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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	17 June 2022
To:	General Secretariat of the Council
No. Cion doc.:	C(2022) 3948 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 17.6.2022 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(2022) 3948 final.

Encl.: C(2022) 3948 final

EUROPEAN
COMMISSION

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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

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 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 2020 and 2021.

The last adjustment of the abovementioned amounts was carried out in 2020 based on the cumulative inflation rates of 2018 and 2019. Equally, for this adjustment a cumulative approach will be applied, taking into account the inflation rate both for 2020 (0,3%) and for 2021 (5,3%). For this purpose, the amounts in this regulation were calculated by first applying the 0,3% rate and rounding the results to the nearest 10 (with the exception of the annual fee, rounded to the nearest 1) and then applying to the newly calculated amounts the 5,3% rate, 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 24th February to the 03rd March 2022. No objections were raised.

The draft Regulation was subject to a feedback period of 4 weeks, in line with the Better Regulation guidelines. Input has been received from 22 stakeholders. Views from stakeholders have not been taken into account in the present act as out of scope for the proposed amendment.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

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

Article 1 of this 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 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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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 includes fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, and for services provided 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 last adjustment of the fees and remuneration amounts laid down in Regulation (EU) No 658/2014 was carried out in 2020 based on the cumulative inflation rate of 2018 and 2019. The inflation rate of the Union for the years 2020 and 2021, as published by the Statistical Office of the European Union, was respectively 0,3 % and 5,3 %[4]. Taking into consideration the level of the inflation rates for those years, it is considered justified to adjust, in accordance with Article 15(6) of Regulation (EU) No 658/2014, the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs referred to in Parts I to IV of the Annex to that Regulation. A cumulative adjustment taking into account the inflation rates for both 2020 and 2021 should therefore 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

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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 Union procedures for the authorisation and supervision of medicinal products for human 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).

4 Eurostat, euroindicators 11/2022, published on 20 January 2022

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.

(5) In accordance with Article 15(6) of Regulation (EU) No 658/2014, where an 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 act. The date of application for this Regulation should be laid down in accordance with that provision.

(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 20 780’is replaced by ‘EUR 21 940’;

(b) ‘EUR 13 970’is replaced by 14 750’;

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

(a) in the introductory sentence, ‘EUR 45 810’ is replaced by ‘EUR 48 370’;

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

(i) ‘EUR 18 330’ is replaced by ‘EUR 19 350’;

(ii) ‘EUR 7 760’ is replaced by ‘EUR 8 190’;

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

(i) ‘EUR 27 480’ is replaced by ‘EUR 29 020’;

(ii) ‘EUR 11 630’ is replaced by ‘EUR 12 280’;

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

(a) the first subparagraph is amended as follows:

(i) ‘EUR 190 740’ is replaced by ‘EUR 201 450’;

(ii) ‘EUR 41 350’ is replaced by ‘EUR 43 670’;

(iii) ‘EUR 314 790’ is replaced by ‘EUR 332 460’;

(b) the second subparagraph is amended as follows:

(i) in point (a), ‘EUR 127 150’ is replaced by ‘EUR 134 290’;

(ii) in point (b), ‘EUR 154 730’ is replaced by ‘EUR 163 420’;

(iii) in point (c), ‘EUR 182 290’ is replaced by ‘EUR 192 530’;

(iv) in point (d), ‘EUR 209 840’ is replaced by ‘EUR 221 620’;

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

(i) ‘EUR 1 070’ is replaced by ‘EUR 1 130’;

(ii) ‘EUR 2 110’ is replaced by ‘EUR 2 230’;

(iii) ‘EUR 3 200’ is replaced by ‘EUR 3 380’;

(4) in point 1 of Part IV, ‘EUR 71’ is replaced by ‘EUR 75’.

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 2022, please insert–"1 July 2022", if the date of entry into force is after 30 June 2022, 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, 17.6.2022

For the Commission
The President
Ursula VON DER LEYEN