Guidelines for the Prequalification of Finished Pharmaceutical Products and their Manufacturers.

March 2024

Abbreviations

- BP – British Pharmacopoeia
- CoA – Certificate of Analysis
- CoPP – Certificate of Pharmaceutical Product
- FCCC – Fiji Competition and Consumer Council
- Fiji MHMS – Fiji Ministry of Health and Medical Services
- Fiji MRA – Fiji Medicines Regulatory Authority
- FPBS – Fiji Pharmaceutical & Biomedical Services
- FPP - Finished Pharmaceutical Product (including vaccines)
- GMP – Good Manufacturing Practices
- MAH – Market Authorisation Holder (also known as the Sponsor)
- NRA – National Regulatory Authority
- Ph. Eur. – European Pharmacopoeia
- Ph. Int. – International Pharmacopoeia
- PIC/S – Pharmaceutical Inspection Cooperation Scheme
- SRA – Stringent Regulatory Authority
- USP – United States Pharmacopoeia
- WHO – World Health Organisation
- WLA – WHO Listed Authority

1. Purpose and Principles

a) The *National Medicinal Products Policy 2013* & *Medicinal Products Act 2011* apply to the prequalification of FPPs and their manufacturers.

b) The Act provides for the Medicinal Products Board (the Board) to require that medicinal products in Fiji meet prescribed standards of quality, safety, and efficacy.

c) The Board has assigned to the Fiji MRA the functions of receiving, assessing, and referring applications for prequalification of finished pharmaceutical products and their manufacturers 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 prequalification 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) The Fiji MRA utilises processes of reliance and recognition to assess applications for prequalification. 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.

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

g) These Guidelines apply to all Medicinal Products included in Schedules 1, 2, 3, 4 and 8 of the *Medicinal Products (Classification Scheme) Regulations 2021*.

h) Medicinal Products have the same definition as in the *Medicinal Products Act 2011* [s3 Interpretation].

2. General Information on Prequalification

a) Suppliers of FPPs to the Fiji MHMS must apply to have the products they wish to supply, and the manufacturers of those products, prequalified by the Fiji MRA.

b) All FPPs must be prequalified by the Fiji MRA before they can be supplied to the Fiji MHMS.

c) The Fiji MRA Online Services Portal.

   i. All suppliers are required to register an account on the Fiji MRA Online Services Portal at https://fijimedreg.conforma.systems/login

   ii. All applications for prequalification must be submitted through the portal.

   iii. Instructions for using the portal and the application process are available on the Fiji MRA website at https://www.health.gov.fj/fiji-mra/ , and within the portal.

   iv. All communication between applicants and the Fiji MRA is through the portal or electronic communication.

d) Prequalification does not constitute a solicitation to supply the Fiji MHMS.

   i. Prequalification will generate a list of manufacturers and FPPs which the Fiji MHMS may use to inform requests for supply.

   ii. Applying for prequalification does not guarantee that a solicitation to supply will be received by the applicant.

   iii. The Fiji MRA reserves the right to change or cancel the application requirements at any time during the prequalification or solicitation process.

   iv. The Fiji MRA reserves the right to require compliance with additional conditions when issuing a solicitation to supply.

e) New applications are required to be submitted for all current suppliers, manufacturers, and products supplied or contracted for supply to the Fiji MHMS.

f) The Fiji MRA recognises NRAs which are:

   i. designated by the WHO as an SRA or WLA; or

   ii. the NRA of New Zealand; or

   iii. the NRA of a country which is a member of the PIC/S.

   iv. The Fiji MRA reserves the right to consider recognising other NRAs on a case-by-case basis.

g) The Fiji MRA accepts the quality standards of the:

   i. BP; and

   ii. Ph. Eur; and

   iii. Ph. Int; and

   iv. USP; and

   v. other standards that meet or exceed these standards as considered by the Fiji MRA on a case-by-case basis.

3. Requirements for Suppliers

a) Suppliers of FPPs to the Fiji MHMS must:

i. if based in Fiji, be registered by the FCCC, and have a current valid license authorising them to operate as a supplier of medicinal products in Fiji; or

ii. if not based in Fiji, provide evidence of license to operate as a supplier of FPPs in, and to export FPPs from, the country in which they are based.

b) Prequalification is specific to each supplier. All suppliers of FPPs are required to:

i. apply to prequalify each manufacturer of the FPPs they wish to supply; and

ii. apply to prequalify each of the FPPs they wish to supply.

4. Requirements for Prequalification of Manufacturers

a) All manufacturers of FPPs must be prequalified by the Fiji MRA before that manufacturer's FPPs are supplied to the Fiji MHMS.

b) A separate application must be made to prequalify each manufacturing site responsible for the manufacturing step 'manufacture of the dosage form'.

c) A manufacturer of FPPs will be considered for prequalification if:

i. the manufacturing site is licensed to operate by the NRA of the country in which it is located; and

ii. the manufacturing site has a current valid GMP inspection certificate issued by a NRA recognised by the Fiji MRA; and

iii. the applicant has a valid legal agreement to supply FPPs manufactured by that manufacturer to the Fiji MHMS.

d) Applications for manufacturer prequalification must include evidence that the site is approved to manufacture FPPs as described by PIC/S GMP requirements. GMP certificates submitted in evidence must:

i. be issued by a NRA recognised by the Fiji MRA; and

ii. show the correct, specific address of each separate site where manufacturing of the dosage form occurs; and

iii. include each production step and dosage form certified at each manufacturing site.

iv. Each separate site where any part of a FPP is manufactured must be certified for that process, however evidence of GMP is only required for the site that performs manufacture of the dosage form.

e) Applications for manufacturer prequalification must include a Letter of Authorisation or similar evidence of a legal agreement permitting the applicant to supply the manufacturer's products to the Fiji MHMS. This must:

i. be written in plain English; and

ii. specify the start and finish dates of the agreement (as relevant); and

iii. specify that the supplier is authorised to supply the manufacturer's products to the Fiji MHMS; and

iv. be written on the official letterhead of the manufacturer; and

v. be signed by an authorised representative of the manufacturer; and

vi. confirm the identity and business location of the supplier; and

vii. confirm the identity, business location and manufacturing site(s) of the manufacturer.

viii. A Letter of Authorisation which meets the same requirements may be accepted from the sponsor of the FPP in another country (i.e., Australia or New Zealand). This will be assessed by the Fiji MRA on a case-by-case basis.

5. Requirements for Prequalification of Finished Pharmaceutical Products

a) All FPPs must be prequalified by the Fiji MRA before they are supplied to the Fiji MHMS.
    i. For the avoidance of doubt, FPPs includes all medicinal products including vaccines.

b) A FPP will be considered for prequalification if it:
    i. is manufactured by a manufacturer prequalified by the Fiji MRA; and
    ii. is currently registered or has market authorisation in a country with a NRA recognised by the Fiji MRA; and
    iii. meets pharmacopeial standards recognised by the Fiji MRA; and
    iv. meets the Fiji MRA standards for labelling and packaging; or
    v. is included on the WHO List of Prequalified Medicines.

c) Applications must include evidence that the FPP is currently:
    i. registered or has market authorisation in:
        i. a country with a WHO SRA or WLA; or
        ii. New Zealand; or
        iii. the PIC/S member country in which it is manufactured; or
        iv. another country as considered by the Fiji MRA on a case-by-case basis; or
    ii. included on the WHO List of Prequalified Medicines.
    iii. Suitable evidence includes:
        i. a CoPP in WHO approved format from the country of export, showing market authorisation status; or
        ii. a Certificate of Registration or Market Authorisation issued by a NRA to the manufacturer, market authorisation holder or sponsor in that country; or
        iii. evidence of inclusion on the WHO List of Prequalified Medicines.

d) Applications must include evidence that the quality standard applied to the product by the manufacturer complies with a quality standard accepted by the Fiji MRA. Suitable evidence includes:
    i. Finished Product Specifications; or
    ii. Certificate of Analysis representative of the product supplied to Fiji.

e) Applications must include a declaration that the FPP meets the Fiji MRA standards for labelling and packaging.
    i. The Fiji MRA may require images of labelling and packaging to provide evidence of meeting these standards. Applicants may submit images to support their application.
    ii. The Fiji MRA standards for labelling and packaging of FPPs are:
        i. All products must be suitably packaged and labelled in the English language.

ii. Any package inserts, co-branding, relabelling or similar must be authorised by the product or mark owner and be in the English language.

iii. All labelling and packaging must be identical to the labelling and packaging that the product is supplied with in the country of registration relied upon in the application.

iv. All labels must be indelibly printed on, or securely fastened to, the main container.

v. All labels must remain intact and legible for the shelf-life of the product.

vi. Labels on blister packaging, small dose unit packaging, or similar, must clearly identify the FPP and include the same batch number and expiry date as the main container.

vii. Labels must clearly display:

1. The generic or International Non-proprietary Name(s) (INN) of the active pharmaceutical ingredient(s).
2. The brand / trade name (if applicable).
3. The dosage form.
4. The quantity of active ingredient(s) in the dosage form (strength).
5. The volume, number of units or number of doses per package.
6. The batch number.
7. The expiry date, in clear language (not code).
8. Instructions for storage and storage conditions, including any special instructions required for the safe and effective use of the FPP.
9. The name of the manufacturer and manufacturing site address, or the name of the sponsor for products from countries where that is the standard.

viii. All packaging must ensure the FPP is protected from adverse conditions, including light and humidity, throughout its shelf-life.

f) All applicants must confirm and declare that:

i. The product supplied to the Fiji MHMS will be identical to the product supplied in the country of registration relied upon in the application.

ii. The information contained in the application is true and correct.

iii. The application has been completed by the applicant identified.