European Parliament
2014 - 2019

Committee on the Environment, Public Health and Food Safety

2014/0256(COD)

17.6.2015

AMENDMENTS
16 - 53

Draft report
Claudiu Ciprian Tănăsescu
(PE552.048v01-00)

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

Proposal for a regulation
(COM(2014)0557 – C8-0142/2014 – 2014/0256(COD))

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Amendment 16
Aldo Patriciello

Proposal for a regulation
Recital 3

Text proposed by the Commission	*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. ***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.	(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. ***The*** fees payable to the Agency ***should ensure that it functions normally and independently***. The provisions regulating fees should be brought into line with the Treaty of Lisbon.

Or. it

Amendment 17
Aldo Patriciello

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(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.	(5) ***During the initial stage of the preparatory work,*** the Commission ***is requested to carry out*** consultations ***with panels of experts, who should be as independent as possible. The appointment of these experts should also secure the consent of the European Parliament.*** 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 ***and should examine any feedback***.

Or. it

Amendment 18
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) The Commission should be able to include, in its general report on the experience acquired as a result of the application of the procedures laid down in this Regulation, information concerning a proposal to revise Council Regulation No (EC) 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products;

Or. it

Amendment 19
Martin Häusling

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) Advances in alternative testing require the creation of a validation framework capable of adapting to new developments in this field, particularly in relation to the recognition and evaluation of in silico testing.

Or. en

Amendment 20
Martin Häusling

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 is subject to Directive 2010/63/EU relating to the replacement, reduction or refinement of animal testing.

Or. en

Amendment 21
Elisabetta Gardini, Alberto Cirio

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy, and taking into consideration cost-effectiveness of the medicinal product concerned.

Or. en

Justification

To decrease the timeframe by which Member States adopt the decisions of marketing authorisation of the EMA it is necessary to include non-binding, reference cost-effectiveness assessment of newly approved drugs.

Amendment 22
Elisabetta Gardini, Alberto Cirio

Proposal for a regulation
Recital 7 b (new)

Text proposed by the Commission	*Amendment*
	(7b) Provision should be made for the quality, safety and efficacy criteria in Directives 2001/83/EC and 2001/82/EC to apply to medicinal products authorised by the Community and it should be possible to assess both the risk-benefit balance and the cost-effectiveness 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.

Or. en

Justification

Cost effectiveness assessment is particularly relevant at the time of renewal of the authorisation, given that the Agency can rely on real-world data.

Amendment 23
Elisabetta Gardini, Alberto Cirio

Proposal for a regulation
Recital 7 c (new)

Text proposed by the Commission	*Amendment*
	(7c) 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. This evaluation should be conducted in the context of the marketing authorisation, in order to provide Member States with a non-binding assessment of comparative efficacy and cost-

	effectiveness, to be used as a reference assessment by the competent reimbursement agencies of the Member States.

Or. en

Justification

To decrease the timeframe by which Member States adopt the decisions of marketing authorisation of the EMA, it is necessary to include non-binding, reference cost-effectiveness assessment of newly approved drugs

Amendment 24
Elisabetta Gardini, Alberto Cirio

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 covered by their social security bodies.	"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 in due consideration the reference comparative efficacy and reference cost-effective evaluation of medicinal product as per the provisions stated 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."

Or. en

Amendment 25
Martin Häusling

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 validation of in silico models and take into consideration the opportunities presented by in silico concepts developed in toxicology aiming for predictive medicine. These can be based on human-relevant computer or cellular models, pathways of toxicity, or adverse outcome pathways."

Or. en

Justification

It is important that EMA checks whether applicants acted in accordance with the 3Rs of the animal testing Directive. To advance the development of alternative models, EMA should develop a framework for the validation of such models.

Amendment 26
Elisabetta Gardini, Alberto Cirio

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

Present text	*Amendment*
	(5a) In Article 9(1) the following point is

added:

"(da) the reference comparative efficacy and cost-effective evaluation of the medicinal product."

Or. en

Amendment 27
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 1 – point 7
Regulation (EC) No 726/2004
Article 10b– paragraph 1

Text proposed by the Commission	*Amendment*
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).	The Commission shall ***propose acts*** to ***Parliament and the Council 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).

Or. fr

Amendment 28
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EC) No 726/2004
Article 14 – paragraph 7 – subparagraph 3

Text proposed by the Commission	*Amendment*
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.	The Commission shall ***propose acts*** to ***Parliament and the Council*** in order to lay down provisions and requirements for granting such marketing authorisation and for its renewal.

Or. fr

Amendment 29
Elisabetta Gardini, Alberto Cirio

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

Present text	*Amendment*
	(10a) In Article 57(1), subparagraph 1 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 cost effectiveness*** 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."

Or. en

Amendment 30
Elisabetta Gardini, Alberto Cirio

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

Present text	*Amendment*
	(10b) In subparagraph 2 of Article 57(1), the following point is inserted after point (i):
	"(ia) in the framework of the market authorisation, providing a framework health technology assessment evaluation of medicinal products, in cooperation with

Member States national HTA assessment bodies;"

Or. en

Amendment 31
Martin Häusling

Proposal for a regulation
Article 1 – point 10 a (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 1– subparagraph 2 – points t a, t b and t c (new)

Text proposed by the Commission	*Amendment*
	(10a) In subparagraph 2 of Article 57(1), the following points are added:
	"(ta) co-ordination of the provision of information on active substances of veterinary medicinal products authorised under community procedures, for the purpose of implementing a review system (Monograph system);
	(tb) assisting Member States in providing information on active substances of veterinary medicinal products authorised under procedures other than the community procedures, for the purpose of implementing a review system (Monograph System);
	(tc) setting up a free of charge public database that lists information on active substances of veterinary medicinal products according to the review system (Monograph System), and updating on a regular basis. The respective information should be presented in an easily understandable manner."

Or. en

Amendment 32
Fredrick Federley

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

Text proposed by the Commission	*Amendment*
	(10a) In subparagraph 2 of Article 57(1), the following point is added:
	"(ta) in cooperation with EFSA and ECDC annually publish 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."

Or. en

Amendment 33
Matthias Groote

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

Present text	*Amendment*
	(10a) In subparagraph 2 of Article 57(1), the following point is added:
	"(ta) cooperating with health technology assessment bodies and other national authorities involved in market access, in particular to facilitate their assessment."

Or. en

Justification

In order to improve timely access to medicines and to acknowledge the Agency's role in facilitating the assessments done by health technology (HTA) bodies or other authorities involved at national level in market access decisions, it is important to reflect this ongoing activity in the list of tasks of the Agency. The need to share data or assessments between medicines agencies and HTA bodies was also acknowledged in Article 13 of the draft amended Transparency Directive and complements Article 15(1) of Directive 2011/24/EU

which states that "the Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States."

Amendment 34
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(11a) In Article 57, the following paragraph is added:
	"2a. The database according to point (tc) of paragraph 1 of this Article contains data on physico-chemical, ecotoxicological and behavioural properties of the active substance and its respective metabolites. The database lists information of all veterinary medicines marketed in the Union. Therefore, the Agency shall prepare a list of all veterinary medicines and active substances marketed in the Union in accordance with Article 51 of Regulation (EU) 2015/xxx of the European Parliament and of the Council[1a+].
	[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

Amendment 35
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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*
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.	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***. ***Full and alternate members may be dismissed ad nutum by the appointing Member State and dismissed where there is a conflict of interest.***

Or. fr

Amendment 36
Matthias Groote

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 amended as follows:
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	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.	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."

Or. en

Justification

There are also other experts appointed by the Agency or the Commission that participate in the Agency's activities. The more generic wording includes, for instance, experts in veterinary medicinal products.

Amendment 37
Matthias Groote

Proposal for a regulation
Article 1 – point 14
Regulation (EC) No 726/2004
Article 62 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
(14) in Article 62(3), the second subparagraph is deleted;	***deleted***

Or. en

Justification

In order to maintain a legal basis for the Agency to remunerate the experts for certain services provided, for instance, rapporteurs.

Amendment 38
Matthias Groote

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 amended as follows:
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."

Or. en

Justification

Clarification of the role of the Management Board at the time of renewal of the mandate of the Agency's Executive Director.

Amendment 39
Soledad Cabezón Ruiz

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

Present text	*Amendment*
	(14a) In Article 66, point (j) is amended as follows:
(j) adopt provisions for providing assistance to pharmaceutical companies	(j) adopt provisions for providing ***‘***assistance to ***small and medium-sized***

(Article 79);	pharmaceutical companies (Article 79)*'*;

Or. xm

Amendment 40
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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*
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 ***come*** from the ***general budget of the*** Union.

Or. fr

Amendment 41
Matthias Groote

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 subparagraph 1:
	"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 should actual fee revenue be below

budgeted appropriations. The total amount of such safeguard fund shall not exceed the Agency's appropriations for the fee revenue of the past year."

Or. en

Justification

It is necessary to ensure that the Agency can deliver the services required by the legislation. A reserve fund could help to deal with potential unpredicted shortfalls in fee revenue.

Amendment 42
Matthias Groote

Proposal for a regulation
Article 1 – point 15 b (new)
Regulation (EC) No 726/2005
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."

Or. en

Justification

It is necessary to ensure that the Agency has sufficient resources to deliver the services required by the legislation.

Amendment 43
Matthias Groote

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 amended as follows:
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.	"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."

Or. en

Justification

It is necessary to ensure that the Agency has sufficient resources to deliver the services required by the legislation.

Amendment 44
Matthias Groote

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), subparagraph 2 is amended as follows:
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 EU budget*** for the Agency."

Or. en

Justification

It is necessary to ensure that the Agency has sufficient resources to deliver the services required by the legislation.

Amendment 45
Claudiu Ciprian Tănăsescu

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 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").***	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***
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	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***

Agency's final accounts ***under his own responsibility*** and submit them to the Management Board for an opinion.	***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 Management Board***.	8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September.
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	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

implementation of the budget for year N.	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."

Or. en

Amendment 46
Tibor Szanyi

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

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. en

Amendment 47
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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

Text proposed by the Commission	*Amendment*
The Commission shall, on the basis of the principles set out in paragraph 2, ***adopt***	The Commission shall ***propose to Parliament and the Council***, on the basis

implementing acts ***in accordance with the procedure laid down in Article 87(2)*** specifying:	of the principles set out in paragraph 2, acts specifying:

Or. fr

Amendment 48
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 1 – point 16
Regulation (EC) No 726/2004
Article 70 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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***.	The fees shall be set at such a level as to avoid a deficit in the budget of the Agency. ***They shall be collected by the Agency, which shall pay them back in their entirety into the general budget of the Union.***

Or. fr

Justification

The fees must be paid back into the EU budget, thereby ensuring a higher degree of independence with regard to applicants.

Amendment 49
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 1 – point 16
Regulation (EC) No 726/2004
Article 70 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(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***	(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;

exceed what is necessary to cover the costs;

Or. fr

Amendment 50
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 1 – point 16
Regulation (EC) No 726/2004
Article 70 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(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;	(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**.** ***It shall take account of the economic prospects of the market sought by the applicant and of the place where the medicinal product was manufactured so as to promote production within the Union***;

Or. fr

Amendment 51
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 1 – point 17
Regulation (EC) 726/2004
Article 84 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe obligations laid down in connection with the marketing authorisations granted in	The Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe obligations laid down in connection with the marketing authorisations granted in

accordance with this Regulation.	accordance with this Regulation. ***Member States may suspend authorisations on their territory for the same reasons.***

Or. fr

Amendment 52
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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 and in Chapter 4 of Title III of Directive 2001/83/EC. ***In the general report the Commission may include information concerning a proposal to revise Council Regulation No (EC) 297/95.***

Or. it

Amendment 53
Alberto Cirio, Elisabetta Gardini

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 ***ten years*** from the date of entry into force of this Regulation.

Or. en

Justification

A more limited timeframe gives the Parliament the possibility to keep a tighter control on the delegated power.