



CPME/AD/consultation/140408/074/EN

On 14 April 2008, CPME adopted the following document: **CPME Answer to the EMEA consultation regarding the proposed revision of the “Summary Product Characteristics guideline” (CPME 2008/074 EN)**

Brussels, 14 April 2008

Dear Mr Blædel Lassen,

CPME would like to thank you for the opportunity to comment on the revision of the guideline on SPCs, also as member of the EMEA Healthcare Professionals Working Group.

CPME welcomes the proposed revision of the Summary Product Characteristics guideline.

Precise information on the use and effects of medicinal products in special patient groups, and the specific aspects that should be considered in these cases, serve patient safety and the effectiveness of medicinal treatments.

Any initiative to improve the clarity of the SPCs is highly welcome, being tabulated summaries a good example. This should favour the functioning of the daily medical practices, and at the same time, the empowerment of an informed patient.

The patient-doctor relationship in information is fundamental. The starting point for all exchange of information is the peer to peer dialogue with the patient. In this framework of the patient-doctor conversation, information to support the dialogue is also provided such as medical advice on the product prescribed.

CPME therefore supports the proposed revision of the SPCs guideline as it aims to provide further clarification, and ultimately, to improve patient safety.

Sincerely yours,

Dr Michael Wilks
CPME President

Lisette Tiddens-Engwirda
CPME Secretary General