From: rafaelle.pineau@fr.biogaran.com [mailto:rafaelle.pineau@fr.biogaran.com]
Sent: Friday, September 14, 2012 9:30 PM
To: SANCO FEES PHARMACOVIGILANCE
Cc: rafaelle.pineau@fr.biogaran.com
Subject: FEES PHARMACOVIGILANCE
Dear Sir, Madam,

Please find below the comments of laboratoire Biogaran, company launching generics products on the French market regarding the "Introduction of fees to be charged by the EMA for Pharmacovigilance".
We understand the principle of fee but considering our situation with a large portofolio, it represents important changes.

SME (small medium enterprise)
Our company includes less than 250 employees with a turnover more than 50 million €, could we consider Biogaran as being a SME regarding the number of employees?

PSUR
The mentioned fee for one PSUR is of 80 300 € maximum, this fee seems not be proportional between two drugs launched by two different companies. The number of ADR to be analyzed could be different if the PSUR concerning a princeps or a generic drug. We want to know if these differences have been taken into consideration. It is written 80 300€ maximum, is there a minimum and in which situations?

We agree with the concept of grouping, but we want to be sure that we can share with only a few number of companies in case of reject of this proposal by others. Safety data are usually confidential and some companies could not want to make a grouping.

PHARMACOVIGILANCE SERVICE FEE
1000 € per medicinal product per year, according to the Biogaran portofolio, this represent a very important budget.
We propose a fee per range of drugs.

PASS/REFERRALS
Same comments, and we agree with the concept of grouping. But the question of datasharing between several companies could be a problem.

Yours faithfully
Dr Rafaelle Pineau, Pharmacovigilance Responsible, BIOGARAN
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