Council of the European Union

Brussels, 19 October 2017
(OR. en)

13457/17

PHARM 42
SAN 364
MI 729
COMPET 690
DELACT 192

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	18 October 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2017) 6946 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 18.10.2017 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(2017) 6946 final.

Encl.: C(2017) 6946 final

EUROPEAN
COMMISSION

Brussels, 18.10.2017
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COMMISSION DELEGATED REGULATION (EU) …/...

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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 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 2017.

Taking into consideration the very low inflation rate of the Union in 2015 (0.2%), the adjustment of the abovementioned amounts was not considered justified in 2016. However, in view of the inflation rate for 2016 (1.2%) it is considered justified to proceed to such adjustment and to apply a cumulative adjustment taking into account both 2015 and 2016 inflation rates. For this purpose, the amounts were first adjusted with 0.2% for 2015 and rounded to the nearest 10 (with the exception of the annual fee, rounded to the nearest 1) and then adjusted again to 1.2% for 2016, followed by a second such rounding.

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

1 OJ L 35, 15.2.1995, p. 1.
2 OJ L 189, 27.6.2014, p. 112.

adjusted amount of the fee increase per each additional active substance or combination of active substances which is laid down in the legislation.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Pharmaceutical Committee[3] was consulted as an expert group[4] through written procedure from 21 June 2017 until 7 July 2017. No objections were raised.

A four-week public consultation was held from the 27 July until 24 August 2017 via the Better Regulation portal. No objections were raised.

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[1], 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[2], 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[3].

(2) The inflation rate of the Union, as published by the Statistical Office of the European Union, was 0,2% for 2015 and 1,2% for 2016. Taking into consideration the very low inflation rate in 2015, it was not 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. In view of the inflation rate of the Union for 2016, it is considered justified to adjust those amounts. A cumulative adjustment taking into account the inflation rates for 2015 and for 2016 should be applied.

(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

[1] OJ L 189, 27.6.2014, p. 112.

[2] 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).

[3] 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).

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.

(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) The Annex to 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 19 500' is replaced by 'EUR 19 770';

(b) 'EUR 13 100' is replaced by '13 290';

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

(a) in the introductory sentence, 'EUR 43 000' is replaced by 'EUR 43 600';

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

(i) 'EUR 17 200' is replaced by 'EUR 17 440';

(ii) 'EUR 7 280' is replaced by 'EUR 7 380';

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

(i) 'EUR 25 800' is replaced by 'EUR 26 160';

(ii) 'EUR 10 920' is replaced by '11 070';

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

(a) the first subparagraph is amended as follows:

(i) 'EUR 179 000' is replaced by 'EUR 181 510';

(ii) 'EUR 38 800' is replaced by 'EUR 39 350';

(iii) 'EUR 295 400' is replaced by 'EUR 299 560';

(b) the second subparagraph is amended as follows:

(i) in point (a), 'EUR 119 333' is replaced by 'EUR 121 000';

(ii) in point (b), 'EUR 145 200' is replaced by 'EUR 147 240';

(iii) in point (c), 'EUR 171 066' is replaced by 'EUR 173 470';

(iv) in point (d), 'EUR 196 933' is replaced by 'EUR 199 700';

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

(i) 'EUR 1000' is replaced by 'EUR 1010';

(ii) 'EUR 2000' is replaced by 'EUR 2020';

(iii) 'EUR 3000' is replaced by 'EUR 3050';

(4) in point 1 of Part IV, 'EUR 67' is replaced by 'EUR 68'.

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 [date of entry into force].

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

Done at Brussels, 18.10.2017

For the Commission
The President
Jean-Claude JUNCKER