



European
Commission



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



MANATŪ HAUORA

Working Arrangement for the collaboration and exchange of information on therapeutic products/medicinal products between

DG SANTE/EMA and the New Zealand Ministry of Health (incorporating the New Zealand Medicines and Medical Devices Safety Authority - Medsafe)

The European Commission's Directorate-General Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA), on the one side and the New Zealand Ministry of Health (incorporating the Medicines and Medical Devices Authority (Medsafe)), on the other side (each a "Participant" and collectively the "Participants"), have recognised the need for a working arrangement (this "Arrangement") to enable further increased cooperation as a means to better protect public health and facilitate access to safe and quality therapeutic and medicinal products.

1. Purpose

The purpose of this Arrangement is to strengthen collaboration and exchange of information between the Participants across a range of mutual interests as referred to in section 2. The Participants recognise the importance of this Arrangement as a means to reinforce public health by deepening cooperation and promoting the timely, secure exchange of regulatory and related information.

2. Scope of cooperation

The Participants may wish to collaborate and share certain specific scientific and technical information and documents (collectively "information") related to ensuring the safety, efficacy and quality of therapeutic products/medicinal products for human use, authorised or under review both by Medsafe and in the European Union, exclusively for use in the performance of their respective duties with regard to therapeutic products/ medicinal products, as well as for the protection of public health ("the Purpose").

In this context, therapeutic products in New Zealand refer to medicines and medical devices as defined in the Medicines Act 1981. In the European Union, medicinal products refer to "medicinal products for human use" as defined in Directive 2001/83/EC¹, authorised either through the centralised procedure or nationally, which fall within the scope of EMA's activities as defined in Regulation (EC) No 726/2004² and other applicable legislation.

In light of the above the Participants intend to collaborate and cooperate in several activities, for the fulfilment of the Purpose, including but not limited to, the following:

1. Information exchange on:

- collaboration on the exchange of public and non-public information regarding therapeutic products /medicinal products quality, safety and efficacy, authorisation of clinical trials, product labelling and the development of policies and guidance.
- Information exchange 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 therapeutic products /medicinal products; and,

¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.

- Compliance and enforcement activities with regard to therapeutic products/medicinal products, such as inspections, compliance verification, recalls, investigations and enforcement measures and risk assessment.
2. Participation as observers, experts and other relevant roles in the context of internal procedures (e.g. scientific committee meetings) and multilateral cooperation mechanisms (e.g. OPEN procedures, cluster activities);
 3. Collaboration in other potential areas that the Participants may deem appropriate, and which fall within the scope of the Purpose. In this regard, where appropriate, DG SANTE and EMA may share information with other European Commission Directorates-General on the same terms as defined by the Arrangement.

3. Modalities of cooperation

The modalities of cooperation may include the following:

- Development of guidance on topics related to medicinal products for human-use, in line with the applicable legislation.
- Training activities to support development of regulatory and scientific training capabilities.
- Promote mutual learning, capacity building, and the sharing of best practices in regulatory science and public health.
- Without prejudice to confidentiality requirements, enable the Participants' representatives to participate as observers, experts and other relevant roles where this is possible under the Participants' frameworks and procedures.
- Establish and agree a periodic review of interaction.

4. Other provisions

Non-public information

The kind of information exchanged between the Participants' through this Arrangement may include, inter alia, information of a non-public confidential nature ("non-public information").

- Non-public information can only be shared under this Arrangement according to the procedures and policies of the Participants as permitted by their respective laws. The Participants are not in a position to share information covered by the obligation of professional secrecy (such as business secrets, commercially confidential information, proprietary information) without the explicit consent of the owner of the information.
- Each Participant acknowledges that the applicable laws of each Participant may require a Participant to respond to a request for release of information. Each Participant, in the interest of protecting confidentiality, should consult with the other prior to any such release of non-public information. The Participants acknowledge that it may be appropriate to withhold non-public information noting it is in the public interest that information sharing continues, and that sharing continuity may depend on confidentiality being maintained for non-public information being exchanged.
- The Participants agree that it is essential that non-public information emanating from the other Participant is treated as confidential, and is used only for the Purpose.
- The Participants envisage that their personnel should not disclose, even after their duties have ceased, non-public information accessed under this Arrangement, including information which is of the kind covered by the obligation of professional secrecy.

Personal data

Both Participants should respect any obligations under the applicable legislation in their respective jurisdictions to protect personal data, and identifiable information should not be exchanged under the terms of this Arrangement.

Organisation Change

In case of future changes in the organisation chart of the European Commission regarding assignment of responsibilities between different Directorates-General, this Arrangement will continue to be applicable to the Directorate-General of the Commission which has within its remit responsibility for medicinal products.

In case of future changes in the organisation chart of the Ministry of Health regarding assignment of responsibilities between different branches, this Arrangement should continue to be applicable to the branch of the Ministry of Health which has within its remit responsibility for therapeutic products.

This Arrangement does not intend to compromise each Participant's ability to carry out its responsibilities neither does it intend to result in creating rights or obligations under international law on the part of the Participants and is without prejudice to any obligations that the Participants have under their respective applicable legislation.

Each Participant should bear its own costs of participating in this Arrangement. Either party may give the other three months written notice if they wish to cease participating in this Arrangement.

This Arrangement is not intended to create rights or obligations under international or domestic laws, and does not have any financial implications on either side.

Signed on behalf of DG SANTE

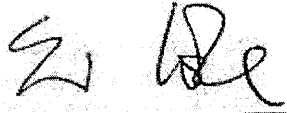


Sandra Gallina
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Date

Signed on behalf of EMA

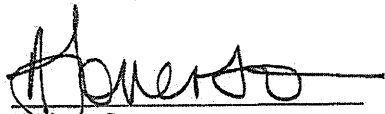


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30/6/2026

Date

Signed on behalf of the Ministry of Health (corporating Medsafe)



Audrey Sonerson
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Date 6.7.2026