

MEMORNDUM OF COOPERATION
BETWEEN
THE EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL
AND
THE MINISTRY OF HEALTH LABOUR AND WELFARE OF JAPAN

The European Centre for Disease Prevention and Control (hereinafter referred to as 'ECDC')

And

The Ministry of Health Labour and Welfare of Japan (hereinafter referred to as 'MHLW')
(hereinafter ECDC and MHLW are referred to individually as an 'Organisation' and jointly as 'the Organisations')

Within their respective mandates, in the joint need to develop information exchange and better mutual understanding between the Organisations;

Deciding to strengthen collaboration and cooperation between the Organisations, relating to different topics including epidemiological issues and infectious diseases and to support global health security and implementation of the International Health Regulations (IHR, 2005);

The Organisations have recognised the following :

Section I: Aim of the MoC

Through the MoC, the Organisations aim to collaborate on matters of mutual interest in communicable diseases prevention and control, in particular through efforts at information exchange, better mutual understanding and increased collaboration.

Section II: Areas covered by the MoC

The MoC is expected to cover the following areas of cooperation and any other areas deemed relevant and decided by the Organisations:

1. Epidemic intelligence, threat detection, surveillance and risk assessment of acute infectious disease events
2. Antimicrobial resistance
3. Immunization and vaccines
4. Risk communication
5. Public health education, training and professional development
6. Other relevant areas of mutual interest

Section III: Modalities of cooperation

1. Taking into account applicable laws and regulations in the European Union as well as in Japan, and in line with the missions, ongoing programs and available resources of the

Organisations, cooperation activities under the MoC may be conducted in the following modalities, in line with their regulatory and technical feasibility and the mutual interest of the Organisations:

- a. Exchange of information.
 - b. Mutual consultation and/or exchange of epidemiological information related to infectious disease events/threats that may affect or concern the European Union and Japan.
 - c. Study visits, once the appropriate legal framework for such exchange is in place.
 - d. Participation in congresses, conferences, symposia, meetings and scientific workshops organised by the Organisations.
 - e. Any other modality of cooperation mutually determined by the Organisations.
2. The Organisations should designate contact persons to ensure the smooth implementation of the MoC, including the development of a workplan which will include details on the joint activities, including any necessary due diligence with respect to data and intellectual property.
 3. Based on the respective annual and multiannual workplans of the Organisations, the contact persons should have a meeting every year to identify joint and/or synergetic activities for the upcoming one to three years. These should be submitted for internal approval within each Organisation in line with its usual internal approval process.
 4. The Organisations should aim to have a meeting at least once every year to carry out an annual review of the areas falling within the scope of the MoC.
 5. Each Organisation should bear its own costs in relation to joint activities resulting from the MoC.
 6. The participation of experts, country representatives and other stakeholders in meetings and tasks performed as a result of the MoC will follow the internal rules of ECDC or the internal rules of MHLW (as applicable) for such participation (e.g. rules on selection of experts; reimbursement of expenses of participants in meetings, where the meeting is funded by ECDC).
 7. Transfers of personal data (other than of administrative nature) between the Organisations and the subsequent processing operations will be regulated in specific instruments.

Section IV: Conflict of interest

1. Each Organisation recalls that it applies its rules on conflict of interests in the pursuit of the activities covered by the MoC.
2. MHLW acknowledges the principles of ECDC's Independence Policy for non-staff and ECDC's Policy on Scientific Integrity and Independence and will act in line with the policies when interacting with ECDC. MHLW will ensure that declarations of interest are obtained and submitted to ECDC from any experts, country representatives and other stakeholders participating in or acting on behalf of MHLW in joint activities with ECDC, where the outcome involves publishing guidelines, recommendations, or any other form of official position on a subject, in order to avoid conflicts of interest.

Section V: Public access to documents, data protection and intellectual property rights

1. Each Organisation should protect the confidentiality of documents, information, materials and/or equipment exchanged during the period of implementation of the activities. However, the Organisations recognise that they are each subject to legal requirements concerning access to documents and protection of personal data, and in particular:
 - a. ECDC observes and is bound by 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 and Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 (the EU Regulations') 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; and
 - b. MHLW observes and is bound by the Act on the Protection of Personal Information (Act No. 57 of 2003), Act on Access to Information Held by Administrative Organs (Act No. 42 of 1999), the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998), and the related regulations under the laws above (the "Japanese Laws and Regulations") on the protection of natural persons with regard to the processing of personal data by the administrative entities in the government.
 - c. All activities carried out by the Organisations related to the MoC fall within the scope of the EU Regulations, and Japanese Laws and Regulations, and will be treated in line with the applicable rules concerning access to documents and protection of personal data.
2. Before any external communication about joint activities, the Organisations should coordinate the content and the method of communication. Neither Organisation may use the name of the other Organisation in any advertising, press release, advertisement or promotional material involving the content of the MoC, without the prior written consent of the other Organisation. It is expected that this will apply for at least one year after the termination of the MoC.
3. The intellectual property of products resulting from the collaboration is outside the scope of the MoC.

Section VI: Checks and audits

The Organisations recognize that these collaborative activities may be subject to any necessary checks and audits undertaken by the internal auditors of the Organisations, the European Court of Auditors, the European Anti-Fraud Office and the European Public Prosecutor's Office. The Organisations will assist and facilitate any such activities in a spirit of good cooperation.

Section VII: Limitations to the cooperation

1. The Organisations acknowledge that the cooperation between them is voluntary and limited according to the available resources and strategic decisions linked to resource allocation, and that the Organisations will act in compliance with the legal framework applicable to it.
2. At no time should one of the Organisations represent the other or behave in any way which would give an impression that it represents the other Organisation.
3. None of the sections of the MoC gives legally enforceable rights to one Organisation against the other.
4. Any dispute arising from the application or interpretation of the MoC should be resolved amicably by negotiations between the Organisations.
5. The collaboration under the MoC may vary or be discontinued at any time depending on what is in the best interests of the Organisations. If the MoC is discontinued, the Organisations should ensure that the cessation of collaboration between the Organisations is handled in a timely and orderly manner.

The activities of the MoC commence on 17th October, 2024.

For: The European Centre for Disease Prevention and Control

Name: Dr Pamela Rendi-Wagner

Title: Director

Date: 10/17/2024

For: The Ministry of Health Labour and Welfare of Japan

Name: Dr Manabu Sumi

Title: Director-General, Department of Infectious Disease Prevention and Control

Date: 10/17/2024