FUEHRING Stefan (SANCO)

From: christine.marey@fr.netgrs.com

Sent: jeudi 30 septembre 2010 18:48

To: SANCO PHARMACEUTICALS

Cc: patricia.maillere@fr.netgrs.com; catherine.salvadori@fr.netgrs.com

Subject: Comments on Draft implementing guidance "List of fields for results-related information to be submitted to the EudraCT clinical trial database and to be made public"

Attachments: Implementing Technical Guidance-Servier comments.pdf

Dear all,

Please find attached Servier comments on the draft implementing guidance *"List of fields for results-related information to be submitted to the EudraCT clinical trial database and to be made public".*

The Commission requires that results of unapproved products are to be submitted and made publicly available within 6 or 12 months of completion. When compared to the US where posting is made once the first approval is granted, this measure will bring serious competitive disadvantages for the European pharmaceutical industries which performed the clinical development in Europe and possibly have consequences on the conduct of clinical research in Europe.

Thank you for taking all comments into consideration.

Best regards

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