



MEMORANDUM OF UNDERSTANDING
BETWEEN
THE HEALTH CARE INSPECTORATE OF
THE KINGDOM OF THE NETHERLANDS
AND
THE STATE FOOD AND DRUG ADMINISTRATION OF
THE PEOPLE'S REPUBLIC OF CHINA

The Health Care Inspectorate of the Kingdom of the Netherlands (hereafter named IGZ) and the State Food and Drug Administration of the People's Republic of China (hereafter named SFDA), hereafter referred to as Party of Parties, desiring to enhance cooperation in the field of regulation on medicines (including pharmaceutical products, biologic products and Traditional Chinese medicines) and medical devices, through amicable negotiation, have set out the following understanding which they have jointly agreed:

Purpose

The purpose of this MOU is to establish a mechanism of cooperation under which the Parties, in accordance with their respective laws and regulations and on the basis of equality and reciprocity, facilitate the exchange and cooperation in the field of regulation on medicines and medical devices between the states of the Parties.

Areas of Cooperation

The main possible areas on which the participants have agreed to cooperate are set out below. These areas are not exclusive and are not intended to exclude other areas from cooperation.

- i. Exchange of information on laws and regulations regarding medicines and medical devices;
- ii. Exchange of safety information regarding medicines and medical devices;



- iii. Exchange and cooperation regarding GLP, GCP and GMP inspections;
- iv. Cooperation on drug standards;
- v. Discussions on sharing information about the materials used in Traditional Chinese and herbal products, including the authentication of reference materials;
- vi. Collaboration on detection of and enforcement against counterfeit and substandard health care products;
- vii. Other areas agreed by the Parties.

Activities

Under the framework of this MOU, the Parties may arrange senior official meetings, exchange of visits at working level, training of staff, information sharing and other specific activities.

Expenditure

The Parties will meet their own costs for activities under this MOU. In principle, each Party is responsible for the expenses of its staff on any relevant visits.

Confidentiality

Any information shared by the Parties, under this MOU shall, in so far as it is possible in accordance with their respective national laws, be treated as confidential. Where information is required to be shared under national legislation, the Party concerned will give notice to the other Party and take all measures open to it to protect it from disclosure.

Amendments

Any change to this MOU shall be made by mutual consent of the Parties.

Disputes

Any dispute between the Parties concerning the implementation and interpretation of



the MOU shall be settled amicably through bilateral consultations and negotiations.

Supplementary Provisions

This MOU shall come into effect on the date of its signature and will remain in force for a period of three years unless ended earlier by either Party.

Signed at The Hague, on the 19th of April 2012, in duplicate in the English and Chinese languages, both texts being equally authentic.

Gerrit van der Wal
Inspector-General
Dutch Healthcare Inspectorate
The Kingdom of the Netherlands

Yu Xiancheng
Deputy Commissioner
State Food and Drug Administration
The People's Republic of China