ANNEX 8C: SECTORAL ANNEX ON GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS

Pursuant to Chapter 8 (Technical Barriers to Trade and Mutual Recognition), the Parties agree to this Sectoral Annex on Good Manufacturing Practice for Medicinal Products.

Section 1 Scope and Definitions

1. This Sectoral Annex applies to the conformity assessment requirements for Good Manufacturing Practice for investigational medicinal products, active pharmaceutical ingredients, chemical pharmaceuticals, biopharmaceuticals (including biologicals) or herbal medicinal products as listed in Table I, which are subject to Good Manufacturing Practice requirements and the conformity assessment procedures as listed in Table II. This Sectoral Annex shall not apply to medicinal products which are not subject to conformity assessment requirements for Good Manufacturing Practice by either Party.

2. For the purposes of this Sectoral Annex:

a. through membership in the Pharmaceutical Inspection Co-operation Scheme (hereinafter referred to as the "PIC/S"), each Party shall assume the Good Manufacturing Practice control system and its enforcement by the other Party to be equivalent;

b. "Competent Authority" means:

i. for Korea, the Ministry of Food and Drug Safety (MFDS); and

ii. for Singapore, the Health Sciences Authority (HSA);

c. “Good Manufacturing Practice” (hereinafter referred to as “GMP”) means the part of quality assurance which ensures that medicinal products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the marketing authorisation and product specifications;

d. “inspection report” means a report, based on the PIC/S format, assessing the compliance of a manufacturing site in relation to the GMP standards based on an inspection by the Competent Authority of a Party. It contains, in particular, the inspectors’ observations, a brief summary of the findings, recommendations, if applicable, and conclusions regarding the compliance of the manufacturing site with GMP; and

e. “mandatory requirements” means the applicable laws, regulations and administrative provisions listed in Table I and Table II.

Section 2 Obligations

1. Korea shall accept, as part of the GMP conformity assessment procedure of a manufacturer, GMP certificates issued by Singapore’s Competent Authority, or, in the event that a GMP certificate is unavailable at the time of assessment, a certificate in accordance with paragraph 5 of Section 2 of this Sectoral Annex.

2. Singapore shall accept, as part of the GMP conformity assessment procedure of a manufacturer, GMP certificates issued by Korea’s Competent Authority, or, in the event that a GMP certificate is unavailable at the time of assessment, a certificate in accordance with paragraph 5 of Section 2 of this Sectoral Annex.

3. At the request of an importer, exporter, or the Competent Authority of a Party, the Competent Authority of the other Party shall assess and certify that the manufacturer:

a. is appropriately authorised to manufacture the relevant categories of medicinal products, or to carry out the relevant specified manufacturing operation;

b. is subject to regular inspections by the Competent Authority of that Party, indicating the date of the last inspection; and

c. complies with the GMP of the PIC/S.

4. The GMP certificate shall be issued within thirty (30) calendar days from the request mentioned in paragraph 3. In exceptional circumstances, *inter alia*, if a new inspection has to be undertaken prior to issuing a GMP certificate, the time limit of thirty (30) calendar days shall commence from the conclusion of the inspection and may be extended to sixty (60) calendar days.

5. The format of the certificate is attached as Appendix 1 and may be modified upon the agreement of the Parties.

Section 3 Exchange of Information

1. At the request of the Competent Authority of a Party, the Competent Authorities of both Parties shall, within sixty (60) calendar days, exchange GMP compliance information (e.g., inspection reports) unless the inspected manufacturer disagrees. The requesting Competent Authority shall justify such requests, and the GMP compliance information shall be used exclusively by the requesting Competent Authority for the purpose of this Sectoral Annex.

2. The Competent Authority of a Party may request an extension of the sixty (60) calendar days' time limit to submit the requested GMP compliance information. If the request is duly justified, the Competent Authority of the other Party shall allow for an extension for a mutually agreed period.

3. The requested GMP compliance information shall be provided in English.

4. The Competent Authority of a Party shall notify the Competent Authority of the other Party of any scheduled significant changes in its mandatory requirements for GMP whenever they are made. The Competent Authority of the former Party shall notify the Competent Authority of the latter Party of the changes at least sixty (60) calendar days before the changes enter into force, except where considerations of health or safety warrant more urgent action.

Section 4 Safeguard Clause for Inspections

1. The Competent Authority of a Party may request the right to conduct its own inspections of manufacturing sites located in the territory of the other Party. The requesting Party shall justify such inspections in advance to the other Party.

2. Such inspections may be observed by the other Party. The Parties may agree on joint inspections.

3. This safeguard clause shall only be exercised in exceptional circumstances for the purpose of health and safety.

Section 5 Confidentiality

The Parties shall treat all information exchanged under this Sectoral Annex as confidential, unless otherwise agreed by the Parties.

Section 6 Contact Points

1. For the purpose of this Sectoral Annex, the contact points for any technical question and the exchange of GMP compliance information (e.g., GMP certificates and inspection reports) shall be:

For Korea:
Division Director, Pharmaceutical Quality Division
Pharmaceutical Safety Bureau
Ministry of Food and Drug Safety
Email: gmpkorea@korea.kr

For Singapore:
Division Director, Audit and Licensing Division
Health Products Regulation Group
Health Sciences Authority
Email: hsa_gmp@hsa.gov.sg

2. The Parties shall notify each other of any significant changes to their contact points when necessary.

Section 7 Entry into Force

This Sectoral Annex shall enter into force on the first day of the second month following the date on which the Parties have exchanged notes confirming the completion of their respective domestic legal procedures for the entry into force of this Sectoral Annex.

TABLE I

APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING PRODUCTS COVERED BY THIS SECTORAL ANNEX

Republic of Korea	Republic of Singapore
Pharmaceutical Affairs Act (No. 300, 1953) and amendments thereto.	1. Health Products Act 2007 and amendments thereto, 2. Medicines Act 1975 and amendments thereto.

TABLE II

APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE REQUIREMENTS AND THE CONFORMITY ASSESSMENT PROCEDURES

Republic of Korea	Republic of Singapore
1. Pharmaceutical Affairs Act (No. 300, 1953) and amendments thereto, 2. Regulation on Safety of Medicinal Products, etc. (No. 1022, 2013) and amendments thereto, 3. Regulation on Good Manufacturing Practices (GMP) for Medicinal Products (2015-35) and amendments thereto.	1. Health Products Act 2007 and amendments thereto, 2. Health Products (Therapeutic Products) Regulations 2016 and amendments thereto, 3. Medicines Act 1975 and amendments thereto, 4. Medicines (Good Manufacturing Practice Certificate) Regulations 2002 and amendments thereto.

APPENDIX 1

(Letterhead of Competent Authority)

Certificate No: _ _ _/_ _ _/_ _

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ISSUED UNDER THE PROVISIONS OF THE SECTORAL ANNEX 8C OF THE FREE TRADE AGREEMENT BETWEEN THE GOVERNMENT OF THE REPUBLIC OF KOREA AND THE GOVERNMENT OF THE REPUBLIC OF SINGAPORE

As requested by ……..……..…… on …/…/… *(date)*, the Competent Authority of …….....…… *(Country)* confirms the following:

The company ……., whose legally registered address is:
…….
…….

has been authorised, in accordance with ……..,

under the authorisation reference number ……..., covering the following site(s) of manufacture:

1. …….
2. …….

to carry out the following manufacturing operations:
+ complete manufacture, or
+ partial manufacture*

in the following dosage forms/product types (see attached list of categories):

……

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on …/…/… *(date)*, it is considered that the company complies with the mandatory Good Manufacturing Practice requirements referred to in the Sectoral Annex on Good Manufacturing Practice for Medicinal Products of the Free Trade Agreement between the Government of the Republic of Korea and the Government of the Republic of Singapore.

This certificate remains valid for three years from the date of last inspection.

…/…/… *(date)*

Name and signature of a responsible officer
of the Competent Authority of *(country)*
…….
(name)
(title)
(national authority)
(phone and fax numbers)

(* delete that which does not apply)