HELLENIC PARLIAMENT

REASONED OPINION

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 COM(2013) 472 final

JOINT SESSION

SPECIAL STANDING COMMITTEE FOR EUROPEAN AFFAIRS

STANDING COMMITTEE FOR SOCIAL AFFAIRS

September 4, 2013

Members of the aforementioned Committees having considered:

- The Proposal's text
- Its legal basis (article 114 and article 168 (4) (c) of the Treaty on the Functioning of the European Union (TFEU).
- The informational note by the Greek National Organization for Medicines
- The oral briefing by the Minister for Health, mr. Adonis Georgiadis

Unanimously adopted the following opinion:

The Proposal for a Regulation introduces fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities, such as assessment of periodic safety update reports (PSUR), post-authorisation safety studies (PASS) and pharmacovigilance referrals on safety, as well as an annual flat fee for all marketing authorisation holders (member-states) for all medicinal products authorised in the EU and registered in the database provided for in Article 57(1)(l) of the Regulation, with the exception of Marketing authorisation holders for medicinal products authorised

under Regulation (EC) No 726/2004 who already pay an annual fee to the Agency for the maintenance of their authorisations.

According to the proposal's grounds, the said fees aim at financing pharmacovigilance activities carried out at the EU level, especially in the context of assessment procedures. However, these procedures include scientific evaluation carried out by rapporteurs acting on behalf of the competent national authorities within member-states. Nevertheless, according to the proposal, the said fees are not intended to cover pharmacovigilance activities of national authorities performed at a national level.

Competent national authorities are responsible not only for expertise and evaluations provision, but also for maintaining national pharmacovigilance systems; for these activities, member-states should be entitled to charge remuneration fees.

According to the proposal, 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. Moreover, it is mentioned that only pharmacovigilance activities that are performed at EU level and involving the Agency are covered by the proposal.

As regards pharmacovigilance activities remaining at national level, the EU is not competent and Member States may still continue charging national fees accordingly. However, this is not accurate. It must be noted that several referral procedures include the evaluation of products authorised at a national level, which will be conducted by member-states, but they will not have the possibility of charging fees at a national level.

More specifically:

- In Article 5 there is provision for a "fee for assessment of post-authorisation safety studies", stating that " 6. Marketing authorisation holders who are charged the fee under this Article shall be exempted from any other fee charged by a competent authority for the submission of studies referred to in paragraph 1."

It seems that, according to the proposal, fees for EMA will prevail; as a result, in certain cases, member states' competent national authorities, and, in our case the Greek National Organization for Medicines shall be deprived from charging fees or claimed fees, as EMA becomes the only beneficiary. So, in the case where the GNOM asks for a study to be conducted in more than one member - states, the fee will be collected by EMA.

- Article 7 introduces an "annual flat fee", stating that "2. The fee shall be levied on holders of marketing authorisations for all medicinal products authorised in the Union in accordance with Directive 2001/83/EC, on the basis of the chargeable units corresponding to those products. Chargeable units corresponding to products authorised in accordance with Regulation (EC) No 726/2004 shall not be subject to the annual flat fee."

Article 2 defines as "chargeable unit" "each individual entry in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 based on information from the list of all medicinal products for human use authorised in the Union referred to in Article 57(2) thereof."

The database will expand in order to include all medicinal products sold in the EU market. The database contains both centrally and nationally authorised products since companies have registered their products' SPCs and PLs.

On the basis of these provisions, the database referred to in Article 57(1),(2) shall contain all medicinal products in the EU and the EMA will collect an annual fee for all EU authorised medicinal products, whereas the competent national authority having authorised them shall not have the right to charge a comparable fee.

According to the views of the Hellenic Parliament Committees, the aforementioned case constitutes **violation of both proportionality and subsidiarity principles** as although holding member-states responsible for authorisations issued by them, a fee is levied to the sole benefit of EMA, whereas no fees are levied for EU authorised

medicinal products, resulting in violation of equality principle as well. Besides, databases of national pharmacovigilance systems and EMA's database are already interlinked..

The following are also noteworthy:

- Article 8 containing provisions on fees reduction and exemptions in certain cases should be linked to article 9 concerning rapporteurs' remuneration payment by the Agency, so as to achieve proportionate reduction in rapporteurs' remuneration received in case of fees' reduction.
- The definition of "micro enterprise" explained in Article 2 as a micro enterprise within the meaning of Recommendation 2003/361/EC should be improved to involve limits, both on the basis of employed personnel and the basis of enterprise's profits or turnover, so as to favour the really small-sized and micro enterprises either in terms of personnel or in terms of economic values.

All the aforementioned indicate issues violating both subsidiarity and proportionality principles, since the proposed regulations go far beyond what is necessary to achieved the pursued aim, namely ensuring sufficient resources for the EMA to conduct pharmacovigilance activities; they also entail overlap or delegation of rights on the part of member-states to the EU for services not offered or provided, while not taking into account their services supply to the EU.