Finished Pharmaceutical Product Prequalification: Frequently Asked Questions

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These FAQs are about the process for suppliers to apply to prequalify Finished Pharmaceutical Products (FPPs) that they wish to supply to the Fiji Ministry of Health and Medical Services (MHMS).

Refer to the Fiji Medicines Regulatory Authority (MRA) website at https://www.health.gov.fj/fiji-mra/ for information about manufacturer and FPP prequalification, including the *Guidelines for the Prequalification of Pharmaceutical Products and their Manufacturers*. This includes specific detail about the documents required.

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

1. What documents are required to apply for FPP prequalification? Why? Where can I get them?

Document	Description	Purpose	Source
Manufacturer Prequalification by Fiji MRA.	Inclusion of the manufacturer on the Fiji MRA list of prequalified manufacturers.	To provide evidence that a manufacturer meets the Fiji MRA requirements.	The Fiji MRA Online Services Portal. • Each supplier must have prequalification for each manufacturer of FPPs they wish to supply.
Certificate of Registration or Market Authorisation	A document showing the regulatory status of the FPP in another country.	To provide evidence of the regulatory status of the FPP in another country.	The National Regulatory Authority (NRA) of the country where the FPP is registered. • The NRA must be recognised by the Fiji MRA. See FAQ #2. • The registration or market authorisation must be recognised by the Fiji MRA. See FAQ #3. • A CoPP may also contain the required evidence.
Entry on the WHO List of Prequalified Medicines.	Entry of the FPP on the WHO List of Prequalified Medicines	To provide evidence of the FPP being assessed by WHO as meeting suitable quality standards. See FAQ #2.	The WHO List of Prequalified Medicines, online. See FAQ #4.
Certificate of Pharmaceutical Product (CoPP/CPP).	An internationally recognised certificate issued under the WHO Certification Scheme showing detailed information about the FPP.	To provide evidence of: • product details (i.e.: name, ingredients, dosage form). • country of origin. • supply chain. • compliance with GMP. • regulatory status in the exporting country.	The NRA of the country where the FPP is exported from. • A CoPP can only be issued by participants in the WHO Certification Scheme. See FAQ #5. • The CoPP must be in the WHO format. See FAQ #6.

Certificate of Analysis (CofA).	A document showing the results of a series of laboratory tests applied to a sample of the FPP.	To provide evidence of the quality standards applied to the product by the manufacturer.	The manufacturer or sponsor of the FPP. • Every batch produced has a unique Certificate of Analysis. • The FPS may provide the required evidence.
Finished Product Specifications (FPS)	A document showing the laboratory tests and associated limits that control the quality of the FPP.	To provide evidence of the quality standards applied to the product by the manufacturer.	The manufacturer or sponsor of the FPP. • A CoA may provide the required evidence.
Images of Labelling and Packaging.	Images showing the labelling and packaging that the FPP will be supplied with.	To provide evidence that the labelling and packaging of the FPP meet the Fiji MRA requirements.	The manufacturer or sponsor of the FPP.

Where does the FPP have registration / market authorisation?	**Where is the FPP manufactured?**	**Evidence required**
• A country with a NRA designated as a SRA or WLA. • New Zealand.	Any country.	• Manufacturer prequalification by the Fiji MRA. • Evidence of registration / market authorisation in that country. • Finished product specifications or a representative CoA. • Declaration of meeting labelling and packaging requirements.
WHO Medicines Prequalification.	Any country.	• Manufacturer prequalification by the Fiji MRA. • Evidence of inclusion on the WHO List of Prequalified Medicines. • Finished product specifications or a representative CoA. • Declaration of meeting labelling and packaging requirements.
The PIC/S member country where it is manufactured.	A PIC/S member country.	• Manufacturer prequalification by the Fiji MRA. • Evidence of registration / market authorisation in that country. • Finished product specifications or a representative CoA. • Declaration of meeting labelling and packaging requirements.
A different PIC/S member country from where it is manufactured.	A PIC/S member country.	• Considered by the Fiji MRA on a case-by-case basis.

A non-PIC/S member country.	A PIC/S member country.	• Considered by the Fiji MRA on a case-by-case basis.
A non-PIC/S member country.	A non-PIC/S member country.	• Not accepted for prequalification.
No country.	Any country.	• Not accepted for prequalification.

2. Which medicines regulatory organisations does the Fiji MRA recognise? Why?

The Fiji MRA uses processes of Recognition and Reliance to assess the quality of FPPs supplied to the Fiji MHMS.

This involves relying on regulatory decisions made by recognised NRAs and the WHO to provide confidence in the quality of a FPP.

The Fiji MRA recognises:

- NRAs that are designated by the WHO as a Stringent Regulatory Authority (SRA) or WHO Listed Authority (WLA).
- The NRA of New Zealand (Medsafe).
- NRAs of a country that is a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).
- The WHO.

SRAs and WLAs are listed at https://www.who.int/initiatives/who-listed-authority-reg-authorities (the WHO is currently transitioning from SRAs to WLAs – these lists will change over time).

PIC/S member countries are listed at https://picscheme.org/en/members

3. What registration or market authorisation does the Fiji MRA recognise? Why?

The Fiji MRA recognises registration or market authorisation for FPPs in:

- a country with a WHO designated SRA or WLA.
- New Zealand.
- the PIC/S member country in which the FPP is manufactured.

The Fiji MRA cannot accept applications for prequalification of FPPs that do not meet these criteria, except where there is the risk of a shortage of that FPP in Fiji and the quality of the FPP is at least equivalent. This will be assessed on a case-by-case basis.

4. What is the List of WHO Prequalified Medicines?

The WHO maintains a list of medicines which have been assessed as meeting suitable quality standards, and whose manufacturers meet suitable GMP standards.

The List is available at https://extranet.who.int/pqweb/medicines/finished-pharmaceutical-products/prequalified

Each product on the List has a unique WHO Reference Number to assist in identifying it.

5. What is the WHO Certification Scheme?

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

Participants in the WHO Certification Scheme are listed at https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/certification-scheme/contacts

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

6. What is the WHO format for a Certificate of Pharmaceutical Product?

The format of the *Model Certificate of a Pharmaceutical Product* is described at https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/certification-scheme/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.

7. The FPP I am applying to supply has registration or market authorisation in another country recognised by the Fiji MRA. Do I still have to submit all the documents in my application?

Yes. The Fiji MRA requires primary evidence about the identity, quality, regulatory status, and details of the supply chain for all FPPs supplied to the Fiji MHMS.

This primary evidence cannot be provided by only referencing a link to the approval status of the product in another country.

8. Another supplier has also applied to prequalify the FPP I am applying for. Do I also have to apply to prequalify that FPP?

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

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

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