

20 December 2012
Reference: EMA 12012

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Subject: ePMF implementation postponement

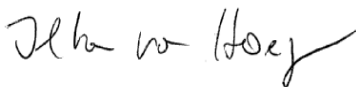
Dear Dr. Domingo, dear Dr. Silvester

PPTA would like to follow up on the development of the ePMF data base, particularly pertaining to its implementation. We have informed you previously that the data base in its current form is not workable for PMF holders. We understand that your experts make all efforts to address the technical and procedural shortcomings, but we must insist to postpone the implementation of the data base until all issues are resolved and there is a common agreement between EMA and PMF holders that the data base can go into operation. We do not see any value of testing the data base with individual PMF holders while it is still under development.

Also, a policy on confidentiality should be in place prior to coming into operation.

We would appreciate your feed-back on the progress of the data base and your anticipated timelines for its completion.

Yours sincerely,



Dr. Ilka von Hoegen
Senior Director, Quality and Safety