EUROPEAN PARLIAMENT 2009 - 2014

*Committee on the Environment, Public Health and Food Safety*

**2013/0222(COD)**

11.11.2013

# AMENDMENTS
# 15 - 112

**Draft report**
**Linda McAvan**
(PE519.514v02-00)

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

Proposal for a regulation
(COM(2013)0472 – C7-0196/2013 – 2013/0222(COD))

AM_Com_LegReport

**Amendment 15**
**Thomas Ulmer, Ingeborg Gräßle**

**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 | (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 |

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|---|---|
| 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. | 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. ***However, taking into account the benefit for society as a whole, due respect should be given to pharmacovigilance as a sovereign task. Therefore, the percentage share of EU funding in the financing of the EMA budget should be kept, at least, at the status quo before the implementation of this Regulation. The contribution should be used to reduce the costs for financing the routine tasks and hence the annual flat fee.*** New categories of fees should therefore be created to cover the new and specific tasks of the Agency. |
| [12] OJ L 311, 28.11.2001, p. 67. | [12] OJ L 311, 28.11.2001, p. 67. |
| [13] OJ L 348, 31.12.2010, p.74. | [13] OJ L 348, 31.12.2010, p.74. |
| [14] OJ L 348, 31.12.2010, p.1. | [14] OJ L 348, 31.12.2010, p.1. |
| [15] OJ L 299, 27.10.2012, p.1. | [15] OJ L 299, 27.10.2012, p.1. |
| [16] OJ L 316, 14.11.2012, p.38. | [16] OJ L 316, 14.11.2012, p.38. |

Or. en

*Justification*

*The protection of public health is a sovereign task. Pharmacovigilance activities serve this purpose. Currently, the financing of the EMA consist of a contribution from the Union and fees paid by industry. The proposal of the Commission foresees, however, that the additional tasks are financed solely by industry. Full fee-financed pharmacovigilance exposes the system to the danger of no longer being seen as independent from the interests of the pharmaceutical industry.*

**Amendment 16**
**Georgios Koumoutsakos, Spyros Danellis**

**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 the provision of more information to the general public. Furthermore, the | (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.

pharmacovigilance legislation stipulates that the Agency should be enabled to fund those activities from fees charged to marketing authorisation holders ***and a contribution from the Union***. New categories of fees should therefore be created to cover the new and specific tasks of the Agency. ***The European Parliament and the Council should examine the level of the Union contribution on the basis of an evaluation of needs and taking account of the level of fees. The level of the fees charged to marketing authorisation holders will take into account the current financial situation and entrepreneurial environment of Member States.***

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[12] OJ L 311, 28.11.2001, p. 67.

[13] OJ L 348, 31.12.2010, p.74.

[14] OJ L 348, 31.12.2010, p.1.

[15] OJ L 299, 27.10.2012, p.1.

[16] OJ L 316, 14.11.2012, p.38.

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[12] OJ L 311, 28.11.2001, p. 67.

[13] OJ L 348, 31.12.2010, p.74.

[14] OJ L 348, 31.12.2010, p.1.

[15] OJ L 299, 27.10.2012, p.1.

[16] OJ L 316, 14.11.2012, p.38.

Or. en

**Amendment 17**
**Françoise Grossetête**

**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 | (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.

[12] JO L 311, 28.11.2001, p. 67.

[13] JO L 348, 31.12.2010, p. 74.

[14] JO L 348, 31.12.2010, p. 1.

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***, in addition to public funding provided from the EU budget***. New categories of fees should therefore be created to cover the new and specific tasks of the Agency.

[12] JO L 311 du 28.11.2001, p. 67.

[13] JO L 348 du 31.12.2010, p. 74.

[14] JO L 348 du 31.12.2010, p. 1.

[15] JO L 299, 27.10.2012, p. 1.

[16] JO L 316, 14.11.2012, p. 38.

[15] JO L 299 du 27.10.2012, p. 1.

[16] JO L 316 du 14.11.2012, p. 38.

Or. fr

*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 18**
**Antonyia Parvanova, Pilar Ayuso**

**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 these fees should be publicly available.*** |

Or. en

**Amendment 19**
**Marina Yannakoudakis**

**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*** | (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. |

***not levy fees for the activities which are covered by this Regulation.***

Or. en

**Amendment 20**
**Françoise Grossetête**

**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 should remain with the Member States. 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. |

Or. fr

*Justification*

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

**Amendment 21**
**Michèle Rivasi**

**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, | (8) This Regulation should only refer to fees which are to be levied by the Agency, |

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|---|---|
| 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. | whereas the competence to decide on possible fees levied by the competent authorities of the Member States***, notably for 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. |

Or. en

*Justification*

*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.*

**Amendment 22**
**Linda McAvan**

**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 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***, including fees for follow-on variations to marketing authorisations***. |

Or. en

*Justification*

*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 23**
**Alda Sousa**

**Proposal for a regulation**
**Recital 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (12) The work carried out at Union level in respect of the assessment of ***non-interventional*** post-authorisation safety studies imposed by an authority and of which the protocol has been endorsed by the Pharmacovigilance Risk Assessment Committee, involves the supervision of these studies, starting from the assessment of the draft protocol, and is not limited to the assessment of the final study reports. Therefore, the fee levied for this procedure in respect of studies that have been finalised should cover all the work relating to the study. In order to avoid double charging, marketing authorisation holders who are charged the fee for the assessment of ***non-interventional*** post-authorisation safety studies imposed by an authority, should be exempted from any other fee charged by a competent authority for the submission of those studies. | (12) The work carried out at Union level in respect of the assessment of post-authorisation safety studies imposed by an authority and of which the protocol has been endorsed by the Pharmacovigilance Risk Assessment Committee, involves the supervision of these studies, starting from the assessment of the draft protocol, and is not limited to the assessment of the final study reports. Therefore, the fee levied for this procedure in respect of studies that have been finalised should cover all the work relating to the study. In order to avoid double charging, marketing authorisation holders who are charged the fee for the assessment of post-authorisation safety studies imposed by an authority, should be exempted from any other fee charged by a competent authority for the submission of those studies. |

Or. en

**Amendment 24**
**Antonyia Parvanova**

**Proposal for a regulation**
**Recital 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (12) The work carried out at Union level in respect of the assessment of ***non-interventional*** post-authorisation safety studies imposed by an authority and of which the protocol has been endorsed by the Pharmacovigilance Risk Assessment Committee, involves the supervision of these studies, starting from the assessment of the draft protocol, and is not limited to the assessment of the final study reports. Therefore, the fee levied for this procedure in respect of studies that have been finalised should cover all the work relating to the study. In order to avoid double charging, marketing authorisation holders who are charged the fee for the assessment of ***non-interventional*** post-authorisation safety studies imposed by an authority, should be exempted from any other fee charged by a competent authority for the submission of those studies. | (12) The work carried out at Union level in respect of the assessment of post-authorisation safety studies imposed by an authority and of which the protocol has been endorsed by the Pharmacovigilance Risk Assessment Committee, involves the supervision of these studies, starting from the assessment of the draft protocol, and is not limited to the assessment of the final study reports. Therefore, the fee levied for this procedure in respect of studies that have been finalised should cover all the work relating to the study. In order to avoid double charging, marketing authorisation holders who are charged the fee for the assessment of post-authorisation safety studies imposed by an authority, should be exempted from any other fee charged by a competent authority for the submission of those studies. |

Or. en

**Amendment 25**
**Dagmar Roth-Behrendt**

**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 | (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 procedures.

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. ***However, in order to ensure that activities linked to Union-wide pharmacovigilance procedures are only connected with the need to ensure patient safety, the rapporteur of a referral should not be the Member State which asked for that referral. Concerning*** the level of remuneration for the work carried out by ***rapporteurs and co-rapporteurs, the payment*** should be based on ***clear and transparent invoices, which provide a precise indication*** of the ***number of working hours spent on each assessment by the rapporteur and the co-rapporteur(s) and of the related costs,*** and should be taken into account in setting the level of the fees for Union-wide pharmacovigilance procedures.

Or. en

*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 26**
**Michèle Rivasi**

**Proposal for a regulation**
**Recital 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (13) Rapporteurs rely for their assessment | (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 procedures. | 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. 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. |
| | Or. en |

**Amendment 27**
**Peter Liese**

**Proposal for a regulation**
**Recital 14 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(14a) If marketing authorisation holders demonstrate that the revenue for a medicinal product is lower than or as high as the costs of the product, and that the medicinal product is of great diagnostic or therapeutic value, involves new substances or new indications for existing substances, or that it concerns serious disease patterns without any existing test*** |

***or therapy methods, or if the target group is small, fees should be subject to a reduction.***

Or. en

**Amendment 28**
**Antonyia Parvanova, Françoise Grossetête**

**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').*** |

Or. en

*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 29**
**Georgios Koumoutsakos, Spyros Danellis**

**Proposal for a regulation**
**Recital 15**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (15) In line with the policy of the Union to support small and medium-sized enterprises, reduced fees should apply to | (15) In line with the policy of the Union to support small and medium-sized enterprises, reduced fees***, deferral of*** |

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|---|---|
| small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises[18] . Consistent with this policy, micro enterprises within the meaning of that Recommendation should be exempted from all fees under this Regulation. | ***payment of fees and administrative assistance*** should apply to small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises[18]. Consistent with this policy, micro enterprises within the meaning of that Recommendation should be exempted from all fees under this Regulation. |
| [18] OJ L 124, 20.5.2003, p.36. | [18] OJ L 124, 20.5.2003, p.36. |

Or. en

*Justification*

*Reduced fees, deferral of payment of fees and administrative assistance were already established in Regulation (EC) No 726/2004.*

**Amendment 30**
**Dagmar Roth-Behrendt**

**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 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, | (16) 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 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 |

| | |
|---|---|
| marketing authorisation holders should share the applicable fee in case a joint study is submitted. | share the applicable fee in case a joint study is submitted. |

Or. en

*Justification*

*The principle of a systematic reduction of the annual flat fee for all generic medicinal products cannot be justified and this reduction shall therefore be removed.*

**Amendment 31**
**Antonyia Parvanova, Françoise Grossetête**

**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 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. | (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 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. |

Or. en

**Amendment 32**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Recital 18**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (18) In order to avoid disproportionate administrative workload for the Agency, reductions and exemptions provided for in this Regulation should apply on the basis of a declaration of the marketing authorisation holder that claims to be entitled to the reduction or the exemption. The submission of incorrect information should therefore be ***discouraged*** through an increase of the applicable amount of the fee. | (18) In order to avoid disproportionate administrative workload for the Agency, reductions and exemptions provided for in this Regulation should apply on the basis of a declaration of the marketing authorisation holder that claims to be entitled to the reduction or the exemption***, and whose accuracy could be verified by the Agency***. The submission of incorrect information should therefore be ***strongly prevented*** through an increase of the applicable amount of the fee. |

Or. en

*Justification*

*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 33**
**Marina Yannakoudakis**

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

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. Registered homeopathic and herbal medicinal products shall be exempt from the scope of this regulation.*** |

Or. en

*Justification*

*As per Article 14 and Article 16a of Directive 2001/83/EC. The phamacovigilance activities for these products are within the competency of the Member States.*

**Amendment 34**
**Alda Sousa**

**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***. |

Or. en

**Amendment 35**
**Françoise Grossetête, Pilar Ayuso**

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

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

Or. fr

*Justification*

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

**Amendment 36**
**Marina Yannakoudakis**

**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 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(s);*** |
| | ***(d) pharmaceutical form***. |

Or. en

*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 37**
**Linda McAvan**

**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 included*** in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004***:*** |
| | ***(a) marketing authorisation holder;*** |
| | ***(b) country of authorisation;*** |
| | ***(c) active ingredient(s);*** |

***(d) pharmaceutical form***.

Or. en

*Justification*

*The Commission's proposal would have meant that companies would be charged according to the number of different market authorisations they have - which would be calculated at the level of 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 pharmaceutical form (i.e. whether the product is a spray, a tablet or an injectable solution etc). Using the 'name of the medicinal product' to determine a chargeable unit could mean charging according to the strength of the product - as the name sometimes includes information about the strength - and this introduces an unnecessary level of detail.*

**Amendment 38**
**Antonyia Parvanova, Françoise Grossetête**

**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 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(s);*** |
| | ***(d) pharmaceutical form***. |

Or. en

*Justification*

*The 'chargeable unit' should be defined on the level of pharmaceutical form. In order to ensure coherence in the number of records, the definition should exclude 'name of the*

*medicinal product'. This will prevent problems for medical products being named in different ways.*

**Amendment 39**
**Pilar Ayuso**

**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 act 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. |

Or. en

*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 40**
**Thomas Ulmer, Ingeborg Gräßle**

**Proposal for a regulation**
**Article 4 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004. | 1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004 ***with assessment criteria according to Annex I of Directive 2001/83/EC***. |

Or. en

*Justification*

*The Agency is an international EU entity. It does have a legal base to assess concerning periodic safety update reports, when the concerning technical criteria are in force EU wide.*

**Amendment 41**
**Alojz Peterle**

**Proposal for a regulation**
**Article 4 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004. | 1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004 ***with assessment criteria according to Annex I of Directive 2001/83/EC***. |

Or. en

**Amendment 42**
**Michèle Rivasi**

**Proposal for a regulation**
**Article 4 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004. | 1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004 ***with assessment criteria according to Annex I of Directive 2001/83/EC***. |

Or. en

*Justification*

*It needs to be clarified that the Agency has a legal base to assess periodic safety update reports only when the concerning technical criteria are in force throughout the EU.*

**Amendment 43**
**Peter Liese**

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

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. A reduced fee, as laid down in Part I of the Annex, shall apply in respect of homeopathic medicinal products as defined in Article 1(5) of Directive 2001/83/EC and herbal medicinal products as defined in Article 1(30) of Directive 2001/83/EC.*** |

Or. en

*Justification*

*In line with the principles outlined in the Explanatory Memorandum of the Proposal, namely fairness, adequacy of the relation between the work carried out and the type and level of fee and proportionality but also simplicity and practicability for the product category of homeopathic medicinal products the PSUR fee should be generally reduced to 10 % of the general fee per PSUR.*

**Amendment 44**
**Thomas Ulmer, Ingeborg Gräßle**

**Proposal for a regulation**
**Article 4 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The amount of the fee is laid down in Part I of the Annex. | 2. The amount of the fee is laid down in Part I of the Annex. ***The Agency shall define 3 clusters of PSUR assessments reflecting the workload.*** |

Or. en

*Justification*

*One single assessment fee for PSURs – utterly irrespective of the workload involved – is inadequate. But in the concrete case, it would be appropriate to categorise the relevant active substances into three clusters for PSUR assessment, depending on the assessment workload involved – and with differentiated fees. This would be a well-balanced approach between a prerequisite standardised method on the one hand and avoiding unequal treatment on the other.*

**Amendment 45**
**Thomas Ulmer, Ingeborg Gräßle**

**Proposal for a regulation**
**Article 4 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 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. | 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. ***However, in hardship cases, e.g. for economic reasons related to the concerned product, a maximum upper limit of the fee shall apply***. |

Or. en

*Justification*

*According to the Commission proposal, a procedure-based fee is planned for the PSUR assessment: 19,500 EUR per active substance. In cases, where only one marketing authorisation holder is affected, this fee could be unjustifiably high, especially in hardship cases. Such cases could be, inter alia, when the annual turnover with the concerned product is low and the additional costs would lead to a situation that the marketing authorisation would have to be given up due to economic reasons.*

**Amendment 46**
**Georgios Koumoutsakos, Spyros Danellis**

**Proposal for a regulation**
**Article 4 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 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. | 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. ***The Agency, in exceptional circumstances, may allow for a settlement to be negotiated in order to assist the single marketing authorisation holder in paying the applicable fee.*** |

Or. en

*Justification*

*This provision could for example assist old pharmaceutical drugs, which in many cases are produced by one marketing authorisation holder and when the marketing authorisation holder shows evidence that profits from the specific product do not suffice to pay the before-mentioned fees.*

**Amendment 47**
**Peter Liese**

**Proposal for a regulation**
**Article 4 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. If the marketing authorisation holder cannot expect an economic benefit in relation to the fee and if:*** |
| | ***(a) there is public interest in the marketing of the product due to the therapeutic indication or*** |
| | ***(b) the target group of the product is small,*** |
| | ***the amount payable shall be reduced upon application by the marketing authorisation holder as laid down in Part I paragraph 2 subparagraph 2 of the Annex.*** |

Or. en

**Amendment 48**
**Antonyia Parvanova, Pilar Ayuso, Françoise Grossetête**

**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 exempted 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.*** |

Or. en

*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 49**
**Georgios Koumoutsakos, Spyros Danellis**

**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 States*** 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. |

Or. en

*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 50**
**Peter Liese**

**Proposal for a regulation**
**Article 5 – paragraph 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***4a. If the marketing authorisation holder cannot expect an economic benefit in relation to the fee and if:*** |
| | ***(a) there is public interest in the marketing of the product due to the therapeutic indication or*** |
| | ***(b) the target group of the product is*** |

***small,***

***the amount payable shall be reduced upon application by the marketing authorisation holder as laid down in Part II paragraph 2 subparagraph 2 of the Annex.***

Or. en

**Amendment 51**
**Antonyia Parvanova, Pilar Ayuso, Françoise Grossetête**

**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***. |

Or. en

*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 52**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Article 6 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 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 Articles 107i to 107k of Directive 2001/83/EC***, under*** the second subparagraph of Article 31(1) ***thereof*** or ***under*** Article 20(8) of Regulation (EC) No 726/2004. | 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 Articles 107i to 107k of Directive 2001/83/EC***. Costs arising from procedures referred to in*** the second subparagraph of Article 31(1) ***of Directive 2001/83/EC,*** or ***in*** Article 20(8) of Regulation (EC) No 726/2004 ***shall include a participation of the referring Member State***. |

Or. en

*Justification*

*Ensuring drug safety through pharmacovigilance activities is as well a public health responsibility. Member States shall therefore also partly contribute financially. Such a limited contribution from Member States and the EU should however not prevent signals reporting and necessary referrals. A participation of a Member State is therefore not required in cases of urgent Union procedures (referred to in Art. 107i to 107k of Directive 2001/83/EC).*

**Amendment 53**
**Peter Liese**

**Proposal for a regulation**
**Article 6 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5 a. If the marketing authorisation holder cannot expect an economic benefit in relation to the fee and if:*** |
| | ***(a) there is public interest in the marketing of the product due to the therapeutic indication or*** |
| | ***(b) the target group of the product is small,*** |
| | ***the amount payable shall be reduced upon application by the marketing*** |

***authorisation holder as laid down in Part III paragraph 2 subparagraph 2 of the Annex.***

Or. en

**Amendment 54**
**Antonyia Parvanova, Pilar Ayuso, Françoise Grossetête**

**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 exempted 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.*** |

Or. en

*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 55**
**Georgios Koumoutsakos, Spyros Danellis**

**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, monitoring of selected medical literature under Article 27 thereof and signal detection under Article 28a thereof, the Agency shall levy once a flat fee as laid down in Part IV of the Annex. |

Or. en

*Justification*

*The database will be constructed once. Afterwards, the new Regulation is foreseen to be adopted.*

**Amendment 56**
**Peter Liese**

**Proposal for a regulation**
**Article 7 – paragraph 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***4a. If the marketing authorisation holder cannot expect an economic benefit in relation to the fee and if:*** |
| | ***(a) there is public interest in the marketing of the product due to the therapeutic indication or*** |
| | ***(b) the target group of the product is small,*** |
| | ***the amount payable shall be reduced upon application by the marketing authorisation holder as laid down in Part IV paragraph 2 subparagraph 2 of the Annex.*** |

Or. en

**Amendment 57**
**Peter Liese**

**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 in respect of medicinal products referred to in Article 10(1) and Article 10a of Directive 2001/83/EC and in respect of authorised ***herbal*** medicinal products***, as defined in Article 1(30) of Directive 2001/83/EC. For*** authorised ***homeopathic*** medicinal products, as defined in Article 1(5) of Directive 2001/83/EC***, no flat fee shall apply***. |

Or. en

*Justification*

*Regarding homeopathic medicinal products to be entered into the database the EMA services rendered in return are rather negligible compared to other categories of medicinal products, including generic medicinal products and well-established use products. For homeopathic medicinal products the volume of reported adverse reactions is too small for signal detection by the EMA and risk management based thereon, as long-term experience with national PSUR submission shows. It can also not be expected that literature surveillance will be conducted for a range of 1,000 starting materials (all of known and long term used natural substances) which are used in the concerned authorized homeopathic medicinal products.*

**Amendment 58**
**Dagmar Roth-Behrendt**

**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 | 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 10a of Directive 2001/83/EC and in respect of authorised homeopathic medicinal products and authorised herbal medicinal products, as defined respectively |

| | |
|---|---|
| defined respectively in Article 1(5) and Article 1(30) of Directive 2001/83/EC. | in Article 1(5) and Article 1(30) of Directive 2001/83/EC. |

Or. en

*Justification*

*The principle of a systematic reduction of the annual flat fee for all generic medicinal products cannot be justified and this reduction shall therefore be removed.*

**Amendment 59**
**Antonyia Parvanova, Françoise Grossetête**

**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 authorised in the Community 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. |

Or. en

*Justification*

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

**Amendment 60**
**Marina Yannakoudakis**

**Proposal for a regulation**
**Article 7 – paragraph 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 7. The Agency shall levy the annual flat fee by issuing invoices to marketing authorisation holders at the latest on 31 January of every calendar year for that calendar year. Fees due under this Article shall be paid within ***30 calendar days*** from the date on which the invoice is received by the marketing authorisation holder. | 7. The Agency shall levy the annual flat fee by issuing invoices to marketing authorisation holders at the latest on 31 January of every calendar year for that calendar year. Fees due under this Article shall be paid within ***the timeframe set in Directive 2011/7/EC*** from the date on which the invoice is received by ***the marketing authorisation holder, or in exceptional circumstances through an independently agreed timeframe negotiated between the agency and*** the marketing authorisation holder. |

Or. en

*Justification*

*The deadline for the market authorisation holder to pay the flat fee should be in accordance with Directive 2011/7/EC which states 30 calendar days, or 60 calendar days in justified exceptional circumstances. However, it should be possible for extra flexibility in this process if there is an independently agreed timeframe negotiated between the agency and the marketing authorisation holder. This can help businesses with their cash flow during the current economic climate.*

**Amendment 61**
**Alda Sousa**

**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 | 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. | 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. ***For the purpose of this paragraph, the Commission shall publish guidelines on how this declaration is to be formulated by the marketing authorisation holder.*** |

Or. en

**Amendment 62**
**Antonyia Parvanova, Pilar Ayuso**

**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. |

Or. en

*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 63**
**Dagmar Roth-Behrendt**

**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 the information necessary to demonstrate compliance with the relevant conditions***, in order for the latter to be able to verify that these conditions are fulfilled***. |

Or. en

*Justification*

*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 64**
**Michèle Rivasi**

**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 | 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. | necessary to demonstrate compliance with the relevant conditions ***within seven calendar days from receipt of the Agency's request***. |

Or. en

*Justification*

*A deadline for this demonstration should be set.*

**Amendment 65**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Article 8 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. Where a marketing authorisation holder claiming or having claimed to be entitled to a reduction of or an exemption from fees 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 to the resulting full applicable amount. | 5. Where a marketing authorisation holder claiming or having claimed to be entitled to a reduction of or an exemption from fees 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 ***20%*** and the Agency shall levy the resulting full applicable amount or, as appropriate, the balance to the resulting full applicable amount. |

Or. en

*Justification*

*To claim the reduction of or an exemption from fees includes the thorough investigation by the marketing authorisation holder that it foresaw the reason for that reduction or exemption.*

**Amendment 66**
**Marina Yannakoudakis**

**Proposal for a regulation**
**Article 8 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. Where a marketing authorisation holder claiming or having claimed to be entitled to a reduction of or an exemption from fees 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 to the resulting full applicable amount.*** | 5. Where a marketing authorisation holder claiming or having claimed to be entitled to a reduction of or an exemption from fees under this Regulation fails to demonstrate that it is entitled to such a reduction or exemption, the ***full*** amount of the fee laid down in the Annex shall ***then*** be applicable***;*** |

Or. en

*Justification*

*In the case of a failed claim for a reduction on the procedural fee the penalty increase would be disproportionally high – potentially thousands of euros for businesses. There is no need for such a high penalty and reverting to the original basic fee should suffice.*

**Amendment 67**
**Michèle Rivasi**

**Proposal for a regulation**
**Article 8 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. Where a marketing authorisation holder claiming or having claimed to be entitled to a reduction of or an exemption from fees 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 to the resulting full applicable amount. | 5. Where a marketing authorisation holder claiming or having claimed to be entitled to a reduction of or an exemption from fees 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 ***50%*** and the Agency shall levy the resulting full applicable amount or, as appropriate, the balance to the resulting full applicable amount. |

Or. en

*Justification*

*In order to be efficient, the measures against submission of incorrect information should be strict.*

**Amendment 68**
**Michèle Rivasi**

**Proposal for a regulation**
**Article 9 – paragraph 1 – subparagraph 1 – point c**

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

Or. en

**Amendment 69**
**Michèle Rivasi**

**Proposal for a regulation**
**Article 9 – paragraph 1 – subparagraph 1 – point d**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 Member State has appointed a representative in the coordination group who acts as rapporteur ***or co-rapporteur*** in the context of the assessment of periodic safety update reports referred to in Article 4; |

Or. en

**Amendment 70**
**Michèle Rivasi**

**Proposal for a regulation**
**Article 9 – paragraph 1 – subparagraph 1 – point e**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (e) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur for the assessment of post-authorisation safety studies referred to in Article 5; | (e) 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 post-authorisation safety studies referred to in Article 5; |

Or. en

**Amendment 71**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Article 9 – paragraph 1 – subparagraph 1 – point f**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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, Member State(s) which triggered the referral shall provide all necessary data on signals, but shall not be chosen as rapporteur or co-rapporteur for that referral.*** |

Or. en

*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 72**
**Linda McAvan**

**Proposal for a regulation**
**Article 9 – paragraph 1 – subparagraph 1 – point f**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. ***Where a Member State voluntarily initiates a referral, and is appointed rapporteur or co-rapporteur, they shall only receive 50% of their remuneration.*** |

Or. en

*Justification*

*Where a Member State chooses to trigger a referral, they may be appointed rapporteur or co-rapporteur, but they should make a financial participation towards the cost of the referral, in order to avoid any conflict of interest.*

**Amendment 73**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Article 9 – paragraph 1 – subparagraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Where the Pharmacovigilance Risk Assessment Committee or the coordination group decides to appoint a co-rapporteur, the remuneration shall be divided between the rapporteur and the co-rapporteur. | Where the Pharmacovigilance Risk Assessment Committee or the coordination group decides to appoint a co-rapporteur, the remuneration shall be divided between the rapporteur and the co-rapporteur***, on the basis of clear and transparent invoices, which provide a precise indication of the number of working hours spent on each part of the assessment by the rapporteur and co-rapporteurs, and of the related costs. This amount of working hours shall be presented in an understandable, justified*** |

***and provable way***.

Or. en

*Justification*

*Detailed costs for services of rapporteurs and co-rapporteurs shall be clearly stated on invoices sent to the Agency.*

**Amendment 74**
**Dagmar Roth-Behrendt**

**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 fully and workable version translated into the working language of the Agency.*** |

Or. en

*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 75**
**Marina Yannakoudakis**

**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 the timeframe set in Directive 2011/7/EC***. Any bank charges related to the payment of that remuneration shall be borne by the Agency. |

Or. en

*Justification*

*The deadline for the Agency to pay the Member State rapporteur should be in accordance with Directive 2011/7/EC which states 30 calendar days, or 60 calendar days in justified exceptional circumstances.*

**Amendment 76**
**Dagmar Roth-Behrendt**

**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. |

Or. en

*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 77**
**Marina Yannakoudakis**

**Proposal for a regulation**
**Article 14 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The Agency shall, when producing an estimate of the overall expenditure and income 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***.** ***This information shall distinguish between the annual flat fee and the fees for each procedure referred to in Article 3(a)***. The Agency shall also provide specific analytical information on its revenue and expenditure related to pharmacovigilance activities, allowing to distinguish between the annual flat fee and each of the fees for procedures referred to in Article 3(a). | The Agency shall, when producing an estimate of the overall expenditure and income 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 ***which will be based on the number of chargeable unit entries in the database***. The Agency shall also provide specific analytical information on its revenue and expenditure related to pharmacovigilance activities, allowing to distinguish between the annual flat fee and each of the fees for procedures referred to in Article 3(a). |

Or. en

*Justification*

*To accurately forecast and predict the total budget it is advisable to link its size to the annual flat fee only. This also allows the Member State rapporteurs to receive a larger part of the sum of fees for procedures.*

**Amendment 78**
**Marina Yannakoudakis**

**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 the Commission**,** the Management Board***, the Court of Auditors and the Member States*** 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 ***openly publish this overview 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 |

Or. en

*Justification*

*It is important to have transparency and openness in the fees process as to prevent and challenge financial irregularities in accounts, and to help businesses to appeal against legitimate grievances against existing costs, or to budget successfully for any future costs.*

**Amendment 79**
**Alda Sousa**

**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. | 2. The Executive Director of the Agency shall provide ***in 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*** |

| | |
|---|---|
| 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***. | ***according to Article 65 paragraph 10 of Regulation (EC) No 726/2004*** with 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 this overview 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. |

Or. en

**Amendment 80**
**Antonyia Parvanova, Pilar Ayuso**

**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 ***in 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 according to Article 65 paragraph 10 of Regulation (EC) No 726/2004*** with 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 this overview 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.

Or. en

*Justification*

*It is important to ensure visible and transparent financial reporting, provided by the EMA.*

**Amendment 81**
**Michèle Rivasi**

**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 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. | 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 ***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. |

Or. en

**Amendment 82**
**Marina Yannakoudakis**

**Proposal for a regulation**
**Article 16 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The Commission shall be empowered to adopt delegated acts to amend Parts I to V of the Annex. | 1. The Commission shall be empowered to adopt delegated acts to amend Parts I to V of the Annex ***to take account of inflationary fluctuations only. Increasing or decreasing the fees shall be decided as part of the overall review of the Agency´s*** |

***fees regime which has been planned for early 2015***.

Or. en

*Justification*

*The Commission will adopt a proposal in 2015 to review all of the fees which the Agency charges. At this point the Commission will propose to annul the fees regulation and incorporate fees into this new overarching legal instrument. Therefore, there will be no need to change the fees before 2015 with the exception of taking into account inflationary fluctuations.*

**Amendment 83**
**Marina Yannakoudakis**

**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). |

Or. en

**Amendment 84**
**Alda Sousa**

**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 | 2. Any amendments to the amounts shall be based on ***a transparent*** 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). | laid down in Article 9 or on the monitoring of the inflation rate referred to in Article 15(4). |

Or. en

**Amendment 85**
**Antonyia Parvanova, Pilar Ayuso**

**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*** 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). |

Or. en

**Amendment 86**
**Michèle Rivasi**

**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 [...].*** |

Or. en

*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 87**
**Dagmar Roth-Behrendt**

**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 only enter into force six months after the date when Eudravigilance is declared by the Agency as fully functioning, in application of Article 24(2) third subparagraph of Regulation EC No 726/2004.*** |

Or. en

*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 88**
**Michèle Rivasi**

**Proposal for a regulation**
**Annex – part I – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The fee for the assessment of periodic safety update reports is EUR 19 500 per procedure. The corresponding remuneration of the rapporteur is EUR 13 100. | 1. The fee for the assessment of periodic safety update reports is EUR 19 500 per procedure. The corresponding remuneration of the rapporteur is EUR 13 100 ***and the corresponding remuneration of the co-rapporteur is EUR 1.500***. |

Or. en

*Justification*

*For the assessment of the PSUR most of the work is done by the rapporteur, but the work of the co-rapporteur should be reimbursed as well.*

**Amendment 89**
**Thomas Ulmer, Ingeborg Gräßle**

**Proposal for a regulation**
**Annex – part I – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. In application of Article 4(2), the following fees apply:*** |
| | ***(i) category 1: 100 % of the applicable amount;*** |
| | ***(ii) category 2: 50 % of the applicable amount;*** |
| | ***(iii) category 3: 10 % of the applicable amount.*** |

Or. en

*Justification*

*One single assessment fee for PSURs – utterly irrespective of the workload involved – is inadequate. Up to a certain extent, it is legitimate to pursue a standardised method in fee calculation. But in the concrete case, it would be appropriate to categorise the relevant active substances into three clusters for PSUR assessment, depending on the assessment workload involved – and with differentiated fees.*

**Amendment 90**
**Peter Liese**

**Proposal for a regulation**
**Annex – part I – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. Holders of marketing authorizations or registrations of homeopathic or herbal medicinal products referred to in Article*** |

***4(1a) shall pay 10 % of the amount laid down in paragraph 1.***

Or. en

*Justification*

*In line with the principles outlined in the Explanatory Memorandum of the Proposal, namely fairness, adequacy of the relation between the work carried out and the type and level of fee and proportionality but also simplicity and practicability for the product category of homeopathic medicinal products the PSUR fee should be generally reduced to 10 % of the general fee per PSUR.*

**Amendment 91**
**Peter Liese**

**Proposal for a regulation**
**Annex – part I – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. In application of Article 4(5), small and medium-sized enterprises shall pay 60 % of the applicable amount. | 2. In application of ***the first subparagraph of*** Article 4(5), small and medium-sized enterprises shall pay 60 % of the applicable amount.<br>***In application of the second subparagraph of Article 4(5), marketing authorisation holders shall pay up to 60 % of the applicable amount.*** |

Or. en

**Amendment 92**
**Thomas Ulmer, Ingeborg Gräßle**

**Proposal for a regulation**
**Annex – part I – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. In application of Article 4(3), in hardship cases, the concerned marketing authorisation holder shall pay a*** |

***maximum fee of 40 % of the applicable amount.***

Or. en

*Justification*

*According to the Commission proposal, a procedure-based fee is planned for the PSUR assessment: 19,500 EUR per active substance. In cases, where only one marketing authorisation holder is affected, this fee could be unjustifiably high, especially in hardship cases. Such cases could be, inter alia, when the annual turnover with the concerned product is low and the additional costs would lead to a situation that the marketing authorisation would have to be given up due to economic reasons.*

**Amendment 93**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Annex – part I – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall 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 of the rapporteur shall be adapted proportionally. | 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall be adapted proportionally. Where the Agency subsequently collects the full applicable amount including the ***20*** % increase as provided for in Article 8(5), the remuneration of the rapporteur shall be adapted proportionally. |

Or. en

*Justification*

*To claim the reduction of or an exemption from fees includes the thorough investigation by the marketing authorisation holder that it foresaw the reason for that reduction or exemption.*

**Amendment 94**
**Michèle Rivasi**

**Proposal for a regulation**
**Annex – part I – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall 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 of the rapporteur shall be adapted proportionally. | 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall be adapted proportionally. Where the Agency subsequently collects the full applicable amount including the ***50*** % increase as provided for in Article 8(5), the remuneration of the rapporteur shall be adapted proportionally. |

Or. en

**Amendment 95**
**Michèle Rivasi**

**Proposal for a regulation**
**Annex – part II – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The fee for the assessment of a post authorisation safety study is EUR 43 000. The corresponding remuneration of the rapporteur is EUR ***18 200***. | 1. The fee for the assessment of a post authorisation safety study is EUR 43 000. The corresponding remuneration of the rapporteur is EUR ***30.000 and corresponding remuneration of the co-rapporteur is EUR 10.000***. |

Or. en

*Justification*

*Assessment of the PASS is a lot of work the National Competent Authority that takes up the rapporteurship and the co-rapporteur should also get a part of the fee for the work done.*

**Amendment 96**
**Peter Liese**

**Proposal for a regulation**
**Annex – part II – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. In application of Article 5(4), small and medium-sized enterprises shall pay 60 % of the applicable amount. | 2. In application of ***the first subparagraph of*** Article 5(4), small and medium-sized enterprises shall pay 60 % of the applicable amount.<br>***In application of the second subparagraph of Article 5(4), marketing authorisation holders shall pay up to 60 % of the applicable amount.*** |

Or. en

**Amendment 97**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Annex – part II – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall 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 of the rapporteur shall be adapted proportionally. | 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall be adapted proportionally. Where the Agency subsequently collects the full applicable amount including the ***20*** % increase as provided for in Article 8(5), the remuneration of the rapporteur shall be adapted proportionally. |

Or. en

*Justification*

*To claim the reduction of or an exemption from fees includes the thorough investigation by the marketing authorisation holder that it foresaw the reason for that reduction or exemption.*

**Amendment 98**
**Michèle Rivasi**

**Proposal for a regulation**
**Annex – part II – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall 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 of the rapporteur shall be adapted proportionally. | 4. Where reductions and exemptions apply, the remuneration of the rapporteur shall be adapted proportionally. Where the Agency subsequently collects the full applicable amount including the ***50*** % increase as provided for in Article 8(5), the remuneration of the rapporteur shall be adapted proportionally. |

Or. en

**Amendment 99**
**Pilar Ayuso**

**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 with 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***. |

Or. en

*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 100**
**Michèle Rivasi**

**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 EUR 168 600. The corresponding remuneration of the rapporteur is EUR ***70.000 and corresponding remuneration of the co-rapporteur is EUR 70.000***. |

Or. en

*Justification*

*Assessment of the safety referral is a lot of work: around 500-800 assessment working hours for both rapporteur and co-rapporteur each.*

**Amendment 101**
**Linda McAvan**

**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 EUR 168 ***600 when 1 or 2 active substances are involved***. ***This fee is increased by 15% for every additional active substance involved in the procedure.***<br>***The*** corresponding remuneration of the rapporteur ***and co-rapporteur(s)*** is EUR ***78 400. This remuneration is increased by 15% for every additional active substance assessed***. |

Or. en

*Justification*

*The Commission's impact assessment estimates that 360 hours of evaluation/assessment would be needed for an average referral (by one rapporteur). This works out at €39,200 (360 hours x the hourly rate of €109 in the Commission's impact assessment). A co-rapporteur is always appointed for a referral, and would draft their own assessment report, in order to provide two independent views to the PRAC - so co-rapporteurs undertake the same amount of work as rapporteurs. As a result, they should also receive €39,200, and so this corresponds to €78,400 of the total fee. Referrals can be simple or complex (i.e. wide in scope and involve many different active substances). Instead of charging the same average fee whatever the workload involved, a more cost-based approach would be to move to a tiered system. In the year since the PRAC has been set up, the biggest referral has involved eight active substances.*

**Amendment 102**
**Françoise Grossetête**

**Proposal for a regulation**
**Annex – part III – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. That fee shall be paid partly from the public funding provided for these new pharmacovigilance tasks and partly by the marketing authorisation holder.*** |

Or. fr

*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 103**
**Peter Liese**

**Proposal for a regulation**
**Annex – part III – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. In application of Article 6(5), small and medium-sized enterprises shall pay 60 % | 2. In application of ***the first subparagraph of*** Article 6(5), small and medium-sized |

| | |
|---|---|
| of the applicable amount. | enterprises shall pay 60 % of the applicable amount.<br>***In application of the second subparagraph of Article 6(5), marketing authorisation holders shall pay up to 60 % of the applicable amount.*** |

Or. en

**Amendment 104**
**Marina Yannakoudakis**

**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. |

Or. en

*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 105**
**Dagmar Roth-Behrendt**

**Proposal for a regulation**
**Annex – part III – paragraph 3 – subparagraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Where reductions and exemptions apply, the remuneration of the rapporteur shall be adapted proportionally. Where the Agency subsequently collects the full applicable amount including the ***10*** % increase as | Where reductions and exemptions apply, the remuneration of the rapporteur shall be adapted proportionally. Where the Agency subsequently collects the full applicable amount including the ***20*** % increase as |

| | |
|---|---|
| provided for in Article 8(5), the remuneration of the rapporteur shall be adapted proportionally. | provided for in Article 8(5), the remuneration of the rapporteur shall be adapted proportionally. |

Or. en

*Justification*

*To claim the reduction of or an exemption from fees includes the thorough investigation by the marketing authorisation holder that it foresaw the reason for that reduction or exemption.*

**Amendment 106**
**Michèle Rivasi**

**Proposal for a regulation**
**Annex – part III – paragraph 3 – subparagraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Where reductions and exemptions apply, the remuneration of the rapporteur shall 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 of the rapporteur shall be adapted proportionally. | Where reductions and exemptions apply, the remuneration of the rapporteur shall be adapted proportionally. Where the Agency subsequently collects the full applicable amount including the ***50*** % increase as provided for in Article 8(5), the remuneration of the rapporteur shall be adapted proportionally. |

Or. en

**Amendment 107**
**Michèle Rivasi**

**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 ***XX*** per chargeable unit. |

Or. en

*Justification*

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

**Amendment 108**
**Peter Liese**

**Proposal for a regulation**
**Annex – part IV – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. In application of Article 7(4), small and medium-sized enterprises shall pay 60 % of the applicable amount. | 2. In application of ***the first subparagraph of*** Article 7(4), small and medium-sized enterprises shall pay 60 % of the applicable amount.<br>***In application of the second subparagraph of Article 7(4), marketing authorisation holders shall pay up to 60 % of the applicable amount.*** |

Or. en

**Amendment 109**
**Thomas Ulmer, Ingeborg Gräßle**

**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 corresponding to those products.*** |

Or. en

*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.*

**Amendment 110**
**Alojz Peterle**

**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 corresponding to those products.*** |

Or. en

**Amendment 111**
**Dagmar Roth-Behrendt**

**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 referred to in Article 7(5) shall pay ***50*** % of the amount applicable to the chargeable units corresponding to those products. |

Or. en

*Justification*

*Medicinal products of well-established use have a known safety profile and should benefit from a 50% reduction of the annual flat fee.*

**Amendment 112**
**Michèle Rivasi**

**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 referred to in Article ***10a of Directive 2001/83/EC shall pay 80% of the amount applicable to the chargeable units corresponding to those products. Holders of marketing authorisations for authorised homeopathic medicinal products and for authorised herbal medicinal products as defined respectively in Article 1(5) and Article 1(30) of Directive 2001/83/EC*** shall pay ***25%*** of the amount applicable to the chargeable units corresponding to those products. |

Or. en

*Justification*

*The 75% reduction for authorised homeopathic and herbal medicinal products is in line with the already existing annual flat fee reduction for the centrally authorised generic medicines. As there is a tendency to more and more central authorisations for generic medicines but not for homeopathic and herbal medicinal products, the latest should not get commercially disadvantaged in the future because of the pharmacovigilance fees.*