EUROPEAN
COMMISSION

Brussels, 10.9.2014
COM(2014) 557 final

2014/0256 (COD)

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Justification and objectives

Following the proposal that will repeal and replace Directive 2001/82/EC on veterinary medicinal products, 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 must be amended to take account of the fact that centralised marketing authorisation for veterinary products is being decoupled from that for medicines for humans.

Legal basis

The legal basis for legislative measures on animal health, which are essential to public and animal health, environmental protection, trade and single market policy are:

- Article 114 of the Treaty on the Functioning of the European Union (TFEU), which provides for the establishment and functioning of the internal market and the approximation of relevant legal, regulatory and administrative provisions; and
- Article 168(4)(c) TFEU, which covers measures setting high standards of quality and safety for medicinal products and devices for medical uses.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

Better regulation of veterinary pharmaceuticals: how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies, a public consultation on the key issues of the envisaged legal proposal, was launched on the Commission's website on 13 April 2010 and was available through the interactive policy-making (IPM) tool until 15 July 2010.[1]

The consultation and a study, *An assessment of the impact of the revision of veterinary pharmaceutical legislation*, formed the basis of an impact assessment carried out for the Commission between November 2009 and June 2011.[2]

The Commission's Impact Assessment Board (IAB) released its final opinion in September 2013.

3. LEGAL ELEMENTS OF THE PROPOSAL

Provisions regarding granting and maintaining marketing authorisations for veterinary medicinal products are deleted from Regulation (EC) No 726/2004. The rules on marketing authorisations valid in all EU Member States are part of the proposal for a Regulation on veterinary medicinal products. The new Regulation on veterinary medicinal products will cover all routes granting marketing authorisations for veterinary medicinal products in the Union – both at centralised and national level.

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

[1] For a summary of the responses, see: http://ec.europa.eu/health/files/veterinary/vet_pubcons_rep2011.pdf

[2] Study carried out by GHK Consulting, a member of the European Policy Evaluation Consortium (EPEC), assisted by Triveritas

seeking authorisation. Therefore, 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.

As a consequence of the entry into force of the Treaty of Lisbon, the powers conferred on the Commission under Regulation (EC) No 726/2004 should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union. In order to supplement or amend certain non-essential elements of Regulation (EC) No 726/2004, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of amending the Annex to technical and scientific progress, determining the situations in which post-authorisation efficacy studies may be required, laying down provisions and requirements for granting marketing authorisations subject to certain specific obligations, establishing procedures for the examination of applications for variations to the terms of marketing authorisations and for the examination of 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.

The entry into force and application of this Regulation should be on the same date as of the new Regulation on veterinary medicinal products.

4. BUDGETARY IMPLICATION

It is planned that the costs for the EMA for implementing and applying the new rules are entirely covered by fees charged to industry.

Therefore, the proposal is not expected to have any financial impact on the budget of the EU.

As set out in the legislative financial statement the additional resource needs for EMA are approximately 8 staff plus expenditure for meetings, translation, IT, etc.

The level of fees, their structure and modalities and exceptions will be set at a later stage by the Commission by way of implementing acts. This holds not only for the fees for new tasks for the EMA set out in this proposal, but for all fees in general.

5. OPTIONAL ELEMENTS

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[3],

Having regard to the opinion of the Committee of the Regions[4],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(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 authorisation and supervision of veterinary medicinal products has been adopted.

(2) Regulation (EU) No […] also provides for centralised marketing authorisations for veterinary medicinal products. The parts of Regulation (EC) 726/2004 relating to procedures for those marketing authorisation should therefore be repealed.

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3 OJ C , , p. .

4 OJ C , , p. .

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).

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

(3) The costs of the procedures and services associated with the operation of this Regulation need to be recovered from those making medicinal products available on the market and from those seeking authorisation. 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.

(4) As a consequence of the entry into force of the Treaty of Lisbon, the powers conferred on the Commission under Regulation (EC) No 726/2004 should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union In order to supplement or amend certain non-essential elements of Regulation (EC) No 726/2004, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of amending the Annex to technical and scientific progress, determining the situations in which post-authorisation efficacy studies may be required, laying down provisions and requirements for granting marketing authorisations subject to certain specific obligations, establishing procedures for the examination of applications for variations to the terms of marketing authorisations and for the examination of applications for the transfer of marketing authorisations and laying down the procedure for investigating the infringements and the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection.

(5) It is of particular importance that the Commission carries 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.

(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[8].

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

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 726/2004 is amended as follows:

(1) the title is replaced by the following:

‘Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency’;

(2) in Article 1, the first paragraph is replaced by the following:

[8] 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).

‘The purpose of this Regulation is to lay down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use and to establish a European Medicines Agency (hereinafter referred to as ‘the Agency’).’

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

‘The definitions laid down in Article 1 of Directive 2001/83/EC shall apply for the purposes of this Regulation.’

(4) Article 3 is amended as follows:

(a) in paragraph 2, point (b) is replaced by the following:

‘(b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients health at Union level.’,

(b) in paragraph 3, the introductory phrase and point (a) are replaced by the following:

‘A generic medicinal product of a reference medicinal product authorised by the Union may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC under the following conditions:

(a) the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC;’ ,

(c) paragraph 4 is replaced by the following:

‘The Commission shall be empowered to adopt delegated acts in accordance with Article 87b in order to amend the Annex to technical and scientific progress without extending the scope of the centralised procedure.’;

(5) Article 4(3) is deleted;

(6) Article 10 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. The Commission shall, by means of implementing acts, take a final decision within 15 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2). ’,

(b) paragraph 5 is replaced by the following:

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

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

‘The Commission shall be 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).’;

(8) Article 14(7) is replaced by the following:

‘7. In the interests of public health a marketing authorisation may be granted subject to certain specific obligations, to be reviewed annually by the Agency. Those obligations and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation. The summary of product characteristics and the package leaflet shall clearly mention that the marketing authorisation for the medicinal product has been granted subject to those obligations.

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

The Commission shall be empowered to adopt delegated acts in accordance with Article 87b in order to lay down provisions and requirements for granting such marketing authorisation and for its renewal.’ ;

(9) Article 16(4) is replaced by the following:

‘4. The Commission shall be empowered to adopt delegated acts in accordance with Article 87b establishing procedures for the examination of applications for variations to the terms of marketing authorisations and for the examination of applications for the transfer of marketing authorisations.’;

(10) Article 20 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. At any stage of the procedure laid down in this Article the Commission may take temporary measures. Those temporary measures shall be applied immediately.

The Commission shall, by means of implementing acts, adopt a final decision concerning the measures to be taken in respect of the medicinal product concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

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

(b) paragraph 6 is replaced by the following:

‘6. The suspensive measures referred to in paragraph 4 may be maintained in force until such time as a final decision has been reached in accordance with paragraph 3.’;

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

‘2. The database provided for in paragraph 1(l) shall include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC. The database shall subsequently be extended to include any medicinal product authorised in the Union.’;

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

‘4. Save as otherwise provided in this Regulation, in Regulation (EU) No […] or in Directive 2001/83/EC, where there is a fundamental conflict over scientific points and the body concerned is a body in a Member State, the Agency and the national body concerned shall work together either to resolve the conflict or to prepare a joint document clarifying the scientific points of conflict. This document shall be published immediately after its adoption.’;

(13) Article 61(1) is replaced by the following:

‘1. Each Member State shall, after consultation of the Management Board, appoint, for a three-year term which may be renewed, one member and one alternate to the Committee for Medicinal Products for Human.

The alternates shall represent and vote for the members in their absence and may act as rapporteurs in accordance with Article 62.

Members and alternates shall be chosen for their role and experience in the evaluation of medicinal products for human use as appropriate and shall represent the competent national authorities.’

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

(15) the first subparagraph of Article 67(3) is replaced by the following:

‘The Agency’s revenue shall consist of a contribution from the Union, fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, or by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC and charges for other services provided by the Agency.’;

(16) Article 70 is replaced by the following:

‘Article 70

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

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

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

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

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

(e) the conditions for payment and remuneration.

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

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

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

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

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

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

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

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

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

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

(17) Article 84(3) is replaced by the following:

'3. 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.

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

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

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

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

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

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

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

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

(18) Article 86 is replaced by the following:

‘Article 86

At least every ten years, the Commission shall publish a general report on the experience acquired as a result of the operation of the procedures laid down in this Regulation and in Chapter 4 of Title III of Directive 2001/83/EC.’;

(19) Article 87 is replaced by the following:

‘Article 87

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use established by Article 121 of Directive 2001/83/EC. The Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.’

(20) Article 87b is replaced by the following:

‘Article 87b

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power 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.

3. The delegation of power referred to in Articles 3(4), 10b (1), 14(7), 16(4) and 84(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

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

Article 2

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

[*the entry into force and application should be on the same date as of the new Regulation on veterinary medicinal products]*

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

Done at Brussels,

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