IPRP International Pharmaceutical Regulators Programme

25 January 2014 Rev.1

Information Sharing Pilot based on the European Decentralised Procedure (DCP) and Centralised Procedure (CP)

Questions & Answers:

1. Q: Will companies have another opportunity to express interest in the information-sharing pilot after the 26 September deadline?/within 2-3 years?

   A: Yes. The pilot will remain in place until such time we have sufficient experience.

2. Q: The IPRP notice foresees that companies submit their Expression of Interest (EOI) to the Co-ordination Group for the Mutual Recognition and Decentralised Procedure (CMDh) Secretariat, the foreseen Reference Member State (RMS) of the foreseen DCP the CMDh member of the foreseen RMS and the respective candidate non-EU Agencies selected by the applicant at least 8 weeks prior to the intended submission using the EOI Request Form. Can applications with a shorter notice period be accepted?

   A: As this is a pilot and applications must be assessed against selection criteria, 8 weeks is the preferred option. In agreement with the chosen partners, a shorter timetable may be possible. All information requested in the EOI must be provided for the application to be considered for the pilot.

3. Q: If a company applies for this pilot, how will the company receive the feedback that the product is admitted to the pilot? Who will provide the information?

   A: The company will receive confirmation from the participating Agencies. As the procedure itself is based on the European DCP, you will receive the information about the start of the procedure by the Reference Member State (RMS) of the European DCP.

4. Q: According to Annex 2 of the IPRP notice, it seems that questions from non-EU countries will not be taken into account for the DCP itself. Is this interpretation correct?

   A: Yes

5. Q: If the non-EU countries raise questions, should these questions be answered separately with these countries only?

   A: Yes

6. Q: When should the applicant participating in the pilot submit the application to the respective non-EU Agencies?

   A: Ideally this should be after the validation of the DCP submission in the EU. However, due to the different legal provisions and review processes agreement must be obtained in advance from respective non-EU agencies on acceptable submission dates.

7. Q: Are Centrally Authorised Products (CAPs) included in the Information Sharing Pilot?

   A: Yes, the IPRP Steering Committee and the European Medicines Agency (EMA) have agreed to extend the pilot to CAPs. Further information has been published on 19 January 2015

   (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/01/news_detail_002251.jsp&mid=WC0b01ac058004d5c1)

Disclaimer

This document reflects the views of subject matter experts participating in the IPRP Information Sharing Working Group for Generics (IWGG) and should not be construed to represent the official views of any given regulatory authority participating in the IPRP.