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THE EUROPEAN PARLIAMENT **THE COUNCIL**

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Subject:	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use

REGULATION (EU) No .../2014

OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use

(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 point (c) of Article 168(4) 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[1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[2],

[1] OJ C 67, 6.3.2014, p. 92.

[2] Position of the European Parliament of 16 April 2014. (not yet published in the Official Journal) and decision of the Council of .....

Whereas:

(1) The revenue of the European Medicines Agency (the "Agency") consists of a contribution from the Union and fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services as referred to in Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council[1].

[1] 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).

(2) The provisions on pharmacovigilance relating to medicinal products for human use ("medicinal products") laid down in Regulation (EC) No 726/2004 and in Directive 2001/83/EC of the European Parliament and of the Council[1] were amended by Directive 2010/84/EU of the European Parliament and of the Council[2], Regulation (EU) No 1235/2010 of the European Parliament and of the Council[3], Directive 2012/26/EU of the European Parliament and of the Council[4] and Regulation (EU) No 1027/2012 of the European Parliament and of the Council[5]. Those amendments provide for new pharmacovigilance tasks for the Agency, including pharmacovigilance procedures carried out at Union level, the monitoring of literature cases and the improved use of information technology tools. Furthermore, those amendments provide that the Agency should be enabled to fund those activities from fees charged to marketing authorisation holders. New types of fees should therefore be created to cover the new and specific tasks of the Agency.

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1 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

2 Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 348, 31.12.2010, p. 74).

3 Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, 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, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1).

4 Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p.1).

5 Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38).

(3) In order to enable the Agency to charge fees for those new pharmacovigilance tasks, and pending an overall legislative revision of the fees regimes in the medicinal products sector, this Regulation should be adopted. The fees provided for in this Regulation should be applicable without prejudice to the fees laid down in Council Regulation (EC) No 297/95[1].

(4) This Regulation should be based on the dual legal basis of Article 114 and point (c) of Article 168(4) of the Treaty on the Functioning of the European Union (TFEU). It is aimed at financing pharmacovigilance activities that contribute to achieving an internal market as regards medicinal products, taking as a basis a high level of protection of health. At the same time, this Regulation aims to ensure financial resources to support the activities addressing common safety concerns, in order to maintain high standards of quality, safety and efficacy of medicinal products. Both objectives are pursued simultaneously and are inseparably linked, so that one is not secondary to the other.

(5) The structure and amounts of the fees for pharmacovigilance collected by the Agency, as well as the rules for their payment, should be established. The structure of the fees should be as simple as possible to apply in order to minimise the related administrative burden.

[1] Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

(6) In line with the Joint Statement of the European Parliament, the Council of the EU and the European Commission of 19 July 2012 on decentralised agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case. Therefore, the fees set out in this Regulation should be based on an evaluation of the Agency's estimations and forecasts as regards its workload and related costs, and on the basis of an evaluation of the costs of the work carried out by the national competent authorities of the Member States which act as rapporteurs and, where applicable, co-rapporteurs in accordance with Articles 61(6) and 62(1) of Regulation (EC) No 726/2004 and Articles 107e, 107j and 107q of Directive 2001/83/EC.

(7) The fees established in this Regulation should be transparent, fair and proportionate to the work carried out. Information on those fees should be publicly available. Any future revisions of the pharmacovigilance fees or other fees levied by the Agency should be based on a transparent and independent evaluation of the costs of the Agency and the costs of the tasks carried out by the national competent authorities.

(8) This Regulation should only regulate fees which are to be levied by the Agency, whereas the competence to decide on possible fees levied by the national competent authorities should remain with the Member States, including in relation to signal detection tasks. Marketing authorisation holders should not be charged twice for the same pharmacovigilance activity. Member States should therefore not levy fees for the activities which are covered by this Regulation.

(9) For reasons of predictability and clarity, the amounts of the fees should be provided in euro.

(10) Two different types of fees should be levied under this Regulation in order to take account of the diversity of the tasks of the Agency and of the rapporteurs and, where applicable, co-rapporteurs. First, fees for the pharmacovigilance procedures carried out at Union level should be charged to those marketing authorisation holders whose medicinal products are part of the procedure. Those procedures relate to the assessment of periodic safety update reports, the assessment of post-authorisation safety studies and assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data. Second, an annual fee should be charged for other pharmacovigilance activities carried out by the Agency that benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the Eudravigilance database referred to in Article 24 of Regulation (EC) No 726/2004, and the monitoring of selected medical literature.

(11) Marketing authorisation holders for medicinal products authorised under Regulation (EC) No 726/2004 already pay an annual fee to the Agency for the maintenance of their authorisations, which includes pharmacovigilance activities that are covered by the annual fee established by this Regulation. In order to avoid double charging for those pharmacovigilance activities of the Agency, the annual fee established by this Regulation should not be charged for marketing authorisations granted under Regulation (EC) No 726/2004.

(12) The work carried out at Union level in respect of the assessment of non-interventional post-authorisation safety studies imposed by the Agency or the national competent authority to be conducted in more than one Member State and of which the protocol has to be endorsed by the Pharmacovigilance Risk Assessment Committee, involves the supervision of those studies, including the assessment of the draft protocol and the assessment of the final study reports. Therefore, the fee levied for that procedure should cover all the work relating to the study. As the legislation on pharmacovigilance encourages the conduct of joint post-authorisation safety studies, marketing authorisation holders should share the applicable fee in cases where a joint study is submitted. In order to avoid double charging, marketing authorisation holders who are charged the fee for the assessment of such post-authorisation safety studies should be exempted from any other fee charged by the Agency or a national competent authority for the submission of those studies.

(13) For their assessments, rapporteurs rely on the scientific evaluations and resources of national competent authorities, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States. In view of that, and to ensure the existence of adequate resources for the scientific assessments relating to the pharmacovigilance procedures carried out at Union level, the Agency should remunerate the scientific assessment services provided by the rapporteurs and, where applicable, co-rapporteurs appointed by Member States as members of the Pharmacovigilance Risk Assessment Committee referred to in point (aa) of Article 56(1) of Regulation (EC) No 726/2004 or, where relevant, provided by rapporteurs and co-rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based exclusively on estimations of the workload involved and should be taken into account in setting the level of the fees for pharmacovigilance procedures carried out at Union level. It is recalled that as a matter of good practice, in the context of referrals initiated as a result of the evaluation of pharmacovigilance data, the Pharmacovigilance Risk Assessment Committee generally seeks to avoid appointing as rapporteur the member nominated by the Member State that initiated the referral procedure.

(14) Fees should be levied on all marketing authorisation holders on a fair basis. Therefore, a chargeable unit should be established, irrespective of the procedure under which the medicinal product has been authorised, either under Regulation (EC) No 726/2004 or under Directive 2001/83/EC, and of the way in which authorisation numbers are assigned by the Member States or the Commission. That objective is met by establishing the chargeable unit on the basis of the active substance(s) and the pharmaceutical form of the medicinal products that are subject to the obligation to be registered in the database referred to in point (l) of the second subparagraph of Article 57(1) of Regulation (EC) No 726/2004, based on information from the list of all medicinal products authorised in the Union referred to in Article 57(2) thereof. The active substance(s) should not be taken into account when establishing the chargeable unit in respect of authorised homeopathic medicinal products or authorised herbal medicinal products.

(15) In order to take into account the scope of the marketing authorisations of medicinal products granted to marketing authorisation holders, the number of chargeable units corresponding to those authorisations should take into account the number of Member States in which the marketing authorisation is valid.

(16) In line with the policy of the Union to support small and medium-sized enterprises, reduced fees should apply to small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC[1]. Such fees should be established on a basis which takes due account of the ability of small and medium-sized enterprises to pay. Consistent with that policy, micro enterprises within the meaning of that Recommendation should be exempted from all fees under this Regulation.

[1] Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

(17) Generic medicinal products, medicinal products authorised under the provisions relating to well-established medicinal use, authorised homeopathic medicinal products and authorised herbal medicinal products should be subject to a reduced annual fee, as those medicinal products generally have a well-established safety profile. However, in cases where those medicinal products are part of any of the pharmacovigilance procedures carried out at Union level, the full fee should be charged in view of the work involved.

(18) Homeopathic and herbal medicinal products registered in accordance with, respectively, Article 14 and Article 16a of Directive 2001/83/EC should be excluded from the scope of this Regulation as the pharmacovigilance activities for those medicinal products are carried out by the Member States. Medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC should also be excluded from the scope of this Regulation.

(19) In order to avoid a disproportionate administrative workload for the Agency, the fee reductions and the fee exemption provided for in this Regulation should be applied on the basis of a declaration of the marketing authorisation holder claiming to be entitled to such a fee reduction or exemption. The submission of incorrect information should be discouraged by means of the application of an increase in the amount of the applicable fee in such circumstances.

(20) For reasons of consistency, deadlines for the payment of fees levied under this Regulation should be established, taking due account of the deadlines of the procedures relating to pharmacovigilance provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC.

(21) The amounts of the fees and of the remuneration for the rapporteurs and co-rapporteurs provided for under this Regulation should be adjusted, where appropriate, to take account of inflation. For that purpose, the European Index of Consumer Prices published by Eurostat pursuant to Council Regulation (EC) No 2494/95[1] should be used. For the purpose of such an adjustment, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, 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 to the Council.

(22) Since the objective of this Regulation, namely to ensure adequate funding of pharmacovigilance activities carried out at Union level, cannot sufficiently be achieved by the Member States but can rather, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

[1] Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonised indices of consumer prices (OJ L 257, 27.10.1995, p. 1).

(23) For reasons of predictability, legal certainty and proportionality, the annual fee for the information technology systems and literature monitoring should be levied for the first time on 1 July 2015,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation shall apply to fees for pharmacovigilance activities relating to medicinal products for human use ("medicinal products") authorised in the Union under Regulation (EC) No 726/2004 and Directive 2001/83/EC which shall be levied by the European Medicines Agency (the "Agency") on marketing authorisation holders.

2. Homeopathic and herbal medicinal products registered in accordance with, respectively, Article 14 and Article 16a of Directive 2001/83/EC, and medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC, shall be excluded from the scope of this Regulation.

3. This Regulation establishes the pharmacovigilance activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees to the Agency, and the amounts of remuneration by the Agency for the services provided by the rapporteurs and, where applicable, the co-rapporteurs.

4. Micro enterprises shall be exempted from the payment of any fee under this Regulation.

5. The fees laid down in this Regulation shall apply without prejudice to the fees laid down in Regulation (EC) No 297/95.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) "chargeable unit" means a unit defined by a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency, and consistent with the obligation of marketing authorisation holders referred to in points (b) and (c) of Article 57(2) of Regulation (EC) No 726/2004 to submit such information to the database referred to in point (l) of the second subparagraph of Article 57(1) of that Regulation:

(a) name of the medicinal product, as defined in point 20 of Article 1 of Directive 2001/83/EC;

(b) marketing authorisation holder;

(c) the Member State in which the marketing authorisation is valid;

(d) active substance or a combination of active substances; and

(e) pharmaceutical form.

Point (d) of the first subparagraph is not applicable in the case of authorised homeopathic medicinal products or authorised herbal medicinal products, as defined, respectively, in points 5 and 30 of Article 1 of Directive 2001/83/EC;

(2) "medium-sized enterprise" means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;

(3) "small enterprise" means a small enterprise within the meaning of Recommendation 2003/361/EC;

(4) "micro enterprise" means a micro enterprise within the meaning of Recommendation 2003/361/EC.

Article 3

Types of fees

1. The fees for pharmacovigilance activities shall consist of the following:

(a) fees for procedures carried out at Union level as provided for in Articles 4, 5 and 6;

(b) an annual fee as provided for in Article 7.

2. Where a fee is levied by the Agency in accordance with point (a) of paragraph 1 of this Article, the Agency shall pay remuneration, in accordance with Article 9, to the national competent authorities:

(a) for the services provided by the rapporteurs and, where applicable, the co-rapporteurs in the Pharmacovigilance Risk Assessment Committee appointed as members of that Committee by Member States;

(b) for the work carried out by the Member States which act as the rapporteurs and, where applicable, co-rapporteurs in the coordination group.

Article 4

Fee for assessment of periodic safety update reports

1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in Articles 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004.

2. The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part I of the Annex.

3. Where only one marketing authorisation holder is subject to the obligation to submit a periodic safety update report in the context of the procedures referred to in paragraph 1, the Agency shall levy the total amount of the applicable fee on that marketing authorisation holder.

4. Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in paragraph 1, the Agency shall divide the total amount of the fee among those marketing authorisation holders in accordance with point 2 of Part I of the Annex.

5. Where the marketing authorisation holder referred to in paragraphs 3 and 4 is a small or medium-sized enterprise, the amount payable by the marketing authorisation holder shall be reduced as laid down in point 3 of Part I of the Annex.

6. The Agency shall levy the fee under this Article by issuing an invoice to each marketing authorisation holder concerned. The fee shall be due at the date of the start of the procedure for the assessment of the periodic safety update report. Fees due under this Article shall be paid to the Agency within 30 calendar days from the date of the invoice.

Article 5

Fee for assessment of post-authorisation safety studies

1. The Agency shall levy a fee for the assessment carried out under Articles 107n to 107q of Directive 2001/83/EC and Article 28b of Regulation (EC) No 726/2004 of post-authorisation safety studies referred to in point (b) of Article 21a and point (a) of Article 22a(1) of Directive 2001/83/EC, and in point (cb) of Article 9(4) and point (a) of Article 10a(1) of Regulation (EC) No 726/2004 that are conducted in more than one Member State.

2. The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part II of the Annex.

3. Where the obligation to conduct a post-authorisation safety study is imposed on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the amount payable by each marketing authorisation holder shall be levied as laid down in point 2 of Part II of the Annex.

4. Where the obligation to conduct a post-authorisation safety study is imposed on a marketing authorisation holder which is a small or medium-sized enterprise, the amount payable by the marketing authorisation holder shall be reduced as laid down in point 3 of Part II of the Annex.

5. The Agency shall levy the fee by issuing two invoices to each marketing authorisation holder concerned, one for the assessment of the draft protocol and one for the assessment of the final study report. The relevant part of the fee shall be due at the start of the procedure for the assessment of the draft protocol and at the start of the procedure for the assessment of the final study report, and shall be paid to the Agency within 30 calendar days from the date of the respective invoice.

6. Marketing authorisation holders who are charged the fee under this Article shall be exempted from the payment of any other fee charged by the Agency or a national competent authority for the submission of the studies referred to in paragraph 1.

Article 6

Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data

1. The Agency shall levy a fee for the assessment carried out in the context of a procedure initiated as a result of the evaluation of pharmacovigilance data under the second subparagraph of Article 31(1), Article 31(2) and Articles 107i to 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004.

2. The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part III of the Annex.

3. Where only one marketing authorisation holder is involved in the procedure referred to in paragraph 1 of this Article, the Agency shall levy the total amount of the fee on that marketing authorisation holder, as laid down in point 1 of Part III of the Annex, except in the cases specified in paragraph 5 of this Article.

4. Where two or more marketing authorisation holders are involved in the procedure referred to in paragraph 1 of this Article, the Agency shall divide the total amount of the fee among those marketing authorisation holders in accordance with point 2 of Part III of the Annex.

5. Where the procedure referred to in paragraph 1 of this Article involves one substance or one combination of substances and one marketing authorisation holder, the Agency shall levy a reduced amount of the fee on that marketing authorisation holder and shall remunerate the national competent authority for the services provided by the rapporteur or the co-rapporteur as laid down in point 3 of Part III of the Annex. Where that marketing authorisation holder is a small or medium-sized enterprise, the amount payable shall be reduced as laid down in point 3 of Part III of the Annex.

6. Where the marketing authorisation holder referred to in paragraphs 3 and 4 of this Article is a small or medium-sized enterprise, the amount payable by that marketing authorisation holder shall be reduced as laid down in point 4 of Part III of the Annex.

7. The Agency shall levy the fee by issuing a separate invoice to each marketing authorisation holder involved in the procedure. The fee shall be due at the date of the start of the procedure. Fees due under this Article shall be paid to the Agency within 30 calendar days from the date of the invoice.

Article 7

Annual fee for information technology systems and literature monitoring

1. For its pharmacovigilance activities relating to information technology systems under Article 24, Article 25a, Article 26, point (l) of the second subparagraph of Article 57(1) and Article 57(2) of Regulation (EC) No 726/2004 and the monitoring of selected medical literature under Article 27 thereof, the Agency shall levy once per year a fee as laid down in point 1 of Part IV of the Annex (the "annual fee").

2. The annual fee shall be levied on holders of marketing authorisations for all medicinal products authorised in the Union in accordance with Directive 2001/83/EC, on the basis of the chargeable units corresponding to those medicinal products. Chargeable units corresponding to medicinal products authorised in accordance with Regulation (EC) No 726/2004 shall not be subject to the annual fee.

The total payable amount of the annual fee for each marketing authorisation holder shall be calculated by the Agency on the basis of the chargeable units which correspond to the information recorded on 1 July of each year. That amount shall cover the period from 1 January to 31 December of the year concerned.

3. Where the marketing authorisation holder is a small or medium-sized enterprise, the amount of the annual fee payable by that marketing authorisation holder shall be reduced as laid down in point 2 of Part IV of the Annex.

4. An annual fee which has been reduced as laid down in point 3 of Part IV of the Annex shall apply in respect of medicinal products referred to in Article 10(1) and Article 10a of Directive 2001/83/EC, and in respect of authorised homeopathic medicinal products and authorised herbal medicinal products.

5. Where the marketing authorisation holder of medicinal products referred to in paragraph 4 is a small or medium-sized enterprise, only the fee reduction set out in paragraph 3 shall apply.

6. The annual fee shall be due on 1 July of every year in respect of that calendar year.

The fees due under this Article shall be paid within 30 calendar days from the date of the invoice.

7. The Agency shall retain the fee revenue from the annual fee.

Article 8

Fee reductions and fee exemption

1. Any marketing authorisation holder claiming to be a small or medium-sized enterprise entitled to a fee reduction under Article 4(5), Article 5(4), Article 6(5), Article 6(6) or Article 7(3), shall make a declaration to that effect to the Agency within 30 calendar days from the date of the invoice from the Agency. The Agency shall apply the fee reduction on the basis of that declaration.

2. Any marketing authorisation holder claiming to be a micro enterprise entitled to the fee exemption under Article 1(4) shall make a declaration to that effect to the Agency within 30 calendar days from the date of the invoice from the Agency. The Agency shall apply the exemption on the basis of that declaration.

3. Any marketing authorisation holder claiming to be entitled to a reduced annual fee under Article 7(4) shall make a declaration to that effect to the Agency. The Agency shall publish guidance on how that declaration is to be formulated by the marketing authorisation holder. The Agency shall apply the fee reduction on the basis of that declaration. Where the declaration is made by the marketing authorisation holder after the receipt of the invoice from the Agency, the declaration shall be made within 30 calendar days from the date of that invoice.

4. The Agency may at any time request evidence that the conditions for a fee reduction or fee exemption are fulfilled. In such a case, the marketing authorisation holder claiming or having claimed to be entitled to a fee reduction or fee exemption under this Regulation shall submit to the Agency, within 30 calendar days from receipt of the Agency's request, the information necessary to enable the Agency to verify that those conditions are fulfilled.

5. Where a marketing authorisation holder claiming or having claimed to be entitled to a fee reduction or fee exemption under this Regulation fails to demonstrate that it is entitled to such a reduction or exemption, the amount of the fee laid down in the Annex shall be increased by 10 % and the Agency shall levy the resulting full applicable amount or, as appropriate, the balance of the resulting full applicable amount.

Article 9

Payment of remuneration by the Agency to national competent authorities

1. The Agency shall remunerate the national competent authorities for the services provided by rapporteurs and, where applicable, co-rapporteurs in accordance with Article 3(2) in the following cases:

   (a) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the assessment of the periodic safety update reports referred to in Article 4;

   (b) where the coordination group has appointed a Member State which acts as rapporteur and, where applicable, co-rapporteur in the context of the assessment of the periodic safety update reports referred to in Article 4;

(c) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the assessment of the post-authorisation safety studies referred to in Article 5;

(d) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the referrals referred to in Article 6.

Where the Pharmacovigilance Risk Assessment Committee or the coordination group decides to appoint a co-rapporteur, the remuneration for the rapporteur and the co-rapporteur shall be determined in accordance with Parts I, II and III of the Annex.

2. The corresponding amounts of the remuneration for each of the activities listed in the first subparagraph of paragraph 1 of this Article are laid down in Parts I, II and III of the Annex.

3. The remuneration provided for in points (a), (b) and (d) of the first subparagraph of paragraph 1 shall be paid only after the final assessment report for a recommendation, which is intended for adoption by the Pharmacovigilance Risk Assessment Committee, has been made available to the Agency. The remuneration for the assessment of post-authorisation safety studies referred to in point (c) of the first subparagraph of paragraph 1 shall be paid in two instalments. The first instalment, relating to the assessment of the draft protocol, and the second instalment, relating to the assessment of the final study report, shall be paid after the respective final assessment reports have been submitted to the Pharmacovigilance Risk Assessment Committee.

4. The remuneration for the services provided by the rapporteur and the co-rapporteur and any related scientific and technical support shall be without prejudice to the obligation of Member States to refrain from giving the members and experts of the Pharmacovigilance Risk Assessment Committee instructions incompatible with the individual tasks of those members and experts in their capacity as rapporteur or co-rapporteur, or incompatible with the tasks and responsibilities of the Agency.

5. The remuneration shall be paid in accordance with the written contract referred to in the first subparagraph of Article 62(3) of Regulation (EC) No 726/2004. Any bank charges related to the payment of that remuneration shall be borne by the Agency.

Article 10

Method of payment of the fee

1. The fees shall be paid in euro.

2. Payment of the fees shall be made only after the marketing authorisation holder has received an invoice issued by the Agency.

3. Payment of the fees shall be made by means of a transfer to the bank account of the Agency. Any bank charges related to that payment shall be borne by the marketing authorisation holder.

Article 11

Identification of the payment of the fee

In every payment the marketing authorisation holder shall indicate the invoice reference number. For payments made via the on-line payment system, the reference number shall be the number automatically generated by the Agency's invoicing system.

Article 12

Date of payment of the fee

The date on which the full amount of the payment is received in the bank account held by the Agency shall be considered to be the date on which the payment has been made. A deadline for payment shall be considered to have been complied with only if the full amount of the fee due has been paid in time.

Article 13

Refund of fee amounts paid in excess

Any amount paid in excess of a fee amount due shall be refunded by the Agency to the marketing authorisation holder, unless otherwise explicitly agreed with the marketing authorisation holder. However, where such an excess amount is less than EUR 100 and the marketing authorisation holder concerned has not expressly requested a refund, the excess amount shall not be refunded.

Article 14

Provisional estimate of Agency budget

The Agency shall, when producing an estimate of revenue and expenditure for the following financial year in accordance with Article 67(6) of Regulation (EC) No 726/2004, include detailed information on income from fees relating to pharmacovigilance activities. That information shall distinguish between the annual fee and the fees for each procedure referred to in point (a) of Article 3(1). The Agency shall also provide specific analytical information on its revenue and expenditure related to pharmacovigilance activities, allowing the annual fee and the fees for each procedure referred to in point (a) of Article 3(1) to be distinguished.

Article 15

Transparency and monitoring

1. The amounts and rates laid down in Parts I to IV of the Annex shall be published on the website of the Agency.

2. The Executive Director of the Agency shall provide, as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, the information on the components that may have a bearing on the costs to be covered by the fees provided for in this Regulation. That information shall include a cost breakdown related to the previous year and a forecast for the following year. The Agency shall also publish an overview of that information in its annual report.

3. The Executive Director of the Agency shall also provide the Commission and the Management Board once per year with the performance information set out in Part V of the Annex based on the performance indicators referred to in paragraph 4 of this Article.

4. By ...* the Agency shall adopt a set of performance indicators taking into account the information listed in Part V of the Annex.

5. The inflation rate, measured by means of the European Index of Consumer prices published by Eurostat pursuant to Regulation (EC) No 2494/95, shall be monitored in relation to the amounts set out in the Annex. The monitoring shall take place for the first time after this Regulation has been applied during a full calendar year, and thereafter it shall take place annually.

6. Where justified in light of the monitoring referred to in paragraph 5 of this Article, the Commission shall adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs referred to in Parts I to IV of the Annex. Where the delegated act enters into force before 1 July, those adjustments shall take effect as from 1 July. Where the delegated act enters into force after 30 June, they shall take effect as from the date of entry into force of the delegated act.

* OJ: please insert the date: one year from the date of entry into force of this Regulation.

Article 16

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 15(6) shall be conferred on the Commission for a period of five years from ...[*]. 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.

3. The delegation of power referred to in Article 15(6) 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.

[*] OJ: please insert the date of entry into force of this Regulation.

5. A delegated act adopted pursuant to Article 15(6) 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.

Article 17

Transitional provisions

The fees referred to in Articles 4, 5 and 6 shall not apply to those procedures carried out at Union level for which the assessment has started before ...[*].

[*] OJ please insert the date: the fortieth day following the entry into force of this Regulation.

Article 18

Entry into force and application

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

2. The annual fee referred to in Article 7 shall be levied as from 1 July 2015.

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

Done at …,

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

ANNEX

PART I

Fee for assessment of periodic safety update reports referred to in Article 4

1. The fee for the assessment of periodic safety update reports shall be EUR 19 500 per procedure. From that amount, the remuneration for the rapporteur shall be EUR 13 100. That remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).

2. For the purpose of calculating the amount to be levied on each marketing authorisation holder in application of Article 4(4), the Agency shall calculate the proportion of chargeable units held by each marketing authorisation holder concerned of the total number of chargeable units held by all marketing authorisation holders involved in the procedure.

   The share payable by each marketing authorisation holder shall be calculated by:

   (a) dividing the total amount of the fee among the marketing authorisation holders concerned proportionately to the number of chargeable units; and

   (b) subsequently applying the fee reduction as set out in point 3 of this Part and the fee exemption referred to in Article 1(4), where relevant.

3. In application of Article 4(5), small and medium-sized enterprises shall pay 60 % of the applicable amount.

4. Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally.

PART II

Fee for assessment of a post-authorisation safety studies referred to in Article 5

1. The fee for the assessment of each post-authorisation safety study shall be EUR 43 000 to be paid in two instalments as follows:

   (a) EUR 17 200 shall be due at the date of the start of the procedure for the assessment of the draft protocol referred to in Article 107n of Directive 2001/83/EC; from that amount, the remuneration for the rapporteur shall be EUR 7 280, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s);

   (b) EUR 25 800 shall be due at the date of the start of the procedure for the assessment of the final study report by the Pharmacovigilance Risk Assessment Committee as referred to in Article 107p of Directive 2001/83/EC; from that amount, the remuneration for the rapporteur shall be EUR 10 920, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).

2. Where marketing authorisation holders conduct a joint post-authorisation safety study as referred to in Article 5(3), the amount payable by each marketing authorisation holder shall be levied by the Agency by evenly dividing the total amount of the fee among those marketing authorisation holders. Where relevant, the fee reduction laid down in point 3 of this Part or, where appropriate, the fee exemption referred to in Article 1(4), shall be applied to the share payable by the marketing authorisation holder.

3. In application of Article 5(4), small and medium-sized enterprises shall pay 60 % of the applicable amount.

4. Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally.

PART III

Fee for assessment in the context of referrals initiated as a result of the evaluation of pharmacovigilance data referred to in Article 6

1. The fee for the assessment of the procedure referred to in Article 6(1) shall be EUR 179 000 where one or two active substances and/or combinations of active substances are included in the assessment. That fee shall be increased by EUR 38 800 per each additional active substance or combination of active substances as of the third active substance or combination of substances. That fee shall not exceed EUR 295 400 irrespective of the number of active substances and/or combinations of active substances.

   From the amount of the fee, the total amount of remuneration for the rapporteur and the co-rapporteur(s) shall be as follows:

   (a) EUR 119 333 where one or two active substances and/or combinations of active substances are included in the assessment;

   (b) EUR 145 200 where three active substances and/or combinations of active substances are included in the assessment;

   (c) EUR 171 066 where four active substances and/or combinations of active substances are included in the assessment;

   (d) EUR 196 933 where five or more active substances and/or combinations of active substances are included in the assessment.

Where one or two active substances and/or combinations of active substances are included in the assessment, the Agency shall remunerate the national competent authorities for the services provided by the rapporteur and co-rapporteur(s) by dividing equally the total amount of the remuneration.

Where three or more active substances and/or combinations of active substances are included in the assessment, the Agency shall remunerate the national competent authorities for the services provided by the rapporteur and co-rapporteur(s) by:

(a) dividing the total amount of the remuneration equally between the national competent authorities; and

(b) subsequently increasing the resulting amount of the remuneration for the rapporteur by EUR 1 000 where three substances and/or combinations of active substances are included, by EUR 2 000 where four substances and/or combinations of active substances are included and by EUR 3 000 where five or more active substances and/or combinations of active substances are included. That increase shall be paid from the parts of the fee attributed to the Agency and the co-rapporteur(s), each of which shall contribute the same amount.

2. For the purpose of calculating the amount to be levied on each marketing authorisation holder in application of Article 6(4), the Agency shall calculate the proportion of chargeable units held by each marketing authorisation holder concerned of the total number of chargeable units held by all marketing authorisation holders involved in the procedure.

The amount payable by each marketing authorisation holder shall be calculated by:

(a) dividing the total amount of the fee among the marketing authorisation holders proportionately to the number of chargeable units; and

(b) subsequently applying the fee reduction laid down in point 4 of this Part and the fee exemption referred to in Article 1(4), where relevant.

Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and co-rapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and co-rapporteur(s) shall be adapted proportionally.

3. In application of Article 6(5), the amount payable by the marketing authorisation holder shall be two thirds of the applicable fee laid down in point 1 of this Part. Small and medium-sized enterprises shall pay 60 % of that amount.

   The total amount of remuneration for the rapporteur and the co-rapporteur(s) from either of the reduced amounts of the fee referred to in the first subparagraph shall correspond to the same proportion as the total amount of remuneration for the rapporteur and the co-rapporteur(s) from the fee laid down in point 1 of this Part for assessments involving one or two active substances and/or combinations of active substances. The Agency shall divide that amount equally between the national competent authorities for the services provided by the rapporteur and the co-rapporteur(s).

4. In application of Article 6(6), small and medium-sized enterprises shall pay 60 % of the applicable amount.

PART IV

Annual fee for information technology systems and literature monitoring referred to in Article 7

1. The annual fee shall be EUR 67 per chargeable unit.

2. In application of Article 7(3), small and medium-sized enterprises shall pay 60 % of the applicable amount.

3. Holders of marketing authorisations for medicinal products referred to in Article 7(4) shall pay 80 % of the amount applicable to the chargeable units corresponding to those medicinal products.

PART V

Performance information

The following information shall relate to each calendar year:

Number of Agency staff involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of hours outsourced to third parties with specification of the activities concerned and cost incurred.
Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of procedures relating to the assessment of periodic safety update reports, as well as number of marketing authorisation holders and number of chargeable units per procedure; number of reports submitted per procedure and number of marketing authorisation holders that have submitted a joint periodic safety update report.
Number of procedures relating to the assessment of draft protocols and of final reports of post-authorisation safety studies; number of marketing authorisation holders having submitted a draft protocol; number of marketing authorisation holders having submitted a final study report; number of marketing authorisation holders that have submitted a joint study.
Number of procedures relating to the referrals initiated as a result of the evaluation of pharmacovigilance data as well as number of marketing authorisation holders and number of chargeable units involved per marketing authorisation holder and per procedure.

Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure; number of marketing authorisation holders whose claim has been denied. Number of marketing authorisation holders that have claimed a micro enterprise status; number of marketing authorisation holders whose claim for fee exemption has been denied.
Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees; number of chargeable units per marketing authorisation holder concerned.
Number of invoices sent out and annual fees charged in respect of the annual fee and average and overall amount invoiced to marketing authorisation holders. Number of marketing authorisation holders that have claimed a small and medium-sized enterprise or a micro enterprise status for each application of the annual fee; number of marketing authorisation holders whose claim has been denied.
Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure.
Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.