

From: Bahri Priya [Priya.Bahri@emea.eu.int]
Sent: 15 June 2006 19:08
To: ARLETT Peter (ENTR)
Cc: Brosch Sabine (EMEA); Tsintis Panos (EMEA); Wathion Noel (EMEA);
Stang Anya (EMEA)
Subject: Technical comments for EC PhV Rev

Dear Peter,

In the framework of the PhV System Review undertaken by the EC, you ask for proposals to change the legislation.

One change which would simplify the procedures and description with view to comprehensive data collection would be to re-formulate the adverse reaction definition with view to being independent of dose. This would be in line with the spirit of ICH-E2D, on which I am sure you will remember the discussion.

As this is a rather technical comment, it has been agreed with Noel that I send this in an informal way.

With kind regards

Priya