

**Consultation and Cooperation Mechanism between the
Directorate-General for Health and Consumers of the European
Commission and the State Food and Drug Administration of the
People's Republic of China**

1. General Principles

Aiming to promote information exchange, mutual understanding and co-operation between the EU and China on pharmaceuticals, medical devices, cosmetics and related administrative, regulatory or scientific matters, the Directorate-General for Health and Consumers of the European Commission and the State Food and Drug Administration of the People's Republic of China have decided to set up an EU-China Consultation and Cooperation Mechanism (hereinafter referred to as the Mechanism) in the areas lying within their respective competences.

The Mechanism will be open to any EU or Chinese authority which would be interested to participate, subject to mutual agreement by both parties.

The two sides have approved the following Terms of Reference for their consultation and cooperation mechanism.

2. Objectives

The two sides aim at ensuring the safety and health of European and Chinese consumers and believe that the Mechanism will provide trust, and help enhance mutual understanding and co-operation in the pharmaceutical, medical devices and cosmetics areas.

The two sides are willing to engage in a constructive dialogue on Legislation, Regulations and Related Issues dealing with pharmaceuticals, medical devices and cosmetics. Within this framework, current and forthcoming legislation and related developments, regulatory and control systems in the EU and China will be addressed.

Both sides intend to contribute to sustainable trade relations between EU and China in the pharmaceuticals, medical devices and cosmetics sectors in accordance with international commitments.

3. Working Procedure

The two sides decide, under the present Terms of Reference, to hold annual meetings to discuss major issues related to the protection of consumer safety and health and related legislation or regulations, to compare and assess their differences in regulatory or legislative approaches, to explore possibilities for co-operation in the field of harmonisation and standards and to set out the working plan for the following year.

The annual meeting will be held alternatively in Europe and in China.

Both sides will participate with representatives mandated to take position on the identified issues. Furthermore both sides accept that the level and composition of representation will be equivalent and reflect the subject matters to be dealt with, while taking into account the differences in the organisational structure of the respective administrations.

The working languages will be English and Chinese.

4. Working groups

The establishment of appropriate working groups will be decided at the annual meeting. Each working group will be responsible for making and implementing its working plan.

The two sides will use best endeavours to guarantee the efficiency of the work. Hence industry association representatives, at appropriate level, should - on the basis of mutual agreement by both sides - be invited to participate in the working groups, depending on the subject and if deemed necessary.

Both sides agree to setup three working groups, one on "Pharmaceuticals", one on "Medical devices" and the other one on "Cosmetics". Other working groups under the Consultation and Cooperation Mechanism could be established at any time should both sides so decide.

5. Contact points

Each side will set up one contact point to liaise on the practical arrangements for organising the meetings, to focus on exchanging information related to the Mechanism and to answer questions about them.

On the European Commission side, units responsible for issues related to "Pharmaceuticals", "Medical Devices" and "Cosmetics" of the Directorate-General for Health and Consumers,

On the Chinese side, Division of European, Asian and African Affairs of the Department of International Cooperation of the State Food and Drug Administration.

6. Costs

Each side will be responsible for bearing its own costs, including international and domestic travel and accommodation costs. The respective host should offer appropriate support and assistance to the visiting delegation.

7. Minutes

Minutes will be written in both English and Chinese after each session of the annual meeting.

Signed on the 26th day of October, 2010, at Shanghai in the English and Chinese languages.

Paula Fern Coff 王 澍

**For the Directorate-General for
Health and Consumers**

**For the State Food and Drug
Administration**