MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

12 September 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022010590

Dear s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (Ministry of Health) on 18 August 2022. You specifically requested:

> *"This document on Medsafe's website refers to a 1993 MOU relating to Harmonisation in therapeutic goods administration. Can I have a copy of it please"*

A copy of the requested document is attached to this letter and is released to you in full.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe

MEMORANDUM OF UNDERSTANDING
BETWEEN THE DEPARTMENT OF HEALTH OF NEW ZEALAND
AND
THE DEPARTMENT OF HEALTH HOUSING LOCAL GOVERNMENT AND COMMUNITY SERVICES OF AUSTRALIA

The Department of Health of New Zealand and the Department of Health Housing Local Government and Community Services of Australia ("the parties"):

- supporting the May 1992 World Health Organisation resolution encouraging international initiatives to harmonise drug regulatory requirements,
- acknowledging the Australia New Zealand Closer Economic Relations-Trade Agreement,
- acknowledging the close geographical, historical and political ties that bind Australia and New Zealand,
- being concerned to develop co-operation in the field of therapeutic goods regulation, particularly as regards the assessment of safety, quality and efficacy and the removal of sub-standard products from distribution and use,
- wishing to share advances in therapeutic goods by increasing the exchange of information in areas of mutual interest,
- wishing to co-operate to the maximum extent possible in the enforcement of the legislation regulating therapeutic goods in each country,
- wishing, wherever practicable, to harmonise policies, procedures and standards for the regulation of therapeutic goods in each country,
- have reached the understanding that they will co-operate, so far as each of them is able, to achieve those objectives.

1. Co-operation of the Parties

The co-operation of the parties will include such forms of collaboration as:

(1) exchange of therapeutic goods evaluation reports;

(2) exchange of evaluation reports of the synthesis of active raw materials and their impurities;

(3) exchange of information on experiences in the fields of evaluation, manufacturing, handling, testing, monitoring, prescribing and use of therapeutic goods;

(4) exchange of scientific and technical information;

(5) exchange of personnel for the purposes of in-service training and of advancing understanding of the techniques used by each party;

(6) participation in joint training meetings and programmes;

(7) consultation where possible during the development of new standards or guidelines for the regulation of therapeutic goods;

(8) assistance in the prevention, detection and investigation of offences under their respective legislation regulating therapeutic goods;

(9) exchange of information concerning the investigation of offences or suspected offences under the parties respective legislation regulating therapeutic goods;

(10) exchange, where possible and upon request, of copies of Good Manufacturing Practice inspection reports of therapeutic goods manufacturers inspected by either party;

(11) joint Good Manufacturing Practice inspections of manufacturers of therapeutic goods;

(12) consultation where possible when planning a proposed programme of testing for therapeutic goods;

(13) development of joint testing programmes for therapeutic goods;

(14) exchange of results from testing programmes for therapeutic goods;

(15) exchange of information about adverse reactions, problem reporting and the recall of therapeutic goods in each country;

(16) exchange of minutes of advisory committees concerned with the regulation of therapeutic goods;

(17) attendance at meetings of advisory committees concerned with the regulation of therapeutic goods,

but may include other forms of mutually acceptable collaboration which are consistent with the objectives set out in the preamble of this Memorandum.

2. Confidentiality

(1) Information that is exchanged shall be treated as confidential for use of the participating parties only and, subject to subclause 2 (2), should not be released without prior written approval from the other party.

(2) Information that is exchanged may be subject to such laws relating to its use and release as may be in force from time to time.

3. Financial Arrangements

(1) The co-operative activities under this Memorandum of Understanding will be financed through resources available to the participating parties.

(2) Each participating party will bear the costs it incurs in relation to this Memorandum of Understanding.

4. Status of Memorandum of Understanding

This Memorandum of Understanding reflects the intentions of the participating parties and is not intended to create legal obligations of any nature either in domestic or international law.

5. Amendment to Memorandum of Understanding

Any of the provisions of this Memorandum of Understanding may be amended or extended at any time by mutual agreement in writing of the participating parties.

6. Effective Date

This Memorandum of Understanding will come into effect upon the date of signature of both participating parties and will continue in effect unless terminated in accordance with paragraph 7 of this document.

7. Termination

This Memorandum of Understanding may be terminated by either participating party on six months notice in writing to the other party.

8. Liaison Between Authorities

(1) Further communications on matters covered in this Memorandum will occur in the first instance through the National Manager, Therapeutic Goods Administration, on behalf of the Australian Authority and through the Manager, Therapeutics Section for the New Zealand Authority.

(2) The parties will, at least annually, review progress made towards achieving the objectives of the Memorandum and will develop further guiding principles and priorities for co-operation taking into account experience gained

9. Definitions

For the purposes of this Memorandum of Understanding:

(1) "Therapeutic Goods" means products regulated in Australia under the Therapeutic Goods Act 1989 and products regulated in New Zealand under the Medicines Act 1981.

Approved and signed for the Department of Health of New Zealand

on the 23 **day of** April **1993**

by_____

Christopher Lovelace
Director General of Health

Approved and signed on behalf of the Department of Health Housing Local Government and Community Services of Australia

on the 6th **day of** May **1993**

by_____

Geoffrey Norman Vaughan
National Manager, Therapeutic Goods Administration