

## **Audrey Rondepierre**

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**From:** France Capon  
**Sent:** mercredi 22 mars 2017 13:56  
**To:** Dr Holger ZITT; Dr Rudolf Eller; Dr. Heinz-Günter SCHENZEL; Dr. Jörn MÜHLENFELD; Dr. Nissanka RAJAPAKSE; Mr. Francisco BOO; Mr. Guy ETHIER; Mr. Juha PARKKINEN; Ms Audrey RONDEPIERRE; Ms France CAPON  
**Subject:** FOR INPUT: Recommendation of the PGM WG regarding the IPA request to postpone Pt registration dossiers submission (by 24th March 2017)  
**Attachments:** IPA request - postponement of Pt registration.pdf  
**Importance:** High

### **TO THE PMC MANAGEMENT COMMITTEE**

#### **Copy to the Chair of the PGM WG**

*For input*

Dear Members,

As requested at the last Management Committee, the Secretariat conduct a risks/benefits analysis regarding the IPA request to postpone Pt registration dossiers submission.

Based on the benefits/risks analysis and the discussions, the WG recommends to the Management Committee:

- To **keep PMC internal timing unchanged** and keep the TP in the registration dossiers.
- To leave IPA to make their own decisions and developing their workplan regarding additional testing but ensuring that the decisions taken are not hampering the PMC workplan/deadlines.
- Evaluate the need to update the PMC dossiers when new data will be available.

For more information on the discussion and the analysis, please find enclosed a summary note.

May I kindly ask you to send me **your feedback/support by 24<sup>th</sup> March 2017** at latest?

I will prepare a reply to IPA and send it after having received your feedback.

Many thanks in advance.

Best regards,

France

#### **France Capon**

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