Guidelines for Import of Medicinal Products into Fiji.

Including for Commercial Import, Donation, Personal Use and by Travellers.

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Abbreviations

- FCCC - Fiji Competition and Consumer Commission
- Fiji MRA – Fiji Medicines Regulatory Authority
- Fiji MPB – Fiji Medicinal Products Board (also known as the Board)
- FRCS – Fiji Revenue and Customs Service

1. Purpose and Principles

a) The *Medicinal Products Act 2011* (the Act) & *National Medicinal Products Policy 2013* apply to the regulation of medicinal products in Fiji.

b) The Act provides for the Medicinal Products Board (the Board) to require that medicinal products imported into Fiji meet prescribed standards of quality, safety, and efficacy, and that they are imported only by authorised and licensed persons.

c) The Board has assigned to the Fiji MRA the functions of receiving, assessing, and referring applications for import permits to the Board for decision, implementing the decisions of the Board, and supporting the Board to promote the objects of the Act.

d) The Fiji MRA assesses applications for import permits against criteria to ensure that medicinal products supplied in Fiji meet acceptable standards of quality, safety, and efficacy, and that they are sourced from reputable manufacturers through legitimate supply chains.

e) These Guidelines are endorsed by the Board to promote the objects of the Act.

f) These Guidelines apply to all Medicinal Products included in Schedules 1, 2, 3 and 4 of the *Medicinal Products (Classification Scheme) Regulations 2021*.

   a. Medicinal Products have the same definition as in the Act [s3 Interpretation].

   b. Complementary medicines in Schedule 1 are exempted from listing until the Board notifies otherwise and are thereby exempted from the requirements of these Guidelines.

   c. Complementary medicines have the same definition as in the *Medicinal Products (Classification Scheme) Regulations 2021* [reg2 Interpretation].

   d. Schedule 8 (Dangerous Drugs) may only be imported by the Chief Pharmacist.

g) Medicinal products that are also included in Schedule 1 of the *Illicit Drugs Control Act 2004* also require a separate import permit issued by the Fiji MRA.

2. Applying for an Import Permit

a) The Fiji MRA Online Services Portal is used by applicants and the Fiji MRA to apply for, receive, process, and record import permits.

   i. The Portal is accessible from the Fiji MRA website at https://www.health.gov.fj/fiji-mra/

   ii. All applicants are required to register an account on the Portal.

   iii. Instructions for using the Portal are available on the Fiji MRA website and from the Help menu within the Portal.

   iv. All communication between applicants and the Fiji MRA is through the Portal or by email.

b) An application to import a medicinal product must be approved by the Board before the applicant may import that medicinal product.

c) The Fiji MRA reserves the right to:

   i. issue, or not issue, all or part of an import permit; and

   ii. change the requirements for an import permit; and

   iii. require compliance with special conditions of an import permit.

3. Requirements for Import of Medicinal Products for Commerce

a) This section does not apply to donors of medicinal products into Fiji.

b) Commercial importers of medicinal products into Fiji must:

   i. be registered by the FCCC, and have a current valid license authorising them to import medicinal products into Fiji; and

   ii. comply with every other law in Fiji that relates to medicinal products; and

   iii. meet every other requirement that relates to importing goods into Fiji, including those set by the FRCS.

c) Commercial importers must apply for an import permit for each medicinal product they wish to import into Fiji, for each importation of that product.

d) Commercial importers may only apply to import medicinal products which they have either:

   a. listed on the Provisionally Authorised Medicinal Products Register; or

   b. registered on the Registered Medicinal Products Register.

4. Requirements for Import of Medicinal Products for Donation

a) This section applies to all donations of medicinal products into Fiji for any purpose, including all medicinal products that enter Fiji with visiting medical teams or similar arrangements.

b) Donors must apply for an import permit for each medicinal product they wish to donate into Fiji, for each donation of that product.

c) Donors of medicinal products into Fiji must:

   i. comply with every other law in Fiji that relates to medicinal products; and

   ii. meet the requirements for donations of medicinal products in the:

      i. *National Medicinal Products Policy* at https://www.health.gov.fj/wp-content/uploads/2018/02/Fiji-National-Medicinal-Products-Policy-2013.pdf ; and

   iii. receive approval for the proposed donation as evidenced by a valid certified copy of the duly signed *Donations Checklist* available on the Fiji MRA website.

d) A donor who wishes to donate a medicinal product which does not meet these requirements must include the reason in their application for an import permit.

   i. Fiji MRA will assess the reason on a case-by-case basis and determine if the medicinal product:

      i. meets acceptable standards of quality, safety, and efficacy for donation into Fiji; and

ii. is sourced from a reputable manufacturer through a legitimate supply chain, and

iii. meets a need of the Fiji MHMS.

5. Assessing and Issuing an Import Permit

a) Upon receipt of an application for an import permit, the Fiji MRA will:

i. assess each application for completeness and accuracy; and

ii. at its discretion, provide feedback to applicants and opportunity for corrections to be made to the application.

b) When Fiji MRA is satisfied that an application for an import permit is complete and accurate, it may issue an import permit authorising the importation or donation of the medicinal products described in the permit.

6. Use of an Import Permit

a) An import permit is valid only for the importer or donor, products, and importation or donation specified in the permit.

b) Any special conditions specified in an import permit must be met for it to be valid.

c) The import permit must accompany the imported or donated products until such time as FRCS no longer requires.

d) Import permits remain the property of the Fiji MRA and must be returned, surrendered, or destroyed upon request by the Fiji MRA.

e) An import permit is conditional on the importer or donor complying with every other law in Fiji that relates to medicinal products.

7. Requirements for Import of Medicinal Products for Personal Use

a) A person who wishes to import a medicinal product into Fiji for their personal use, or use by a person under their care, must make suitable arrangements with a licensed pharmacy to import the medicinal product on their behalf.

i. The pharmacy must meet the requirements of Section 3: Requirements for Import of Medicinal Products for Commerce.

b) The pharmacy, upon receipt of a valid prescription, will import the medicinal product and dispense it to the person with appropriate labelling and instructions for use.

8. Requirements for Import of Medicinal Products by Travellers

a) A person who is entering, leaving, or transiting through Fiji with a medicinal product for their personal use, or use by a person under their care, must provide evidence at the Fiji border that the medicinal product has been legally prescribed and supplied to that person. Evidence may include:

a. An original or certified copy of a valid prescription; or

b. An original or certified copy of a signed letter from the prescriber, including their contact details; or

c. Labelling on the medicinal product that identifies the person, the prescriber, and the supplier, including their contact details.

b) The *Illicit Drugs Control Act 2004* [s11 Exempted persons] includes the exemption:

a. "a person undergoing treatment of a medical condition, who is entering, leaving or transiting through Fiji, may possess such quantities of an illicit drug that have been lawfully prescribed or supplied to that person or person under his or her care for the purpose of treating a medical condition for a period of not more than one month".