

Memorandum of Understanding
between
the Ministry of Food and Drug Safety of the Republic of Korea and
the Indonesian Food and Drug Authority of the Republic of Indonesia
Concerning the Safety and Quality of Food and
Pharmaceutical Products

The Ministry of Food and Drug Safety (“MFDS”) of the Republic of Korea and the Indonesian Food and Drug Authority (“Indonesian FDA”) of the Republic of Indonesia (hereinafter collectively referred to as “the Sides” and individually referred to as “the Side”),

Recognizing the importance of ensuring quality and safety of food (including health functional food, health supplements), pharmaceuticals (including biological products, traditional medicines) and cosmetics to protect and promote health of their respective people;

Desiring to set up a framework for a long-term cooperation between the Sides and facilitate exchange of information, experience and visits on the basis of equality, reciprocity and mutual benefit;

Pursuant to their respective laws and regulations,

Have reached the following understanding:

1. Objective

The Sides hereby confirm their intention to promote cooperation in the area of food (including health functional food, health supplements), pharmaceuticals (including biological products, traditional medicines) and cosmetics in accordance with this Memorandum of Understanding (hereinafter referred to as “MOU”).

2. Scope of Cooperation

The Sides will promote mutual cooperation in the following areas:

- a. exchange of information on the relevant laws, regulations, standards, and administrative procedures regarding control system of food, pharmaceuticals and cosmetics;

- b. exchange of experiences, consultations and visits in the area of regulations, standards, evaluations, laboratory testing techniques;
- c. exchange of inspection or investigation results as may be requested by one of the Sides;
- d. conducting joint research in the areas of common interests in the area of drug and food control; and
- e. any other areas of cooperation that may be jointly decided upon by the Sides.

3. Confidentiality

Neither Side may disclose or distribute any confidential information received or generated under this MOU to any third party or to the public, without prior written consent of the other Side.

4. Financial Arrangement

- 1) Each Side is responsible for the administration and expenditure of its own resources associated with 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.

5. Working Level Consultations

The Sides may establish a working-level consultation or a technical panel of specialists to discuss priority areas of interests and cooperative activities under this MOU.

6. Contact Points

The Sides hereby designate the following contact points for the ongoing communication between the Sides to implement this MOU:

- for MFDS: Director of International Cooperation Office
- for Indonesian FDA: Head of Cooperation Bureau

7. Implementation

- 1) This MOU will be carried out within the framework of the respective laws, regulations, institutional guidelines and any other applicable legal provisions of each Side.
- 2) All activities conducted under this MOU shall be subject to the availability of funds and resources of the respective Sides.
- 3) This MOU shall not create any legally binding obligations or rights between the Sides under national or international laws.

8. Resolution of Difference

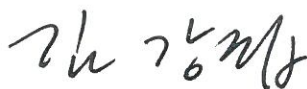
Any differences, controversies or disputes arising from the interpretation and/or implementation of this MOU will be resolved amicably through consultation between the Sides.

9. Validity, Amendment and Termination

- 1) This MOU will come into effect on the date of its signature by the Sides. It will remain effective for a period of three (3) years and will be automatically renewed for another period of three (3) years, unless either Side notifies the other Side in writing of its intention to terminate this MOU ninety (90) days in advance.
- 2) 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 termination of this MOU.
- 3) This MOU may be amended by mutual written consent of the Sides.

SIGNED in Osong and in Jakarta on Jan 28, 2021, in two original copies in the Korean, Indonesian and English languages, all texts being equally valid. In case of any divergence of interpretation, the English text will prevail.

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



Dr. Kim Ganglip
Minister

**For the Indonesian Food and Drug
Authority of the Republic of Indonesia**



Dr. Penny K. Lukito, MCP
Chairperson

대한민국 식품의약품안전처와 인도네시아 식품의약품청 간 식품 및 의료제품의 안전 및 품질에 대한 양해각서

대한민국 식품의약품안전처와 인도네시아 식품의약품청(이하 집합적으로는 '양측', 개별적으로는 '한 측'이라 함)은,

양국 국민의 건강을 보호하고 증진하기 위하여 식품(건강기능식품을 포함), 의약품(바이오의약품, 한약 및 생약제제 포함) 및 화장품의 품질과 안전확보의 중요성을 인식하며,

동등, 호혜, 상호 이익의 원칙에 입각하여 양측 간 장기적인 협력의 기틀을 마련하고, 정보, 경험의 교환과 교역의 활성화를 희망하면서,

양측의 법과 규정에 따라 다음과 같이 합의하였다.

1. 목적

양측은 이 양해각서에 따라 식품(건강기능식품을 포함), 의약품(바이오의약품, 한약 및 한약제제 포함) 및 화장품 분야에서의 협력을 촉진하고자 함을 확인한다.

2. 협력 범위

양측은 다음과 같은 분야에서 상호 협력을 제고한다.

- 1) 식품, 의약품, 화장품의 관리체계에 대한 관련 법령, 규정, 기준 및 절차에 대한 정보교환
- 2) 법령, 기준, 평가, 실험실 실험 기술에 대한 경험 공유, 자문 및 방문 교류
- 3) 한 측의 요청 시 검사 또는 점검 결과에 대한 공유
- 4) 식품 및 의약품 분야 공통 관심 사안에 대한 공동연구
- 5) 양측이 공동으로 결정하는 그 외 협력 분야

3. 비밀 유지

양측은 동 양해각서에 따라 제공받았거나 발생한 어떠한 비밀 정보도 상대 측의 서면 동의없이 제 3 자나 공공에게 누설하거나 배포할 수 없다.

4. 비용 부담

- 1) 동 양해각서에 따른 활동과 관련한 행정사항이나 소요 비용은 각 측이 책임진다.
- 2) 양측이 달리 공동으로 정하지 않는 한, 한 측의 요청에 따라 상대 측이 제공하는 지원에 대한 비용은 요청한 측이 부담한다.

5. 실무급 협의체

양측은 관심사안에 대한 우선순위 및 동 양해각서에 기반한 협력 활동 논의를 위하여 실무급 협의체 또는 전문가 기술 자문단을 설치할 수 있다.

6. 연락관

양측은 동 양해각서를 효율적으로 이행하기 위한 목적으로 양측간 지속적인 의사소통을 위하여 다음의 연락관을 지정한다.

- 식품의약품안전처 : 국제협력담당관
- 식품의약품청 : 협력담당관

7. 이행

- 1) 동 양해각서는 각 측의 법, 규정, 기관의 지침 및 기타 적용가능한 법 조항의 틀 내에서 이행된다.
- 2) 동 양해각서에 따른 모든 활동은 각측의 자금과 자원의 가용성에 따라야 한다.
- 3) 동 양해각서는 국내법 또는 국제법상의 어떠한 법적 구속력 있는 의무도 생성하지 않는다.

8. 이견의 해결

동 양해각서의 해석 및/또는 이행에서 발생하는 차이 또는 분쟁은 양측간 합의를 통해 우호적으로 해결한다.

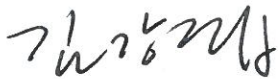
9. 유효기간, 개정 및 종료

- 1) 동 양해각서는 양측이 서명한 날부터 유효하다. 효력은 3 년간 지속되고 어느 한 측이 상대 측에 종료의사를 90 일 전에 서면으로 통보하지 않는 한 자동으로 3 년간 연장될 수 있다.
- 2) 동 양해각서의 종료는 동 양해각서의 종료가 통보된 시점에 진행 중이던 동 양해각서에 따른 어떠한 협력 활동의 기간이나 효력에 영향을 주지 않는다.
- 3) 동 양해각서는 양측의 서면 합의로 개정될 수 있다.

동 양해각서는 2021년 1월 28일 오송과 자카르타에서 각각 서명하였으며, 동등하게 정본인 한국어, 인도네시아어, 영어로 각 2 부씩 작성하였다. 해석에 대한 분쟁이 있는 경우 영어본이 우선한다.

대한민국

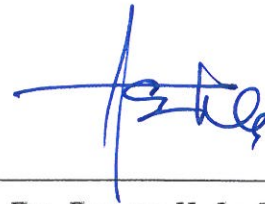
식품의약품안전처를 대표하여



처 장 김 강 립

인도네시아

식품의약품청을 대표하여



청 장 Dr. Penny K. Lukito, MCP

Memorandum Saling Pengertian
antara
Kementerian Keamanan Pangan dan Obat Republik Korea dan
Badan Pengawas Obat dan Makanan Republik Indonesia
Tentang Pengawasan Keamanan dan Mutu Produk
Pangan dan Farmasi

Kementerian Keamanan Pangan dan Obat, Republik Korea dan Badan Pengawas Obat dan Makanan (Badan POM) Republik Indonesia (selanjutnya secara kolektif disebut “Para Pihak” dan secara individu disebut “Pihak”).

Menyadari pentingnya penjaminan mutu dan keamanan pangan (termasuk pangan fungsional kesehatan, suplemen kesehatan), obat (termasuk produk biologi dan obat tradisional) dan kosmetik untuk melindungi dan meningkatkan kesehatan masyarakat;

Menginginkan kerja sama jangka panjang antara Para Pihak dan memfasilitasi pertukaran informasi, pengalaman dan kunjungan yang berlandaskan asas kesetaraan, timbal balik dan saling menguntungkan;

Berdasarkan hukum dan peraturan masing-masing;

Telah mencapai kesepakatan sebagai berikut:

1. Tujuan

Para Pihak dengan ini mengkonfirmasi keinginannya untuk mempromosikan kerja sama di bidang pangan (termasuk pangan fungsional kesehatan, suplemen kesehatan), obat (termasuk produk biologi dan obat tradisional) dan kosmetik sesuai dengan Memorandum Saling Pengertian ini (selanjutnya disebut “MSP”).

2. Bidang Kerja Sama

Para Pihak akan mempromosikan kerja sama yang saling menguntungkan di bidang-bidang berikut:

- a. pertukaran informasi tentang hukum, peraturan, standar, dan prosedur administrasi yang relevan terkait sistem pengawasan pangan, obat-obatan, dan kosmetik;

- b. pertukaran pengalaman, konsultasi dan kunjungan di bidang regulasi, standar, evaluasi, teknik pengujian laboratorium;
- c. pertukaran hasil inspeksi atau investigasi sebagaimana diminta oleh salah satu Pihak;
- d. melakukan penelitian bersama di bidang-bidang yang menjadi kepentingan bersama di bidang pengawasan obat dan makanan; dan
- e. bidang kerja sama lainnya yang dapat diputuskan bersama oleh Para Pihak.

3. Kerahasiaan

Tidak satu pun Pihak dapat mengungkapkan atau menyebarkan segala informasi rahasia yang diterima atau dihasilkan melalui MSP ini kepada pihak ketiga atau kepada publik, tanpa persetujuan tertulis sebelumnya dari Pihak lainnya.

4. Pengaturan Keuangan

- 1) Masing-masing pihak bertanggung jawab atas administrasi dan pengeluaran sumber dayanya sendiri yang terkait dengan kegiatan-kegiatan di bawah MSP ini.
- 2) Biaya dari setiap bantuan yang diberikan oleh salah satu Pihak atas permintaan Pihak lain akan ditanggung oleh Pihak pemohon, kecuali jika diputuskan bersama oleh Para Pihak.

5. Konsultasi Tingkat Kerja

Para Pihak dapat membentuk konsultasi tingkat kerja atau panel teknis spesialis untuk membahas bidang prioritas kepentingan dan kegiatan kerja sama berdasarkan MSP ini.

6. Kontak

Para Pihak dengan ini menunjuk kontak berikut untuk komunikasi antara Para Pihak dalam mengimplementasikan MSP ini:

- untuk Kementerian Keamanan Pangan dan Obat: Direktur Kerja Sama Internasional
- untuk Badan Pengawas Obat dan Makanan: Kepala Biro Kerja Sama

7. Implementasi

- 1) MSP ini akan dilaksanakan dalam kerangka hukum, peraturan, pedoman kelembagaan masing-masing dan ketentuan hukum lainnya yang berlaku dari masing-masing pihak.
- 2) Semua kegiatan yang dilakukan berdasarkan MSP ini tunduk pada ketersediaan dana dan sumber daya dari masing-masing Pihak.

- 3) MSP ini tidak akan menciptakan kewajiban atau hak yang mengikat secara hukum antara Para Pihak di bawah hukum nasional atau internasional.

8. Resolusi Perbedaan

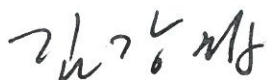
Setiap perbedaan, kontroversi atau perselisihan yang timbul dari interpretasi dan / atau implementasi MSP ini akan diselesaikan secara damai melalui konsultasi antara Para Pihak.

9. Validitas, Amandemen, dan Pengakhiran

- 1) MSP ini akan mulai berlaku pada tanggal penandatanganan oleh Para Pihak. MSP akan berlaku untuk jangka waktu tiga (3) tahun dan akan secara otomatis diperpanjang untuk periode tiga (3) tahun selanjutnya, kecuali jika salah satu Pihak memberitahukan pihak lain secara tertulis tentang keinginannya untuk mengakhiri MSP ini pada sembilan puluh (90) hari lebih awal.
- 2) Pengakhiran MSP ini tidak akan mempengaruhi durasi atau keabsahan kegiatan kerja sama berdasarkan MSP ini yang sedang berlangsung pada saat pemberitahuan pengakhiran MSP ini.
- 3) MSP ini dapat diamandemen dengan persetujuan tertulis dari kedua belah pihak.

DITANDATANGANI di Osong dan di Jakarta pada tanggal Jan 28, 2021, dalam dua rangkap asli masing-masing dalam bahasa Korea, Indonesia, dan Inggris, semua naskah memiliki keabsahan yang sama. Dalam hal terjadi perbedaan penafsiran, naskah Bahasa Inggris wajib berlaku.

**Untuk Kementerian Keamanan
Pangan dan Obat Republik Korea**



Dr. Kim Ganglip
Menteri

**Untuk Badan Pengawas Obat dan
Makanan Republik Indonesia**



Dr. Penny K. Lukito, MCP
Kepala