)~~ is ~~replaced by the following~~ ***added before Article 14a***: ‘***Article 14aa***
40	Article 1 Point (8) [Art. 14aa(1) (new)]	7. In the interests of public health a marketing authorisation may be granted	**No EP Amendment**	~~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.***	~~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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
41	Article 1 Point (8) [Art. 14aa(2) (new)]			***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.***	***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.***
42	Article 1 Point (8) [Art. 14aa(3) (new)]			***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.***	***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.***
43	Article 1 Point (8) [Art. 14aa(4) (new)]	subject to certain specific obligations, to be reviewed annually by the Agency.		***4. Marketing authorisations granted pursuant to this Article shall be*** subject to certain specific obligations, to be reviewed annually by the Agency.	***4. Marketing authorisations granted pursuant to this Article shall be*** subject to certain specific obligations, to be reviewed annually by the Agency.
44	Article 1 Point (8) [Art. 14aa(5) (new)]			***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.***	***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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
45	Article 1 Point (8) [Art. 14aa(6) (new)]	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.		***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.	***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.
46	Article 1 Point (8) [Art. 14aa(7) (new)]	By way of derogation from paragraph 1, such authorisation shall be valid for one year, on a renewable basis.		***7.*** By way of derogation from paragraph 1 ***of Article 14***, such authorisation shall be valid for one year, on a renewable basis.	***7.*** By way of derogation from paragraph 1 ***of Article 14***, such authorisation shall be valid for one year, on a renewable basis.
47	Article 1 Point (8) [Art. 14aa(8) (new)]			***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.***	***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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
48	Article 1 Point (8) [Art. 14aa(9) (new)]	The Commission shall be empowered to adopt delegated acts in accordance with Article 87b in order to lay down provisions and requirements for granting such marketing authorisation and for its renewal.’;		***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.*** 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.’;
49	Article 1 Point (9) [Art. 16(4)]	(9) Article 16(4) is replaced by the following:		(9) Article 16(4) is ***deleted.*** ~~replaced by the following:~~	(9) Article 16(4) is ***deleted.*** ~~replaced by the following:~~
50	Article 1 Point (9a) (new) [Art. 16a (new)]			***(9a) The following Article 16a is added:*** ‘***Article 16a***	***(9a) The following Article 16a is added:*** ‘***Article 16a***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
51	Article 1 Point (9a) (new) [Art. 16a(1) (new)]			***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.***	***1. For the purposes of this Regulation 'variation' and 'variation to the terms of a marketing authorisation' mean <u>an</u> amendment to <u>the contents of the particulars and documents referred to in</u>:*** ***(a) 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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
52	Article 1 Point (9a) (new) [Art. 16a(2) (new)]			***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.***	***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 <u>terms of the</u> 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.***
53	Article 1 Point (9a) (new) [Art. 16a(3) (new)]			***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 notification by the marketing authorisation holder to the Agency.***	***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 notification by the marketing authorisation holder to the Agency.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
54	Article 1 Point (9a) (new) [Art. 16a(4) (new)]	4. The Commission shall be empowered to adopt delegated acts in accordance with Article 87b 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.’;		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)*** 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~~.’;	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)*** 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~~.’;

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
55	Article 1 Point (9b) (new) [Art. 16b (new)]			***(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.';***	***(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.';***
56	Article 1 Point (10)	(10) Article 20 is amended as follows:		(10) Article 20 is amended as follows:	(10) Article 20 is amended as follows:
57	Article 1 Point (10)(a)	(a) paragraph 3 is replaced by the following:		(a) paragraph 3 is replaced by the following:	(a) paragraph 3 is replaced by the following:

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
57 continued	Article 1 Point (10)(a) [Art. 20(3)]	'3. At any stage of the procedure laid down in this Article the Commission may take temporary measures. Those temporary measures shall be applied immediately. 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.',		'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.',	'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.',
58	Article 1 Point (10)(b) [Art. 20(3)]	(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 in accordance with paragraph 3.';		(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.';	(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.';

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
59	Article 1 Point (10a) (new) [Art. 20a (new)]			***(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.';***	***(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.';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
60	Article 1 Point (10b) (new) [Art. 55]	**No corresponding proposal by the Commission** *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.	**Amendment 14** ***(10a) In Article 55, the second paragraph is replaced by the following:*** ***"***The Agency shall be responsible for coordinating the scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products ***for human use, as provided for in this Regulation, and for veterinary use, as provided for in Regulation (EU) .../... [reference to the VMP Regulation.]***"	***(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.';***	***(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.';***
61	Article 1 Point (10c) (new) [Art. 56(1)(b)]	**No corresponding proposal by the Commission** (b) the Committee for Medicinal Products for Veterinary Use, which shall be responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for veterinary use;		***(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];';***	***(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];';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
62	Article 1 Point (10d) (new) [Art. 56(2)]	**No corresponding proposal by the Commission** The committees referred to in paragraph 1(a) to (da) may each establish standing and temporary working parties. The committees referred to in paragraph 1(a) and (b) 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 ***Articles*** 5 and ***30***.	**Amendment 15** ***(10b) In Article 56(2), the first subparagraph is replaced by the following:*** "The committees referred to in paragraph 1(a) to (da) may each establish standing and temporary working parties. The committees referred to in paragraph 1(a) and (b) 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 ***of this Regulation*** and ***in Article 141(1) of Regulation (EU) .../... [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.';***	***(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.';***
63*	Article 1 Points (10e) and (10ea) (new) [Art. 56(3),(4)]			***(10e) In Articles56(3) and 56(4) 'the Committee for Medicinal Products for Veterinary use' is replaced by 'the Committee for Veterinary Medicinal Products;';***	*See next page.*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
63* continued	Article 1 Points (10e) and (10ea) (new) [Art. 56(3),(4)]	**No corresponding proposal by the Commission** 3. The Executive Director, in close consultation with the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use, shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n), particularly regarding the development of new therapies. Each committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings.		**Presidency compromise proposal approved by Coreper on 14 February 2018:** ***(10e) Articles56(3) is replaced by the following:*** ***'***3. The Executive Director, in close consultation with the Committee for Medicinal Products for Human Use and the Committee for ***Veterinary*** Medicinal Products ~~for Veterinary use~~, shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n), particularly regarding the development of new therapies***, including advice on the use of novel methodologies and tools in the research and development of such therapies***. Each committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings.***';*** ***(10ea) In Article 56(4) 'the Committee for Medicinal Products for Veterinary use' is replaced by 'the Committee for Veterinary Medicinal Products';***	***(10e) Articles56(3) is replaced by the following:*** ***'***3. The Executive Director, in close 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 Article 57(1)(n), ***including advice on the use of novel methodologies and tools in research and development***, particularly regarding the development of new therapies***.*** Each committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings.***';*** ***(10ea) In Article 56(4) 'the Committee for Medicinal Products for Veterinary use' is replaced by 'the Committee for Veterinary Medicinal Products';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
64	Article 1 Point (10f) (new) [Art. 57(1)]	**No corresponding proposal by the Commission** 1. The Agency shall provide the Member States and the institutions of the Community 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 Community legislation relating to medicinal products.	**Amendment 16** ***(10c) In Article 57(1), the first subparagraph is replaced by the following:*** "1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety***,*** efficacy ***and comparative assessment*** of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Community legislation relating to 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 use or veterinary medicinal products which is referred to it in accordance with the provisions of Union legislation relating to 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 use or veterinary medicinal products which is referred to it in accordance with the provisions of Union legislation relating to medicinal products.***
65	Article 1 Point (10f) (new) [Art. 57(1)]	**No corresponding proposal by the Commission** 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 which are subject to Community marketing authorisation procedures;		***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;***	***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;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
65 continued	Article 1 Point (10f) (new) [Art. 57(1)]	(b) transmitting on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets or inserts for these medicinal products; (c) coordinating the monitoring of 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 authorised in the Union by means of a database which is permanently accessible to all Member States;		***(b) transmitting on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets for these medicinal products <u>for human use</u>;*** ***(c) coordinating the monitoring of medicinal products <u>for human use and of veterinary medicinal products</u> 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 <u>for human use and to veterinary medicinal products</u> authorised in the Union by means of <u>data bases that are</u> permanently accessible to all Member States;***	***(b) transmitting on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets for these medicinal products <u>for human use</u>;*** ***(c) coordinating the monitoring of medicinal products <u>for human use and of veterinary medicinal products</u> 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 <u>for human use and to veterinary medicinal products</u> authorised in the Union by means of <u>data bases that are</u> permanently accessible to all Member States;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
65 continued	Article 1 Point (10f) (new) [Art. 57(1)]	(e) assisting Member States with the rapid communication of information on pharmacovigilance concerns to healthcare professionals and coordinating the safety announcements of the national competent authorities (f) distributing appropriate information on pharmacovigilance concerns to the general public, in particular by setting up and maintaining a European medicines web-portal; (g) advising on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin		***(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;***	***(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;*** *Deleted since this is regulated in the VMP Regulation.*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
65 continued	Article 1 Point (10f) (new) [Art. 57(1)]	(h) providing scientific advice on the use of antibiotics in food-producing animals in order to minimise the occurrence of bacterial resistance in the Community; this advice shall be updated when needed; (i) coordinating the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice and the verification of compliance with pharmacovigilance obligations; (j) upon request, providing technical and scientific support in order to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the evaluation of medicinal products, in particular in the context of discussions organised in the framework of international conferences on harmonisation;		***(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;***	*Deleted since this is regulated in the VMP Regulation.* ***(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;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
65 continued	Article 1 Point (10f) (new) [Art. 57(1)]	(k) recording the status of marketing authorisations for medicinal products granted in accordance with Community procedures; (l) creating a database on medicinal products, 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; (m) assisting the Community and Member States in the provision of information to health-care professionals and the general public about medicinal products evaluated by the Agency;		***(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 <u>for human use</u>, 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;*** ***(m) assisting the <u>Union</u> and Member States in the provision of information to health-care professionals and the general public about medicinal products <u>for human use and about veterinary medicinal products</u> evaluated by the Agency;***	***(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 <u>for human use</u>, 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;*** ***(m) assisting the <u>Union</u> and Member States in the provision of information to health-care professionals and the general public about medicinal products <u>for human use and about veterinary medicinal products</u> evaluated by the Agency;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
65 continued	Article 1 Point (10f) (new) [Art. 57(1)]	(n) advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products; (o) checking that the conditions laid down in Community legislation on medicinal products and in the marketing authorisations are observed in the case of parallel distribution of medicinal products authorised in accordance with this Regulation; (p) drawing up, at the Commission's request, any other scientific opinion concerning the evaluation of medicinal products or the starting materials used in the manufacture of medicinal products;		***(n) advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products <u>for human use and of veterinary medicinal products</u>;*** ***(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 <u>for human use and on veterinary medicinal products</u> authorised in accordance with this Regulation <u>or Regulation [reference to the VMP Regulation], as applicable</u>;*** ***(p) drawing up, at the Commission's request, any other scientific opinion concerning the evaluation of medicinal products <u>for human use and of veterinary medicinal products</u> or the starting materials used in the manufacture of medicinal products <u>for human use and of veterinary medicinal products</u>;***	***(n) advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products <u>for human use and of veterinary medicinal products</u>;*** ***(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 <u>for human use and on veterinary medicinal products</u> authorised in accordance with this Regulation <u>or Regulation [reference to the VMP Regulation], as applicable</u>;*** ***(p) drawing up, at the Commission's request, any other scientific opinion concerning the evaluation of medicinal products <u>for human use and of veterinary medicinal products</u> or the starting materials used in the manufacture of medicinal products <u>for human use and of veterinary medicinal products</u>;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
65 continued	Article 1 Point (10f) (new) [Art. 57(1)]	(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 available to prevent, or to treat, the effects of such agents; (r) coordination of the supervision of the quality of 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;		***(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 <u>for human use and other veterinary medicinal products</u> available to prevent, or to treat, the effects of such agents;*** ***(r) coordination of the supervision of the quality of medicinal products <u>for human use and of veterinary medicinal products</u> 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;***	***(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 <u>for human use and other veterinary medicinal products</u> available to prevent, or to treat, the effects of such agents;*** ***(r) coordination of the supervision of the quality of medicinal products <u>for human use and of veterinary medicinal products</u> 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 <u>for medicinal products for human use and veterinary medicinal products</u>;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
65 continued	Article 1 Point (10f) (new) [Art. 57(1)]	(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		***(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.';***	***(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;***
65a*	Article 1 Point (10f) (new) [Art. 57(1)]	**No corresponding proposal by the Commission**	**Amendment 18** ***(10e) In the second subparagraph of Article 57(1), the following point is added:*** ***"(tb) in cooperation with EFSA and ECDC annually publishing a report on the use of antimicrobials for human and veterinary medicine as well as the current situation on the antimicrobial resistance in the Union."***	*No corresponding item in the text of 20 December* **Presidency compromise proposal approved by Coreper on 14 February 2018:** ***(u) contributing to the joint reporting with EFSA and ECDC 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 54 of the VMP Regulation. Such reporting shall be carried out at least every three years.***	***(u) contributing to the joint reporting with EFSA and ECDC 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 54 of the VMP Regulation. Such reporting shall be carried out at least every [three*] years.';*** **** to be verified that this reporting frequency is not incompatible with what is agreed for the VMP Regulation.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
66	Article 1 Point (10d) (new) (EP) [Art. 57(1)]	**No corresponding proposal by the Commission**	**Amendment 17** ***(10d) In the second subparagraph of Article 57(1), the following point is added: "(ta) cooperating with the Health Technology Assessment Network, with health technology assessment bodies and other national authorities involved in market access, in particular to facilitate their assessment and reduce disparities in patients' access to health technologies***."	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*
67	Article 1 Point (10e) (new) (EP) [Art. 57(1)]	**No corresponding proposal by the Commission**	**Amendment 18** ***(10e) In the second subparagraph of Article 57(1), the following point is added: "(tb) in cooperation with EFSA and ECDC annually publishing a report on the use of antimicrobials for human and veterinary medicine as well as the current situation on the antimicrobial resistance in the Union."***	**No corresponding proposal by the Council**	*See Item 65a.*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
68	Article 1 Point (11) [Art. 57(2)]	(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 authorised in the Union.';	**Amendment 19** 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.	(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.';	(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.';

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
69	Article 1 Point (12) [Art. 59(4)]	(12) Article 59(4) is replaced by the following: '4. Save as otherwise provided in this Regulation, in Regulation (EU) No […] 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.';		(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.';	(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.';

Article 1, Points (13) to (23), Article 1a, Article 2 and Annex

This Annex contains the last Points in Article 1 of the Proposal for a Regulation amending Regulation (EC) No 726/2004. These Points set out changes to some of the Articles in Regulation (EC) No 726/2004, starting with Article 61 and ending with article 87b. This Annex also contains the new Articles 1aa, 1ab and 1a proposed by Council, Article 2 and an Annex intended to become Annex II of Regulation (EC) No 726/2004. For explanations of layout and fonts see Annex A.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
70	Article 1 Point (13)(a) [Art. 61(1)]	(13) Article 61(1) is replaced by the following:	**Amendment 20**	(13) Article 61~~(1)~~ ***is amended as follows:*** ***(a) paragraph 1*** is replaced by the following:	(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. The alternates shall represent and vote for the members in their absence and may act as rapporteurs in accordance with Article 62.	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***.	‘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.	‘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.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
70 continued	Article 1 Point (13)(a) [Art. 61(1)]	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.’;		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.’;	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.’;
71	Article 1 Point (13)(b) [Art. 61(2),(6)]			***(b) in paragraphs 2 and 6 ‘the committees’ is replaced by ‘the Committee for Medicinal Products for Human Use’;***	***(b) in paragraphs 2 and 6 ‘the committees’ is replaced by ‘the Committee for Medicinal Products for Human Use’;***
72	Article 1 Point (13)(c) [61(3),(5),(8)]			***(c) in paragraphs 3, 5 and 8 ‘each committee’ 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’;***
73	Article 1 Point (13)(d) [Art. 61(4)]			***(d) in paragraph 4 ‘the committees’ is replaced by ‘the committees referred to in Article 56(1)’;***	***(d) in paragraph 4 ‘the committees’ is replaced by ‘the committees referred to in Article 56(1)’;***
74	Article 1 Point (13)(e) [Art. 61(7)]			***(e) in paragraph 7 ‘each committee’ 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)’;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
75	Article 1 Point (13a) (new) [Art. 62(1)]	**No corresponding proposal by the Commission**	**From Amendment 22** (14) Article 62 ***is amended as follows:***	***(13a) The third and fourth paragraph of Article 62(1) are replaced by the following:***	***(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) and Article ***31(3)*** are met.	***(a) in paragraph 1, the third subparagraph is 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) ***of this Regulation*** and ***in*** Article ***40(3) of Regulation (EU) .../... [reference to the VMP Regulation]*** are met."; ***(b) in paragraph 1, the fourth subparagraph is 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.***	***'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) and Article ***38(3)***.	"The substance of the opinion shall be included in the assessment report published ***in accordance with*** Article 13(3) ***of this Regulation*** and Article ***40(11) of Regulation (EU) .../... [reference to the VMP Reg].";***	***The substance of the opinion shall be included in the assessment report published pursuant to Article 13(3).';***	***The substance of the opinion shall be included in the assessment report published pursuant to Article 13(3).';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
76	Article 1 Point (13b) (new) [Art. 62(2)]	**No corresponding proposal by the Commission** 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*** 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.	**Amendment 21 (First part)** ***(13a) Article 62(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 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.	***(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 <u>and veterinary medicinal products</u> 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. ';***	***(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 <u>and veterinary medicinal products</u> 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. ';***
77	Article 1 Point (13a) (new)(EP) [Art. 62(2)]	**No corresponding proposal by the Commission** The Agency shall keep an up-to-date list of accredited experts. The list shall include the experts referred to in the first subparagraph and other experts appointed ***directly*** by the Agency. The list shall be updated.	**Amendment 21 (Second part)** The Agency shall keep an up-to-date list of accredited experts. The list shall include the experts referred to in the first subparagraph and ***any*** other experts appointed by the Agency ***or the Commission***. The list shall be updated."	**No corresponding proposal by the Council**	The Agency shall keep an up-to-date list of accredited experts. The list shall include the experts referred to in the first subparagraph and ***any*** other experts appointed by the Agency ***or the Commission***. The list shall be updated."

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
78	Article 1 Point (14) [Art. 62(3)]	(14) ***in*** Article 62***(3), the second subparagraph is deleted;***	**Amendment 22 (First part)** (14) Article 62 ***is amended as follows:***	~~(14) in Article 62(3), the second subparagraph is deleted;~~	~~(14) in Article 62(3), the second subparagraph is deleted;~~
79	Article 1 Point (14) [Art. 62(1)]		**Amendment 22 (Second part)** ***(a) in paragraph 1, the third subparagraph is 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) ***of this Regulation*** and ***in*** Article ***40(3) of Regulation (EU) .../... [reference to the VMP Regulation]*** are met.";"		*See Item 75*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
80	Article 1 Point (14) [Art. 62(1)]		**Amendment 22 (Third part)** ***(b) in paragraph 1, the fourth subparagraph is replaced by the following:*** "The substance of the opinion shall be included in the assessment report published ***in accordance with*** Article 13(3) ***of this Regulation*** and Article ***40(11) of Regulation (EU) .../... [reference to the VMP Regulation].";***		*See Item 75*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
81	Article 1 Point (14a) (new) (EP) [Art. 64(1)]	**No corresponding proposal by the Commission** 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 elsewhere. Before appointment, the candidate nominated by the Management Board shall be invited forthwith to make a statement to the European Parliament and to answer any questions put by its Members. His mandate may be renewed once. The Management Board may, upon a proposal from the Commission, remove the Executive Director from his post.	**Amendment 23** ***(14a) Article 64(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 elsewhere. Before appointment, the candidate nominated by the Management Board shall be invited forthwith to make a statement to the European Parliament and to answer any questions put by its Members. His mandate may be renewed once ***by the Management Board, in consultation with the Commission***. The Management Board may, upon a proposal from the Commission, remove the Executive Director from his post."	**No corresponding proposal by the Council**	***(14a) Article 64(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 elsewhere. Before appointment, the candidate nominated by the Management Board shall be invited forthwith to make a statement to the European Parliament and to answer any questions put by its Members. His mandate 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 post."

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
82	Article 1 Point (14a) (new) [Art. 64(3)]	**No corresponding proposal by the Commission** 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 authorised, rejected or withdrawn	**No EP Amendment**	***(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.';***	***(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.';***
83	Article 1 Point (14b)(a) (new) [Art. 66(a)]	**No corresponding proposal by the Commission** (a) adopt an opinion on the rules of procedures of the Committee for Medicinal Products for Human Use ***and the Committee for Medicinal Products for Veterinary Use*** (Article 61);	**Amendment 24 (First part)** ***(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 ***of this Regulation***) ***and the Committee for Medicinal Products for Veterinary Use (Article 140 of Regulation (EU) ..../... [reference to the VMP Regulation]);";***	***(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]);';***	***(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]);';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
84	Article 1 Point (14b)(b) (new)(EP) [Art. 66(j)]	**No corresponding proposal by the Commission** ***(j) adopt provisions for providing assistance to pharmaceutical companies (Article 79);***	**Amendment 24 (Second part)** ***(b) point (j) is deleted.***		***(aa) point (j) is deleted.***
85	Article 1 Point (14b)(b) (new) [Art. 66(k)]	**No corresponding proposal by the Commission** (k) adopt rules to ensure the availability to the public of information concerning the authorisation or supervision of medicinal products (Article 80).		***(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 <u>for human use and of veterinary medicinal products</u> (Article 80).';***	***(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 <u>for human use and of veterinary medicinal products</u> (Article 80).';***
86	Article 1 Point (15) [Art. 67(3)]	(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**,**	**Amendment 25** (15) Article 67(3) is replaced by the following: "The Agency's revenue shall consist of***:*** ***(a)*** a contribution from the Union***;***	(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,	(15) Article 67(3) is replaced by the following: 'The Agency's revenue shall consist of ***(a)*** a contribution from the Union***;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
87	Article 1 Point (15) [Art. 67(3)]		***(b) a contribution from any European third country with which the Union has concluded agreements;***		***(b) a contribution from third countries participating in the work of the Agency with which the Union has concluded international agreements;***
88	Article 1 Point (15) [Art. 67(3)]	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	***(c) the*** fees paid by undertakings for obtaining and maintaining Union marketing authorisations ***for human and veterinary medicinal products*** and for other services provided by the Agency, ***as provided for in this Regulation and in Regulation (EU) .../... [reference to the VMP Regulation],*** 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***;***	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	***(c)*** fees paid by undertakings 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 [reference to the VMP Regulation],*** 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***;***
89	Article 1 Point (15) [Art. 67(3)]	***and*** charges for other services provided by the Agency.’;	***(d)*** charges for ***any*** other services provided by the Agency***; and***	and charges for other services provided by the Agency.’;	***(d)*** charges for ***any*** other services provided by the Agency***; and***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
90	Article 1 Point (15) [Art. 67(3)]		***(e) other sources of income, including any ad-hoc grants within the scope of Title VI of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council [Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, s. 1).].***		***(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.***
91	Article 1 Point (15) [Art. 67(3)]	The European Parliament and the Council (***hereinafter referred to as*** 'the budgetary authority') shall re-examine, when necessary, the level of the ***Community*** contribution on the basis of an evaluation of needs and taking account of the level of fees.	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.';	**No corresponding proposal by the Council**	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.';

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
92	Article 1 Point (15a) (new) (EP) [Art. 67(3)]	**No corresponding proposal by the Commission**	**Amendment 26** ***(15a) In Article 67(3), the following subparagraph is inserted after the first subparagraph:*** ***"In order to safeguard fluctuations in fee revenue, any positive budget outturn of a financial year (N) shall be set aside as assigned revenue and serve as a reserve in the event that actual fee revenue be below budgeted appropriations. The total amount of such a safeguard fund shall not exceed the Agency's appropriations for the fee revenue of the past year***."	**No corresponding proposal by the Council**	*See Item 4.*
93	Article 1 Point (15b) (new) (EP) [Art. 67(6)]	**No corresponding proposal by the Commission**	**Amendment 27** ***(15b) In Article 67(6), the following subparagraph is added:*** ***"The draft establishment plan shall contain the number of staff required by the Agency to provide the services financed through fees and the number of staff financed by the Union budget***."	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
94	Article 1 Point (15c) (new) (EP) [Art. 67(8)]	**No corresponding proposal by the Commission** 8. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.	**Amendment 28** ***(15c) Article 67(8) is replaced by the following:*** "8. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan ***concerning the staff financed by the Union budget*** and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty."	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
95	Article 1 Point (15d) (new) (EP) [Art. 67(9)]	**No corresponding proposal by the Commission** The budgetary authority shall adopt the establishment plan for the Agency.	**Amendment 29** ***(15d) In Article 67(9), the second subparagraph is replaced by the following:*** "The budgetary authority shall adopt the establishment plan ***for the staff financed by the Union budget*** for the Agency."	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*
96	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** "1. The Executive Director shall implement the budget of the Agency.	**Amendment 30 (First part)** ***(15e) Article 68 is replaced by the following:*** "1. The Executive Director shall implement the budget of the Agency.	**No corresponding proposal by the Council**	***(15e) Article 68 is replaced by the following:*** ***'1. The Executive Director shall implement the budget of the Agency <u>in accordance with the provisions of the regulation on the financial rules applicable to the general budget of the Union</u>.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
97	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 2. By 1 March ***at*** the ***latest*** following ***each*** financial year, the Agency's accounting officer shall ***communicate*** the provisional accounts to the Commission's accounting officer ***together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the Financial Regulation applicable to the general budget of the European Communities(19) (hereinafter referred to as the "general Financial Regulation").***	**Amendment 30 (Second part)** 2. By 1 March ***of*** the following financial year, the Agency's accounting officer shall ***send*** the provisional accounts to the Commission's Accounting Officer ***and to the Court of Auditors.***	**No corresponding proposal by the Council**	2. By 1 March ***of*** the following financial year, the Agency's accounting officer shall ***send*** the provisional accounts to the Commission's Accounting Officer ***and to the Court of Auditors.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
98	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 3. By 31 March ***at*** the ***latest*** following ***each*** financial year, the ***Commission's accounting officer*** shall ***submit the Agency's provisional accounts to the Court of Auditors, together with a*** report on the budgetary and financial management ***for that financial year. The report on the budgetary and financial management for the financial year shall also be forwarded*** to the European Parliament ***and*** the Council.	**Amendment 30 (Third part)** 3. By 31 March ***of*** the following financial year, the ***Executive Director*** shall ***send the*** report on the budgetary and financial management to the European Parliament, ***the Commission,*** the Council ***and the Court of Auditors***.	**No corresponding proposal by the Council**	3. By 31 March ***of*** the following financial year, the ***Executive Director*** shall ***send the*** report on the budgetary and financial management to the European Parliament, ***the Commission,*** the Council ***and the Court of Auditors***.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
99	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article ***129*** of the ***general*** Financial Regulation***, the Executive Director*** shall draw up the Agency's final accounts ***under his own responsibility*** and submit them to the Management Board for an opinion.	**Amendment 30 (Fourth part)** 4. ***By 31 March of the following financial year, the Commission's accounting officer shall send the Agency's provisional accounts, 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 ***148*** of the Financial Regulation ***applicable to the general budget of the Union, the accounting officer*** shall draw up the Agency's final accounts and ***the Executive Director shall*** submit them to the Management Board for an opinion.	**No corresponding proposal by the Council**	4. ***By 31 March of the following financial year, the Commission's accounting officer shall send the Agency's provisional accounts, 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 ***148*** of the Financial Regulation ***applicable to the general budget of the Union, the accounting officer*** shall draw up the Agency's final accounts and ***the Executive Director shall*** submit them to the Management Board for an opinion.
100	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 5. The Management Board ***of the Agency*** shall deliver an opinion on the Agency's final accounts.	**Amendment 30 (Fifth part)** 5. The Management Board shall deliver an opinion on the Agency's final accounts.	**No corresponding proposal by the Council**	5. The Management Board shall deliver an opinion on the Agency's final accounts.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
101	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 6. The ***Executive Director*** shall, by 1 July ***at the latest*** following each financial year, ***forward*** the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.	**Amendment 30 (Sixth part)** 6. The ***accounting officer*** shall, by 1 July following each financial year, ***send*** the final accounts to the European Parliament, the Council, ***the accounting officer of*** the Commission and the Court of Auditors, together with the Management Board's opinion.	**No corresponding proposal by the Council**	6. The ***accounting officer*** shall, by 1 July following each financial year, ***send*** the final accounts to the European Parliament, the Council, ***the accounting officer of*** the Commission and the Court of Auditors, together with the Management Board's opinion..
102	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 7. The final accounts shall be published.	**Amendment 30 (Seventh part)** 7. The final accounts shall be published ***in the Official Journal of the European Union by 15 November of the following year.***	**No corresponding proposal by the Council**	7. The final accounts shall be published ***in the Official Journal of the European Union by 15 November of the following year.***
103	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 8. The ***Agency's*** Executive Director shall send the Court of Auditors a reply to its observations by 30 September ***at the latest. He shall also send this reply to the Management Board***.	**Amendment 30 (Eighth part)** 8. The Executive Director shall send ***to*** the Court of Auditors a reply to its observations by 30 September.	**No corresponding proposal by the Council**	***8. The Executive Director shall send to the Court of Auditors a reply to its observations by 30 September. He or she shall also send this reply to the Management Board.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
104	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 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 in question, ***as laid down in Article 146(3) of the general*** Financial Regulation.	**Amendment 30 (Ninth part)** 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 in question, ***in accordance with Article 165(3) of the*** Financial Regulation ***applicable to the general budget of the Union.***	**No corresponding proposal by the Council**	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 in question, ***in accordance with Article 165(3) of the*** Financial Regulation ***applicable to the general budget of the Union.***
105	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 10. ***The European Parliament***, on a recommendation from the Council ***acting by a qualified majority,*** shall, before ***30 April*** of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.	**Amendment 30 (Tenth part)** 10. On a recommendation from the Council***, the European Parliament*** shall, before ***15 May*** of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.	**No corresponding proposal by the Council**	10. On a recommendation from the Council***, the European Parliament*** shall, before ***15 May*** of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
106	Article 1 Point (15e) (new) (EP) [Art. 68]	**No corresponding proposal by the Commission** 11. The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They ***may*** not depart from Commission ***Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities(20),*** unless specifically required for the Agency's operation and with the Commission's prior consent.	**Amendment 30 (Eleventh part)** 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."	**No corresponding proposal by the Council**	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.***';***
107	Article 1 Point (16) [Art. 70]	***(16) Article 70 is 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:***	**Amendment 31** ***deleted***	(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:~~	(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:~~

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
107 continued	Article 1 Point (16) [Art. 70]	***(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.***		~~(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.~~	~~(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.~~

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
107 continued	Article 1 Point (16) [Art. 70]	***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;***		~~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;~~	~~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;~~

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
107 continued	Article 1 Point (16) [Art. 70]	***(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 […]';***		~~(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 […]';~~	~~(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 […]';~~

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
108	Article 1 Point (16a) (new) (EP) [Art. 70a (new)]	**No corresponding proposal by the Commission**	**Amendment 32** ***(16a) The following Article is inserted:*** "***Article 70a*** ***With regard to the level and the structure of the fees referred to in Article 67(3) of this Regulation, Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 shall be applicable until an amendment of Regulation (EC) No 297/95 or any other relevant provisions on fees are adopted and become applicable.***"	**No corresponding proposal by the Council**	*This amendment is not included in the compromise text.*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
109	Article 1 Point (16a) (new) [Art. 77]	**No corresponding proposal by the Commission** 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 to participate as observers in the work of the Agency. The conditions for participation shall be determined beforehand by the Commission.	**No EP Amendment**	***(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 <u>for human use and to veterinary medicinal products</u> to participate as observers in the work of the Agency. The conditions for participation shall be determined beforehand by the Commission.';***	***(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 <u>for human use and to veterinary medicinal products</u> to participate as observers in the work of the Agency. The conditions for participation shall be determined beforehand by the Commission.';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
110	Article 1 Point (16b) (new) [Art. 78(2)]	**No corresponding proposal by the Commission** 2. The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of 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 concerned.	**No EP Amendment**	***(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.';***	***(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.';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
111	Article 1 Point (16c) (new) [Art. 80]	**No corresponding proposal by the Commission** 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 which is not of a confidential nature.	**No EP Amendment**	***(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.';***	***(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.';***
112	Article 1 Point (16d) (new) [Art. 82(3)]	**No corresponding proposal by the Commission** 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) ***and in points (a) to (e) of Article 34(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.	**Amendment 33** ***(16b) Article 82(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."	***(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.';***	***(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.';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
113	Article 1 Point (17) [Art. 84(3)]	(17) Article 84(3) is replaced by the following:	**No EP Amendment**	(17) Article 84(3) is ***deleted.*** ~~replaced by the following:~~	(17) Article 84(3) is ***deleted.*** ~~replaced by the following:~~
114	Article 1 Point (17a) (new) [Art. 84a (new)]	~~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*** in connection with the marketing authorisations ~~granted in accordance with this Regulation~~.		***(17a) The following Article 84a is inserted after Article 84:*** '***Article 84a*** ~~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*** in connection with the marketing authorisations ~~granted in accordance with this Regulation~~.	***(17a) The following Article 84a is inserted after Article 84:*** '***Article 84a*** ~~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*** in connection with the marketing authorisations ~~granted in accordance with this Regulation~~.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
115	Article 1 Point (17a) (new) [Art. 84a (new)]			***1a. 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.***	***1a. 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.***
116	Article 1 Point (17a) (new) [Art. 84a (new)]			***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.***	***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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
117	Article 1 Point (17a) (new) [Art. 84a (new)]			***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.***	***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.***
118	Article 1 Point (17a) (new) [Art. 84a (new)]			***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.***	***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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
119	Article 1 Point (17a) (new) [Art. 84a (new)]			***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***.	***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***.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
120	Article 1 Point (17a) (new) [Art. 84a (new)]	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.		~~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.~~	~~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.~~

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
121	Article 1 Point (17a) (new) [Art. 84a (new)]	For the conduct of the investigation, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency. 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. 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.		***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.	***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.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
122	Article 1 Point (17a) (new) [Art. 84a (new)]			***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.'';***	***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.'';***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
123	Article 1 Point (18) [Art. 86]	(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.	**Amendment 34** At least every ***five*** 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**,** in Chapter 4 of Title III of Directive 2001/83/EC ***and in Regulation (EU) .../... [reference to the VMP Regulation].***	(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.';	(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.';

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
123a*	Article 1 Point (18a) [Art. 86a (new)]		**EP compromise proposal:** ***Article 86a*** ***By (2019) the Commission shall review the legal framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products, and shall put forward, as appropriate, legislative proposals with a view to updating that framework.***	*No corresponding item in the text of 20 December* **Presidency compromise proposal approved by Coreper on 14 February 2018:** ***(18a) The following Article is inserted:*** ***Article 86a*** ***By (2019) the Commission shall review the legal framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products, and shall put forward, as appropriate, legislative proposals with a view to update that framework.***	***(18a) The following Article is inserted:*** ***Article 86a*** ***By 2019 the Commission shall review the legal 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 legal 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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
124	[Art. 86] [Art. 87]	(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.'	**No EP Amendment**	(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.'	(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.'

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
125	Article 1 Point (20) [Art. 87b]	(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 referred to in Articles 3(4), 10b(1), 14(7), 16(4) and 84(3) shall be conferred on the Commission for ***an indeterminate*** period of ***time*** from the date of entry into force of this Regulation.	**Amendment 35** 2. The delegation of power referred to in Articles 3(4), 10b (1), 14(7), 16(4) and 84(3) shall be conferred on the Commission for ***a*** period of ***five years*** from 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 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.***	(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 ***[Date to be decided based on current reporting obligations.]*** ~~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.***	(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 ***[Date to be decided based on current reporting obligations.]*** ~~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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
125 continued	Article 1 Point (20) [Art. 87b]	3. The delegation of power referred to in Articles 3(4), 10b(1), 14(7), 16(4) and 84(3) 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. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		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.*** 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	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.*** 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
126	Article 1 Point (20) [Art. 87b]	5. A delegated act adopted pursuant to Articles 3(4), 10b(1), 14(7), 16(4) and 84(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two 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 months at the initiative of the European Parliament or of the Council.';		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.';	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.';
127	Article 1 Point (21)	(21) Articles 30 to 54, Articles 79, 87c and 87d and point 2 of the Annex are deleted.		(21) Articles 30 to 54, Articles 79, 87c and 87d and point 2 of the Annex are deleted***;***	(21) Articles 30 to 54, Articles 79, 87c and 87d and point 2 of the Annex are deleted***;***
128	Article 1 Point (22) (new)	**No corresponding proposal by the Commission**	**No EP Amendment**	***(22) The Annex becomes Annex I;***	***(22) The Annex becomes Annex I;***
129	Article 1 Point (23) (new)	**No corresponding proposal by the Commission**	**No EP Amendment**	***(23) The Annex set out in the Annex to this Regulation is added as Annex II***.	***(23) The Annex set out in the Annex to this Regulation is added as Annex II***.

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
129a	Article 1aa (new)			*No directly corresponding text in the Coreper text.*	***Article 1aa*** ***Amendments to Directive 2001/83/EC*** ***Directive 2001/83/EC is hereby amended as follows:***
129b	Article 1aa (point (1) (new)			*Corresponding text in the Coreper text (Item 158):* (2) in Article 23b, paragraph***s 1 and*** 2 ***are*** ~~is~~ replaced by the following:	***(1) in Article 23b, paragraphs 1 and 2 are replaced by the following:***
129c				*Corresponding text in the Coreper text (Item 159):* ***"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:***	***"1. For the purposes of this Directive 'variation' and 'variation to the term of a marketing authorisation' means an amendment to the contents of the particulars and documents referred to in:***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
129c continued				***(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.***	***(a) 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.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
129d				*Corresponding text in the Coreper text (Item 160):* ***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.***	***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 <u>terms of the</u> 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.***
129e				*Corresponding text in the Coreper text (Item 161):* ***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 notification by the marketing authorisation holder to the competent authority.***	***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 notification by the marketing authorisation holder to the competent authority.***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
129f				*Corresponding text in the Coreper text (Item 162):* 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~~."; 	***2b. 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.";***
129g				*Corresponding text in the Coreper text (Item 163):* ***(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.***	***(2) 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.";***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
129h				*Corresponding text in the Coreper text (Item 164):* ***(2b) in Article 23b(4), the words "the implementing regulation" are replaced by "Commission Regulation No 1234/2008".***	***(3) in Article 23b(4) and in Article 23b(5), the words "the implementing regulation" are replaced by "Commission Regulation (EC) No 1234/2008".***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
129i				*No directly corresponding text in the Coreper text.*	***Article 1ab*** ***Amendments to Regulation (EC) No 1901/2006*** ***Regulation (EC) No 1901/2006 is hereby amended as follows:***
129j				*Corresponding text in the Coreper text (Item 165):* (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. […]	***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 this Regulation that are listed in Annex II to Regulation (EC) No 726/2004.").***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
130	Article 1a (new)			***Article 1a*** ***1. Commission Regulation (EC) No 2049/2005[1], Commission Regulation (EC) No 2141/96[2] and Commission Delegated Regulation (EU) No 357/2014[3] shall remain in force and continue to apply unless and until repealed.*** ***[1]Commission Regulation (EC) No 2049/2005 on fees to EMA for SMEs.*** ***[2]Commission Regulation (EC) No 2141/96 on transfer of a marketing authorisation*** ***[3]Commission Delegated Regulation (EU) No 357/2014 on post-authorisation efficacy studies***	***1. Commission Regulation (EC) No 2049/2005[1], Commission Regulation (EC) No 2141/96[2] shall remain in force and continue to apply unless and until repealed.*** ***[1]Commission Regulation (EC) No 2049/2005 on fees to EMA for SMEs.*** ***[2]Commission Regulation (EC) No 2141/96 on transfer of a marketing authorisation***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
131	Article 1a (new)			***2. Commission Regulation (EC) No 507/2006[1] shall, with the exception of Articles […[2]] that are repealed, continue to apply unless and until repealed.*** ***[1]Commission Regulation (EC) No 507/2006 on conditional marketing authorisations.*** *[2]to be examined at technical level in the light of the negotiations exactly what provisions must be deleted in order to avoid duplication of provisions in Regulation (EC) No 726/2004.*	***2. Commission Regulation (EC) No 507/2006[1] shall continue to apply unless and until repealed.*** ***[1]Commission Regulation (EC) No 507/2006 on conditional marketing authorisations.***
132	Article 1a (new)			***3. Commission Regulation (EC) No 658/2007[1] shall, with the exception of Articles […[2]] that are repealed, continue to apply unless and until repealed.*** ***[1]Commission Regulation (EC) No 658/2007 concerning financial penalties relating to marketing authorisations*** *[2]to be examined at technical level in the light of the negotiations exactly what provisions must be deleted in order to avoid duplication of provisions in Regulation (EC) No 726/2004.*	***3. Commission Regulation (EC) No 658/2007[1] shall continue to apply unless and until repealed.*** ***[1]Commission Regulation (EC) No 658/2007 concerning financial penalties relating to marketing authorisations***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
133	Article 1a (new)			***4. Commission Regulation (EC) No 1234/2008[1] 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 […[2]] of Regulation (EC) No 1234/2008 shall however be repealed.*** ***[1]Commission Regulation (EC) No 1234/2008 on variations*** *[2]to be examined at technical level in the light of the negotiations exactly what provisions must be deleted in order to avoid duplication of provisions in Regulation (EC) No 726/2004 and in Directive 2001/83/EC.*	***4. Commission Regulation (EC) No 1234/2008[1] 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.*** ***[1]Commission Regulation (EC) No 1234/2008 on variations***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
134	Article 2	*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 application should be on the same dates as of the new Regulation on veterinary medicinal products]* This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, *Signatures for the EP and the Council*	**No EP Amendment**	*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, *Signatures for the EP and the Council*	*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. *Presidency comment: The entry into force and dates of application, which might be different for different provisions in the Regulation will be established once the corresponding dates of the VMP Regulation are known.* Done at Brussels, *Signatures for the EP and the Council*

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
135	Annex [Annex II (new)]			***'ANNEX II*** ***List of the obligations referred to in Article 84a***	*To be checked, in the light of negotiations on the VMP Regulation if there is a need to add in provisions from Commission Regulation (EC) No 658/2007 that relate to VMP.* ***'ANNEX II*** ***List of the obligations referred to in Article 84a***
136	Annex [Annex II (new)]			***(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;*** ***[1]Regulation (EC) No 1901/2006 on paediatric medicines***	***(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;*** ***[1]Regulation (EC) No 1901/2006 on paediatric medicines***
137	Annex [Annex II (new)]			***(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);***	***(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);***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
138	Annex [Annex II (new)]			***(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);***	***(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);***
139	Annex [Annex II (new)]			***(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);***	***(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);***
140	Annex [Annex II (new)]			***(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);***	***(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);***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
141	Annex [Annex II (new)]			***(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);***	***(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);***
142	Annex [Annex II (new)]			***(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);***	***(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);***
143	Annex [Annex II (new)]			***(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;***	***(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;***
144	Annex [Annex II (new)]			***(9) the obligation to comply with the conditions referred to in Article 14(8) and 14aa;***	***(9) the obligation to comply with the conditions referred to in Article 14(8) and 14aa;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
145	Annex [Annex II (new)]			***(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);***	***(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);***
146	Annex [Annex II (new)]			***(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;***	***(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;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
147	Annex [Annex II (new)]			***(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);***	***(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);***
148	Annex [Annex II (new)]			***(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;***	***(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;***
149	Annex [Annex II (new)]			***(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;***	***(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;***
150	Annex [Annex II (new)]			***(15) the obligation to submit periodic safety update reports, in accordance with Article 28(2) read together Article 107b 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;***
151	Annex [Annex II (new)]			***(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;***	***(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;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
152	Annex [Annex II (new)]			***(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;***	***(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;***
153	Annex [Annex II (new)]			***(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;***	***(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;***
154	Annex [Annex II (new)]			***(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;***	***(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;***

Item	Article/ Recital Number [Art. in 726/2004]	Commission text (Doc 13240/14)	EP amendment voted on 10 March 2016 (Doc. 6874/16)	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Tentatively agreed Compromise text of 21 February 2018
155	Annex [Annex II (new)]			***(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;***	***(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;***
156	Annex [Annex II (new)]			***(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;***	***(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;***
157	Annex [Annex II (new)]			***(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.***	***(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.***

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 contains the changes to Directive 2001/83/EC that must be done in order to keep the alignment with Regulation (EC) No 726/2004 and in particular its Article 16a.

The text is based on that of Entry 140 in the Lisbonisation omnibus proposal (Doc. 5623/17 ADD 1 REV 1). For explanations of layout and fonts see Annex A. **In accordance with the Presidency proposal in document WK 1295/2018, the alignment is done by adding a new Article 1aa in the proposal for a Regulation amending Regulation (EC) No 726/2004. The resulting text in the Regulation amending Regulation (EC) No 726/2004 is set out in the new Items 129a-129h in Annex D. The text below shows the consequential changes to the Lisbonisation omnibus proposal.**

140. 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

The "Article/Recital Number" here refers to the Lisbonisation omnibus proposal.

Item	Article/ Recital Number [Art. in 2001/83/EC]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
158	Entry 140 Point (2) [Article 23b]	(2) in Article 23b, paragraph 2 is replaced by the following:		(2) in Article 23b, paragraph***s 1 and*** 2 ***are*** ~~is~~ replaced by the following:	~~(2) in Article 23b, paragraph 2 is replaced by the following:~~

Item	Article/ Recital Number [Art. in 2001/83/EC]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
159	Entry 140 Point (2) [Article 23b(1)]			***"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.***	*This paragraph is moved to Article 1aa, Point (1), see item 129c.*

Item	Article/ Recital Number [Art. in 2001/83/EC]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
160	Entry 140 Point (2) [Article 23b(2)]			***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.***	*This paragraph is moved to Article 1aa, Point (1), see item 129d.*
161	Entry 140 Point (2) [Article 23b(2a)]			***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 notification by the marketing authorisation holder to the competent authority.***	*This paragraph is moved to Article 1aa, Point (1), see item 129e.*

Item	Article/ Recital Number [Art. in 2001/83/EC]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
162	Entry 140 Point (2) [Article 23b(2b)]	2. The Commission is empowered to adopt delegated acts in accordance with Article 121a		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~~.";	*This paragraph is moved to Article 1aa, Point (1), see item 129f.* ~~2. The Commission is empowered to adopt delegated acts in accordance with Article 121a~~ ~~establishing the arrangements referred to in in paragraph 1~~.";

Item	Article/ Recital Number [Art. in 2001/83/EC]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
163	Entry 140 Point (2a) (new) [Article 23b(3)]			***(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.***	*This paragraph is moved to Article 1aa, Point (2), see item 129g.*
164	Entry 140 Point (2b) (new) [Article 23b(3)]			***(2b) in Article 23b(4), the words "the implementing regulation" are replaced by "Commission Regulation No 1234/2008".***	*This paragraph is moved to Article 1aa, Point (3), see item 129h.*

ANNEX F

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 contains the changes to Regulation (EC) No 1901/2006 that must be done in order to keep the alignment with Regulation (EC) No 726/2004 and in particular its Article 84a.

The text is based on that of Entry 157 in the Lisbonisation omnibus proposal (Doc. 5623/17 ADD 1 REV 1). For explanations of layout and fonts see Annex A. **In accordance with the Presidency proposal in document WK 1295/2018, the alignment is done by adding a new Article 1ab in the proposal for a Regulation amending Regulation (EC) No 726/2004. The resulting text in the Regulation amending Regulation (EC) No 726/2004 is set out in the new Items 129i and 129j in Annex D. The text below shows the consequential changes to the Lisbonisation omnibus proposal.**

157. 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

The "Article/Recital Number" here refers to the Lisbonisation omnibus proposal.

Item	Article/ Recital Number [Art. in 1901/2006]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
165	Entry 157 Point (2) [Art. 49(3)]	(2) in Article 49, paragraph 3 is replaced by the following:		(2) in Article 49, paragraph 3 is replaced by the following:	~~(2) in Article 49, paragraph 3 is replaced by the following:~~

Item	Article/ Recital Number [Art. in 1901/2006]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
165 continued	Entry 157 Point (2) [Art. 49(3)]	"3. The Commission may impose financial penalties in the form of fines or periodic penalty payments for the infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it 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;		"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;~~	*This paragraph is moved to Article 1ab, see item 129j.* ~~"3. The Commission may impose financial penalties in the form of fines or periodic penalty payments for the infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it 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;~~

Item	Article/ Recital Number [Art. in 1901/2006]	Commission text (Doc. 5623/17 ADD 1 REV 1)	EP amendment	Text approved by Coreper on 20 December 2017 (Doc. 15911/17)	Presidency proposals and explanations
165 continued	Entry 157 Point (2) [Art. 49(3)]	(c) rules on duration of procedure and limitation periods; (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.";		~~(c) rules on duration of procedure and limitation periods;~~ ~~(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.~~";	~~(c) rules on duration of procedure and limitation periods;~~ ~~(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.";~~