



MEMORANDUM OF UNDERSTANDING

BETWEEN

THE GOVERNMENT OF AUSTRALIA

AS REPRESENTED BY THE DEPARTMENT OF FOREIGN AFFAIRS
AND TRADE

AND

THE COMMONWEALTH DEPARTMENT OF HEALTH SPECIFICALLY
THAT PART ENTITLED THERAPEUTIC GOODS ADMINISTRATION
(‘TGA’)

AND

THE GOVERNMENT OF PAPUA NEW GUINEA

CONCERNING COOPERATION IN THE TESTING OF THERAPEUTIC
GOODS

1. BACKGROUND

The Government of Australia as represented by the Department of Foreign Affairs and Trade ('DFAT') and the Commonwealth Department of Health - Therapeutic Goods Administration ('TGA') and the Government of Papua New Guinea (hereafter referred to as 'the Participants') wish to cooperate in the provision of assistance to the Government of Papua New Guinea with testing of Therapeutic Goods used in Papua New Guinea.

This is a subsidiary arrangement under the Treaty on Development Cooperation ('the Treaty') between the Government of Australia and the Government of Papua New Guinea signed on 31 July 2000. All provisions of the Treaty relating to development cooperation between the two Partners will extend to this MOU.

2. OBJECTIVES

The objectives of this Memorandum of Understanding ('MOU') are:

- (a) for the Participants to cooperate in the provision of assistance to the Government of PNG with testing of Therapeutic Goods used in Papua New Guinea; and
- (b) to enable the testing of samples of certain Therapeutic Goods by the TGA with a focus on those that treat non-communicable diseases.

3. DEFINITIONS

In this MOU:

"Australian Financial Year" means the period that is from 1 July to 30 June;

"Confidential Information" means information that:

- a) Is designated by either of the Participants as confidential; or
- b) Each Participant knows or could reasonably be expected to know is confidential, including without limitation relating to the business affairs of the Government of Australia, the Government of Papua New Guinea or the Government of another country;

"Specified Therapeutic Goods" means those Therapeutic Goods identified in paragraph 4;

"Therapeutic Goods" is as defined in Section 3 of the Australian *Therapeutic Goods Act 1989* as amended from time to time.

4. UNDERSTANDING

This MOU articulates the understanding reached by the Participants to conduct the following Activity. In particular, the Government of Australia offers limited access to its laboratory testing for the Government of Papua New Guinea for the following Specified Therapeutic Goods categories:

Category 1


- antibiotics;
- medicines treating diabetes;
- cardiovascular medicines;



- medicines notified to the Government of Papua New Guinea by TGA; and

Category 2

- medicines of the Government of Papua New Guinea's choice where testing of that medicine is within the capability of TGA.
- (a) The following medicines are not Specified Therapeutic Goods:
- expired medicines;
 - radioactive medicines;
 - medical gasses and anaesthetics;
 - cytotoxic medicines;
 - drugs of addiction listed in Schedule 8 of the current Poisons Standard of the Australian *Therapeutic Goods Act 1989*;
 - World Health Organisation prequalified vaccines and medicines on the Australian Register of Therapeutic Goods or regulated by Medsafe in New Zealand unless there has been an adverse event, problem or complaint;
 - complementary medicines; and
 - medicines or products that have been in contact with patients' bodily fluids.
- (b) Subject to the TGA and the Government of Papua New Guinea entering into a Deed in a form approved by the TGA, including TGA information to the Government of Papua New Guinea on relevant Australian *Customs Act 1901* requirements, the TGA will provide to the Government of Papua New Guinea testing, at no charge, five samples from the Categories of Specified Therapeutic Goods in total for each Australian Financial Year over a period of four Australian Financial Years or part thereof from the Effective Date of this MOU until 31 March 2021. For each Australian Financial Year the five samples will include three medicines from Category 1 and two from Category 2;
- (c) Where the Government of Papua New Guinea has not submitted five samples to TGA for testing in accordance with paragraph 4(b) in an Australian Financial Year, TGA may issue a reminder to the Government of Papua New Guinea. If the Government of Papua New Guinea has not submitted the forms and sample(s) requesting testing by no later than 1 May of the Australian Financial Year or 1 February in the case of the last Australian Financial Year TGA may, in its absolute discretion, choose not to test any further remaining sample(s) for the relevant Australian Financial Year.
- (d) In lodging a request for testing, the Government of Papua New Guinea should identify the reason it has nominated the particular Therapeutic Good, for example, an adverse event has occurred, suspected counterfeit, failed visual inspection, suspected tampering, suspected incorrect formulation, other problems;
- (e) TGA will provide the Government of Papua New Guinea with a Certificate of Analysis specifying whether or not the sample provided conforms with the relevant pharmacopoeia standard and any conditions of use ('Electronic Statement');
- (f) TGA will not return samples to the Government of Papua New Guinea;
- (g) Except as identified in (h) below, the activities contemplated within this MOU are not within the purview of the *Therapeutic Goods Act 1989*;



- (h) Separate to the TGA's testing activities for the Government of Papua New Guinea under this MOU, the TGA, in compliance with its powers under the *Therapeutic Goods Act 1989*, may investigate any Therapeutic Good which is on the Australian Register of Therapeutic Goods or is otherwise available for supply in Australia where the testing of the Therapeutic Good for the Government of Papua New Guinea raises quality concerns for the Australian market;
- (i) TGA may, with the Government of Papua New Guinea's written permission, contact the manufacturer and/or supplier of a sample for additional information such as certificates of analysis held by a manufacturer or supplier, test methods or additional samples;
- (j) Each Participant may, in particular circumstances, limit the scope of disclosure of information, particularly if the disclosure may be prejudicial to the commercial interests of a third-party, breach a duty of confidence or privacy, disclose a trade secret, is contrary to the public interest or interests of the Participant concerned, would be in breach or inconsistent with statutory obligations or requirements or other obligations and requirements imposed by the respective laws of Papua New Guinea and the Commonwealth of Australia. Nothing in this paragraph or in the MOU prevents the use or disclosure of information in compliance with the statutory provisions of the Australian *Therapeutic Goods Act 1989*.

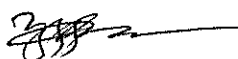
5. PROCESSES

- (a) The Participants, having reached the above understanding, may enter into arrangements and establish acceptance processes to facilitate the transport of the Specified Therapeutic Goods for testing to the TGA, noting that the Government of Papua New Guinea is responsible for transport costs.
- (b) The TGA will specify the relevant arrangements and forms to be completed by the Government of Papua New Guinea for TGA acceptance prior to any sample being sent to ensure safe and accountable processes.
- (c) Nothing in this MOU entitles the TGA to enter into negotiations on behalf of the Government of Papua New Guinea or to undertake liaison with any manufacturer or supplier on behalf of the Government of Papua New Guinea.

6. CONFIDENTIALITY

Government of Papua New Guinea

- (a) While the Government of Papua New Guinea may provide Confidential Information to the TGA for the purposes of TGA conducting testing under this MOU, nothing in this MOU requires the Government of Papua New Guinea to release Confidential Information to TGA.
- (b) Except as set out in paragraph (d), and unless otherwise required or authorised by law or for the purposes of Government, the Government of Papua New Guinea will not disclose any Confidential Information received from TGA under this MOU, except with the written consent of the TGA.
- (c) Except as set out in paragraph (d), and unless otherwise required or authorised by law or for the purposes of Government, the Government of Papua New Guinea and its authorised employees, contractors and agents will not use the Confidential Information disclosed to it under this MOU, for any other purpose than the performance of its therapeutic products regulatory activities.



- (d) The TGA notes that the Government of Papua New Guinea may upload test results for Specified Therapeutic Goods tested by the TGA contained in Electronic Statements under this MOU onto the secure platform operated by the World Health Organisation for sharing with other Pacific Island Countries.

TGA

- (e) While the TGA may provide Confidential Information to the Government of Papua New Guinea in connection with TGA testing under this MOU, nothing in this MOU requires the TGA or the Government of Australia to release Confidential Information to the Government of Papua New Guinea except in accordance with law.
- (f) Unless otherwise required or authorised by law or for the purposes of Government, the TGA will not disclose any Confidential Information received from the Government of Papua New Guinea under this MOU except with the written consent of the Government of Papua New Guinea.
- (g) Unless otherwise required or authorised by law or for the purposes of Government, the TGA and its authorised employees, contractors and agents will not use the Confidential Information disclosed to it under this MOU for any purpose other than conducting testing and related activities under this MOU.

7. FINANCIAL ARRANGEMENTS

- (a) Subject to paragraph 7(b), each Participant will undertake the administration and expenditure of its own resources associated with activities conducted under the MOU including but not limited to postage, courier, and packaging.
- (b) Subject to the Participants entering into specific arrangements for the exchange of the Therapeutic Goods for testing, the TGA will not levy any charge against the Government of Papua New Guinea for the actual testing of the Specified Therapeutic Goods.

8. VARIATION

The Participants may amend this MOU at any time, by mutual consent in writing, in the form of an exchange of letters between the Participants.

9. STATUS OF MEMORANDUM OF UNDERSTANDING

This MOU reflects the intentions of the Participants and is not an international treaty. It is a non-binding arrangement and is not intended to create legal obligations of any nature, either in domestic or international law.

10. EFFECTIVE DATE

This MOU comes into effect upon the date of signature of both signatories and will continue in effect until 1 June 2021 unless terminated in accordance with paragraph 12.



11. AGENCY CONTACT

The liaison officers for this MOU are:

- (a) for the Government of Papua New Guinea the person holding the position of Manager Pharmaceutical Service Standards; and
- (b) for the TGA the person holding the position of Scientific Operations Advisor.

12. TERMINATION

- (a) Either Participant may, at any time, give notice of termination to the other Participant in writing, giving at least three months' notice.
- (b) The termination of this MOU does not affect any commitments given under or as a consequence of this MOU in respect of any arrangement or action taken during the period before the termination takes effect.

Signed in duplicate in the English language.

For the Government of Australia

For the Government of Papua New Guinea



(signature)



(signature)

Benedict Daud

(name)

Pascoe Kase

(name)

At: ACC, POM.
On: 26/10/18

At: Waigani, PNG.
On: 5th Oct. 2018.