MEMORANDUM OF UNDERSTANDING

BETWEEN

THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS OF THE REPUBLIC OF POLAND

AND

CHINA FOOD AND DRUG ADMINISTRATION OF THE PEOPLE'S REPUBLIC OF CHINA

ON REGULATORY COOPERATION IN MEDICINAL PRODUCTS AND MEDICAL DEVICES

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland ("URPLWMiPB") and China Food and Drug Administration of the People's Republic of China ("CFDA") (hereinafter referred to as "the Parties"), desiring to further enhance the cooperation in the field of regulation on medicinal products and medical devices, through amicable negotiation, have agreed to the following:

Article I Purpose

The purpose of this Memorandum of Understanding ("MoU") is to establish a mechanism of cooperation under which the Parties, in accordance with respective laws and regulations and on the basis of equality and reciprocity, facilitate the exchange and cooperation in the field of medicinal products and medical devices regulation between the two countries, so as to enhance their capacity of safeguarding public health.

Article II Basic Principles

1. The Parties will:
    1) endeavour to exchange information on the areas of cooperation;
    2) establish and expand partnership in carrying out cooperative activities provided for in Article 3, based on the principles of mutual interest and respect;
    3) discuss opinions on a regular basis concerning areas in need of cooperation between the Parties including *inter alia* teleconferences, exchange of experts and study visits and bilateral meetings.
2. Except that each Party will observe their confidentiality obligations, this MoU is not intended to create any legal obligations on either Party under national or international law.
3. This MoU will not modify existing cooperative activities nor will it preclude entering into separate arrangements for special programs that can be handled more efficiently and expeditiously by such arrangements.
4. Nothing in this MoU is intended to diminish or otherwise affect the authority of either Party in carrying out its regulatory responsibilities.

Article III Areas of Cooperation

The Parties of this MoU agree to conduct cooperation and exchange mainly in, but not limited to, the following areas:

1) exchange of knowledge and experience in scope of market authorization, safety monitoring and medicinal products efficacy monitoring as well as clinical trials;
2) mutual support in scope of a fast and full access to legal regulations and technical requirements in scope of clinical trials, medicinal products registration and surveillance of their safety of use, and traditional herbal medicinal products regulation on the territory of the Republic of Poland and the People's Republic of China;
3) exchange of knowledge and experience on requirements regarding assessment of documentation in the process of marketing authorization of medicinal products for human use, immunological, biological products and blood-derivates;
4) exchange of information on medicines, including traditional herbal medicinal products, and pharmaceutical raw materials used in the manufacturing process of pharmaceuticals;
5) information sharing in scope of drug clinical trials;

6) strengthening exchange of regulations on adverse drug reaction (ADR) reporting and monitoring, enhancing exchange and cooperation of monitoring and analysis of ADRs, and promoting communication and exchange of ADR monitoring information, especially serious adverse events;

7) Information exchange and cooperation on supervision of medical devices:

   a) Exchange of information on organization and structure of market surveillance;

   b) Exchange of information on medical devices manufactured on territories of the parties and being imported on the territories of Parties;

   c) Enhancing collaboration and information sharing on non-complying medical devices;

8) promotion of the establishment of cooperation between stakeholders associations active in the scope relevant to the CFDA and URPLWMiPB's responsibilities;

9) other areas for cooperation agreed by both parties.

Article IV Activities

Under the framework of this MoU, the Parties shall designate contact points, who will coordinate and arrange senior official meetings, study visits, staff training, information sharing and other specific activities.

Article V Expenditure

Activities conducted by the Parties under this MoU are subject to the budget of each Party. In principle, each Party is responsible for its own expenditure for relevant activities.

Article VI 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.

Article VII Amendments

The alterations and amendments to this MoU shall be made by written consent of the Parties.

Article VIII Disputes

Any dispute between the Parties concerning the implementation and interpretation of this MoU shall be settled amicably through consultations and negotiations.

Article IX Supplementary Provisions

This MoU shall enter into force on the date of its signature and remains in force for a period of five years, unless any Party informs the other Party of its intent to terminate this MoU in writing six month in advance.

Signed in duplicate in Warsaw on the 4th day of November, 2013 in the Polish, English and Chinese languages, all three texts being equally authentic. In case of any divergence of interpretation, the English text shall prevail.

FOR THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS OF THE REPUBLIC OF POLAND

FOR CHINA FOOD AND DRUG ADMINISTRATION OF THE PEOPLE'S REPUBLIC OF CHINA