Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (Text with EEA relevance)

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

of 15 May 2014

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[(1)],

After consulting the Committee of the Regions,

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

Whereas:

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

(2) The provisions on pharmacovigilance relating to medicinal products for human use ('medicinal products') laid down in Regulation (EC) No 726/2004 and in Directive 2001/83/EC of the European Parliament and of the Council[(4)] were amended by Directive 2010/84/EU of the European Parliament and of the Council[(5)], Regulation (EU) No 1235/2010 of the European Parliament and of the Council[(6)], Directive 2012/26/EU of the European Parliament and of the Council[(7)] and Regulation (EU) No 1027/2012 of the European Parliament and of the Council[(8)]. Those amendments provide for new pharmacovigilance tasks for the Agency, including pharmacovigilance procedures carried out at Union level, the monitoring of literature cases and the improved use of information technology tools. Furthermore, those amendments provide that the Agency should be enabled to fund those activities from fees charged to

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marketing authorisation holders. New types of fees should therefore be created to cover the new and specific tasks of the Agency.

(3) In order to enable the Agency to charge fees for those new pharmacovigilance tasks, and pending an overall legislative revision of the fees regimes in the medicinal products sector, this Regulation should be adopted. The fees provided for in this Regulation should be applicable without prejudice to the fees laid down in Council Regulation (EC) No 297/95[(9)].

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

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

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

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

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

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

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

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

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

(13) For their assessments, rapporteurs rely on the scientific evaluations and resources of national competent authorities, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States. In view of that, and to ensure the existence of adequate resources for the scientific assessments relating to the pharmacovigilance procedures carried out at Union level, the Agency should remunerate the scientific assessment services provided by the rapporteurs and, where applicable, co-rapporteurs appointed by Member States as members of the Pharmacovigilance Risk Assessment Committee referred to in point (aa) of Article 56(1) of Regulation (EC) No 726/2004 or, where relevant, provided by rapporteurs and

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co-rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based exclusively on estimations of the workload involved and should be taken into account in setting the level of the fees for pharmacovigilance procedures carried out at Union level. It is recalled that as a matter of good practice, in the context of referrals initiated as a result of the evaluation of pharmacovigilance data, the Pharmacovigilance Risk Assessment Committee generally seeks to avoid appointing as rapporteur the member nominated by the Member State that initiated the referral procedure.

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

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

(16) In line with the policy of the Union to support small and medium-sized enterprises, reduced fees should apply to small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC[(10)]. Such fees should be established on a basis which takes due account of the ability of small and medium-sized enterprises to pay. Consistent with that policy, micro enterprises within the meaning of that Recommendation should be exempted from all fees under this Regulation.

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

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

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on the market in accordance with Article 126a of Directive 2001/83/EC should also be excluded from the scope of this Regulation.

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

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

(21) The amounts of the fees and of the remuneration for the rapporteurs and co-rapporteurs provided for under this Regulation should be adjusted, where appropriate, to take account of inflation. For that purpose, the European Index of Consumer Prices published by Eurostat pursuant to Council Regulation (EC) No 2494/95[(11)] should be used. For the purpose of such an adjustment, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

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

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

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

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