REASONED OPINION 8/2013 OF THE JOINT COMMITTEE FOR THE EUROPEAN UNION OF 24 SEPTEMBER 2013 ON INFRINGEMENT OF THE PRINCIPLE OF SUBSIDIARITY BY THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON 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) [COM(2013) 472 FINAL] [2013/0222 (COD)] {SWD(2013) 234 FINAL) {SWD (2013) 235 FINAL}

BACKGROUND

A. The Protocol on the application of the principles of subsidiarity and proportionality, annexed to the Treaty of Lisbon of 2007, in force since 1 December 2009, established a procedure whereby the national parliaments can check whether draft EU legislation complies with the principle of subsidiarity. This Protocol was implemented in Spain by Law 24/2009 of 22 December, amending Law 8/1994 of 19 May. In particular, the new Articles 3(j), 5 and 6 of Law 8/1994 constitute the legal foundation for this reasoned opinion.

B. 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 was approved by the European Commission and submitted to the national Parliaments, which have a period of eight weeks to check the compliance of the initiative, ending on 26 September 2013.

C. On 5 September 2013, the Bureau and Spokespersons of the Joint Committee for the European Union decided to examine the proposed EU legislative initiative mentioned above. MEP Rubén Moreno Palanques was appointed as rapporteur and the Government was asked to draw up the report provided for in Article 3(j) of Law 8/1994.

D. In accordance with Article 3(j) of Law 8/1994 of 19 May 1994 governing the Joint Committee on the European Union, a report was received from the Government which concluded that the proposed Regulation infringed the principle of subsidiarity. Letters from the Parliament of La Rioja, the Parliament of Cantabria, the Parliament of Catalonia, the Parliament of Aragon and the Parliament of Galicia were also received, informing us that the file had been archived, no reasoned opinion had been issued, and that note had been taken of the matter.

E. At its meeting on 24 September 2013, the Joint Committee for the European Union approved this

REASONED OPINION

1. - Article 5(1) of the Treaty on European Union states that *"The use of Union competences is governed by the principles of subsidiarity and proportionality"*. In accordance with Article 5(3) of the TEU, *"Under the principle of subsidiarity, in areas which do not fall within its exclusively competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level"*.

2. - Like the EU pharmacovigilance legislation, the proposed Regulation has a double legal basis: Article 114; and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

Article 114 establishes that *"Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market."*

In this respect, the proposed Regulation is based on Article 114 of the TFEU because the differences between the national legislative, regulatory and administrative provisions on medicinal products tend to impede trade within the EU, directly affecting the functioning of the internal market. This Regulation would guarantee the availability of the financial resources needed to apply the streamlined Union procedures to the assessment of serious safety issues for medicinal products authorised at national level. Such procedures were introduced partly in order to avoid or eliminate obstacles which could arise due to parallel procedures at national level. This Regulation therefore contributes to the smooth functioning of the internal market and to the common post-marketing surveillance of medicinal products.

The proposed Regulation is also based on Article 168(4)(c) of the TFEU because its purpose is to contribute to the objective of establishing high quality and safety standards for medicinal products.

Article 168(4)(c) establishes that:

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet safety concerns:

c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

In accordance with Article 168(4) and with Article 4(2)(k) of the TFEU, this Union competence is – as in the case of Article 114 TFEU – a shared competence, which is exercised with the adoption of the proposed Regulation.

The proposed Regulation pursues the objective of establishing high quality and safety standards for medicinal products, since it guarantees that sufficient financial resources are available to perform the pharmacovigilance activities needed to guarantee that these standards are maintained at a high level after the medicinal product has been authorised.

However, Article 168(4)(c) TFEU cannot be used as the sole legal basis since, as indicated above, its objectives also include the establishment and functioning of the internal market and the establishment of high quality and safety standards for medicinal products. It must therefore be supplemented with Article 114 TFEU.

3. The ordinary legislative procedure is being followed. Since the enforcement of the Treaty on the Functioning of the European Union, all legislative procedures are in principle based on the previous "codecision procedure" in which the European Parliament and the Council participate. Therefore, in the interests of legal certainty, it is proposed that a new Regulation of the European Parliament and of the Council be created for pharmacovigilance fees, subject to the ordinary legislative procedure (Article 294 TFEU).

4. The legal framework for pharmacovigilance relating to medicinal products for human use placed on the market in the European Union stems from Regulation (EC) No 726/2004 (hereinafter "the Regulation") and Directive 2001/83/EC ("the Directive").

This framework underwent substantial revision and an impact assessment, following which revised legislation was adopted in 2010 (Regulation (EU) No 1235/2010 of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004, and Directive 2010/84/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC [OJ L 348 of

31.12.2010]), which consolidates and streamlines the system for monitoring the safety of medicinal products in the European market.

This legislation has been applicable since July 2012. It establishes various procedures at EU level to assess the pharmacovigilance information which could give rise to the application of regulatory measures.

5. In 2012, after the case of the "Mediator" medicinal product, a number of additional amendments were made to pharmacovigilance legislation (Directive 2012/26/EU [OJ L 299 of 27.10.2012) and Regulation (EU) No 1027/2012 [OJ L 316 of 14.11.2012]).

When the assessment and monitoring of the safety of medicinal products was being streamlined after authorisation at EU level, the new legislation on pharmacovigilance considerably extended the tasks of the European Medicines Agency (EMA) as regards pharmacovigilance, irrespective of the medicinal products which were authorised through the centralised procedure (pursuant to the Regulation) or through national procedures (in accordance with the Directive). EMA thus acquired pharmacovigilance competences also for medicinal products authorised at national level, in addition to strengthening its competences for medicinal products authorised centrally.

6. In order to finance these activities, the revised pharmacovigilance legislation provides for the collection of fees from holders of marketing authorisation. These fees must relate to pharmacovigilance activities performed at EU level, particularly in the context of assessment procedures at EU level. Such procedures include a scientific evaluation completed by rapporteurs of the competent national authorities of the Member States. The fees are therefore not intended to pay for pharmacovigilance activities conducted at national level by the competent national authorities. Consequently, the Member States can continue paying fees for activities at national level, although these must not overlap with the fees established in this legislative proposal.

7. On the other hand, the adoption of a proposed Regulation on pharmacovigilance fees should ensure that the EMA can have sufficient financing to duly apply the already applicable pharmacovigilance legislation. Therefore, Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products would continue to apply, whereas the proposed Regulation would be applied to pharmacovigilance fees for activities established in the applicable pharmacovigilance legislation. The two legal instruments would supplement each other.

8. Since the new pharmacovigilance legislation refers only to medicinal products for human use, this proposal on pharmacovigilance fees includes only these medicinal products.

9. The Commission held a public consultation in the third quarter of 2012, and received 85 contributions, most of which came from industry and anticipated the establishment of excessively high fees, the need to avoid a double burden at European and national level caused by overlapping activities, and the need to bear in mind the existence of many small- and medium-sized businesses, as well as businesses with a large portfolio of services whose safety is

sufficiently monitored, as could be the case for generic medicines.

10. On the one hand, the proposal sets out fees for the procedures to assess the updated periodical safety reports, post-authorisation safety studies and pharmacovigilance referrals; on the other hand, it sets a fixed annual fee to cover the costs of EMA pharmacovigilance activities, which differ from those linked to the above-mentioned procedures and is paid by the holders of marketing authorisation with at least one authorised medicinal product in the European Union which is registered in the corresponding database. The proposal offers exemptions for small- and medium-sized businesses in relation to the risk profile of medicinal products, as would be the case for generics, or for authorisation-holders which already pay an annual fee to EMA.

11. Generally speaking, the proposal is necessary since the tasks imposed by the new pharmacovigilance legislation must be adequately remunerated.

12. However, this Regulation has significant repercussions for Spain and for the functioning of the *Agencia Española de Medicamentos y Productos Sanitarios* (Spanish Agency for Medicinal Products and Health Products).

It is considered that the fees are not fairly divided between the EMA and the Member State acting as rapporteur for a specific procedure. The main and most complex workload is assumed by the Member State acting as rapporteur, since it must be responsible for completing the scientific assessment, which is time-consuming and calls for highly qualified staff. The EMA coordinates the procedure. We therefore do not understand why there is sometimes such disproportion between the EMA fee and the fee of the rapporteur Member State (e.g. for the post-authorisation safety studies: EUR 43 000 for the EMA and EUR 18 200 for the rapporteur Member State). On the other hand, the fee to be paid by the Member State acting as rapporteur is unpredictable, since it depends on the number of pharmaceutical companies involved and on their level of income. Yet scientific work calls for a stable prediction of the fee.

The flat-rate to be collected by the EMA for medicinal products authorised in the European Union corresponds to a number of tasks which are already provided for in pharmacovigilance legislation, although it does not provide for the collection of fees for these tasks. On the one hand, this can clash with the flat-rate paid by Member States for medicinal products authorised by national procedures; on the other, the Member States are also involved in some of the tasks listed for the collection of such a fee, without provision having been made for any collection of fees: renewal of *EudraVigilance*, signal generation.

The proposed Regulation states that amendments to the fees are made by a delegated act of the European Commission. This should under no circumstances be the case when it is possible that a reduction in existing fees for the Member States is a possibility.

13. With regard to the application and conformity of this proposal with the principle of subsidiarity, the explanatory memorandum of the proposed Regulation establishes that:

"The Agency is a European decentralised Agency established under the Regulation and hence the decision on its funding and charging of fees is to be taken at the EU level. The new pharmacovigilance legislation provides for a legal basis for the Agency to charge fees for pharmacovigilance. Hence, only the Union can act to enable the Agency to charge fees for pharmacovigilance. Only pharmacovigilance activities that are performed at EU level and involving the Agency are covered by this proposal. As regards pharmacovigilance activities remaining at national level, the EU is not competent and Member States may still continue charging national fees accordingly."

Four fees are established in the proposed Regulation:

1. fee for assessment of periodical safety update reports;
2. fee for assessment of post-authorisation safety studies;
3. fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data;
4. flat annual fee.

Article 9 establishes the system of remuneration of the Member States, in accordance with their activity as rapporteurs in relation to the first three fees, and sets the last fee for pharmacovigilance activities related to IT systems, the monitoring of the selected medical bibliography and signal detection.

Likewise, the explanatory memorandum of the proposed Regulation establishes that reference is made only to the fees to be collected by the Agency, whereas the competence to decide on any fees received by the competent authorities of the Member States must continue to be held by the Member States. It also points out that payment should not be taken twice from holders of marketing authorisation for the same pharmacovigilance activity.

Therefore, the Member States must not collect fees for the activities indicated in the proposed Regulation.

At national level, although provision is still currently made for two types of fees for the assessment of the periodical safety report for a medicinal product, which is either half-yearly, annual or quarterly, these disappear with the entry into force of the new Pharmacovigilance Directive, to be implemented by draft Law amending Law 29/2006 of 26 July 2006, becoming fee 1.9 in Article 111.1, intended to cover all transversal activities which are not subject to any fee and to include the fee for pharmacovigilance activities which, as established by Directive 2001/83/EC, in the wording given to Article 105 thereof by Directive 2010/84/EU, may be collected by the Member States for the purpose of renewal. The national fee therefore remains EUR 370.

This fee was calculated to avoid any impact on the current income from the periodical safety report, instead transforming it into a flat rate linked to the pharmacovigilance activities other than

the report itself. As already mentioned, provision for this has been made in the Directive (Article 105).

Following the examination of the two resulting taxation frameworks in the field of pharmacovigilance, European and national, it should be pointed out that there may be a certain clash between the fixed fee referred to in Article 7 of the proposed Regulation and the annual pharmacovigilance renewal fee referred to in the draft Law amending Law 29/2006 of 26 July 2006 since, according to the Directive, the Member States will receive a renewal fee for medicinal products authorised by national procedure and, depending on the provisions of the proposed Regulation, the European Agency will also collect another fee for these same medicinal products, which could likewise be considered as a renewal fee, and for which no provision was in any case made in European pharmacovigilance legislation, although provision was made for the task (access to the European database on medicinal products and bibliographic notification searches). In contrast, this would not be the case for centralised medicinal products, for which a renewal fee would have to be paid only to the European Agency, although the various Member States also participate in these systems by performing their task of recording adverse reactions.

The proposed Regulation does not imply an infringement of the principle of subsidiarity in relation to the establishment of the three types of fees initially mentioned. However, there may be an infringement of the principle of subsidiarity if the fixed annual fee was renewed for the performance of pharmacovigilance activities in the case of medicinal products authorised by national procedure, since this would constitute double taxation for renewal of the pharmacovigilance systems at European and national level for this type of medicinal product, clearly with proportionate and discriminatory effects on other medicinal products, which would be subject to the European tax, now provided for in the proposed Regulation.

Consequently, we consider that the fixed annual fee for medicinal products registered by national procedure must be applied exclusively at national level, by the Member States of the European Union and not by the European Medicines Agency, since there would otherwise be an infringement of the principle of subsidiarity.

The proposed act would be of relevance to the European Economic Area.

CONCLUSION

For the above-mentioned reasons, the Joint Committee on the European Union considers that 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 infringes the principle of subsidiarity established in the current Treaty on European Union.

This opinion is to be forwarded to the European Parliament, the Council and the European Commission in the context of the political dialogue between national parliaments and the EU institutions.