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Gebro Pharma's Comment on
"INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE", (EU Commission, Ref. Ares(2012)723154 - 18/06/2012)

We are a relatively small private company in Austria with limited international structure. We are licensing products but are also developing own products, which are generics or hybrid generics and only very rarely NCEs.

We refer to our Austrian MAs only and to both companies we represent, one is a 100% private company, the other one is a joint venture with a foreign company.

Both companies together hold about 150 approvals in Austria, with about 60 active ingredients concerned with the EMA pharmacovigilance fee proposal.

1. Current PSUR fee costs for all approvals in AT are (national, RMS, CMS):

2010	32,600
2011	30,900
2012	35,000 (estimated)

2. Costs with regard to EMA fee proposal

2.1 Routine PSUR costs

Assumptions:
According to the EURD list we are concerned with the following number of products:

PSUR Frequency	**Own products All fees to be paid**	**License products Estmated 25%, rest is paid by licensee**
3 years	3	2
5 years	2	2
>5 years calculated 7.5 years	2	
Multiplied with the proposed 80,300.- €		
3 years	240,900	40,150
5 years	160,600	40,150
>5 years calculated 7.5 years	160,600	
Annually (spread over the 3, 5 or 7.5 years concerned)	80,300	13,383
	32,120	8,030
	21,413	
Annual fee	133,833	21,413

Sum: 155,247

2.2 Annual fee for 60 active ingredients (or different combinations)

Sum: 60,000

2.3 New registrations (possibility, that a full 5 year PSUR program is requested)

We are approximately submitting about 3 license applications annually.

As a mean two are generic and one of these is a hybrid generic and competent authorities might decide due to the novelty of the hybrid product that routine PSURs have to be submitted over the first 5 years, because the safety of the new form has to be monitored carefully. A full 5 year course of PSUR submission costs 401,500 €.
That is 80.300.- per year as annual costs.
We count it only with half amount as in some cases the frequency might be reduced or a licensee takes the costs. Nevertheless, there is the potential of even much higher costs.

Sum 40,150.- €

2.4 Referrals

Taken the experience over the last 10 years we can consider that cases which were in the past of the type of Urgent Safety Restrictions, resulting in type II variations of the SmPC might now become referrals.

We consider 1 case in every 3 years according to experience, with the lower fee limit of 80,300.-

This results in an annual sum of **26,767.- €**

Another calculation would be to consider a full fee for a full risk benefit evaluation with 267,400.- €. But in some situations a grouping would apply.

Comment on grouping:
In many cases this will just be an instrument of bigger companies to pressure on smaller ones, which then have also to pay the full fee or would often leave the market.

These estimates result in the following annual costs

Routine PSUR fees:	155,247
Annual fees:	60,000
New licenses:	40,150
Referrals:	26,767
Sum per year	**282,164€**

Compared to current annual costs of 30,000 € to 35,000 € this is a nearly 10-fold increase of fees for pharmacovigilance, which is not justified, even if some improvement can be expected with regard to drug safety.

Unclear rules and possible different approaches of national HA concerning PSUR submission frequencies after approval and triggering referrals could also lead to an unfair situation on the EU pharmaceutical markets.
The EMA fees proposed, which exceed current costs for life cycle in an enormous amount, would have a serious negative impact on planning of our product portfolio, especially for those products with a more innovative background.