

**Memorandum of Understanding
between
the Ministry of Health, Labour and Welfare of Japan
and
the State Food and Drug Administration of the People's Republic of China
regarding
Framework for Dialogue and Cooperation***

1. Principle

The Ministry of Health, Labour and Welfare of Japan and the State Food and Drug Administration of the People's Republic of China (hereinafter referred to as "both sides") agree to establish a framework of dialogue and cooperation (hereinafter referred to as "the Framework"), in order to promote exchange of information, mutual understanding, and cooperation pertinent to pharmaceuticals, medical devices, cosmetics, and relevant administrative and regulatory matters over which they have jurisdiction.

Both sides confirm the following understanding on the Framework.

2. Purpose

Both sides believe that the Framework will build trust and contribute to promoting mutual understanding and cooperation in areas of pharmaceuticals, medical devices, and cosmetics, to secure the safety and health of the consumers in Japan and the People's Republic of China.

Both sides actively conduct constructive dialogue on laws and regulations pertinent to pharmaceuticals, medical devices and cosmetics, as well as other pertinent matters. The Framework deals with existing and future relevant laws and regulations in Japan and the People's Republic of China, as well as management and progressive implementation thereof.

Both sides, furthermore, intend to contribute to the continuing relationship between Japan and the People's Republic of China in areas of pharmaceuticals, medical devices and cosmetics in accordance with their international responsibilities.

3. Procedures

Both sides agree to hold a meeting once a year, to discuss major topics related to the laws and regulations pertinent to pharmaceuticals, medical devices and cosmetics, to make comparative analysis of the differences in the laws and regulations of both countries, to consider possible cooperation in areas of regulatory harmonization and promulgation of standards, and to adopt an annual plan for the following year.

** This English document has been translated by the Pharmaceuticals and Medical Devices Agency from the Japanese original Memorandum of Understanding for reference purposes only. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

The annual meetings are held alternately in Japan and the People's Republic of China. The languages for use are Japanese and Chinese.

4. Creation of Working Group

Creation of a Working Group (hereinafter referred to as "WG") is determined in the annual meeting. Each WG is responsible for developing and implementing its work plan, and undertakes it with agreement of both sides at the annual meeting.

Both sides agree on forming two WGs: one for "Pharmaceuticals" and the other for "Medical Devices." Creation of other WGs may be considered, as necessary, with agreement of both sides.

Both sides put forth their very best efforts to ensure the efficiency of WGs' work. If deemed necessary and agreed upon, both sides may invite representatives of appropriate level from the relevant industries to WGs, depending on the agenda.

5. Points of Contacts

Each of both sides establishes its point of contact in order to communicate with the other side for the preparation of the annual meetings, to exchange information on the Framework intensively, and to reply to relevant inquiries.

The Japanese point of contact is Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare of Japan.

The Chinese point of contact is Division of European, Asian and African Affairs, Department of International Cooperation, the State Food and Drug Administration of the People's Republic of China.

6. Expenses

Both sides are each responsible for defraying any of their necessary expenses incurred in relation to the Framework including travel and accommodation costs spent within and outside of their country. The side that hosts the annual meeting provides appropriate support to the delegation of the other side.

7. Minutes

The minutes of the annual meetings are drawn up in the Japanese and the Chinese languages after the meetings.

8. Modification of Memorandum of Understanding

Both sides may modify the contents of this Memorandum of Understanding, as necessary, at the annual meeting.

Signed at Tokyo and Beijing in January 2009 in two original copies: one in the Japanese language and the other in the Chinese language.
Each text being equally authentic.

For and on behalf of
the Ministry of Health, Labour and
Welfare of Japan

Erikawa, Takeshi
Administrative Vice-Minister of the
Ministry of Health, Labour and
Welfare of Japan

For and on behalf of
the State Food and Drug Administration
of the People's Republic of China

Shao Mingli
Commissioner of the State Food and
Drug Administration of the People's
Republic of China