AGREEMENT ON MUTUAL RELIANCE ON INSPECTION RESULTS OF GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS

BETWEEN

THE GOVERNMENT OF THE REPUBLIC OF KOREA

AND

THE SWISS FEDERAL COUNCIL

PREAMBLE

The Government of the Republic of Korea and the Swiss Federal Council, hereinafter individually referred to as a "Party" or collectively as "the Partics";

In consideration of the Free Trade Agreement of 15 December 2005 between the Republic of Korea and the European Free Trade Association (EFTA) States and the Memorandum of Understanding of 20 January 2014 between the Ministry of Food and Drug Safety of the Republic of Korea and the Federal Department of Home Affairs of the Swiss Confederation concerning cooperation in the regulation of therapeutic products;

Recognising that the strengthening of cooperation reduces barriers to trade and produces mutual benefits for the Republic of Korea and Switzerland;

Mindful that reducing, wherever possible, unnecessary costs associated with trade between the Republic of Korea and Switzerland will encourage further trade;

Desiring to facilitate market access and further the implementation of the WTO Agreement on Technical Barriers to Trade;

Reaffirming the importance of international standards to enhance trade and to ensure the high quality of production as well as integrity in a globalised supply chain for medicinal products;

Acknowledging the importance of the establishment and enforcement of internationally recognised Good Manufacturing Practice (GMP) standards on all manufacturing sites involved in the production of medicinal products; and

Taking into account the positive outcome of the pilot project on GMP between the competent authorities of the Parties;

Have reached the following Agreement on mutual reliance on GMP inspection results for medicinal products:

/ ARTICLE 1

ARTICLE 1
Scope and Definitions

1. This Agreement applies to all medicinal products for human use industrially manufactured in the Republic of Korea or in Switzerland, including investigational medicinal products (IMP), active pharmaceutical ingredients (API), chemical pharmaceuticals, biopharmaceuticals (including biologicals) or herbal medicinal products, and to which GMP requirements apply.

2. For the purposes of this Agreement:
   (a) "GMP standards" mean internationally recognised standards by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), reflecting the state of the art of quality assurance which ensures that medicinal products are consistently produced and controlled;
   (b) "GMP 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. It contains, in particular, the inspectors' observations, a brief summary of the findings, recommendations, if applicable, and conclusions regarding the GMP status of the inspected site;
   (c) "competent authority" means:
   (i) for the Republic of Korea, the Ministry of Food and Drug Safety (MFDS);
   (ii) for Switzerland, the Swiss Agency for Therapeutic Products (Swissmedic).

ARTICLE 2
Objectives

The objectives of this Agreement are to:
   (a) promote an understanding between the Parties of each other's GMP control system and GMP enforcement;
   (b) facilitate the exchange of information and documentation relating to GMP inspections between the competent authorities;
   (c) enable each competent authority to rely on the GMP inspection results of the other competent authority.

/ ARTICLE 3

ARTICLE 3
Equivalence

Through membership in PIC/S, the Parties shall assume the GMP control system and GMP enforcement of the other Party to be equivalent to the PIC/S standards for GMP inspectorates.

ARTICLE 4
Reliance on GMP Certificates

1. Following equivalence of a Party's GMP control system and GMP enforcement in accordance with Article 3, a Party shall rely, in particular as part of the GMP conformity assessment procedure of a manufacturing site, on the GMP Certificates of the other Party.

2. Upon request of the competent authority of a Party, the competent authority of the other Party responsible for granting manufacturing authorisations and for supervising the manufacturer of medicinal products shall certify that the manufacturer:

(a) is appropriately authorised to manufacture the relevant categories of medicinal products, or to carry out the relevant specified manufacturing operations;

(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 current PIC/S GMP standards.

3. The certificates shall be issued within 30 days from the request. In exceptional circumstances, inter alia, if a new inspection has to be undertaken prior to issuing a certificate, the time-limit of 30 days shall commence from the conclusion of the inspection and may be extended to 60 days.

ARTICLE 5
Exchange of GMP Data

1. Upon request of the competent authority of a Party and for use exclusively for / the purposes

the purposes of this Agreement and by this authority, the competent authorities of the Parties shall, within 60 days, exchange GMP inspection reports and the related Corrective Action Preventive Action (CAPA) Plan, unless the inspected manufacturer disagrees. The requesting competent authority should justify such request.

2. The competent authority of a Party may request an extension of the 60 day time limit to submit the requested GMP data.

ARTICLE 6
Safeguard Clause for Inspections

1. Either Party may request the right to conduct its own inspections of manufacturing sites in the other Party. The inspecting Party shall justify such inspections in advance to the inspected Party.

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

ARTICLE 7
Confidentiality

The Parties shall treat as confidential information submitted by the other Party which that Party has designated as confidential.

ARTICLE 8
Contact Points

1. The Parties shall exchange names and addresses of contact points for matters related to this Agreement, in order to facilitate communication and the exchange of information, such as exchange of inspection reports or technical requirements.

2. The Parties shall notify each other of any significant changes in the structures and responsibilities of the authorities acting as contact points.

/ ARTICLE 9

ARTICLE 9
Consultations

The Parties shall endeavour to resolve disputes concerning the application and interpretation of this Agreement through consultations.

ARTICLE 10
Amendment

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

ARTICLE 11
Entry into Force

After signing this Agreement, the Parties shall notify each other when their domestic requirements for the entry into force of this Agreement have been complied with. This Agreement shall enter into force on the date of receipt of the later notification.

ARTICLE 12
Termination

Either Party may terminate this Agreement by means of a written notification to the other Party. This Agreement shall expire six months after the date on which the notification is received by the other Party. Information which a Party has designated as confidential remains confidential, notwithstanding the termination of the Agreement.

IN WITNESS WHEREOF the undersigned, being duly authorised thereto, have signed this Agreement.

Done in duplicate at Bern, Switzerland, on this 18 December 2019, in the Korean, German, and English languages, all texts being equally authentic. In case of / differences in

differences in interpretation, the English text shall prevail.

For the Government of
the Republic of Korea

For the Swiss Federal Council