Listing Medicinal Products on the Provisionally Authorised Medicinal Products Register: Frequently Asked Questions

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These FAQs are about the process to apply to list medicinal products on the Provisionally Authorised Medicinal Products Register in Fiji.

1. Why does the Fiji MRA require that medicinal products be listed on the Provisionally Authorised Medicinal Products Register?

The Fiji Medicinal Products Act 2011 [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…"

This requirement supports the objective of the Fiji National Medicinal Products Policy 2013 to ensure the quality, safety and efficacy of medicinal products supplied in Fiji.

The Act [s30] describes the process for registration of medicinal products, including the Provisionally Authorised Medicinal Products Register and the Registered Medicinal Products Register.

Listing products provides visibility to the Fiji MRA of the medicinal products supplied in Fiji and informs the registration process.

The Fiji MRA will issue import permits only for listed products, to applicants with an approved application for listing.

Refer to the Fiji Medicines Regulatory Authority website at https://www.health.gov.fj/fiji-mra/ for information about listing and registering medicinal products and import permits for medicinal products.

2. Who can apply to list a medicinal product?

Applicants must be registered by the Fiji Competition and Consumer Commission and have a current valid license authorising them to deal with medicinal products in Fiji.

3. How are applications to list medicinal products made?

Applications are made through the Fiji MRA Online Services Portal at https://fijimedreg.conforma.systems/login

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

4. Which products are required to be listed?

All medicinal products included in Schedules 1, 2, 3, 4 and 8 of the Fiji Medicinal Products (Classification Scheme) Regulations 2021 are required to be listed.

- Medicinal products are defined in the Fiji Medicinal Products Act 2011 [s3 Interpretation].
- If a product makes a therapeutic claim of any sort, it may be a medicinal product.

Products mentioned in Schedule 1 that do not meet the definition of medicinal products are not required to be listed.

- For example, sodium bicarbonate and glycerol/glycerine sold for baking, with no therapeutic claims, are not required to be listed.

Complementary medicines in Schedule 1 are exempted from listing until the Medicinal Products Board notifies otherwise. This is to allow the Fiji MRA to take a risk-based approach to product listing and registration.

- Complementary medicines are defined in the Fiji Medicinal Products (Classification Scheme) Regulations 2021 [reg2 Interpretation].

5. What information is required to apply for listing? Why? Where can I get it?

Information	Purpose	Document	Source
Registration status in Australia or New Zealand.	To assist the Fiji MRA to assess the quality of the product. See FAQ#6	• Australian Register of Therapeutic Goods (ARTG) Public Summary. • Medsafe NZ Product Detail. • Certificate of Registration or Market Authorisation • Certificate of Pharmaceutical Product (CoPP). See FAQ #7.	• ARTG website at: https://www.tga.gov.au/resources/artg • Medsafe NZ website at: https://www.medsafe.govt.nz/regulatory/DBSearch.asp • Sponsor or market authorisation holder. • Manufacturer. • This may be pre-populated in the online application form. See FAQ #8.
Registration status in other countries.	To assist the Fiji MRA to assess the quality of the product. See FAQ#6	• Certificate of Registration or Market Authorisation • CoPP. See FAQ #7.	• The National Regulatory Authority (NRA) of the country where the product is registered. • Sponsor or market authorisation holder. • Manufacturer.

Product details, including: • Brand / trade name • International non-proprietary name (INN) / generic name • Strength • Dosage form • Route of administration • Packaging sizes • Shelf life • Finished product manufacturer(s) • Pharmacopeial standard	To identify and describe the specific product, and to provide information about its source and quality.	• Australian Register of Therapeutic Goods (ARTG) Public Summary. • Medsafe NZ Product Detail. • Certificate of Registration or Market Authorisation • Certificate of Pharmaceutical Product (CoPP). See FAQ #7.	• The National Regulatory Authority (NRA) of the country where the product is registered. • Sponsor or market authorisation holder. • Manufacturer. • This may be pre-populated in the online application form for products registered in Australia or NZ. See FAQ #8.
Medicinal Products Classification (Schedule) in Fiji.	Optional. To assist the Fiji MRA to assess the application.	Select from the list in the application form.	Fiji Medicinal Products (Classification Scheme) Regulations 2021 at: https://www.laws.gov.fj/Acts/DisplayAct/551#
Anatomical Therapeutic Chemical (ATC) code and category	Optional. To assist the Fiji MRA to assess the application.	Select from the list in the application form.	Database within the application form.
Good Manufacturing Practices (GMP) certification	Optional. To provide evidence of: • the GMP compliance of specific manufacturing activities and steps at the manufacturing site. • any limitations or exclusions to the GMP compliance at the site. • the traceability of the manufacturing process.	• A GMP certificate issued by the NRA of a country where the product is registered. • A CoPP may also contain the required evidence. See FAQ #7.	• The NRA of a country where the product is registered. • GMP certificates issued by an EU member are available at https://eudragmdp.ema.europa.eu/inspections/displayWelcome.do • Sponsor or market authorisation holder. • Manufacturer.
Product registration certificate	Optional. To provide evidence of the regulatory status of the product in another country.	• Australian Register of Therapeutic Goods (ARTG) Public Summary. • Medsafe NZ Product Detail. • Certificate of Registration or Market Authorisation • Certificate of Pharmaceutical Product (CoPP). See FAQ #7.	• The National Regulatory Authority (NRA) of the country where the product is registered. • Sponsor or market authorisation holder. • Manufacturer.

6. Why does the Fiji MRA need to know where a medicinal product is registered?

The Fiji MRA uses processes of recognition and reliance to assess the quality of medicinal products supplied in Fiji.

This involves relying on regulatory decisions made by recognised overseas National Regulatory Authorities (NRAs) to provide confidence in the quality, safety, and efficacy of a medicinal product.

Products that are not registered by a recognised NRA may not meet the quality, safety, and efficacy standards required in Fiji.

Registration is also known as market authorisation in some countries.

7. What is a Certificate of Pharmaceutical Product (CoPP or CPP)? Where do they come from?

A CoPP is an internationally recognised certificate issued under the WHO Certification Scheme showing detailed information about a medicinal product.

It provides evidence of:

- product details (i.e.: name, ingredients, dosage form).
- country of origin.
- supply chain.
- compliance with GMP.
- regulatory status in the exporting country.

CoPPs are issued by the NRA of the country where the medicinal product is exported from.

Only participants in the WHO Certification Scheme are authorised to issue a CoPP.

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is described at https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/certification-scheme

CoPPs must be in the WHO specified format of the *Model Certificate of a Pharmaceutical Product*.

Using the WHO format does not mean that a CoPP is issued by WHO, only that it is in an accepted format.

8. Why do I need to enter more information for products that are not registered in Australia or New Zealand?

The Fiji MRA Online Services Portal accesses the publicly available information for medicinal products that are registered in Australia or New Zealand. This can assist applicants by pre-populating some parts of the application form.

Applicants for products registered in other countries must enter the required information manually.

9. The medicinal product I am applying to list has registration in another country. Do I still have to submit all the information in my application?

Yes. The Fiji MRA requires evidence about the identity, quality, regulatory status, and details of the supply chain for all medicinal products supplied in Fiji.

10. Another applicant has already applied to list a medicinal product I am applying for. Do I also have to apply to list that product?

Yes. Each application for listing is specific to the applicant and will be assessed separately. Approved listing will be specific to the applicant.

11. Another applicant already has an approved listing for a medicinal product that I want to apply for. Can I still apply to list that product?

Yes. Each application for listing is specific to the applicant and will be assessed separately. Approved listing will be specific to the applicant.

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

12. Can another applicant access the information I have provided in my application?

No. Each application for listing is separate and specific to the applicant. No applicant has access to information provided by another applicant.

13. Can I import a medicinal product into Fiji if I do not have an approved listing on the Provisionally Authorised Medicinal Products Register?

No. The Fiji MRA will only issue import permits for listed products, to applicants with an approved listing.

The Fiji MRA is working with the Fiji Revenue and Customs Service to manage the import of medicinal products into Fiji.

14. How long is medicinal product listing valid for?

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

- The expiry date of the listing is reached; or
- An application to register the product on the Registered Medicinal Products Register is received and approved; or
- The Board reviews the product and determines that it should be removed from the Provisionally Authorised Medicinal Products Register; or
- The Board determines an end date for the Provisionally Authorised Medicinal Products Register.

The process is described in detail in the Fiji Medicinal Products Act 2011 Act [s30].