EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

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NOTE FOR THE FILE

The purpose of this note is to present DG SANCO's record of the operational conclusions of the pharmaceutical working group meeting between DG SANCO of the European Commission and the Chinese reached during the meeting on 10 July 2012.

Operational conclusions

- SFDA and EMA will continue with the advanced notification of GMP and GCP inspections. It was confirmed that [redacted] remains the SFDA contact person for these notifications.

- Once the template for the written confirmation for Active Pharmaceutical Ingredients imported to the EU and the Questions and Answers document related to this issue is published, SFDA and the Commission will move forward on their cooperation to get ready for 2 July 2013.

- Concerning Active Pharmaceutical Ingredients originating from the EU (including the issue of multiple testing of Active Pharmaceutical Ingredients) the Commission will inform EU companies that encounter this problem in order to collect data and send it to SFDA.

- SFDA acknowledges certain problems exist in the areas of authorisation and management of clinical trials. These problems will be followed on subsequent meetings of the EU-SFDA working group on pharmaceuticals.

- COM agree to support cooperate with SFDA in the field of traditional herbal medicinal products. The Committee for Herbal Medicinal Products in EMA will include in the work plan monographs for traditional Chinese herbal substances where all the necessary data on safety and efficacy required to prepare the monographs is sent to the Committee.

- EMA will inform SFDA on the training programme regarding GMP and GCP inspectors organised by EMA, in order to facilitate participation of Chinese inspectors.

- Next meeting of the working group will take place in spring in Brussels in 2013. The COM will communicate possible dates for a meeting in late spring/early summer.

- SFDA will inform the Commission on their achievements in the implementation of the written confirmation for Active Pharmaceutical Ingredients imported to the EU.

- SFDA agreed to have joint collaboration with the EU commission in the area of cracking down on falsified medicines.

- SFDA will communicate the Commission their priorities to be included in the framework of the EU-China Trade project (EUTCP).

- EMA will reiterate its invite to SFDA to send a "visiting expert" to its offices.