Guidelines for Listing Medicinal Products on the Provisionally Authorised Medicinal Products Register.

March 2024

Abbreviations

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

Interpretations

- Deal with a medicinal product – to import, manufacture, export, store, sell, distribute, transport, offer for sale, expose to sale, or advertise a medicinal product.
- List / Listing - the listing of medicinal products on the Provisionally Authorised Medicinal Products Register.

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 [s29] requires that:

> *"…no person shall import, manufacture, export, store, sell, distribute, transport, offer for sale, expose to sale or advertise any medicinal product which is not registered with the Fiji Medicinal Products Board…"*

c) The Act provides for the Fiji Medicinal Products Board (the Board) to list medicinal products on the Provisionally Authorised Medicinal Products Register.

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

e) The Fiji MRA assesses applications for listing 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.

f) The Fiji MRA utilises processes of reliance and recognition to assess applications for listing. This involves utilising the regulatory decisions and information available from recognised overseas National Regulatory Authorities to provide confidence that medicinal products meet the needs of the people of Fiji.

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

h) These Guidelines apply to all Medicinal Products included in Schedules 1, 2, 3, 4 and 8 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].

2. Listing Medicinal Products on the Provisionally Authorised Medicinal Product Register

a) The Board may list medicinal products upon receipt of information which is specified in a notification published in the Gazette.

b) Each person must make an application to list each medicinal product they wish to deal with.

c) The Fiji MRA Online Services Portal is used by applicants and the Fiji MRA to apply for, receive, process, and record the listing of medicinal products in Fiji.

   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.

d) An application to list a medicinal product must be approved by the Board before the applicant may deal with that medicinal product.

e) The Board may list a medicinal product for a specified period of time.

f) Where more than one application to list a medicinal product is approved, that medicinal product may be listed separately for each approved application.

g) Each listing for each medicinal product is specific to the applicant approved by the Board.

h) Listing is not transferrable without approval from the Board.

i) The Fiji MRA reserves the right to change the listing requirements for medicinal products.

j) The Fiji MRA reserves the right to require compliance with additional conditions when listing a medicinal product.

3. Requirements for Applicants

a) Applicants to list a medicinal product are required to:

   i. Be registered by the FCCC and have a current valid license authorising them to deal with medicinal products in Fiji; and

   ii. Apply to the Fiji MRA to list each of the medicinal products they wish to deal with; and

   iii. Provide the required information about each medicinal product they wish to deal with.

4. Requirements for Medicinal Products

a) Each application must include the required information about each medicinal product. This includes:

   i. Compulsory:

      i. Registration status in Australia or New Zealand.

      ii. Registration status in other countries.

      iii. Brand / trade name.

      iv. International Non-proprietary Name (INN), also referred to as the ‘generic name’ of the active substance.

v. The amount, that is, the strength and unit of the active substance per dosage form.
vi. Dosage form.
vii. Route of administration.
viii. Packaging sizes.
ix. Shelf life.
x. Finished product manufacturer(s).
xi. Pharmacopeial standard.

ii. Optional, but recommended to support assessment of the application:
i. Medicinal Products Classification (Schedule) in Fiji.
ii. Anatomical Therapeutic Chemical (ATC) Code and Category.
iii. Good Manufacturing Practice (GMP) Certificate(s) of the manufacturer.
iv. Product registration certificate(s) from other countries.

b) Medicinal products registered in Australia or New Zealand will have some of this information pre-filled in the Portal for convenience.
i. Applicants must confirm the accuracy of any pre-filled information before submitting an application.

c) The Fiji MRA reserves the right to request additional information from applicants to support assessment of the application.

d) The Fiji MRA reserves the right to request evidence of the provided information to support assessment of the application.

e) Applicants must confirm and declare for each application that:
i. All the information in the application and accompanying documentation is correct, complete, and true to the best of their knowledge.
ii. They take full responsibility on the quality, safety, and efficacy, of the listed medicinal product over its lifetime and will ensure that each individual batch imported complies with laws in force in Fiji. And, if required, that they will cooperate with any official of the Fiji Medicinal Products Board in performing an inspection.
iii. They confirm and agree that listing of this application onto the Provisionally Authorised Medicinal Products Register does not constitute to a marketing authorisation or registration of the medicinal product in Fiji.
iv. They confirm and agree to furnish the Fiji Medicinal Products Regulatory Authority with registration information as required in respect to a provisionally authorised medicinal product within such time as is stipulated in the communication.
v. They acknowledge that if the required information requested by the Fiji Medicinal Products Board is not without valid reasons submitted the medicinal product shall be delisted from the provisionally authorised medicinal products register.
vi. They confirm and agree that the Fiji Medicinal Products Board shall have the authority to suspend or cancel the provisional authorisation if the medicinal product is found not to have not complied with laws in force in Fiji.
vii. They confirm and agree that the provisional authorisation is not transferable to another company without the written authorisation of the Fiji Medicinal Products Board.

viii. They agree to follow the Fijian legal requirements related to listing of medicinal products.

ix. They provide consent to the processing of information provided to the Fiji Medicinal Products Board.

5. Import Permits

a) The import of a medicinal product into Fiji requires an import permit. This is enforced by the FRCS.

b) The Fiji MRA may issue import permits for medicinal products listed on the Provisionally Authorised Medicinal Products Register.

c) Import permits will only be issued to applicants with an approved listing for that medicinal product.

d) For more detail, refer to the Fiji MRA website section about Import Permits.

6. Transition to Full Registration

a) Products will remain listed on the Provisionally Authorised Medicinal Products Register until:

i. The expiry date of the listing is reached; or

ii. An application to register the product on the Registered Medicinal Products Register is received and approved; or

iii. The Board reviews the product and determines that it should be removed from the Provisionally Authorised Medicinal Products Register; or

iv. The Board determines an end date for the Provisionally Authorised Medicinal Products Register.

b) The Registration process is described in detail in the Act [s30].