

From: Vissani, Gianluca [GPSIT] [GVISSANI@its.jnj.com]  
Sent: jeudi 3 mars 2011 17:05  
To: SANCO PHARMACEUTICALS  
Subject: EC Concept Paper on the EU-CTD -- JnJ comments  
Attachments: concept\_paper\_02-2011.pdf

Dear Sir/Madame,

Would like to bring to your attention a comment from the Johnson & Johnson group on the attached CP document:

“JnJ takes the position in opposition to a mandatory coordinated assessment procedure (CAP). While the application of CAP may be useful in some situations, the application of CAP as a mandatory filing requirement will greatly limit our flexibility in clinical trials and potentially move the review towards more conservative and onerous requirements as seen in clinical trials in Spain, France, Czech republic etc. Our recommendation is for support of a voluntary CAP procedure.”

This comment is coming from a private individual, which is actually not falling into the EU definition of a small and medium-size enterprise (JnJ has currently more than 250 employees in EU).

The comment can be made public.

Thank you and best regards,

Gianluca Vissani Global Compliance, JnJ