

Procedure file

Basic information			
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation		Procedure completed	
Medicinal products for human use: fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities Repealed by 2022/0417(COD)			
Subject 4.20.04 Pharmaceutical products and industry 8.40.08 Agencies and bodies of the EU			
Key players			
European Parliament	Committee responsible ENVI Environment, Public Health and Food Safety	Rapporteur S&D MCAVAN Linda Shadow rapporteur PPE AYUSO Pilar	Appointed 11/07/2013
	Committee for opinion ITRE Industry, Research and Energy	Rapporteur for opinion The committee decided not to give an opinion.	Appointed
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
Council of the European Union	Council configuration Foreign Affairs	Meeting 3311	Date 08/05/2014
European Commission	Commission DG Health and Food Safety	Commissioner BORG Tonio	
European Economic and Social Committee European Committee of the Regions			

Key events			
26/06/2013	Legislative proposal published	COM(2013)0472	Summary
01/07/2013	Committee referral announced in Parliament, 1st reading		
17/12/2013	Vote in committee, 1st reading		
20/12/2013	Committee report tabled for plenary, 1st reading	A7-0476/2013	Summary

16/04/2014	Results of vote in Parliament		
16/04/2014	Decision by Parliament, 1st reading	T7-0438/2014	Summary
08/05/2014	Act adopted by Council after Parliament's 1st reading		
15/05/2014	Final act signed		
15/05/2014	End of procedure in Parliament		
27/06/2014	Final act published in Official Journal		

Technical information

Procedure reference	2013/0222(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealed by 2022/0417(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/13158

Documentation gateway

Legislative proposal	COM(2013)0472	26/06/2013	EC	Summary
Document attached to the procedure	SWD(2013)0234	26/06/2013	EC	
Document attached to the procedure	SWD(2013)0235	26/06/2013	EC	
Economic and Social Committee: opinion, report	CES5169/2013	16/10/2013	ESC	
Committee draft report	PE519.514	24/10/2013	EP	
Amendments tabled in committee	PE523.004	11/11/2013	EP	
Committee report tabled for plenary, 1st reading/single reading	A7-0476/2013	20/12/2013	EP	Summary
Text adopted by Parliament, 1st reading/single reading	T7-0438/2014	16/04/2014	EP	Summary
Draft final act	00044/2014/LEX	15/05/2014	CSL	
Commission response to text adopted in plenary	SP(2014)471	09/07/2014	EC	
Follow-up document	COM(2019)0439	30/09/2019	EC	Summary

Additional information

National parliaments	IPEX
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Final act

[Regulation 2014/658](#)[OJ L 189 27.06.2014, p. 0112](#) Summary

Final legislative act with provisions for delegated acts

Delegated acts

[2018/2805\(DEA\)](#)

Examination of delegated act

[2017/2923\(DEA\)](#)

Examination of delegated act

[2020/2725\(DEA\)](#)

Examination of delegated act

[2023/2771\(DEA\)](#)

Examination of delegated act

[2022/2730\(DEA\)](#)

Examination of delegated act

Medicinal products for human use: fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities

PURPOSE: to contribute to the well-functioning of the internal market and the common post-marketing surveillance of medicinal products.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the legal framework of pharmacovigilance for medicinal products for human use marketed within the EU is provided for in [Regulation \(EC\) No 726/2004](#) and in [Directive 2001/83/EC](#).

Legislation in this area was revised in 2010 through [Regulation \(EU\) No 1235/2010](#) and [Directive 2010/84/EU](#) which strengthen and rationalise the system for safety monitoring of medicines on the European market.

This legislation is applicable as of July 2012. It provides for a number of EU-wide procedures to assess pharmacovigilance data which may lead to regulatory action. Some additional amendments to the pharmacovigilance legislation were introduced in 2012 with [Directive 2012/26/EU](#) following the 'Mediator' case.

The revised pharmacovigilance legislation significantly widened the tasks of the European Medicines Agency with regard to pharmacovigilance, irrespective of whether the medicinal products have been authorised via the 'centralised procedure' (in accordance with the Regulation) or via national procedures (in accordance with the Directive). The Agency has therefore acquired pharmacovigilance competences also for nationally authorised medicines, in addition to reinforced competences for centrally authorised medicines.

Other tasks include the monitoring of literature cases, the improved information technology tools and the provision of more information to the general public.

New categories of fees should therefore be created to cover the new and specific tasks of the Agency.

IMPACT ASSESSMENT: the [Impact Assessment report](#) that accompanies this proposal considered several options, based on estimation of cost.

A combination of procedure-based fees and an annual flat fee has been considered to be the most transparent, cost-based, activity-based and proportionate way of setting the new fees, in order to cover the cost under the new pharmacovigilance legislation.

LEGAL BASIS: Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposed Regulation aims at setting high standards of quality and safety for medicinal products as it ensures the availability of sufficient financial resources to perform the pharmacovigilance activities that are necessary to guarantee that high standards are maintained once the product is authorised.

The revised pharmacovigilance legislation provides for fees to be charged to marketing authorisation holders. These fees should be related to pharmacovigilance activities performed at the level of the EU, notably in the context of the EU-wide assessment procedures. These procedures include scientific assessment carried out by rapporteurs from the national competent authorities of the Member States. These fees are therefore not intended to cover the pharmacovigilance activities of the national competent authorities performed at national level. Member States may accordingly continue to charge fees for the activities performed at national level which should, however, not overlap with the fees laid down in this legal proposal.

The proposal foresees two separate types of fees:

- fees for procedures for the assessment of periodic safety update reports, postauthorisation safety studies and pharmacovigilance

referrals;

- an annual flat fee to be charged to marketing authorisation holders having at least one medicinal product that is authorised in the EU and registered in the database provided for in Regulation (EC) No 726/2004. The fee revenue from the annual flat fee shall be retained by the Agency.

Some fee reductions and fee waivers are foreseen in respect of the proposed fees:

- reductions for medicinal products for which the marketing authorisation holder is a small or medium-sized enterprise would be granted for all types of fees. Micro enterprises would be exempted from all fees;
- a reduction of the annual flat fee is therefore proposed for authorised generic, homeopathic and herbal medicinal products and for medicinal products authorised on grounds of well-established medical use. However, where these medicinal products are included in the Union-wide pharmacovigilance procedures, the full fees for procedures would apply.

Marketing authorisation holders would be charged as follows:

- marketing authorisation holders having at least one product involved in a Unionwide pharmacovigilance procedure would be charged a fee for procedures,
- marketing authorisation holders in the EU, with the exceptions explained above, would be charged the annual flat fee.

Fees referred to in this Regulation should be transparent, fair and proportionate to the work carried out.

In line with the recommendations of the European Court of Auditors and the [European Parliament](#), it is proposed that rapporteurs from the national competent authorities of the Member States be remunerated according to a fixed scale based on estimations of cost.

BUDGETARY IMPLICATION: all options of legislative action, including the option which underpins this proposal, were based on the assumption that the costs related to pharmacovigilance would be covered through fees.

Therefore, no impact on the EU general budget is foreseen in the accompanying financial statement of this proposal.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

Medicinal products for human use: fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities

The Committee on the Environment, Public Health and Food Safety adopted the report by Linda McAVAN (S&D, UK) 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

The committee recommended that Parliaments position in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Purpose and scope: an amendment aimed to confirm that homeopathic and registered herbal medicinal should be excluded from the scope of the Regulation.

Members also specified that the Regulation determined the pharmacovigilance activities performed at Union level for which fees were 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.

In order to ensure a clear separation between fees paid to Member States and fees paid to the European Medicines Agency, Members stated that Member States should not impose fees for pharmacovigilance tasks that are already covered by the Regulation.

Definition of chargeable unit: the Commission proposal had meant that companies would be charged according to the number of different market authorisations they held - and this was calculated down to the size of the pack. Members felt that the number of tablets in a pack was not relevant for pharmacovigilance. It would be more appropriate to charge according to the number of authorisations per active ingredient, and per pharmaceutical form.

Annual flat fee: this had been proposed to cover the costs of other pharmacovigilance activities carried out by the Agency, particularly signal detection.

Members proposed reducing the amount raised by the EMA, and the scope of the flat fee to cover only the tasks to be undertaken by EMA: Eudravigilance, the Article 57 database, PSUR repository and literature review only, turning the flat fee into a maintenance fee for EMA pharmacovigilance work.

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

Fee reduction: the marketing authorisation holder claiming or having claimed to be entitled to a reduction or an exemption under the Regulation, should submit to the Agency, within seven calendar days from receipt of the Agency's request, the information necessary to demonstrate compliance with the relevant conditions in order for the Agency to be able to verify that those conditions were fulfilled.

Fees for safety report: Members felt that the variations were a consequence of periodic safety update 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.

The committee wanted rapporteurs and co-rapporteurs from Member States to be fairly remunerated, in order to incentivise them to volunteer for the work involved in handling referrals. The corresponding remuneration of the rapporteur and co-rapporteur is 50% of the total fee collected.

Medicinal products for human use: fees payable to the European Medicines Agency for the

conduct of pharmacovigilance activities

The European Parliament adopted by 544 votes to 17, with 11 abstentions, a legislative resolution 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.

Parliament adopted its position at first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement reached between the European Parliament and the Council. They amended the proposal as follows:

Subject matter and scope: Parliament and the Council agreed to adopt this Regulation in order to enable the European Medicines Agency (EMA) 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 establish the pharmacovigilance activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees to the Agency, and the amounts of remuneration by the Agency for the services provided by the rapporteurs and, where applicable, the co-rapporteurs.

Homeopathic and herbal medicinal products and medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC, should be excluded from the scope of this Regulation.

Definition of chargeable unit: 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, 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.

Types of fees: it is stipulated that where a fee is levied by the Agency, the Agency shall pay remuneration, to the national competent authorities:

- for the services provided by the rapporteurs and, where applicable, the co-rapporteurs in the Pharmacovigilance Risk Assessment Committee appointed as members of that Committee by Member States;
- for the work carried out by the Member States which act as the rapporteurs and, where applicable, co-rapporteurs in the coordination group.

Annual fee: for its pharmacovigilance activities relating to information technology systems and the monitoring of selected medical literature, the Agency should levy once per year a fee. The annual fee should be due on 1 July of every year in respect of that calendar year.

The amended text emphasises the fact that fees should be established on a basis which takes due account of the ability of small and medium-sized enterprises to pay. Moreover, information on those fees should be publicly available.

Where justified, the Commission should adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs to take account of inflation.

Lastly, 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.

Medicinal products for human use: fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities

PURPOSE: to contribute to the well-functioning of the internal market and the common post-marketing surveillance of medicinal products.

LEGISLATIVE ACT: Regulation (EU) No 658/2014 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.

CONTENT: 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 has been adopted. The revised 2010 legislation provides 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.

Subject matter and scope: this Regulation shall apply to fees for pharmacovigilance activities relating to medicinal products for human use authorised in the Union and which shall be levied by the European Medicines Agency on marketing authorisation holders.

Homeopathic and herbal medicinal products registered in accordance with Directive 2001/83/EC, and medicinal products which are authorised to be placed on the market in accordance with Directive 2001/83/EC, shall be excluded from the scope of this Regulation.

This Regulation establishes the pharmacovigilance activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees to the Agency, and the amounts of remuneration by the Agency for the services provided by the rapporteurs and, where applicable, the co-rapporteurs.

Chargeable unit: a chargeable unit is defined 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.

Types of fees: the types of fees charged to marketing authorisation holders are as follows:

- Fees for the assessment of periodic safety update reports: EUR 19 500 per procedure. From that amount, the remuneration for the rapporteur shall be EUR 13 100. That remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).
- Fees for the assessment of post-authorisation safety studies: EUR 43 000 to be paid in two instalments as follows: (a) EUR 17 200 shall be due at the date of the start of the procedure for the assessment of the draft protocol referred to in Directive 2001/83/EC; (b) EUR 25 800 shall be due at the date of the start of the procedure for the assessment of the final study report by the Pharmacovigilance Risk Assessment Committee as referred to in the same Directive.
- Fees for assessments in the context of referrals initiated as a result of pharmacovigilance data: EUR 179 000 where one or two active substances and/or combinations of active substances are included in the assessment. That fee shall be increased by EUR 38 800 per each additional active substance or combination of active substances as of the third active substance or combination of substances. That fee shall not exceed EUR 295 400 irrespective of the number of active substances and/or combinations of active substances.
- An annual flat-rate fee of EUR 67 per chargeable unit. This fee is intended to cover the costs of general pharmacovigilance activities of EMA, such as safety data management, literature monitoring and information technology, notably maintenance of the EudraVigilance database. The annual flat fee will be charged as from 1 July 2015.

Reductions and exonerations: small and medium-sized enterprises will benefit of a fee reduction of 40% from all fees covered by the regulation and micro-enterprises are exempted from any fees. Micro enterprises should be exempted from all fees. 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.

Transparency: 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.

ENTRY INTO FORCE: 17.07.2014.

DELEGATED ACTS: the Commission shall be empowered to adopt delegated acts in order to adjust the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs to take account of inflation. The power to adopt delegated acts shall be conferred on the Commission for a period of five years from 17 July 2014. The European Parliament or the Council may raise objections to a delegated act within a period of two months from the date of notification (this may be extended by two months). If the European Parliament or Council express objections, the delegated act will not enter into force.

Medicinal products for human use: fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities

The Commission presented its report on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 658/2014 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.

Delimitation of the delegation of powers

The Pharmacovigilance Fee Regulation empowers the Commission to adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs, where such adjustment is considered justified in light of an annual monitoring of the inflation rate, measured by means of the European Index of Consumer prices published by Eurostat.

The present report is a requirement under Article 16(2) of the Pharmacovigilance Fee Regulation. This provision delegates powers to the Commission for five years, starting from 17 July 2014. A report on the exercise of the delegation should be drawn up not later than nine months before the end of this period. The delegation of powers is to be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Exercise of the delegation

To date the Commission has exercised in two instances the delegated powers provided for by Regulation (EU) No 658/2014 to adjust to the inflation the amounts of fees and remuneration laid down in that Regulation :

(1) Delegated act adjusting the amounts laid down in the Pharmacovigilance Fee Regulation taking into account cumulatively the inflation rate of the Union for 2015 and for 2016: the inflation rate of the Union, as made available by Eurostat, was 0.2 % for 2015 and 1.2 % for 2016. In view of these inflation rates, it was considered justified to proceed to an adjustment in 2017. A cumulative adjustment, taking into account the inflation rates for 2015 and for 2016, was therefore applied. The Commission adopted the [Delegated Regulation \(EU\) 2018/92](#) which started to apply from 12 February 2018.

(2) Delegated act adjusting the amounts laid down in the Pharmacovigilance Fee Regulation taking into account the inflation rate of the Union for 2017: the inflation rate of the Union, as made available by Eurostat, was 1.7 % for 2017.

It was considered justified to proceed to an adjustment for 2017. The Commission adopted [Delegated Regulation \(EU\) 2018/1298](#) which started to apply from 18 October 2018.