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To: Charles Lister/PH6/DOH/GB@GRO-C
cc:
Subject: REFACTO

17/12/2002 17:28

Charles,

Thank you very much for faxing me the information on query from Professor Savidge.

The changes to the SmPC already implemented in the German published version and highlighted in Professor Savidge's letter of 14 November 2002 were indeed the subject of a variation to the licence approved through a centralised procedure. This variation was finally approved on 20 August 2002. I understand that this is not yet published on the EMEA website due to a backlog. It is normal for the deadline for national implementation of the changes to be agreed with the EMEA at the time of approval.

I have contacted Wyeth who market the product in the UK and they have confirmed that they committed to introduce the new SmPC by November 2002. I have asked the company to send me an e-mail confirming the exact date on which the new SmPC was introduced in the UK and they will also send me a copy of the SmPC so that I can compare it with our records before I forward it to you. I will send you their response as soon as I receive it and hopefully this will be before your meeting. The SmPC has been updated to comply with the current core SmPC for "human plasma derived and recombinant coagulation Factor VIII".

I can conclude that the English SmPC in Prof Savidge's attachment and dated December 2000 is definitely the old version and the German version which is dated September 2002 (after the CPMP August approval date) is the current version. It would therefore appear that the inconsistencies highlighted do not exist from a licensing point of view. The German version is the same as the UK and the rest of the EU.

As far as publication of the new SmPC in the UK is concerned we await confirmation. I also note in the letter to Frank Hill that Wyeth refer him to a web site www.emc.vhn.net where they have posted the current SmPC. I assume that this is the updated one since the letter is dated 20/11/02. I have tried unsuccessfully to log in to the above site but if you can get access to it would be interesting to check the date of the SmPC. The site is updated daily so there is no reason why the SmPC should not be the current one! If it is (dated after 20 August 2002) it answers that part of Prof Savidge's concerns.

As far as the clinical and financial implications are concerned, it would not be appropriate for me to comment. All I can confirm is that the new SmPC has been approved by all EU states via the centralised procedure and CPMP and in line with CPMP guidelines for the core FVIII SmPC.

I hope this is helpful and I will forward Wyeth's response as promised.

Janice

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