Committee on the Environment, Public Health and Food Safety

2014/0256(COD)

14.4.2015

***I
DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
(COM(2014)0557 – C8-0142/2014 – 2014/0256(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Claudiu Ciprian Tănăsescu

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
(COM(2014)0557 – C8-0142/2014 – 2014/0256(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2014)0557),

– having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0142/2014),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 21 January 2015[1],

– after consulting the Committee of the Regions,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on the Agriculture and Rural Development (A8-0000/2015),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] [OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal].

Amendment 1

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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[1].	(6) In order to ensure uniform conditions for the implementation of Regulation (EC) No 726/2004, implementing powers should be conferred on the Commission to adopt implementing acts in relation to marketing authorisations for medicinal products for human ***and veterinary*** use. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1].
[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

Amendment 2

Proposal for a regulation
Article 1 – point 3
Regulation (EC) No 726/2004
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
'The definitions laid down in Article 1 of Directive 2001/83/EC shall apply for the purposes of this Regulation.'	'The definitions laid down in Article 1 of Directive 2001/83/EC and, ***as appropriate, in Article 4 of Regulation (EU) 2015/xxx of the European Parliament and of the Council***[1a+] shall apply for the purposes of this Regulation.'

[1a] Regulation (EU) 2015/xxx of the European Parliament and of the Council of ... on veterinary medicinal products (OJ L ...).

[+] OJ: please insert the number and in the footnote, the number, date and OJ reference of Regulation in document COD 2014/0257.

Or. en

Justification

It is important to include in this article also a reference to the definitions that will be included in the new Veterinary Medicines Regulation in view of the activities and responsibilities of the European Medicines Agency which will continue to include veterinary medicinal products authorised via the Centralised Procedure.

Amendment 3

Proposal for a regulation
Article 1 – point 4 – point a
<DocAmend2>Regulation (EC) No 726/2004
Article 3 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(a) ***in*** paragraph 2, ***point (b)*** is replaced by the following:	(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 the provisions of 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.’,	(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.’,

Or. en

Justification

The authorisation procedures for veterinary medicinal products- including the centralised procedure- are now detailed in the new Veterinary Medicines Regulation, therefore the last paragraph of Article 3(2) needs to be removed from Article 3 of this Regulation.

Amendment 4

Proposal for a regulation
Article 1 – point 10 a (new)
Regulation (EC) No 726/2004
Article 55 – paragraph 2

Present text	*Amendment*
	(10a) The second paragraph of Article 55 is amended as follows:
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.	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) 2015/xxx[+].'***
	_____
	[+] ***OJ: please, insert the number of Regulation in document COD 2014/0257.***

Or. en

Justification

Centralised authorisation procedure for veterinary medicinal products is now set in the new Veterinary Medicines Regulation, therefore it is necessary to reflect in Regulation (EC) No 726/2004 that the European Medicines Agency will maintain its role in the authorisation and supervision of veterinary products via the centralised procedure.

Amendment 5

Proposal for a regulation
Article 1 – point 10 b (new)
Regulation (EC) No 726/2004
Article 56 – paragraph 2 – subparagraph 1

Present text	*Amendment*
	(10b) The first subparagraph of Article 56(2) is amended as follows:
2. 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***.	***'***2. 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) 2015/xxx[+].'***
	[+] OJ: please, insert the number of Regulation in document COD 2014/0257.

Or. en

Justification

Point 21 of the amending Regulation removes Articles 30-54 of Regulation 726/2004, therefore the reference to Article 30 needs to be corrected and replaced by the corresponding new article of the New Veterinary Medicines Regulation.

Amendment 6

Proposal for a regulation
Article 1 – point 11
Regulation (EC) No 726/2004
Article 57 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Justification

Veterinary medicinal products are no longer included in the Article 57 (database), but will be covered by a new database to be developed under the new Veterinary Medicines Regulation, therefore it is important to clarify that the term of "any medicinal product" referred here in Article 57 concerns medicinal products for human use only.

Amendment 7

Proposal for a regulation
Article 1 – point 13
Regulation (EC) No 726/2004
Article 61 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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***.

Or. en

Justification

Correction.

Amendment 8

Proposal for a regulation
Article 1 – point 14
Regulation (EC) No 726/2004
Article 62

Text proposed by the Commission	*Amendment*
(14) ***in*** Article 62***(3)***, the second subparagraph is deleted;	(14) Article 62 ***is amended as follows:***
	(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) 2015/xxx[+] are met.';
	(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 pursuant to Article 13(3) of this Regulation and Article 40(11) of Regulation (EU) 2015/xxx[+].';
	(c) in paragraph 3, the second subparagraph is deleted;

[+] ***OJ: please, insert the number of Regulation in document COD 2014/0257.***

Or. en

Justification

Point 21 of the amending Regulation removes Articles 30-54 of the Regulation, therefore the references to Article 31(3) and 38(3) need to be corrected and replaced by the corresponding new articles of the New Veterinary Medicines Regulation in subparagraphs 3 and 4 of paragraph 1 - the deletion of second subparagraph in paragraph 3 as per the Commission proposal is maintain under point (c).

Amendment 9

Proposal for a regulation
Article 1 – point 14 a (new)
Regulation (EC) No 726/2004
Article 66 – points a and j

Present text	*Amendment*
	(14a) 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 ***and the Committee for Medicinal Products for Veterinary Use*** (Article 61);	‘(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) 2015/xxx[+])’;***
	(b) point (j) is deleted.
	[+] OJ: please, insert the number of Regulation in document COD 2014/0257.

Or. en

Justification

Point 21 of the amending Regulation removes Article 79 of the Regulation, therefore the reference to Article 79 in Article 66 needs to be eliminated; also the correct references to the new Veterinary Medicines Regulation have to be made.

Amendment 10

Proposal for a regulation
Article 1 – point 15
Regulation (EC) No 726/2004
Article 67 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
(15) ***the first subparagraph of*** Article 67(3) is replaced by the following:	(15) Article 67(3) is replaced by the following:
‘The Agency’s revenue shall consist of a contribution from the Union, fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, or by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC and charges for other services provided by the Agency.’	‘The Agency’s revenue shall consist of:
	(a) a contribution from the Union;
	(b) a contribution from any European third country with which the Union has concluded agreements;
	(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) 2015/xxx[+] ,*** 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;
	(d) charges for ***any*** other services provided by the Agency***; and***
	(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[1a].
	The European Parliament and the Council (hereinafter referred to as ‘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.´

[+] OJ: please, insert the number of Regulation in document COD 2014/0257.

[1a] 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).

Or. en

Justification

It is necessary to make a clarification with regards to the wording of this article, so as to have a clear delineation between the different types of revenues that make up the Agency's budget, including the reflection of the current contribution from EEA countries, the fees payable to the Agency that will continue to cover activities in relation to both human and veterinary medicinal products, as well as other sources of income.

Amendment 11

Proposal for a regulation
Article 1 – point 15 a (new)
Regulation (EC) No 726/2004
Article 68

Present text	*Amendment*
	(15a) Article 68 is replaced by the following:
1. The Executive Director shall implement the budget of the Agency.	**'**1. The Executive Director shall implement the budget of the Agency.
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	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*** ***(21)*** (hereinafter referred to as the 'general Financial Regulation').

officer. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article ***147 of*** Regulation ***(EU, Euratom) No 966/2012*** (hereinafter referred to as the 'general Financial Regulation').

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.

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.

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.

4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article ***148*** of the general Financial Regulation, 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.

5. The Management Board of the Agency shall deliver an opinion on the Agency's final accounts.

5. The Management Board of the Agency shall deliver an opinion on the Agency's final accounts.

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.

6. ***The accounting officer*** shall, by 1 July ***of the*** following 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.

7. The final accounts shall be published.

7. The final accounts shall be published.

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***.

8. The Agency's Executive Director shall send the Court of Auditors a reply to its observations by 30 September ***of the following year*** at the latest.

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.	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 ***165(3)*** of the general Financial Regulation.
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.	10. The European Parliament, on a recommendation from the Council, 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.
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*** [(22)]***,*** unless specifically required for the Agency's operation and with the Commission's prior consent.	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 ***Delegated*** Regulation ***(EU) No 1271/2013***[1a]unless specifically required for the Agency's operation and with the Commission's prior consent.***'***
[21] Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ L 248, 16.9.2002, p. 1).1	
[22] OJ L 357, 31.12.2002, p. 72.	
	[1a] Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 328, 7.12.2013, p. 42).
	Or. en

Justification

It is necessary to update Article 68 in line with the Financial Regulation applicable to the general budget of the Union as from 1 January 2013.

Amendment 12

Proposal for a regulation
Article 1 – point 16
Regulation (EC) No 726/2004
Article 70

Text proposed by the Commission	*Amendment*
(16) Article 70 is replaced by the following:	***deleted***
'Article 70	
1. The Commission shall, on the basis of the principles set out in paragraph 2, adopt implementing acts in accordance with the procedure laid down in Article 87(2) specifying:	
(a) the structure and the level of the fees and charges referred to in Article 67(3);	
(b) the services for which charges may be collected;	
(c) the conditions under which small and medium-sized enterprises may pay reduced fees, defer payment of fees or receive administrative assistance;	
(d) the rules defining the remuneration for work carried out by the member of the relevant committee or the coordination group who acts as a rapporteur; and	
(e) the conditions for payment and remuneration.	
The fees shall be set at such a level as to avoid a deficit or a significant accumulation of surplus in the budget of the Agency and be revised when this is not the case.	
2. When adopting the implementing acts referred to in paragraph 1, the	

Commission shall take the following into account:

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

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

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

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

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

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

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

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

Or. en

Justification

The structure and level of fees payable to the Agency as well as the remuneration to the national competent authorities cannot be set by an implementing act. The Parliament should be fully involved in the setting of Agency fees, throughout a full co-decision process.

Amendment 13

Proposal for a regulation
Article 1 – point 16 a (new)
Regulation (EC) No 726/2004
Article 70 a (new)

Text proposed by the Commission	*Amendment*
	(16a) The following Article is inserted:
	'Article 70a
	With regards to the level and the structure of the fees referred to in Article 67(3), Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 shall be applicable until the revision of Regulation (EC) No 297/95 or any other provisions on fees are adopted and become applicable.'

Or. en

Justification

The current Regulation No 297/95 on the general regime of the European Medicines Agency fees and the Pharmacovigilance Fee Regulation EU (No) 658/2014 should remain as a transitional legal basis until the revision of Regulation (EC) No 297/95 or any other provisions on fees are adopted and become applicable, to ensure that the Agency does not face any period without possibility to charge fees and to remunerate the Rapporteurs.

Amendment 14

Proposal for a regulation
Article 1 – point 16 b (new)
Regulation (EC) No 726/2004
Article 82 – paragraph 3

Present text	*Amendment*
	(16b) Article 82(3) is amended as follows:
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.	***'***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.***'***

Or. en

Justification

Point 21 of the amending Regulation removes Articles 30-54 of the Regulation, therefore the reference to Article 34(4) in Article 82(3) needs to be deleted.

Amendment 15

Proposal for a regulation
Article 1 – point 20
Regulation (EC) No 726/2004
Article 87b – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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.***

Or. en

Justification

Delegated power conferred on the European Commission should be set for a limited period of time.

EXPLANATORY STATEMENT

Background

Directive 2001/82/EC of the European Parliament and of the Council on veterinary medicinal products and the Regulation 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, represent the European Union regulatory framework for the manufacture, authorisation and distribution of veterinary medicinal products.

In September 2014, following an assessment of the functioning of the internal market in this sector, the Commission published a proposal to bring together the rules on Veterinary Medicines under one Regulation on veterinary medicinal products, repealing and replacing Directive 2001/82/EC on veterinary medicinal products and amending Regulation (EC) No 726/2004, in order to delete any references to veterinary medicines and thus completely decouple provisions governing veterinary medicines from those governing human medicines.

Main elements of the proposal

In its current proposal to Amend Regulation 726/2004, the Commission seeks to:

- Delete from Regulation (EC) No 726/2004 the provisions regarding the granting and maintaining of marketing authorisations for veterinary medicinal products and transferring them to the new Regulation:
  - ✓ Title III on the "Authorisation and supervision of veterinary medicinal products" is deleted from the structure of the Regulation as the centralized procedure is being moved to the new Regulation on Veterinary Medicines;
  - ✓ references to veterinary medicines, the Standing Committee on Veterinary Medicinal products and the CVMP are deleted;
  - ✓ references to veterinary medicinal products are deleted from the Annex;
- Establish certain principles applicable to fees payable to the Agency, including the need to take into account the specific case of SMEs
- Adapt the regulation EC No 726/2004 to the Lisbon Treaty;
  - ✓ Align the provisions on regulating fees to the Lisbon Treaty;
  - ✓ Align the powers conferred to the Commission under Regulation (EC) No 726/2004 to Articles 290 and 291 (delegated and implementing acts) of the Treaty on the Functioning of the European Union.

The position of the rapporteur

Your Rapporteur broadly endorses the proposal and welcomes the alignment to the Lisbon Treaty. He welcomes the decoupling of marketing authorisations for veterinary medicinal products from those for human medicinal products, to take account of the specific needs of the veterinary sector.

However, your Rapporteur believes that the proposal should still be improved in some areas. Consequently, he does not agree with the Commission proposal as regards the structure and

level of fees payable to the Agency, nor, the remuneration to the national competent authorities being set by an implementing act. The Parliament should be fully involved in the setting of Agency fees as was in the case of the Pharmacovigilance legislation. Therefore, your rapporteur proposes a full co-decision process in this regard.

Your rapporteur is suggesting some amendments to clarify and update the principles applicable to fees payable to the Agency, including the clarification of Art 67(3) that describes the different sources of Agency revenues for both human and veterinary medicinal products. In the rapporteur's view, the wording of this article should be clarified so as to separate the different types of revenue that make up the Agency's budget. The rapporteur wants to ensure that the current Regulation is in line with the revised Framework Financial Regulation from 1 January 2014, including giving the Agency the right to have access to other sources of financing that would support its work on public health projects, such as the Innovative Medicines Initiative or the FP7.

Furthermore, there is a need for a cross-reference with the new Veterinary Medicines Regulation, and the role of EMA in the authorisation and supervision of veterinary products via the centralised procedure should be clearly stated.

In addition, the Rapporteur reinforces the commitment from the Commission to ensure that the new measures take into account the specificities of the veterinary sector and that the fees remain affordable for the veterinary industry in order to promote the development and availability of new medicines in the EU.

For clarification purposes, the rapporteur has "fine-tuned" the proposal updating terminology and legal references throughout the text.

Finally, the rapporteur firmly believes that the current Regulation No 297/95 on the general regime of EMA fees and the Pharmacovigilance Fee Regulation EU (No) 658/2014 need to remain as the legal basis *until the revision of Regulation (EC) No 297/95, or any other provisions on fees are adopted and become applicable.*