FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: lundi 30 novembre 2009 8:57
To: FUEHRING Stefan (ENTR)
Subject: FW: Consultation on Clinical Trials Directive

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From: Peter J Goadsby [mailto:peterg@ion.ucl.ac.uk]
Sent: Friday, November 27, 2009 10:10 PM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Consultation on Clinical Trials Directive

I am an academic neurologist in the UK.

Regarding consultation item No 14, one could add the dimension of promiting research in rare conditions, and mechanistic studies.

At the moment to do a study of eight patients with a rare problem using a medicine approved for another indication one needs to provide a package of data on safety.

Now the competant authorities in any country have these data and it is onerous to the point of exclusion for non-industry people, such as academics, to prepare such dossiers.

This completely stops studies of condition which are too small to be targets for pharma.

It is, I think, an unintended consequence of the current rule stucture that needs addressing.

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