Memorandum of Understanding
On Cooperation in the Field of Pharmaceutical Products and Medical Devices
Between
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland
And
The Ministry of Food and Drug Safety of the Republic of the Republic Korea

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland (hereinafter referred to as the "URPLWMiPB") and the Ministry of Food and Drug Safety of the Republic of Korea (hereinafter referred to as the "MFDS"), (hereinafter referred to as "the Parties"),

AFFIRMING their wish to promote cooperation between the two countries in the field of the pharmaceutical products and medical devices,

STATING their commitment to support joint efforts to provide efficient and safe pharmaceutical products and medical devices to their respective populations,

SHARING the objective of developing knowledge on pharmaceutical products and medical devices for human use, and

RECOGNISING the need to strengthen the effective exchange of knowledge and experience between Polish and Korean experts,

Have reached the following understanding:

Paragraph 1 Purpose

The Parties share the common goal of protecting the public health in the Republic of Poland and the Republic of Korea by ensuring the safety, quality and efficacy of the pharmaceutical products and medical devices manufactured in, imported into, and exported from, their respective countries.

Paragraph 2 Basic Principles

1. The Parties will:
   (a) exchange information on the areas of cooperation;
   (b) establish and expand a concrete partnership to carry out the cooperative activities provided for in Paragraph 3, based on the principles of mutual interest and respect;
   and
   (c) discuss opinions on a regular basis concerning areas in need of cooperation between the Parties including, inter alia, teleconferences, exchanges of experts and study visits and bilateral meetings.

2. This Memorandum of Understanding (hereinafter referred to as the "MOU") is not intended to create any legal obligations under domestic or international law.

3. Nothing in this MOU is intended to diminish or otherwise affect the authority of either Party in carrying out its regulatory responsibilities.

Paragraph 3 Areas of Cooperation

1. The Parties will:
   (a) exchange knowledge and experience in the field of the marketing authorization and post marketing surveillance of pharmaceutical products;

(b) provide mutual support with respect to a fast and full access to legislation, marketing authorization and post marketing surveillance of pharmaceutical products including herbal medicinal products, in the territories of the Republic of Poland and the Republic of Korea;

(c) exchange information on documentation requirements for the marketing authorization of pharmaceutical and biological products for human use;

(d) exchange information on pharmaceutical products, including herbal medicinal products, and raw materials used in the manufacturing of pharmaceuticals;

(e) exchange information regarding the withdrawal of pharmaceutical product marketing authorization for products known by the MFDS to have been manufactured in the Republic of Poland, or known by the URPLWMiPB to have been manufactured in the Republic of Korea;

(f) exchange information and cooperate in the field of pharmacovigilance and post marketing surveillance of pharmaceutical products, especially regarding new serious adverse events;

(g) exchange information regarding legislation, recommendations and guidelines in related to the reporting and surveillance of adverse events and the assessment of reports;

(h) exchange information related to pharmaceutical products shortages and provide mutual support to counteract these shortages;

(i) exchange information and cooperate in the field of medical devices surveillance, particularly with respect to:

(i) organization and surveillance structure of the market of medical devices;
(ii) medical devices imported into both countries;
(iii) cooperation and exchange of information regarding medical devices noncompliant with the relevant requirements; and
(iv) exchange of information regarding adverse events related to medical devices;

(j) assist marketing authorization holders from both countries by providing them with timely and comprehensive information on the legal provisions governing the marketing authorization and pharmacovigilance of pharmaceutical products in both countries;

(k) promote the establishment of cooperation between associations active in the fields relevant to the Parties' responsibilities;

(l) exchange information regarding international harmonization activities in the field of pharmaceutical products and medical devices; and

(m) exchange information on the relevant laws, regulations and standards of each country related to clinical trials.

2. Where either Party recognizes the need for any on-site inspection of an establishment located in the other Party's country in relation to any safety issues relevant to the cooperation under this MOU, the Parties will cooperate to facilitate such on-site inspections.

3. Collaborative activities may include the planning of joint symposia, workshops, conferences and/or the offering of joint training courses for the mutual benefit of both Parties subject to the availability of the funds and resources of each Party.

Paragraph 4 Working-level Consultation Meetings

1. Working-level Consultation Meetings will be held annually, alternately in the Republic of Poland and the Republic of Korea.

2. The co-chairs heads of the Working-level Consultation Meetings will be appointed by the heads of the two Parties.

3. Where deemed necessary for the implementation of this MOU, the Working-level Consultation Meetings may involve private experts or stakeholders from the industry with the mutual consent of the Parties.

4. The composition and agenda of the Working-level Consultation Meetings will be jointly decided upon by the Parties in advance.

5. The Parties will designate their respective contact points to ensure the efficient operation of the Working-level Consultation Meetings.

Paragraph 5 Financial Arrangements

1. Each Party will bear its own costs in relation to the cooperative activities under this MOU.

2. The costs of any assistance provided by either Party at the request of the other will be borne by the requesting Party, unless otherwise jointly decided by the Parties.

Paragraph 6 Release of Information

1. Neither Party will disclose or distribute to a third party any confidential information provided by the other Party in the process of cooperative activities under this MOU, except as and to the extent authorized in writing to do so by the providing Party.

2. Before either Party receives any confidential information from the other Party, the receiving Party will, if so requested by the providing Party, give the providing Party a written guarantee that it will protect the confidentiality of the information to be provided.

3. Any confidential information to be exchanged between the Parties will be clearly identified as confidential.

Paragraph 7 Resolution of Disputes

Any disputes arising from interpretation and/or implementation of this MOU will be resolved amicably through consultations between the Parties.

Paragraph 8 Validity and Termination

1. This MOU will come into effect on the date of its signature and will remain effective for a period of five (5) years. It will be automatically renewed for successive periods of five (5) years, unless either Party notifies the other in writing of its intention to terminate the MOU six (6) months in advance.

2. This MOU may be amended with the mutual written consent of the Parties.

3. The termination of this MOU will not affect the duration or validity of any cooperative activities under this MOU which are in progress at the time of the notification of the termination of this MOU, unless otherwise jointly decided by the Parties.

Signed in duplicate in Osong, Republic of Korea, on June 5, 2013, in the Polish, Korean and English languages, each text being equally valid. In case of any divergence of interpretation, the English text will prevail.

For the
Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland

For the
Ministry of Food and Drug Safety of the Republic of Korea

Chung Seung