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Sent: 11 July 2012 11:14

To: SANCO FEES PHARMACOVIGILANCE

Subject: PC/12/05 – Public Consultation on pharmacovigilance fees

Dear Sir or Madam,

we are a small enterprise (25 persons and an annual turnover and/or annual balance sheet total about EUR 3,4 million) like many other companies in Germany.

A speciality in Germany is the existence of small pharmaceutical companies that produce a huge range of different pharmaceutical products. These are niche products, that allow special therapies. Some manufacturers produce 100 or more different medicines. Whereby the turnover of the individual drugs is very low. Preparations of this kind are usually prescribed by naturopathic doctors and heilpraktikers.

Naturopathic doctors have a long tradition in Germany. They also have the same views and therapeutic beliefs as heilpraktikers. The „heilpraktiker“ profession is a german speciality. The profession does not exist in any other EU country. Naturopaths and other similar professions can not be compared. In Germany, the term „heilpraktiker“ is a protected professional title and anchored in the law (Heilpraktikergesetz).

The treatment provided by heilpraktikers and naturopathic doctors is generally based on the medicines that are produced by these smaller manufacturers. Large/global manufacturers produce a small range of products with a large turnover. These large/global companies should not be compared to smaller companies which have a large range of products, but who produce small quantities.

The fees being charged by the EMA should not only be based on sales and the number of employees. Smaller companies which produce, for example, 100 to 300 different pharmaceutical products usually only make enough profit to cover their costs. Large/global companies would not accept such small profits and do therefore not produce the products. Only small companies offer such non-profitable products. They should not be punished because of this. They fulfill an important social, cultural and health-policy function. A higher financial burden would mean that they would have to give up the production of these specialised products because the cost would be much higher and the profit would thus go into a negative. As a result, many naturopathic doctors and heilpraktikers wouldn't have the "tools" for their treatment. The result would be that they would no longer be able to treat their patients or perform their profession optimally. This would destroy a therapeutic direction which has proven to p

roduce fewer side effects.

There the EMA should establish a special rule for such companies, in order to ensure their survival. The exorbitantly high fees proposed by the EMA would results in the extinction of a particular therapeutic direction which is important for German therapeutics, culture and tradition.

The following conditions should therefore apply to the payment of fees by these companies:

Fees should not be based on the turnover or the number of employees of a manufacturer, but on the profits made. Furthermore, agents that are prescribed in relation to the entire pharmaceutical market rare and a very low turnover have to be free of charge. Otherwise the result would be, that the EMA would destroy the existence of these drugs, patients could not be provided, what they need.

Yours sincerely

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