

From: Vladimir Vlk [mailto:vlk@ardez.cz]
Sent: Friday, June 22, 2012 7:40 PM
To: SANCO FEES PHARMACOVIGILANCE
Subject: PC/12/05 - Public Consultation on pharmacovigilance

Dear Sirs,

Let me react to this point:

Consultation item n°9: Do you agree with the proposed approach with regard to the pharmacovigilance service fee for SMEs (point 3.5.2)?

I do not agree with the following assumption:

„As the charging of the pharmacovigilance service fee is proposed on the basis of the active substance or combination of substances, SMEs will be charged proportionally less than bigger companies, holding a larger product portfolio. At the same time, this approach reduces the administrative burden for the SMEs as they will not need to provide proof of their eligibility for SME status in relation to the payment of the annual service fee.“

If I understand correctly, this article suggests that SMEs pay less authority fees as they have less products hence no reduction of individual fees is necessary. I think it is in conflict with the existing practices of EU to incentivize the SMEs. Also, once the SME obtains the SME proof, it is easy to provide it - as can be shown in our case, pls. find the SME status attached.

Kind regards,

Vladimir Vlk

ARDEZ Pharma, spol. s r.o.
Popovova 948/1
143 00 Praha 4
Czech Republic
www.ardez.cz
vlk@ardez.cz

Phone: +420 220 400 391 (392 dir)
Mob.:+420 602 264 736
Fax: +420 220 400 395