**From:** Franzen Wilhelm MD TPDE [mailto:Wilhelm.Franzen@Takeda.de]
**Sent:** Wednesday, July 14, 2010 12:20 PM
**To:** SANCO PHARMACEUTICALS
**Subject:** Public consultation ENTR CT-3

Ladies and Gentlemen,

with regard to the public consultation document issued 17.7.2010 I want to send in my comments as follows

- It is understood that the revision of EC2001/20 is planned, but does not align with the revision of this guidance. As it usually takes also time to update processes in the respective organisations which is also linked with reasonable investment in should be considered that the current review will stay for a minimum time of three years – otherwise it should be focused on the revision of the Directive first and then update the guidance documents.
- Reporting to investigators is a still time consuming process which at the end does not really provide the necessary control of information by the investigators as the amount of information cannot be managed by the local sites. A more efficient way would be if the ethic committees would indicate after assessment of the cases whether an information to investigators is deemed necessary with a concrete handling instruction how to communicate to the patients.
- If the reporting of single ICSRs to investigators will be maintained there should be a clear instruction what and how to report – the current wording allows too much interpretation on a local level which in fact creates the risk of several national individualities for reporting.
- The SUSAR reporting after end of study should define a time limit for active follow up – otherwise this becomes a never ending story. One option could be until the first approval in the EU. As there is also no obligation at the site of ethic committees to maintain a documentation after end of the study it is questionable which value this extended reporting obligation would create.
- With regard to the selection of preferred method of reporting it should be clarified that the option chosen by the sponsor must be valid for all concerned EU countries covered by this regulation – otherwise it will not be a real approach forward to a consistent and easy exchange of information.

General proposal

With regard to the amount of similar data transmitted to multiple sites it should be considered whether it wouldn't be the better option that only the CAs of the respective countries serve as a communication point for single case reporting while ethic committees will get granted access to the databases of the local authorities for the respective projects – this would enable the ECs to look into the latest status of data at any time they want and would avoid the current insufficient paper work. Also a duplication of administrative efforts could be avoided.

***Kind regards***


***Willibert Franzen***

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