European Parliament
2014-2019

TEXTS ADOPTED

P8_TA(2016)0088

Authorisation and supervision of veterinary medicinal products ***I

Amendments adopted by the European Parliament on 10 March 2016 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))[1]

(Ordinary legislative procedure: first reading)

Amendment 1

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) Directive 2001/82/EC of the European Parliament and of the Council[5] and Regulation (EC) 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	(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

[1] The matter was referred back to the committee responsible for reconsideration pursuant to Rule 61(2), second subparagraph (A8-0035/2016).

authorisation and supervision of veterinary medicinal products has been adopted.	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***.
[5] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).	[5] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).
[6] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	[6] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
[7] Regulation … of the European Parliament and of the Council of … … … on veterinary medicinal products (OJ L …, … … …, p. …).	[7] Regulation … of the European Parliament and of the Council of … … … on veterinary medicinal products (OJ L …, … … …, p. …).

Amendment 2

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(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	(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

authorisations subject to certain specific obligations, establishing procedures for the examination of applications for variations to the terms of marketing authorisations and for the examination of applications for the transfer of marketing authorisations and laying down the procedure for investigating the infringements and the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection.	may be required, laying down provisions and requirements for granting marketing authorisations subject to certain specific obligations, establishing procedures for the examination of applications for variations to the terms of marketing authorisations and for the examination of applications for the transfer of marketing authorisations and laying down the procedure for investigating the infringements and the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection.

Amendment 3

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).

Amendment 4

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(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 modeling and simulation technologies.

Amendment 5

Proposal for a regulation
Recital 6 b (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 6

Proposal for a regulation
Recital 6 c (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 7

Proposal for a regulation
Recital 6 d (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 8

Proposal for a regulation
Recital 6 e (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 9

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

Present text	*Amendment*
	(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**.** 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	"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,

covered by their social security bodies.	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 10

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) .../... of the European Parliament and of the Council**[1a]* shall apply for the purposes of this Regulation.
	[1a] Regulation (EU) .../... of the European Parliament and of the Council of ... on veterinary medicinal products (OJ L ...) [2014/0257(COD)].

Amendment 11

Proposal for a regulation
Article 1 – point 4 – point a
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 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	(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.’	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 12

Proposal for a regulation
Article 1 – point 5 a (new)
Regulation (EC) No 726/2004
Article 6 – paragraphs 4 a and 4 b (new)

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

Amendment 13

Proposal for a regulation
Article 1 – point 5 b (new)
Regulation (EC) No 726/2004
Article 9 – paragraph 4 – point d a (new)

Present text	*Amendment*
	(5b) In Article 9(4), the following point is inserted:
	"(da) the comparative evaluation of the human medicinal product;"

Amendment 14

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

Present text	*Amendment*
	(10a) In Article 55, the second paragraph is replaced by the following:
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) .../...[+].***"
	_____
	[+] ***2014/0257(COD).***

Amendment 15

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) In Article 56(2), the first subparagraph is replaced by the following:
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) .../...[+].***"
	_____

[+] ***2014/0257(COD).***

Amendment 16

Proposal for a regulation
Article 1 – point 10 c (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 1 – subparagraph 1

Present text	*Amendment*
	(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 ***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.	"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."

Amendment 17

Proposal for a regulation
Article 1 – point 10 d (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 1 – subparagraph 2 – point t a (new)

Present text	*Amendment*
	(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."

Amendment 18

Proposal for a regulation
Article 1 – point 10 e (new)

Regulation (EC) No 726/2004
Article 57 – paragraph 1 – subparagraph 2 – point t b (new)

Text proposed by the Commission	*Amendment*
	(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."

Amendment 19

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.

Amendment 20

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	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.	for Human ***Use***.

Amendment 21

Proposal for a regulation
Article 1 – point 13 a (new)
Regulation (EC) No 726/2004
Article 62 – paragraph 2

Present text	*Amendment*
	(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 ***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.	"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.
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.	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."

Amendment 22

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) .../...[+] 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 in accordance with Article 13(3) of this Regulation and Article 40(11) of Regulation (EU) .../...[+].";***

[+] ***2014/0257(COD).***

Amendment 23

Proposal for a regulation
Article 1 – point 14 a (new)
Regulation (EC) No 726/2004
Article 64 – paragraph 1

Present text	*Amendment*
	(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. The Management Board may, upon a proposal from the Commission, remove the Executive Director from his post.	"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."

Amendment 24

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

Present text	*Amendment*
	(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 ***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) ..../...[+]);***"***;***
	(b) point (j) is deleted.

[+] ***2014/0257(COD).***

Amendment 25

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) .../...[+] ,*** 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 ('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."

[+] ***2014/0257(COD).***

[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, p. 1).***

Amendment 26

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

Present text	*Amendment*
	(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."

Amendment 27

Proposal for a regulation
Article 1 – point 15 b (new)
Regulation (EC) No 726/2004
Article 67 – paragraph 6 – subparagraph 1 a (new)

Present text	*Amendment*
	(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."

Amendment 28

Proposal for a regulation
Article 1 – point 15 c (new)
Regulation (EC) No 726/2004
Article 67 – paragraph 8

Present text	*Amendment*
	(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 and the amount of the	"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***

subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.	***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."

Amendment 29

Proposal for a regulation
Article 1 – point 15 d (new)
Regulation (EC) No 726/2004
Article 67 – paragraph 9 – subparagraph 2

Present text	*Amendment*
	(15d) In Article 67(9), the second subparagraph is replaced by the following:
The budgetary authority shall adopt the establishment plan for the Agency.	"The budgetary authority shall adopt the establishment plan ***for the staff financed by the Union budget*** for the Agency."

Amendment 30

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

Present Text	*Amendment*
	(15e) 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 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***	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.***

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 ***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***.
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. ***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.
5. The Management Board ***of the Agency*** shall deliver an opinion on the Agency's final accounts.	5. The Management Board 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 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.
7. The final accounts shall be published.	7. The final accounts shall be published ***in the Official Journal of the European Union by 15 November of the following year.***
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***	8. The Executive Director shall send ***to*** the Court of Auditors a reply to its observations by 30 September.

Management Board.

9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year 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, ***in accordance with Article 165(3) of the*** Financial Regulation ***applicable to the general budget of the Union.***
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. 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.
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.	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."

Amendment 31

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 […]';

Amendment 32

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 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."

Amendment 33

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 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) ***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."

Amendment 34

Proposal for a regulation
Article 1 – point 18
Regulation (EC) No 726/2004
Article 86

Text proposed by the Commission	*Amendment*
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.	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) .../...*** [+] ***.***
	_____
	[+] ***2014/0257(COD).***

Amendment 35

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.