Manufacturer Prequalification: Frequently Asked Questions

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These FAQs are about the process for suppliers to apply to prequalify the manufacturers of pharmaceutical products 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 product prequalification, including the *Guidelines for the Prequalification of Pharmaceutical Products for the Fiji Ministry of Health and Medical Services*.

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

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

Document	Description	Purpose	Source
Letter of Authorisation from manufacturer.	A document authorising the applicant to deal with the manufacturer's products.	To provide evidence of: • the identity of the applicant and manufacturer. • a legitimate commercial agreement authorising the applicant to supply the manufacturers products to the Fiji MHMS. • permission for the applicant to provide information about the products to the Fiji MRA. • a legitimate, traceable supply chain.	A document from the manufacturer of the products the applicant is applying to supply. In some circumstances, from the Market Authorisation Holder / Sponsor of the products the applicant is applying to supply. See FAQ #2.
Evidence that the site is licensed to manufacture pharmaceutical products.	A document showing that the manufacturing site is regulated by the National Regulatory Authority (NRA) in the country where the site is located.	To provide evidence of: • the identity and location of the site. • approval to manufacture pharmaceutical products at the site.	A license or permit issued by the NRA in the country where the manufacturing site is located. A GMP certificate may also contain the required evidence. See FAQ #4.

Good Manufacturing Practices (GMP) certification.	A document showing that a manufacturing site complies with GMP standards.	To provide evidence of: • the GMP compliance of specific manufacturing activities and steps at the site. • any limitations or exclusions to the GMP compliance at the site. • the traceability of the manufacturing process.	A GMP certificate issued by the local inspecting authority of the country where the manufacturing plant is located, ; and A GMP certificate issued by an NRA recognised by the Fiji MRA. See FAQs #3 & #4. A Certificate of Pharmaceutical Product may also contain the required evidence. See FAQ #4.

Specific detail of the information to be included in each of these documents is listed in the *Guideline for the Prequalification of Pharmaceutical Products for the Fiji Ministry of Health and Medical Services*.

2. Can I submit a Letter of Authorisation from the product Market Authorisation Holder (MAH) or Sponsor in another country instead of from the manufacturer?

This will be assessed on a case-by-case basis. A Letter of Authorisation is required to provide evidence to the Fiji MRA that the MAH or Sponsor is aware that their product is being supplied in Fiji by the applicant, and that the product supply chain is known and legitimate.

MAHs and Sponsors have legal obligations relating to their products, including when exported to other countries. The Fiji MRA requires evidence that these obligations can be met for products supplied in Fiji.

For example:

- Requirements for Australian Sponsors are at https://www.tga.gov.au/role-sponsor
- Requirements for New Zealand Sponsors are at https://www.legislation.govt.nz/act/public/2023/0037/latest/DLM6914502.html?src=qs

3. Which NRAs does the Fiji MRA recognise? Why?

The Fiji MRA uses processes of Recognition and Reliance to assess GMP status of manufacturers supplying products to the Fiji MHMS.

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

The Fiji MRA recognises:

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

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

4. Where can evidence of GMP compliance be found?

Applicants must submit:

- A GMP certificate issued by the local inspecting authority of the country where the manufacturing site is located, and
- A GMP certificate issued by a NRA recognised by the Fiji MRA.

If the manufacturing site is located in a country with a NRA recognised by the Fiji MRA then the local GMP certificate will meet both these requirements.

GMP certificates must include all the separate manufacturing activities and steps for each product approved at each manufacturing site.

GMP certificates from a country with a NRA recognised by the Fiji MRA should comply with the WHO GMP certificate format at https://www.who.int/publications/m/item/Model_certificate_of_Good_Manufacturing_Practices

A Certificate of Pharmaceutical Product (CoPP) issued by a WHO SRA or NRA based in a PIC/S member country may also provide the required information.

GMP certificates issued by an EU member are available at https://eudragmdp.ema.europa.eu/inspections/displayWelcome.do

5. The product I am applying to supply is registered in a country with a NRA 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 relationship between the applicant and the manufacturer, the approval status of the manufacturer, and details of the product supply chain for all pharmaceutical products 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.

6. **Can an exemption be granted to remove the requirement to provide manufacturer details (e.g.: name, manufacturing site) on the grounds of confidentiality?**

No. The Fiji MRA requires primary evidence about the manufacturer and the manufacturing site for all pharmaceutical products supplied to the Fiji MHMS. This information will be treated strictly in-confidence by the Fiji MRA and only used for the lawful purposes for which it is collected.

7. **The manufacturer of the products I am applying to supply has multiple manufacturing sites. Do I have to submit a separate application for each site?**

Yes. The Fiji MRA requires primary evidence about every manufacturing site for products supplied to the Fiji MHMS.

8. **Another supplier has also applied to prequalify the manufacturer of the products I am applying to supply. Do I also have to apply for that manufacturer?**

Yes. The Fiji MRA requires primary evidence about the relationship between each supplier and manufacturer applying to supply pharmaceutical products to the Fiji MHMS.

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

9. **Can another applicant access the manufacturer 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.