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►B REGULATION (EU) No 658/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 May 2014

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)

(OJ L 189, 27.6.2014, p. 112)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Delegated Regulation (EU) 2018/92 of 18 October 2017	L 17	2	23.1.2018

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REGULATION (EU) No 658/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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)

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;

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(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.

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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

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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.

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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.

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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;

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(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.

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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.

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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 18 July 2015 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.

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 17 July 2014. 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.

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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 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 26 August 2014.

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.

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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 ►M1 EUR 19 770 ◄ per procedure. From that amount, the remuneration for the rapporteur shall be ►M1 EUR 13 290 ◄. 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 ►M1 EUR 43 600 ◄ to be paid in two instalments as follows:

   (a) ►M1 EUR 17 440 ◄ 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 ►M1 EUR 7 380 ◄, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s);

   (b) ►M1 EUR 26 160 ◄ 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 ►M1 EUR 11 070 ◄, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).

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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 ►**M1** EUR 181 510 ◄ where one or two active substances and/or combinations of active substances are included in the assessment. That fee shall be increased by ►**M1** EUR 39 350 ◄ 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 ►**M1** EUR 299 560 ◄ 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) ►**M1** EUR 121 000 ◄ where one or two active substances and/or combinations of active substances are included in the assessment;

(b) ►**M1** EUR 147 240 ◄ where three active substances and/or combinations of active substances are included in the assessment;

(c) ►**M1** EUR 173 470 ◄ where four active substances and/or combinations of active substances are included in the assessment;

(d) ►**M1** EUR 199 700 ◄ 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

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(b) subsequently increasing the resulting amount of the remuneration for the rapporteur by ►M1 EUR 1 010 ◄ where three substances and/or combinations of active substances are included, by ►M1 EUR 2 020 ◄ where four substances and/or combinations of active substances are included and by ►M1 EUR 3 050 ◄ 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 ►M1 EUR 68 ◄ per chargeable unit.

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

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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.