

Pharma Liebermann GmbH (DE)

From: Werner Schoder <Werner.Schoder@pharma-liebermann.de>
Sent: 10 September 2012 16:57
To: SANCO FEES PHARMACOVIGILANCE
Subject: Public consultation on the Pharmacovigilance fees

Dear sirs,

having read the concept paper i would like to express the opinion of our company to this item.

Our company is a SME having no CAP's but exclusively national market authorisations. All products are homeopathic with very little sales. Our annual turnover of these medicaments is about €.

Due to the considerable number of national authorized products we are charged with a considerable financial amount for fees of our national authorities (PSURs etc.).

Any additional fee charged by European authorities like the EMEA would have existential consequences for us.

The fees for pharmacovigilance activities of the national authorities are already very burdensome.

So, further fees would rise the question of viability for our market authorisations.

Therefor the only possibility we see, is to discharge SME's of our size of any fees. Otherwise many companies which are in a similiar situation would be forced to give up their market authorisations and consequently to retire from bussiness including the well known impact to the job market.

I hope that the responsible policymakers will consider these aspects when deciding on the topic.

Sincerely,

Werner Schoder

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