EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

The Advisor to the Director General

Brussels,
SANCO/D/3/MFS/an/ddg1.d.3(2011)1090741
(by e-mail only)

Subject: **Follow-up on the Pharmaceutical WG meeting DG SANCO and SFDA May 2011**

Dear Director General,

Thank you for kind letter dated 23 May 2011 stating your wish to enhance our mutual cooperation which we clearly share.

As agreed during the pharmaceutical working group meeting last May, please, find enclosed a draft document to formalise the activities related to our intensified cooperation in the field of GMP and GCP inspections. Please let us know about any comments or amendments you might have. These activities are foreseen as a first step in our cooperation which pave the way for the implementation in 2014 of the legislative measures derived from the new EU legislation on falsified medicines.

In addition, we would like to put forward some of the concerns transmitted by the European pharmaceutical industry which were already raised during the working group meeting. We believe that progressing on these issues will bring benefits to patients.

Concerning clinical trials, we would like to draw your attention to the cumbersome procedures and delays (3-5 yrs.) in the registration of new medicinal products as a result of provisions on clinical trial requirements in particular with regard to the non-acceptance of clinical trials performed outside China. This concern is particularly relevant to vaccines as a consequence of recently amended provisions of the Chinese regulation which have led to the de facto ban of non-Chinese vaccines.

The requirement to submit a Certificate of a Pharmaceutical Product (CPP) together with the registration file, leads to delays in market access if the product has not been launched outside China prior to the submission of the file.

Mr Zhang Wei
Director General
State Food and Drug Administration
Department of Drug Registration
Building 2, 26 Xuanwumen West St.
Beijing 100053
P.R. CHINA

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: BREY 10/130 - Tel. direct line +32 229-86782 - Fax +32 229-98046

Maria-Angeles.Figuerola-Santos@ec.europa.eu

Furthermore the multi-sampling/testing by Chinese authorities on active pharmaceutical ingredients upon entry into China was mentioned as a factor limiting the economic viability of European Active Pharmaceutical Ingredients exports to China.

As regards the review of the Chinese pharmacopoeia, we would support your idea that an early consultation of the European Commission and EU industry might avoid divergences in regulatory approaches. Your concrete suggestions on how to establish collaboration in this field would be most welcome.

As announced in the working group meeting, we are glad to confirm that a seminar on traditional herbal medicinal products registration will be organised in Beijing in the second week of October with the participation of three experts from the Committee for Herbal Medicinal Products of the European Medicines Agency. In addition, two seminars on active pharmaceutical ingredients will also take place in Beijing, both in autumn, one this year and another one next year. These seminars will be supported by the EU-China trade project.

In order to continue deepening our collaboration, we would appreciate very much receiving suggestions for dates of the next meeting of the pharmaceutical working group in Beijing preferably June or July 2012.

We look forward to continuing our cooperation.

Yours sincerely,

Patrick Deboyser

Enclosure: draft exchange of information with SFDA