Memorandum of Understanding
Between
The Korea Food and Drug Administration of the Republic of Korea
And
The Health Sciences Authority of Singapore
Regarding the Safety of Pharmaceutical Products, Cosmetics and Medical Devices

The Korea Food and Drug Administration of the Republic of Korea ("KFDA") and the Health Sciences Authority of Singapore ("HSA") (hereinafter referred to as "the Sides"),

Recognizing the mutual benefits of enhancing cooperation for the sharing of information and experience with respect to the regulation and safety of pharmaceutical products (including herbal medicinal products and quasi drugs), cosmetics and medical devices (hereinafter referred to as "the subject of cooperation") on the basis of equality, reciprocity and mutual benefit, and

Hoping to work together and share information on the regulation, approval, standards, import and export, and safety of the subject of cooperation.

Have reached the following understanding:

Paragraph 1 Background

The Sides share the common goal of protecting the public health of the Republic of Korea and Singapore by ensuring the safety, quality and efficacy of the subject of cooperation manufactured in, imported into, and exported from, the two respective countries.

Paragraph 2 Basic Principles

1. The Sides will:

a. endeavor to exchange information on the regulation, approval, standards, import and export, and safety of the subject 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, on a regular basis, areas in need of cooperation through meetings and the exchange of personnel.

2. This Memorandum of Understanding ("MOU") is not intended to create any legally binding obligations on either Side under domestic or international law.

3. This MOU will not affect existing cooperative activities nor will it preclude the entering into of 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 Side in carrying out its regulatory responsibilities.

Paragraph 3 Areas of Cooperation

1. The types of information and documentation that may be exchanged on a voluntary basis include the following:

a. information regarding the regulation, regulatory approval and other relevant policies related to the subject of cooperation;

b. guidance documents, policies, procedures and other technical documents related to the subject of cooperation for which the Sides have responsibility;

c. at the request of the other Side, information that could have an impact on public health;

d. at the request of the other Side, to the extent possible, information on quality

defects or product recalls of the subject of cooperation known by the KFDA to have been manufactured or distributed in Singapore, or of the subject of cooperation known by the HSA to have been manufactured or distributed in the Republic of Korea;

e. a list of designated clinical trial laboratories operating in each country and information on the procedures for such designation; and

f. information on international harmonization activities related to the regulation of the subject of cooperation.

2. Where either Side recognizes the need for an on-site inspection in the other Side's country in relation to any safety issues related to the subject of cooperation, the Sides will cooperate to facilitate such on-site inspection.

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

Paragraph 4 High-level Consultations

1. The Sides will establish consultations between their high-level officials (hereinafter referred to as "High-level Consultations") to promote and discuss cooperative activities under this MOU.

2. The High-level Consultations will be chaired by the Deputy Commissioner of the KFDA and the Chief Executive Officer (CEO) of the HSA, or any senior official(s) appointed by the respective Chairpersons.

3. The High-level Consultations will be held annually, either face-to-face alternately in the Republic of Korea and Singapore, or through tele- or video-conferencing, unless otherwise decided by the Sides.

4. Working-level Consultations, as set out in Paragraph 5, may be established to support the High-level Consultations and to achieve substantive cooperation in each area. The Working-level Consultations will be in operation in accordance with the High-level Consultations.

5. The composition and agenda for the High-level Consultations will be decided upon by the Sides in advance.

6. Each Side will designate contact points to ensure the efficient operation of the High-level Consultations.

Paragraph 5 Working-level Consultations

1. The Sides will hold Working-level Consultations, which will be divided into specialized areas, with the aim of assisting the High-level Consultations.

2. The Working-level Consultations will be held annually, either face-to-face alternately in the Republic of Korea and Singapore, or through tele- or video-conferencing.

3. The heads of the Working-level Consultations will be officials at the Director level from each Side, unless otherwise decided by the Sides.

4. Where deemed necessary, the Working-level Consultations may involve private experts or stakeholders in the industry, with the mutual consent of the Sides.

5. The composition and agenda for each area of the Working-level Consultations will be decided upon by the Sides in advance.

6. Each Side will designate contact points to ensure the efficient operation of the Working-level Consultations.

Paragraph 6 Financial Arrangements

1. Each Side will bear its own costs arising from cooperative activities under this MOU.

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

Paragraph 7 Release of Information

1. Neither Side may disclose or distribute to any third party any confidential information transmitted by the other Side ("the disclosing Side") in the process of cooperative activities under this MOU, except as and to the extent authorized in writing to do so by the disclosing Side.

2. Before one Side ("the receiving Side") receives any confidential information from the disclosing Side, the receiving Side will, if so requested by the disclosing Side, provide the disclosing Side with a written guarantee that it will protect the confidentiality of the information to be disclosed.

Paragraph 8 Resolution of Disputes

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

Paragraph 9 Validity and Termination

1. This MOU will come into effect on the date of its signature and will remain in effect for a period of five years. It will be automatically renewed for successive periods of five years, unless one Side notifies the other Side in writing of its intention to terminate this MOU, at

least six (6) months in advance.

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

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.

Signed in duplicate in Singapore, on June 5, 2010, in the Korean and English languages, each version being equally valid. In case of any divergence of interpretation, the English text will prevail.

For the
Korea Food and Drug Administration of
The Republic of Korea

Noh Yunhong

Mr Noh Yun-hong
Commissioner

For the
Health Sciences Authority of
Singapore

Dr John C W Lim
Chief Executive Officer