

Dr. Peithner KG nunmehr GmbH & Co

Ein Unternehmen der Schwabe-Gruppe; www.peithner.at

From: Peithner Martin <Martin.Peithner@peithner.at>
Sent: 17 July 2012 12:17
To: SANCO FEES PHARMACOVIGILANCE
Subject: PC/12/05 – Public Consultation on pharmacovigilance
Importance: High

Statement/Commenter: Martin Peithner, general manager of Dr. Peithner KG, a pharmaceutical company specialized in homeopathic products.

Ladies and gentlemen,

This proposal will kill dozens of small and medium sized companies throughout Europe!

While products registered under Art 10 (1), Art.10a, Art.14 und Art.16a are generally exempted from PSURs (and therefore also from the fees), this is NOT the case for products with marketing authorisations according to Art. 16 (2).

In Austria we have currently 428 products on the market with marketing authorizations according to Art. 16 (2). (Source: Arzneispezialitätenregister der AGES, Reg.-Code: "3-"; <https://pharmaweb.ages.at/index.jsf>).

Another approx. 100 marketing authorizations are currently being processed.

From these 428 products only 37 have annual sales of 80.000,- € or more (i.e. 8,7%) and only 23 have sales of 160.000,- € or more i.e. 5,4% (Source: IMS Dataview, HOM/OTC-Report 2011).

Although some of these 428 products are on the market in more than one country, they do not qualify for the grouping, because national rules lead to different ingredients and therefore these products are not identical throughout Europe.

Unless the commission wants to kill 95% of these products and ruin dozens of companies, there are 2 possible solutions:

1. Products with marketing authorizations according to Art. 16 (2) are generally exempted from PSURs.
2. The fees must be limited to a maximum of 5% of annual sales.

Kind regards

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Geschäftsführer

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