REPLIES TO THE Concept paper submitted for public consultation "INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE" Ref. Ares(2012)723154

September 12, 2012

Comments from: Asociación Española de Farmacéuticos de la Industria (AEFI)

Consultation item n°1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.

We consider that the proposed fee for a single assessment of a PSUR is very high. Has the cost of the fees needed for various PSUR in a Drug Safety Deparment from a Marketing Authorisation Holder been assessed? It can be a very high despense to be considerered.

On the other hand, from our point of view, the proposed fee to be paid by the assessment of a PSUR cannot be the same for all products. It's our understanding that it does not depend only on the enterprise size, but also on the medicinal product's safety profile and the extent of data to be analyzed (e.g. PSURs of pricks used for diagnose of allergic diseases have nothing to do with PSURs of antiplatelet monoclonal antibody or antineoplasic drugs). We consider that it should be taken into account to determine the fee to be paid and that it should be specified within the document.
The alternative to be suggestested is to re-assess the proposed fees.

For PSUR assessment, a maximum fee of 80,300 € is proposed for products that have been authorised for 2 years or more whilst a lower fee of 40,150€ is proposed for products which have been authorised for less than 2 years.

- Which will be the minimum fee?
- Who is going to decide the fixed fee for each product?
- Will there be any room for negotiation?

Another concern we foresee is that this fee is to be charged also for nationally Authorised products. In case a National Competent Authority is also charging a fee for assessing PSURs, which of the fees should be considered?

Consultation item n°2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

We consider that the concept of grouping the differents MAHs with the same product can be very difficult to take into practice. It means to contact with

different MAHs, to coordinate the work of preparing a single PSUR, to share information for preparing a PSUR that can be considered confidential, etc.

A possible alternative could be to have the PSUR worksharing procedure, where all PSURs from different MAHs is submitted at the same time, according a syncronised list, to one Member State that makes the assessment of the information provided.

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative

For Pharmacovigilance Service Fee, a maximum fee of 1,000 EUR per year and per medicinal product is proposed.

- Which is the minimum?
- Who is going to decide the fixed fee for each product?
- Will there be any room for negotiation?

In case of Well-Established Use Herbal Medicinal Products: the WEU Herbal Medicinal Products have been evaluated by the group of Traditional Medicinal Plants of the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) with the same requirements demanded in Traditional Use (Article 16c(1)(c) of Directive 2004/24/EC amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use). They should have the same treatment of traditional plants and consequently they are exempted from electronic submission and fees payment of pharmacovigilance in Europe, taking into account that any safety problem that may come up, is going to question the maintenance of the Committee on Herbal Medicinal Products (HMPC) Monograph