Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Fiji Medicinal Products Regulatory Authority
MINISTRY OF HEALTH & MEDICAL SERVICES

Supplier request for Sponsor to authorise sharing of TGA regulatory information with Fiji MRA.

Purpose of this guide:

This is a guide for suppliers of medicines to the Fiji Ministry of Health and Medical Services to seek authority from a Sponsor of a medicine in Australia for the TGA to share regulatory information with Fiji MRA.

Background:

The Australian Government Department of Health and Aged Care Therapeutic Goods Administration Indo-Pacific Regulatory Strengthening Program (TGA RSP) supports the Fiji Government Ministry of Health and Medical Services Medicines Regulatory Authority (MRA) to develop and implement standards and regulations for medicines to ensure they are quality assured, safe, and effective.

The TGA RSP and Fiji MRA have an official agreement about the conditions of exchange of information for carrying out regulatory activities. This agreement requires TGA RSP and Fiji MRA to protect any information shared from further disclosure.

The TGA securely holds commercial-in-confidence information about products registered in Australia, in accordance with Australian Federal Government requirements and legislation.

Commercial-in-confidence information cannot be exchanged without agreement by the owner of that information, in this case the Sponsor of a product in Australia.

When to use this guide:

The Fiji MRA requires primary evidence of a product's manufacturer GMP and registration status to authorise its supply in Fiji. Documents from public sources, such as ARTG public summaries, are not sufficient for this purpose as they do not contain a sufficient level of detail about the product, such as the quantitative formulation and approved manufacturing sites.

Details of the evidence required is available at the Fiji MRA website https://www.health.gov.fj/fiji-mra/

In some circumstances, the Sponsor of a product in Australia may not be able to provide this primary evidence to a supplier, citing commercial-in-confidence reasons. This can delay or prevent an Australian registered product being authorised for supply in Fiji, which is not a desired outcome.

If this occurs, suppliers may request the Australian Sponsor of the product to authorise the sharing of the required evidence directly between TGA RSP and Fiji MRA.

How to use this guide:

1. Supplier provides the following template to the Australian Sponsor of the product.
2. The Australian Sponsor completes the template and sends it to Fiji MRA.
3. Fiji MRA requests the authorised information from TGA RSP.
4. TGA RSP shares the authorised information with Fiji MRA.

< SPONSOR TO INSERT LETTERHEAD HERE>

Authority for TGA to share regulatory information with Fiji MRA

Principal Pharmacist – Medicines Evaluation

Medicines Regulatory Authority, Fiji Pharmaceutical & Biomedical Services Centre

Lot 1 Jerusalem Road, Vatuwaqa, Suva

(+679) 892 1665

FijiMRA@health.gov.fj

<SPONSOR TO INSERT DATE OF AUTHORITY HERE>

Dear Sir/Madam,

We, <SPONSOR TO INSERT NAME HERE>, the Sponsor of the product(s) registered in Australia stated below, hereby grant authority for the Fiji MRA to access the regulatory information held by the TGA about the product(s).

This information is to be accessed with the support of the TGA's Indo-Pacific Regulatory Strengthening Program and is subject to the provisions of the agreement about information sharing between the TGA RSP and Fiji MRA.

This information must not be disclosed to any other party and must only be used for the purpose of assessing compliance with the requirements of Fiji MRA for supplying the product(s) in Fiji.

ARTG Name	**Product Name**	**ARTG ID**

<ADD OR DELETE ROWS AS REQUIRED>

Yours sincerely,

<SPONSOR TO INSERT NAME, TITLE, AND CONTACT DETAILSOF THE PERSON GRANTING THIS AUTHORISATION HERE>