From: Nicola Secchi [mailto:nicola.secchi@adienne.com]
Sent: 14 September 2012 17:42
To: Ziogas Constantinos
Cc: 'paolo.boscani@adienne.com'; 'Antonio Francesco Di Naro'
Subject: comments to the public consultation EMA on the Pharmacovigilance fees

Dear Dr Ziogas,

ADIENNE S.r.l. is a SME working in the orphan drugs field; on 15/03/2010 ADIENNE S.r.l. obtained, by centralized procedure, the exclusive marketing authorization from EMA for its orphan medicinal products TEPADINA® 15 mg and TEPADINA®100 mg, and this is the only Marketing Authorisation we currently have.
As for its own definition, an orphan drug has not a large market and corresponding revenues as for instance in other sectors of the pharmaceutical market and especially for a SME like ADIENNE, who works exclusively for this kind of drugs, the possibility to receive some incentives is crucial.

Concerning the planned introduction of fees related mostly to pharmacovigilance activities, we would like in particular underline that, although reductions are foreseen for both micro-sized enterprises and also for some procedures for SMEs, no reference is made to orphan drugs which have a niche market and small sell volumes.
In particular for a SME like ADIENNE who has currently just a single orphan drug on the market, fees for PSUR , Type II variations and the annual fee could jeopardize the survival of the company despite the proposed reductions.

Please take into consideration the above comments to be forwarded as contribution to the public consultation issued by the European Commission.

Thanking you in advance,
Best regards

Dr. Nicola Secchi
Regulatory Affairs Manager

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