Ministry of Food and Drug Safety

World Health Organization

STATEMENT OF COLLABORATION ARRANGEMENT BETWEEN THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA AND THE WORLD HEALTH ORGANIZATION, ACTING THROUGH ITS DEPARTMENT OF ESSENTIAL MEDICINES AND HEATH PRODUCTS, ON COLLABORATION IN THE PREQUALIFICATION PROCESS FOR VACCINES

The Ministry of Food and Drug Safety of the Republic of Korea (MFDS) and the World Health Organization (WHO), acting through its Department of Essential Medicines and Health Products (EMP);

Desiring to collaborate in the prequalification process for vaccines;

Have reached the following understanding:

Paragraph 1

1. The MFDS states that ongoing regulatory oversight is continuously and regularly performed on the licensed vaccines listed in Annex 2 to this Collaboration Arrangement, and that such ongoing regulatory oversight will continuously and regularly be performed for any other vaccine that is or will be manufactured and has obtained or will obtain regulatory approval in the Republic of Korea, and has been or will be submitted for prequalification or has been or will be prequalified by WHO. Any vaccines as described in this paragraph 1 are hereinafter referred to as "Vaccines". Annex 2 to this Collaboration Arrangement may be updated from time to time to reflect the then current list of Vaccines.

2. The MFDS based on its regulatory system and oversight of the vaccines- is considered to be functional and in compliance with the WHO recommended functions (e.g.: licensing, lot release policy, regulatory inspections, evaluation and authorization of clinical trials, access to laboratories, testing of vaccine samples and control of adverse events following immunization and post marketing surveillance).

Paragraph 2

In relation to the Vaccines, based on the current level of functionality of MFDS, and under a confidentiality arrangement (Annex 1) signed by MFDS and WHO on 7 December 2016, MFDS will provide to the Prequalification Team of WHO/EMP, the following vaccines assessment information:

a. testing of the vaccine lots to be supplied to United Nations agencies;
b. national releases of the vaccine lots to be supplied to United Nations agencies;
c. feedback on findings during regulatory inspections;
d. updates on safety and efficacy data;
e. notifications of serious/unexpected adverse events following immunization (AEFIs) or efficacy related issues with public health implications, notifications of new safety signals, and exchange of findings;
f. variations to the marketing authorizations/licenses that have been notified or approved;
g. any quality issues that may cause the interruption of or delay to global supplies;
h. marketing authorization / license renewals or withdrawal;
i. Good Manufacturing Practices (GMP) certificate (updated); GMP inspection reports (on a case by case basis); and
j. recalls or withdrawals of lots of vaccines.

Paragraph 3

1. In accordance with the signed confidentiality arrangement referred to in Paragraph 2, the Prequalification Team of WHO/EMP will provide MFDS with the following:

a. information on the outcomes of WHO independent testing;
b. any reported quality related defects or the non-compliance of a vaccine in the field;
c. information on any lot subject to recall and/or market withdrawal;
d. notifications of serious/unexpected adverse events following immunization (AEFIs) or efficacy related issues with public health implications reported from the field, notifications of safety signals, and exchange of findings;
e. exchange of views and opinions on relevant regulatory and programmatic issues with impact on the prequalification of a vaccine (it being understood and agreed that such views and opinions are based on the information that the MFDS provides).

2. The MFDS and WHO/EMP will maintain an ongoing dialogue and collaboration regarding ways to optimize their interaction.

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Paragraph 4

This arrangement will come into effect on its last date of signature. This arrangement may be terminated by either party upon 6 (six) months' written notification to the other party.

Signed in duplicate at Geneva on 7 December 2016 in the English language.

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

Name: Mr Jinseok Kim

Title: Director General
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For the World Health Organization

Name: Dr Suzanne Hill

Title: Director
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Annex 1: Mutual confidentiality arrangement and commitment not to publicly disclose non-public information shared by and between the Ministry of Food and Drug Safety of the Republic of Korea and the World Health Organization, acting through its Department of Essential Medicines and Health Products (attached)

Annex 2: List of Vaccines:

Name of the vaccine	Non proprietary name	Date of license / Date PQ
Euvax B (1 Dose)	Hepatitis B	22/11/1996
Euvax B (2 Doses)	Hepatitis B	22/11/1996
Euvax B (6 Doses)	Hepatitis B	22/11/1996
Euvax B (10 Doses)	Hepatitis B	22/11/1996
Hepavax-Gene (10 Doses)	Hepatitis B	23/3/2004
Hepavax-Gene TF (1 Dose)	Hepatitis B	31/7/2012
GC FLU inj (1 Dose)	Influenza, seasonal	12/4/2011
GC FLU Multi inj (10 Doses)	Influenza, seasonal	7/11/2012
Green Flu-S (1 Dose)	Influenza, Pandamic H1N1	11/5/2010
Quinvaxem (1 Dose)	DTwP-HepB-Hib	26/9/2006
Euforvac-Hib Inj (1 Dose)	DTwP-HepB-Hib	24/8/2012
Euforvac-Hib Inj (2 Doses)	DTwP-HepB-Hib	24/8/2012
Eupenta (1 Dose)	DTwP-HepB-Hib	10/2/2016
Eupenta (10 Doses)	DTwP-HepB-Hib	10/2/2016
Quinvaxem MDV (5 Doses)	DTwP-HepB-Hib	29/2/2016
Quinvaxem MDV (10 Doses)	DTwP-HepB-Hib	29/2/2016
Euvichol	Cholera: inactivated oral	23/12/2015