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***I
REPORT

on the proposal for a 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 (COM(2013)0472 – C7-0196/2013 – 2013/0222(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Linda McAvan

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Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: **[...]**.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a 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
(COM(2013)0472 – C7-0196/2013 – 2013/0222(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2013)0472),

– having regard to Article 294(2) and Articles 114 and 168(4) (c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0196/2013),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Greek Parliament and the Spanish Congress of Deputies and the Spanish Senate, asserting that the draft legislative act does not comply with the principle of subsidiarity,

– having regard to the opinion of the European Economic and Social Committee of 16 October 2013[1],

– after consulting the Committee of the Regions,

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0476/2013),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

1 OJ C 0, 0.0.0000, p. 0./ Not yet published in the Official Journal.

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) The provisions on pharmacovigilance relating to medicinal products of human use laid down in Regulation (EC) No 726/2004 and 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[12] were amended by 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[13] , 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[14] , Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance[15] and 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[16] . Those amendments only cover medicinal products for human use. Those amendments provide for new pharmacovigilance tasks for the Agency including Union-wide pharmacovigilance procedures, the monitoring of literature cases, the improved information technology tools and	(2) The provisions on pharmacovigilance relating to medicinal products of human use laid down in Regulation (EC) No 726/2004 and 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[12] were amended by 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[13] , 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[14] , Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance[15] and 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[16]. Those amendments only cover medicinal products for human use. Those amendments provide for new pharmacovigilance tasks for the Agency including Union-wide pharmacovigilance procedures, the monitoring of literature cases, the improved information technology tools and

the provision of more information to the general public. Furthermore, the pharmacovigilance legislation stipulates that the Agency should be enabled to fund those activities from fees charged to marketing authorisation holders. New categories of fees should therefore be created to cover the new and specific tasks of the Agency.	the provision of more information to the general public. Furthermore, the pharmacovigilance legislation stipulates that the Agency should be enabled to fund those activities from fees charged to marketing authorisation holders***, in addition to public funding provided from the Union budget***. New categories of fees should therefore be created to cover the new and specific tasks of the Agency.
[12] JO L 311, 28.11.2001, p. 67.	[12] JO L 311 du 28.11.2001, p. 67.
[13] JO L 348, 31.12.2010, p. 74.	[13] JO L 348 du 31.12.2010, p. 74.
[14] JO L 348, 31.12.2010, p. 1.	[14] JO L 348 du 31.12.2010, p. 1.
[15] JO L 299, 27.10.2012, p. 1.	[15] JO L 299 du 27.10.2012, p. 1.
[16] JO L 316, 14.11.2012, p. 38.	[16] JO L 316 du 14.11.2012, p. 38.

Justification

With a view to ensuring that the assessments are as transparent, objective and independent as possible, EU budget funding should be provided for the new pharmacovigilance tasks.

Amendment 2

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Fees referred to in this Regulation should be transparent, fair and proportionate to the work carried out.	(7) Fees referred to in this Regulation should be transparent, fair and proportionate to the work carried out. ***Information on those fees should be publicly available.***

Amendment 3

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) This Regulation should only refer to fees which are to be levied by the Agency, whereas the competence to decide on possible fees levied by the competent authorities of the Member States should remain with the Member States. 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.	(8) This Regulation should only refer to fees which are to be levied by the Agency, whereas the competence to decide on possible fees levied by the competent authorities of the Member States ***, in particular in relation to signal detection tasks***. Marketing authorisation holders should not ***, however,*** be charged twice for the same pharmacovigilance activity. Member States should therefore not levy fees for the activities which are covered by this Regulation ***, including fees for follow-on variations to marketing authorisations***.

Justification

A clear separation needs to be made between fees paid to Member States and fees paid to the European Medicines Agency. As the signal detection was taken out from the scope of the annual flat fee by the Rapporteur, it should be specified that it still remains a Member States competence. To clarify that companies should not have to pay national fees for any marketing authorisation variations which may result from one of the pharmacovigilance procedures. This is a form of 'double charging', as competent authorities just have to cut and paste the new change into the PIL – the scientific analysis has already been done.

Amendment 4

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) Two different types of fees should be levied under this Regulation in order to take account of the diversity of tasks of the Agency and of the rapporteurs. Firstly, 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, assessment of post-authorisation	(10) Two different types of fees should be levied under this Regulation in order to take account of the diversity of tasks of the Agency and of the rapporteurs. Firstly, 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, assessment of post-authorisation

safety studies and assessments in the context of referrals initiated as a result of pharmacovigilance data. Secondly, an annual flat 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, notably maintenance of the 'Eudravigilance' database referred to in Article 24 of Regulation (EC) No 726/2004 ***signal detection*** and monitoring of selected medical literature.	safety studies and assessments in the context of referrals initiated as a result of pharmacovigilance data. Secondly, an annual flat 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, notably maintenance of the 'Eudravigilance' database referred to in Article 24 of Regulation (EC) No 726/2004 and monitoring of selected medical literature.

Amendment 5

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Rapporteurs rely for their assessment on the scientific evaluation and resources of national marketing authorisation bodies, whilst 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 adequate resources for the scientific assessments relating to the Union-wide pharmacovigilance procedures, the Agency should remunerate the scientific assessment services provided by the rapporteurs appointed by Member States as members of the Pharmacovigilance Risk Assessment Committee referred to in Article 56(1)(aa) of Regulation (EC) No 726/2004 or, where relevant, by rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The level of remuneration for the work carried out by those rapporteurs should be based on average estimations of the workload involved and should be taken into account in setting the level of the fees for Union-wide pharmacovigilance	(13) Rapporteurs rely for their assessment on the scientific evaluation and resources of national marketing authorisation bodies, whilst 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 adequate resources for the scientific assessments relating to the Union-wide pharmacovigilance procedures, the Agency should remunerate the scientific assessment services provided by the rapporteurs appointed by Member States as members of the Pharmacovigilance Risk Assessment Committee referred to in Article 56(1)(aa) of Regulation (EC) No 726/2004 or, where relevant, by rapporteurs ***and co-rapporteurs*** in the coordination group referred to in Article 27 of Directive 2001/83/EC. ***However, in order to ensure that activities linked to Union-wide pharmacovigilance procedures are only related to the need to ensure patient safety, the rapporteur of a referral should not be the Member State***

procedures.	***which asked for that referral.*** The level of remuneration for the work carried out by those rapporteurs ***and co-rapporteurs*** should be based on average estimations of the workload involved and should be taken into account in setting the level of the fees for Union-wide pharmacovigilance procedures.

Justification

In order to ensure that the only reasons to trigger referrals are patient safety, quality, manufacturing or efficacy issues and to prevent the impression of a possible conflict of interests, the Member State(s) which triggers a specific referral shall not be chosen as rapporteur(s) or co-rapporteur(s) for this specific referral.

Amendment 6

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Fees should be levied on a fair basis on all marketing authorisation holders. Therefore, a single 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 the way in which authorisation numbers are assigned by the Member States. ***The individual entries corresponding to authorisations*** in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 ***based on information from the list of all medicinal products for human use authorised in the Union referred to in Article 57(2) thereof meet*** this objective.	(14) Fees should be levied on a fair basis on all marketing authorisation holders. Therefore, a single 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 the way in which authorisation numbers are assigned by the Member States. ***Establishing a single chargeable unit at the level of active ingredient and pharmaceutical form based on information included*** in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 ***meets*** this objective.

Justification

The Commission's proposal would have meant that companies would be charged according to the number of different market authorisations they have - and this is calculated down to the size of the pack. Whether the pack contains 10 or 20 tablets is not relevant for

pharmacovigilance. It would be more appropriate to charge according to the number of authorisations per active ingredient, and per pharmaceutical form (i.e. whether the product is a spray, a tablet or an injectable solution).

Amendment 7

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Marketing authorisation holders belonging to the same mother company or group of companies or having concluded agreements or exercising concerted practices concerning the placing on the market of the relevant medicinal product should be considered as one entity (i.e. a 'single marketing authorisation holder').

Justification

The criteria regarding the definition of the Marketing Authorisation Holder as the 'same entity' is already set out in the 98/C 229/03 European Commission Communication on the Community marketing authorisation procedures for medicinal products shall be followed also for the purpose of Pharmacovigilance fees.

Amendment 8

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) 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 flat fee as those products generally have a well-established safety profile. However, in cases where these products are part of any of the Union-wide	(16) Generic medicinal products, medicinal products authorised under the provisions relating to well-established medicinal use, ***medicinal products*** authorised ***in the Union for at least 10 years and*** authorised ***homeopathic and*** herbal medicinal products should be subject to a reduced annual flat fee as those products generally have a well-established safety profile. However, in cases where these products are

pharmacovigilance procedures, the full fee should be charged in view of the work involved. As the legislation on pharmacovigilance encourages the conduct of joint post authorisation safety studies, marketing authorisation holders should share the applicable fee in case a joint study is submitted.	part of any of the Union-wide pharmacovigilance procedures, the full fee should be charged in view of the work involved. As the legislation on pharmacovigilance encourages the conduct of joint post authorisation safety studies, marketing authorisation holders should share the applicable fee in case a joint study is submitted.

Amendment 9

Proposal for a regulation
Article 1 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Homeopathic and herbal medicinal products registered in accordance with Article 14 and Article 16a of Directive 2001/83/EC shall be excluded from the scope of this Regulation.

Justification

Amendment to legally clarify the exclusion of registered homeopathic and herbal medicinal products as already stated in Recital 17.

Amendment 10

Proposal for a regulation
Article 1 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Regulation determines the activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees and the level of remuneration of the rapporteurs.	2. This Regulation determines the ***pharmacovigilance*** activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees and the level of remuneration of ***the Agency,*** the rapporteurs ***and the co-rapporteurs***.

Amendment 11

Proposal for a regulation
Article 1 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Member States shall not impose fees for pharmacovigilance tasks that are already covered by this Regulation.

Justification

A clear separation needs to be made between fees paid to Member States and fees paid to the European Medicines Agency.

Amendment 12

Proposal for a regulation
Article 2 – paragraph 1 – point 1

Text proposed by the Commission	*Amendment*
1. ***'***Chargeable unit***'*** means ***each individual entry*** in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 ***based on information from the list of all medicinal products for human use authorised in the Union referred to in Article 57(2) thereof***.	1. 'Chargeable unit' means ***a unit defined by the following data set from the medicinal products information that is included*** in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004***:***
	(a) marketing authorisation holder;
	(b) country where the marketing authorisation is valid;
	(c) active ingredient or ingredients; and
	(d) pharmaceutical form.

Justification

The name of the medicinal product (included in the Rapporteur´s Amendment 6) often contains the strength so deleting the name of the medicinal product here would avoid marketing authorisation holders being charged multiple times for the same product.

Amendment 13

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where a fee is levied by the Agency in accordance with paragraph 1(a), the Agency shall remunerate the rapporteur in the Pharmacovigilance Risk Assessment Committee appointed by the Member State or the rapporteur in the coordination group (hereinafter 'the rapporteur') for the work they carry out for the Agency or the coordination group. This remuneration shall be paid in accordance with Article 9.	2. Where a fee is levied by the Agency in accordance with paragraph 1(a), the Agency shall remunerate the rapporteur ***and the co-rapporteur*** in the Pharmacovigilance Risk Assessment Committee appointed by the Member State or the ***Member State who acts as the*** rapporteur in the coordination group (hereinafter 'the rapporteur') for the work they carry out for the Agency or the coordination group. This remuneration shall be paid ***to the Member State appointing, or acting as, the rapporteur or co-rapporteur*** in accordance with Article 9.

Justification

In the coordination group is the Member State who is acting as rapporteur or co-rapporteur. In any case, the remuneration should be paid to the Member State, since the rapporteur and the co-rapporteur always work within a team of assessors from the Member State. Obviously, the remuneration will allow the Member State to carry the pharmacovigilance work. In fact, the fee is received once the assessment report is delivered.

Amendment 14

Proposal for a regulation
Article 4 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Marketing authorisation holders who are charged the fee under this Article shall be exempt from any other fee charged by a competent authority for the assessment referred to in paragraph 1, including, but not limited to, fees for variations submitted in accordance with Articles 107g(2) and (4) of Directive

2001/83/EC.

Justification

The Variations that are a consequence of PSUR assessment, should be seen as an integral part of the entire assessment process and not be charged additionally at national level as no second scientific assessment is required.

Amendment 15

Proposal for a regulation
Article 5 – paragraph 1

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

Justification

In line with Art. 107 N(1) of Directive 2001/83/EC that foresee an exemption for studies to be conducted by one Member State.

Amendment 16

Proposal for a regulation
Article 5 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Marketing authorisation holders who are charged the fee under this Article shall be exempted from any other fee charged by a competent authority for the submission of studies referred to in paragraph 1.	6. Marketing authorisation holders who are charged the fee under this Article shall be exempted from any other fee charged by a competent authority for the submission of studies referred to in paragraph 1**,**

including, but not limited to, fees for variations submitted in accordance with Articles 107p(2) and 107q(2) of Directive 2001/83/EC.

Justification

The Variations that are a consequence of PASS assessment should be seen as an integral part of the entire assessment process and not be charged additionally at national level as no second scientific assessment is required.

Amendment 17

Proposal for a regulation
Article 6 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Marketing authorisation holders who are charged the fee under this Article shall be exempt from any other fee charged by a competent authority for the assessment referred to in paragraph 1, including, but not limited to, fees for variations submitted in accordance with Article 34(3) and Article 35 of Directive 2001/83/EC.

Justification

The Variations that are a consequence of a referral assessment should be seen as an integral part of the entire assessment process and not be charged additionally at national level as no second scientific assessment is required.

Amendment 18

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. For its pharmacovigilance activities relating to information technology systems under Article 24, Article 25a, Article 26,	1. For its pharmacovigilance activities relating to information technology systems under Article 24, Article 25a, Article 26,

Article 57(1)(l) of Regulation (EC) No 726/2004, monitoring of selected medical literature under Article 27 thereof ***and signal detection under Article 28a thereof***, the Agency shall levy once per year a flat fee as laid down in Part IV of the Annex.	Article 57(1)(l) of Regulation (EC) No 726/2004 ***and*** monitoring of selected medical literature under Article 27 thereof, the Agency shall levy once per year a flat fee as laid down in Part IV of the Annex.

Justification

The scope of the annual fee should be clarified so that it only includes activities which are undertaken at EU level. Signal detection is something that some Member States may want to continue to charge fees for.

Amendment 19

Proposal for a regulation
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. A reduced annual flat fee, as laid down in 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, as defined respectively in Article 1(5) and Article 1(30) of Directive 2001/83/EC.	5. A reduced annual flat fee, as laid down in Part IV of the Annex shall apply ***to generic*** medicinal products referred to in Article 10(1) and ***medicinal products authorised under the provisions relating to well-established medicinal use referred to in*** Article 10a of Directive 2001/83/EC**,** ***all products that have been authorised in the Union for at least 10 years,*** and in respect of authorised homeopathic medicinal products and authorised herbal medicinal products, as defined respectively in Article 1(5) and Article 1(30) of Directive 2001/83/EC.

Justification

To create a level playing field, the reduced annual fee should apply to products with 'well-established safety profile'.

Amendment 20

Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Any marketing authorisation holder claiming to be entitled to a reduced annual flat fee under Article 7(5) shall make a declaration to that effect to the Agency. The Agency shall apply the reduction on the basis of that declaration where the required conditions are met. Where the declaration is made by the marketing authorisation holder after the receipt of the invoice from the Agency, the declaration shall be done within 30 calendars days from the receipt of that invoice.	3. Any marketing authorisation holder claiming to be entitled to a reduced annual flat fee under Article 7(5) shall make a declaration to that effect to the Agency***; the Commission shall publish guidelines on how this declaration is to be formulated by the marketing authorisation holder***. The Agency shall apply the reduction on the basis of that declaration where the required conditions are met**,**. Where the declaration is made by the marketing authorisation holder after the receipt of the invoice from the Agency, the declaration shall be done within 30 calendars days from the receipt of that invoice.

Justification

To ensure legal certainty and transparency, the Commission should publish clear guidelines on how the marketing authorisation holder should present the self-declaration, when they request a reduced annual flat fee under Article 7(5).

Amendment 21

Proposal for a regulation
Article 8 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency may request, at any time, evidence that the conditions for a reduction of fees or for an exemption from fees are fulfilled. In that case, the marketing authorisation holder claiming or having claimed to be entitled to a reduction or an exemption under this Regulation, shall submit to the Agency the information necessary to demonstrate compliance with the relevant conditions.	4. The Agency may request, at any time, evidence that the conditions for a reduction of fees or for an exemption from fees are fulfilled. In that case, the marketing authorisation holder claiming or having claimed to be entitled to a reduction or an exemption under this Regulation, shall submit to the Agency, ***within seven calendar days from receipt of the Agency's request,*** the information necessary to demonstrate compliance with the relevant conditions ***in order for the Agency to be able to verify that those conditions are fulfilled***.

Justification

A deadline for this demonstration should be set. Marketing authorisation holders shall actively provide the Agency with all evidence that they are entitled to claim for a fee reduction or exemption in order for the latter to check its exactitude when needed.

Amendment 22

Proposal for a regulation
Article 9 – title

Text proposed by the Commission	*Amendment*
Payment of remuneration by the Agency to rapporteurs	Payment of remuneration by the Agency to rapporteurs ***and co-rapporteurs***

Amendment 23

Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall remunerate rapporteurs in accordance with Article 3(2) in the following cases:	1. The Agency shall remunerate rapporteurs ***and co-rapporteurs*** in accordance with Article 3(2) in the following cases:
(c) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur for the assessment of 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 ***or co-rapporteur*** for the assessment of periodic safety update reports referred to in Article 4;
(d) where the ***Member State*** has appointed a ***representative in the coordination group*** who acts as rapporteur in the context of the assessment of periodic safety update reports referred to in Article 4;	(d) where the ***coordination group*** has appointed a ***Member State*** that acts as rapporteur ***or co-rapporteur*** in the context of the assessment of periodic safety update reports referred to in Article 4;
(e) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur for the assessment of post-	(e) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur ***or co-rapporteur*** for the

authorisation safety studies referred to in Article 5;	assessment of post-authorisation safety studies referred to in Article 5;
(f) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur for the referrals referred to in Article 6.	(f) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur for the referrals referred to in Article 6. ***In that case, the Member State or Member States which triggered the referral shall provide all necessary data on signals, but shall not be chosen as rapporteur for that referral.***

Justification

To clarify that co-rapporteurs should also be paid directly by EMA, as is current practice and to clarify the way that the coordination group works. In order to ensure that the only reasons to trigger referrals are patient safety, quality, manufacturing or efficacy issues and to prevent the impression of a possible conflict of interests, the Member State(s) which triggers a specific referral shall not be chosen as rapporteur(s) for this specific referral.

Amendment 24

Proposal for a regulation
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The remuneration provided for in 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.	3. The remuneration provided for in 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. ***This report shall be submitted in a version that has been entirely and properly translated into the working language of the Agency.***

Justification

Rapporteurs and co-rapporteurs are responsible to deliver their report in a fully translated version into the working language of the Agency. If rapporteurs and co-rapporteurs deliver a report only in their own language or a badly translated version of it, and if the Agency has consequently to work on that translation, the share of the fee should be different.

Amendment 25

Proposal for a regulation
Article 9 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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***, and within 60 calendar days from receipt of the final assessment report, as referred to in paragraph 3 of this Article.*** Any bank charges related to the payment of that remuneration shall be borne by the Agency.

Justification

The proposal already includes a 30 day deadline for companies to pay fees to EMA. There should also be a deadline for EMA to pay the Member State Rapporteur.

Amendment 26

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission	*Amendment*
2. If the purpose of the payment cannot be established***, the Agency shall set a deadline by which the marketing authorisation holder shall notify it*** in writing ***of the purpose of the payment. If*** the Agency ***does not receive a notification of the purpose of the payment before expiry of the deadline***, the payment shall be considered invalid and the amount concerned shall be refunded to the marketing authorisation holder.	2. If the purpose of the payment cannot be established ***and notified*** in writing ***to*** the Agency ***within 30 days***, the payment shall be considered invalid and the amount concerned shall be refunded to the marketing authorisation holder.

Justification

Deadlines to provide detailed information on the purpose of a specific payment should

already be clearly stated in the legislation in order to avoid further administrative burden for the Agency.

Amendment 27

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Executive Director of the Agency shall provide the Commission and the ***Management Board annually*** with information on the components that may have ***a*** bearing on the costs to be covered by the fees provided for in this Regulation. This information shall include a cost breakdown related to the previous year and a forecast for the following year. 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 3.	2. The Executive Director of the Agency shall provide ***as part of the annual report delivered to the European Parliament, the Council,*** the Commission***, the European Economic and Social Committee, the Court of Auditors*** and the ***Member States in accordance with Article 65(10) of Regulation (EC) No 726/2004*** the information on the components that may have bearing on the costs to be covered by the fees provided for in this Regulation. This 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 public annual report.*** 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 3.

Amendment 28

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
5. In view of the monitoring referred to in paragraph 4, the Commission may, where necessary, adjust the amounts of the fees and the amounts of the remuneration of	5. In view of the monitoring referred to in paragraph 4, the Commission may, where necessary, adjust the amounts of the fees and the amounts of the remuneration of

rapporteurs laid down in the Annex, in accordance with Article 16. Those adjustments shall take effect on 1 April following the entry into force of the corresponding amending act.	rapporteurs ***and co-rapporteurs*** laid down in the Annex, in accordance with Article 16. Those adjustments shall take effect on 1 April following the entry into force of the corresponding amending act.

Amendment 29

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any amendments to the amounts shall be based on ***an*** evaluation of the costs of the Agency and the costs of the assessments provided by the rapporteurs as laid down in Article 9 or on the monitoring of the inflation rate referred to in Article 15(4).	2. Any amendments to the amounts shall be based on ***a transparent and open*** evaluation of the costs of the Agency and the costs of the assessments provided by the rapporteurs as laid down in Article 9 or on the monitoring of the inflation rate referred to in Article 15(4).

Amendment 30

Proposal for a regulation
Article 16 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	At the time of adoption of this Regulation, the number of chargeable units used as a basis for the calculations is [...].

Justification

For the sake of clarity and legibility, the number of chargeable units used for the calculation of the fees should be specified directly in the text of the Regulation.

Amendment 31

Proposal for a regulation
Article 19 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The annual flat fee referred to in Article 7 and Part IV of the Annex shall gradually enter into force in accordance with the extent of services delivered, in application of Article 24(2) third subparagraph of Regulation EC No 726/2004.

Justification

The Agency should be able to conduct all the activities covered by the annual flat fee as referred to in the legislation. In order to do so, the Eudravigilance database should be fully operable and properly functioning before the Agency can levy that fee.

Amendment 32

Proposal for a regulation
Annex – part III – paragraph 1

Text proposed by the Commission	*Amendment*
1. The fee for the assessment of the procedure referred to in Article 6(1) is ***EUR 168 600***. The corresponding remuneration of the rapporteur ***is EUR 45 100***.	1. The fee for the assessment of the procedure referred to in Article 6(1) is ***[...] when one or two active substances are involved. This fee is increased by EUR [...] for every additional active substance involved in the procedure***. The corresponding remuneration of the rapporteur ***and co-rapporteur is 50% of the total fee collected***.

Justification

Rapporteurs and co-rapporteurs from the Member States should be fairly remunerated, in order to incentivise them to volunteer for the work involved in handling referrals.

Amendment 33

Proposal for a regulation
Annex – part III– paragraph 3 – subparagraph 2 – point ii

Text proposed by the Commission	*Amendment*
(ii) subsequently applying the reduction laid down in paragraph 2 of Part ***II*** of this Annex and the exemption referred to in Article 1(3), where relevant.	(ii) subsequently applying the reduction laid down in paragraph 2 of Part ***III*** of this Annex and the exemption referred to in Article 1(3), where relevant.

Justification

Part II in the original Commission proposal refers to the Article 5(4) on the Post-authorisation safety studies. While part III refers to Article 6(5) which is the correct article for the Annex Part III on referrals.

Amendment 34

Proposal for a regulation
Annex – part IV – paragraph 1

Text proposed by the Commission	*Amendment*
1. The annual flat fee is EUR ***60*** per chargeable unit.	1. The annual flat fee is EUR ***[...]*** per chargeable unit.

Justification

To be adapted after the final agreement on the reductions and exemptions.

Amendment 35

Proposal for a regulation
Annex – part IV – paragraph 3

Text proposed by the Commission	*Amendment*
3. Holders of marketing authorisations for medicinal products referred to in Article 7(5) shall pay 80 % of the amount applicable to the chargeable units corresponding to those products.	3. Holders of marketing authorisations for medicinal products, ***other than authorised homeopathic medicinal products,*** referred to in Article 7(5) shall pay 80 % of the amount applicable to the chargeable units corresponding to those products. ***Holders of marketing authorisations for homeopathic medicinal products shall pay the percentage equivalent to the ICT***

services applicable to the chargeable unit that corresponds to those products.

Justification

For authorised homeopathic medicinal product, from the services listed in Annex Nr. 4 of the Regulation ('Other costs of the Agency related to Pharmacovigilance'), only IT services for establishment and maintenance of the database apply. It is necessary to explicitly mention the kind of costs, because there are no other services rendered in return for the flat fee.

EXPLANATORY STATEMENT

Why we need a new fees regime

The Commission proposal is to provide funding to implement the new EU Pharmacovigilance Regulation and Directive agreed in 2012. The new law places new tasks on both the EMA (European Medicines Agency) and the National Competent Authorities (NCA) - the national medicines regulators - in each Member State. It is important that a funding mechanism be put in place as soon as possible, in particular because the law has already entered into force.

The new tasks for the Agency include:

- Extension of the Eudravigilance database to cover nationally authorised products, and the addition of new functions, including a public section where people can search online for adverse reactions to a particular drug.
- Setting up a central PSUR (periodic safety update report) repository
- Setting up a database of all authorised products in the EU (art 57)
- Literature monitoring
- Coordinating EU-level assessments of PSURs, PASSs, and referrals for nationally authorised products.
- Setting up a European medicines web-portal which would be a "one stop shop" for people to find information about medicines.
- Holding public hearings

For the first time, EMA will be undertaking pharmacovigilance tasks for products which are authorised on the market by national authorities, as well as centrally authorised products (authorised on the market by EMA).

The system also provides for the NCAs to share the work involved in EU-level assessments of PSURs, PASSs, and referrals for nationally authorised products.

What the Commission Proposes

The Commission estimates the cost of the new tasks at €38.5 million euros and proposes to raise the funds through two separate funding streams:

A new annual flat fee for pharmacovigilance to be raised from pharmaceutical companies through a charge based on the number of "chargeable units" the company has on the art 57 database. This would be €60 per product, defined at the level of pack size, with an exemption for centrally authorised products.

Three new procedure fees for the analysis of PSURs (periodic safety update reports); Post Authorisation Safety Studies (PASS); and for referrals. A referral is the procedure whereby a medicine is referred to the PRAC (pharmacovigilance risk assessment committee) because of safety concerns.

Sharing of costs and fees between EMA and the NCA

The tasks of ensuring a comprehensive medicines safety system at EU level are shared between the EMA and the Member States. The Commission therefore proposes that any fees raised must be shared between them, without charging companies twice for the same work.

Reductions and exemptions

The Commission proposes reductions for SMEs, and for generics, well-established use medicines, and herbal and homeopathic medicines which hold a full marketing authorisation. They propose that registered herbal and homeopathic medicines should be completely exempted from all fees, as should micro-enterprises.

Views of the Rapporteur

Your rapporteur accepts the urgent need to put in place a funding mechanism and is therefore proposing changes to the Commission proposals designed to allow for rapid agreement. A full review of pharmacovigilance fees is due to start next year when a full overhaul of the whole system can be proposed if thought necessary, but in the interim, she makes the following proposals.

Flat fee: this is proposed to cover EMA's costs for a variety of pharmaceutical activities, including signal detection. As some Member states also charge a fee to companies for signal detection, there are concerns that companies may be double-charged. Your rapporteur therefore proposes to reduce the amount raised by EMA, and the scope of the flat fee to cover only the tasks to be undertaken by EMA: Eudravigilance, the article 57 database, PSUR repository and literature review only, turning the flat fee into a maintenance fee for EMA pharmacovigilance work. She also feels that using pack size as a basis for the chargeable unit is not the best system because the number of tablets in a pack is not relevant to pharmacovigilance, and would penalise some companies, such as generics companies. Instead, it would be more appropriate to charge according to the number of authorisations a company has per active ingredient, and per pharmaceutical form. .

The referral fee: the problem here is that the investigation into safety risks can be costly and can involve whole classes of medicines and several different active substances. The amount of work involved can vary depending on the complexity of the referral, so your rapporteur proposes that this be reflected in the fee regime. She also wants to ensure that rapporteurs and co-rapporteurs from the Member states are fairly remunerated, in order to incentivise them to volunteer for the work involved in handling referrals.

Your rapporteur makes no changes at this stage to the procedure fees for PSURs and PASSs, except for the definition of chargeable units.

PROCEDURE

Title	Fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use
References	COM(2013)0472 – C7-0196/2013 – 2013/0222(COD)
Date submitted to Parliament	26.6.2013
Committee responsible Date announced in plenary	ENVI 1.7.2013
Committee(s) asked for opinion(s) Date announced in plenary	ITRE IMCO 1.7.2013 1.7.2013
Not delivering opinions Date of decision	ITRE IMCO 8.7.2013 25.9.2013
Rapporteur(s) Date appointed	Linda McAvan 11.7.2013
Discussed in committee	5.11.2013 27.11.2013
Date adopted	17.12.2013
Result of final vote	+: 49 –: 0 0: 1
Members present for the final vote	Martina Anderson, Pilar Ayuso, Paolo Bartolozzi, Franco Bonanini, Biljana Borzan, Milan Cabrnoch, Martin Callanan, Yves Cochet, Chris Davies, Bas Eickhout, Jill Evans, Elisabetta Gardini, Gerben-Jan Gerbrandy, Matthias Groote, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Martin Kastler, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Jo Leinen, Corinne Lepage, Peter Liese, Kartika Tamara Liotard, Zofija Mazej Kukovič, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Antonyia Parvanova, Mario Pirillo, Pavel Poc, Anna Rosbach, Oreste Rossi, Dagmar Roth-Behrendt, Carl Schlyter, Richard Seeber, Dubravka Šuica, Salvatore Tatarella, Thomas Ulmer, Marina Yannakoudakis
Substitute(s) present for the final vote	Kriton Arsenis, Julie Girling, Jutta Haug, Britta Reimers, Bart Staes, Vladimir Urutchev, Anna Záborská, Andrea Zanoni
Substitute(s) under Rule 187(2) present for the final vote	Sabine Lösing
Date tabled	20.12.2013