SENATE OF THE REPUBLIC

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RESOLUTION OF THE 12th STANDING COMMITTEE

(Hygiene and Health)

*(*Author: Dirindin)

Approved at the session of 7 August 2013

CONCERNING

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 (COM (2013) 472 FINAL)

pursuant to Article 144(1) and (6) of the Regulation

Communicated to the Presidency on 9 August 2013

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The Committee,

Having read the proposal for a Regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency (EMA) for the conduct of pharmacovigilance activities in respect of medicinal products for human use (COM (2013) 472 final);

Whereas the proposal is aimed at introducing fees payable by marketing authorisation holders to cover the costs of the tasks newly assigned to the EMA in the field of pharmacovigilance;

Whereas the goal explicitly pursued by the European legislature is that of ensuring correct implementation of measures for monitoring the safety of medicines by applying EU legislation on pharmacovigilance throughout the Union;

Whereas the anticipated result is one which allows the EMA to levy fees in order to ensure adequate funding to cover the estimated cost of conducting subsequent pharmacovigilance activities which are assigned to it by the relevant legislation adopted in 2010;

Whereas the legal basis for the legislative measures in question can be found in Article 114 and Article 168(4.c) TFEU;

Having evaluated the inputs received in the course of the preliminary hearings, which, *inter alia*, took the form of informal hearings of pharmacovigilance experts and representatives of the pharmaceutical industry;

Having noted, moreover, the results of the public consultations which preceded the publication of the proposal;

Whereas it is opportune to strengthen pharmacovigilance systems so as to ensure adequate coverage of the expenditure necessary for their functioning;

Expresses, "pursuant to Protocol No 2 to the TFEU ("Protocol on the application of the principles of subsidiarity and proportionality"):

* a favourable opinion regarding compliance with the principle of subsidiarity, taking into account that: the tasks of the EMA are established by a regulatory body of the European Union and therefore the relevant legislation can only be amended or supplemented by means of a subsequent EU legislative instrument of the European Union at an equal hierarchical level; moreover, the proposal appears to add value in

the form of guaranteed funding for pharmacovigilance activities at European level;

* a partially favourable opinion regarding compliance with the principle of proportionality, making its unqualified approval contingent upon the performance of a re-evaluation of the additional workload flowing from the above-mentioned legislation of 2010, and of the criteria adopted for quantification of the costs involved, which appear to be insufficiently justified and liable to lead to excessive fees;

Expresses the following criticisms of certain aspects of the text:

The criterion of the chargeable unit, which is relevant for determining the "annual flat fee", appears to be neither unambiguous nor exhaustive for the purpose of identifying the medicinal product, given the significant differences between the systems for coding medicinal products authorised in the various Member States of the European Union;

Despite the provisions of specific legislation aimed at mitigating the impact of the proposal on small businesses, the proposal suggests fees which are excessively high and unaffordable for small and medium-sized enterprises;

It would be opportune to gradate the flat funding as a function of the time required for the new system of pharmacovigilance to become fully operational;

The structure of the funding system, which is based exclusively on fees chargeable to marketing authorisation holders, the proposed combination of flat fees and processing fees, and the provision for fees independent of the value of the market for the individual product, represent potential risks in terms of the autonomy, sustainability and viability of the entire system;

Notes, on a legal level, that Article 16 of the proposal empowers the European Commission to adopt delegated acts amending certain parts of the Annex, and that this delegation appears to be of indefinite duration, whereas Article 290 TFEU states that the duration of a delegation of power must be explicitly defined.

OBSERVATIONS OF THE 14th STANDING COMMITTEE

(POLICIES OF THE EUROPEAN UNION)

(Author: Uras)

10 July 2013

The Committee,

Having examined doc. COM (2013) 472 final,

Whereas the above-mentioned document is aimed at ensuring coverage of the costs of conducting future pharmacovigilance tasks assigned to the European Medicines Agency following the revisions of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, which defines Community procedures for the authorisation and surveillance of medicinal products for human and veterinary use, and which establishes the European Medicines Agency, and of 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;

Whereas the system devised by the European Commission should ensure that "the total cost of pharmacovigilance activities conducted at European Union level (...) is recovered by means of the levying of fees", as illustrated in the "Workload and cost estimate tables";

Having regard to the misgivings expressed by various interest groups during the consultations held by the European Commission between 18 June and 15 September 2010, relating above all to the costs to businesses;

In the hope that the legislation in question does not constitute grounds for an increase in the end prices for pharmaceuticals and that, more generally, the opportuneness of adopting measures to contain those prices is taken into consideration;

Formulates, insofar as it is competent to do so, the following favourable comments:

The legal basis appears to have been correctly identified as Article 114 of the Treaty on the Functioning of the European Union (TFEU), which states: "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" and Article 168(4.c) TFEU, which states: "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 common safety concerns […] measures setting high standards of quality and safety for medicinal products and devices for medical use.";

The document in question is compatible with the principle of subsidiarity with respect to: the need for measures by the institutions of the European Union, in that the tasks of the European Medicines Agency are set out in Regulation (EC) No 726/2004 and the relevant legislation can therefore only be amended or supplemented by means of a subsequent Community instrument at an equal hierarchical level;

There is added value for the Union, in that it ensures the necessary financial coverage for the activities provided for in the current legislation and, as a consequence, adequate functioning of pharmacovigilance at European Union level;

As regards the principle of proportionality, the proposal appears to be compatible with the goals being pursued, and not to go beyond what is necessary to achieve the general goal pursued. It is relevant to this proposal that the legislation applies only to pharmacovigilance activities conducted at European Union level, while for those performed at national level, the levying of fees is a matter for the Member States.

As regards the content of the proposal, we would point out the indefinite duration of the delegation of power set out in Article 17, which should be amended in order to bring it into line with Article 290 TFEU, which states: "The […] duration of the delegation of power shall be explicitly defined in the legislative acts."