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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	11 July 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2018) 4364 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 11.7.2018 amending Regulation (EU) No 658/2014 of the European Parliament and of the Council as regards the adjustment to the inflation rate of the amounts of the fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use

Delegations will find attached document C(2018) 4364 final.

Encl.: C(2018) 4364 final

EUROPEAN
COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of 11.7.2018

amending Regulation (EU) No 658/2014 of the European Parliament and of the Council as regards the adjustment to the inflation rate of the amounts of the 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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Fees collected by the European Medicines Agency are laid down in two legal acts.

Firstly, Council Regulation (EC) 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products[1], sets the level of fees payable to the European Medicines Agency for the activities of authorisation and supervision of medicinal products in respect of medicinal products for human and veterinary use. Article 12(5) of that Regulation provides that with effect from 1 April of each year the Commission shall review the fees by reference of inflation rate as published in the Official Journal of the European Union and update them. This update is not in the scope of this delegated Regulation.

Secondly, 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[2], sets the levels of the fees specifically for pharmacovigilance activities of the Agency and the respective remuneration to rapporteurs and co-rapporteurs for the relevant scientific assessment services provided by the rapporteurs and co-rapporteurs. Article 15(5) of that Regulation provides that the inflation rate, measured by means of the European Index of Consumer prices published by Eurostat pursuant to Regulation (EC) No 2494/95, shall be monitored annually in relation to the amounts set out in the Regulation. Article 15(6) of that Regulation provides that, where justified in light of that monitoring, the Commission shall adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs that are laid down in the Regulation. It also provides that where the delegated act enters into force before 1 July, those adjustments shall take effect as from 1 July and where the delegated act enters into force after 30 June, they shall take effect as from the date of entry into force of the delegated act. The purpose of this delegated Regulation is to set the amounts of those adjustments for 2018.

In view of the inflation rate for 2017 (1,7%) it is considered justified to proceed with the adjustment of the abovementioned amounts. For this purpose, the amounts were adjusted with the 1.7% inflation rate and then rounded to the nearest 10 (with the exception of the annual fee, rounded to the nearest 1).

With regards to the fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data, the same method of adjustment was applied to the amounts set out in Part III of the Annex of the Regulation, except for the maximum amount of the fee, which is applicable when five or more active substances and/or combinations of active substances are included in the assessment. In order to avoid discrepancies due to the rounding, the adjusted maximum amount of that fee was calculated by increasing incrementally each fee level with the adjusted amount of the fee increase per each additional active substance or combination of active substances which is laid down in the legislation.

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1 OJ L 35, 15.2.1995, p. 1.

2 OJ L 189, 27.6.2014, p. 112.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Pharmaceutical Committee[3] was consulted as an expert group[4] through written procedure from 15 February 2018 until 21 February 2018. No objections were raised.

A four-week public consultation was held from the 03 April until 03 May 2018 via the Better Regulation portal. One comment was received from an individual citizen; however, this comment was not relevant to the subject matter of this delegated act.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal base of this delegated Regulation is Article 15(6) of Regulation (EU) No 658/2014.

Article 1 of this delegated Regulation sets the adjusted amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs that are laid down in the Regulation (EU) No 658/2014.

Article 2 of this delegated Regulation sets the rules of its entry into force and application.

[3] Council Decision of 20 May 1975 setting up a pharmaceutical committee, OJ L 147, 9.6.1975, p. 23.

[4] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2858

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[5], and in particular Article 15(6) thereof,

Whereas:

(1) In accordance with Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council[6], the revenue of the European Medicines Agency consists of a contribution from the Union and fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, or by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC of the European Parliament and of the Council[7].

(2) The inflation rate of the Union for 2017, as made available by the Statistical Office of the European Union, was 1,7%. Taking into consideration the level of the inflation rate for that year, it is considered justified to adjust, in accordance with Article 15(6) of Regulation (EU) No 658/2014, the amounts of the fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use.

(3) For the sake of simplicity, the adjusted amounts should be rounded to the nearest EUR 10, with the exception of the annual fee for information technology systems and literature monitoring where the adjusted level should be rounded to the nearest EUR 1.

(4) Fees laid down in Regulation (EU) No 658/2014 are due either at the date of the start of the respective procedure or, in the case of the annual fee for information technology systems and literature monitoring, on 1 July of every year. Consequently, the applicable amount will be determined by the due date of the fee and there is no need to set specific transitional provisions for pending procedures.

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5 OJ L 189, 27.6.2014, p. 112.

6 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

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

(5) According to Article 15(6) of Regulation (EU) No 658/2014, where a delegated act adjusting the amounts of the fees laid down in Parts I to IV of the Annex to that Regulation enters into force before 1 July, the adjustments are to take effect as from 1 July, whereas where it enters into force after 30 June, the adjustments are to take effect from the date of entry into force of the delegated act.

(6) Regulation (EU) No 658/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 658/2014 is amended as follows:

(1) in Part I, point 1 is amended as follows:

(a) 'EUR 19 770' is replaced by 'EUR 20 110';

(b) 'EUR 13 290' is replaced by '13 520';

(2) in Part II, point 1 is amended as follows:

(a) in the introductory sentence, 'EUR 43 600' is replaced by 'EUR 44 340';

(b) point (a) is amended as follows:

(i) 'EUR 17 440' is replaced by 'EUR 17 740';

(ii) 'EUR 7 380' is replaced by 'EUR 7 510';

(c) point (b) is amended as follows:

(i) 'EUR 26 160' is replaced by 'EUR 26 600';

(ii) 'EUR 11 070' is replaced by '11 260';

(3) in Part III, point 1 is amended as follows:

(a) the first subparagraph is amended as follows:

(i) 'EUR 181 510' is replaced by 'EUR 184 600';

(ii) 'EUR 39 350' is replaced by 'EUR 40 020';

(iii) 'EUR 299 560' is replaced by 'EUR 304 660';

(b) the second subparagraph is amended as follows:

(i) in point (a), 'EUR 121 000' is replaced by 'EUR 123 060';

(ii) in point (b), 'EUR 147 240' is replaced by 'EUR 149 740';

(iii) in point (c), 'EUR 173 470' is replaced by 'EUR 176 420';

(iv) in point (d), 'EUR 199 700' is replaced by 'EUR 203 090';

(c) in the fourth subparagraph, point (b) is amended as follows:

(i) 'EUR 1010' is replaced by 'EUR 1030';

(ii) 'EUR 2020' is replaced by 'EUR 2050';

(iii) 'EUR 3050' is replaced by 'EUR 3100';

(4) in point 1 of Part IV, 'EUR 68' is replaced by 'EUR 69'.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall apply from [*if the date of entry into force is prior to 1 July 2018, please insert–"1 July 2018" as date, if the date of entry force is after 30 June 2018, please insert the date of entry into force*].

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

Done at Brussels, 11.7.2018

For the Commission
The President
Jean-Claude JUNCKER