

Maurizio Schiassi, Consultant for PhV

From: assix.data@libero.it
Sent: 13 September 2012 19:13
To: SANCO FEES PHARMACOVIGILANCE
Subject: Consultation paper INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE

Dear Sirs,

with reference to the consultation paper INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE, Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.

I consider that the fee should be proportional to the number of ICSRs because it is a nonsense that e.g. a MAH of “generics” with 20 different products and very few or not at all ICSR/year should pay 20,000 €/year, whereas another MAH with only 10 products and 50 or more ICSRs should pay only 10,000 €/year.

Kind regards,

Maurizio Schiassi

Consultant for PhV