FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: jeudi 7 janvier 2010 17:00
To: FUEHRING Stefan (ENTR)
Subject: FW: ASSESSMENT OF THE FUNCTIONING OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC

A/439

From: Van Schoor, Omer (Antwerpen) [mailto:Omer.VanSchoor@sgs.com]
Sent: Thursday, January 07, 2010 4:48 PM
To: ENTR /F/2 PHARMACEUTICALS
Cc: Anne Van Hecken; Jan de Hoon
Subject: ASSESSMENT OF THE FUNCTIONING OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC

Dear,

Please find enclosed the remarks of the BAPU, the Belgian Association of Phase I Units. Members of the association are all Belgian Clinical Pharmacology Units, including pharma company units, academic units and CRO units. The remarks below have been made by the units.

Remarks :

p.10: Consultation item n°1: Improved protection of study participants
As already pointed out in the ICREL report, we feel that there is a strong need to create a unique European central registration system, used in all European countries, regulating the participation of healthy volunteers in clinical trials and setting a minimum exclusion period between trials.

p.12: Consultation item n°2: multiple and divergent assessments of clinical trials
Here we would like to make an indirect remark as from our experience with multicenter trials performed in more than one MS: we think there is a need for more transparency with regard to comments raised by the different CA/ERC on the protocol/CIB. These comments should be communicated to all ERC/investigators involved in the multicenter study.

p.16 Consultation item n°4 :
After a VHP procedure, which in itself is a good initiative, the file has to be submitted in the different member states and as such will be subject to the different national requirements, which are not harmonised as such. The advantage of an harmonisation via the VHP would therefore be lost and would probably generate an extra submission and consequently an extra delay.

p.19 Consultation item n°6
An important example of the different implementation of the Clinical Trials Directive is in the definition of an investigational medicinal product (IMP)
Different Member States have different definitions of what is to be considered as an IMP and what as a non-IMP (NIMP). There is no clear definition of NIMP in the Directive. Some Member States may consider products such as challenge agents and concomitant and background treatments as an IMP, while others do not.
The same remark applies for the implementation of GMP in early phase clinical trials. Some Member states do apply a very strict interpretation of GMP even for early phase (eg FIM) studies while others have a more practical approach.

Best Regards,

Omer Van Schoor
Secretary of the BAPU