식품의약품안전처
Ministry of Food and Drug Safety

European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Working Arrangement

between

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

and

the Directorate-General for Health and Food Safety of the European Commission and the European Medicines Agency

for the Exchange of Non-Public Information on Medicinal Products

The Ministry of Food and Drug Safety of the Republic of Korea (MFDS), on the one side, and the Directorate-General for Health and Food Safety of the European Commission (DG SANTE) and the European Medicines Agency (EMA), on the other side (each a 'Participant' and collectively 'the Participants');

Recognising the need to enable further increased cooperation as a means to better protect human health and facilitate access to safe and high quality medicinal products;

Seeing value in exchanging regulatory and other similar information, which may include, inter alia, restricted, confidential and/or proprietary information ('non-public information'), which the Participants intend to protect in accordance with their respective applicable laws. The information should not contain personal data as defined in Article 3 of Regulation 2018/1725[1] or personal information as defined in Article 2 of the Personal Information Protection Act[2]. Both sides therefore envisage to keep the exchanged information confidential, to the extent permitted by their respective applicable legislation and/or organisations' policies, and as set forth in this Arrangement;

Considering that the Participants may wish to share certain specific scientific and technical information and documents (collectively 'information') related to ensuring the safety, efficacy and quality of medicinal products for human use, authorised or under review both in the Republic of Korea and in the European Union, exclusively for use in the performance of their respective duties with regard to medicinal products, as well as for the protection of public health (the 'Purpose'); and

Considering further that the term 'medicinal products' refers to 'medicinal products for human use' as defined, in the Republic of Korea, in the Pharmaceutical Affairs Act and, in the European Union, in Directive 2001/83/EC authorised either through the centralised procedure or nationally, which fall within the scope of EMA's activities as defined in Regulation (EC) No 726/2004;

Have come to the following arrangement:

1. The scope of this Arrangement includes, but is not limited to, the exchange of information in the following areas:

a) activities related to the regulation of medicinal products for safety, efficacy and quality, such as licencing, authorisation of clinical trials, product labelling, and the development of policies and guidance;

b) activities related to compliance monitoring, such as the collection, monitoring and analysis of adverse reactions or incident data as well as benefit-risk assessments, and policy development to regulate marketed medicinal products; and

[1] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

[2] Personal Information Protection Act of Korea, Act No. 10465, Mar. 29, 2011. Amended by Act No. 19234, Mar. 14, 2023.

c) compliance and enforcement activities with regard to medicinal products, such as inspections, compliance verification, recalls, investigations and enforcement measures and risk assessment.

2. For the purposes of this Arrangement, when the Participants receive non-public information, they intend to share such information only with persons within their respective organisations on a need-to-know basis and who are bound by commitments of confidentiality and professional secrecy, as defined in their respective laws and in accordance with this Arrangement.

3. For MFDS, 'persons within their organisation' include MFDS employees, agents, contractors, experts or expert committees who:

a) require the information solely for work purposes in respect of this Arrangement,

b) will only use that information for purposes contemplated by this Arrangement; and

c) will have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, confidentiality contract or other document that permits those persons to use the information for the purposes of this Arrangement and requires them to protect the confidentiality of the information in accordance with the laws that are applicable to MFDS.

4. For DG SANTE and EMA, 'persons within their organisation' include DG SANTE staff members and EMA staff members, national experts on secondment, members or experts participating at its scientific committees, working parties, working groups and expert groups and in other EMA activities. EMA, therefore, intends to share information received from MFDS with representatives of national competent authorities in the European Economic Area (EEA) with whom EMA has entered into a cooperation agreement that covers the exchange of confidential information. EMA intends to ensure that the above representatives of national competent authorities in the EEA are made aware of the content of this Arrangement and express their intention to comply herewith.

5. Each Participant may exclude the dissemination or exchange of information if this would undermine specific interests or violate legal obligations. The latter should apply in particular to applicable legal obligations and/or organisational policies as well as rules covering commercial, industrial or professional secrecy, the public interest or the protection of a Participant's interests in the confidentiality of its proceedings. Exchange of information under this Arrangement may be subject to prior authorisation from third parties concerned, including the person and/or organisation from which the information emanated.

6. This Arrangement is not intended to convey data and information that is personal. The Participants intend to make all reasonable efforts to ensure that personal data and personal information are not shared or exchanged with each other. If one Participant discovers that personal data or personal information has been provided or received inadvertently, the Participant should immediately inform the other Participant. The recipient Participant intends to take immediate and appropriate action to permanently destroy the record(s) containing personal data or personal information in accordance with applicable laws, and the providing Participant and the recipient Participant intend to provide an updated record with personal data and/or personal information removed. In case information on legal persons identifies a natural person, both Participants intend to consider such information as personal data and/or personal information and treat it accordingly.

7. It is an essential element of this Arrangement that the Participants intend to treat non-public information emanating from the other Participants as confidential and intend to use such information only for the Purpose.

8. DG SANTE and EMA confirm that they have the authority to protect non-public information, provided by MFDS, if and insofar as that information is covered by the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001[3] as interpreted by the Court of Justice of the European Union. DG SANTE and EMA understand that MFDS considers it crucial that DG SANTE and EMA protect this non-public information from disclosure to any person not identified in this Arrangement; otherwise, it could endanger the commercial interests of the entities concerned and/or international relations between the Participants.

[3] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

Similarly, MFDS confirms that it has the authority to protect non-public information provided by DG SANTE or EMA as information not to be publicly disclosed. MFDS understands that DG SANTE and EMA consider it crucial that MFDS protects this non-public information from disclosure to any person not identified in this Arrangement; otherwise, it could endanger the commercial interests of the entities concerned and/or the international relations between the Participants.

9. On each occasion where there is a request for disclosure to third parties of non-public information received from DG SANTE or EMA, MFDS intends to consult with DG SANTE or EMA. Likewise, on each occasion where there is a request for disclosure to third parties of information received from MFDS, DG SANTE or EMA intend to consult with MFDS.

10. In case of future changes in the organisation chart of the European Commission regarding the assignment of responsibilities among Directorates-General, it is the intention that this Arrangement will continue to be applicable to the Directorate(s)-General of the European Commission which has/have within its/their remit responsibility for medicinal products [for human use].

Similarly, in case of future changes in the organisation chart of MFDS regarding the assignment of responsibilities between different branches, it is the intention that this Arrangement will continue to be applicable to the branch of MFDS which has within its remit responsibility for medicinal products for human use.

11. The Participants may amend this Arrangement at any time upon their mutual written consent. This Arrangement is to be operational from the date of its signature by the Participants and will remain operational until further notice. Either Participant may discontinue this Arrangement at any time and will inform the other Participants of the discontinuation, at least (1) months in advance.

12. This Arrangement does not intend to compromise each Participant's ability to carry out its responsibilities, nor does it intend to result in creating legally binding rights or obligations under international or domestic law on the part of the Participants.

13. This Arrangement is not legally binding under international or domestic law.

SIGNED in triplicate in the English language.

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

25/4/2024

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