Application for a Wholesale Licence under the Medicinal Products Act 2011 Guideline

FIJIAN COMPETITION & CONSUMER COMMISSION

To sell or supply medicines to anyone other than the patient using the medicine, you need a wholesaler licence.

Eligibility:

- Non-pharmacists can only deal with Schedule 1 & 2 medicines or OTC medicines.

General Information:

- Complete a written application with:
    - Applicant & proposed licensee details (if different)
        - Proof of identification
        - Business licence and registration certificate
        - If dealing with Schedule 3 or 4 medicines:
            (a) Valid Pharmacy licence;
            (b) certificate of registration as a pharmacist;
            (c) valid annual practicing licence/certificate, of all directors, shareholders or partners, as applicable
        - Articles of Association or partnership agreement, as applicable
    - Police clearance Desired license duration (if less than 5 years)
    - Description of wholesale dealings:
        - Types of medicines (herbal remedies, non-pharmacy medicines, specific classes)
        - Intended use of medicines (human, animal, ingredient, animal feed)
    - Address for storing & distributing medicines
        - Lease/tenancy agreement or Certificate of title, as applicable
        - Confirmation that no part of the premises is being used for residential purposes
        - Premises floor plan
    - General range of medicines stored at each premise
    - Facilities & equipment for storage & distribution
    - Secure storage arrangements for medicines
    - Procedures for ensuring stock turnover
    - Desired exclusion/modification of standard provisions

Additional Information for Imported Medicines:

- (If applicable) Include details for each imported medicine:
    - Name, form, composition (active & inactive ingredients)
    - Specifications, chemical formula, manufacturing method
    - Quality control procedures, stability & shelf-life evidence
    - Identity, purity & potency determination methods
    - Container description & storage/transport instructions
    - Indications, dosage, administration methods, warnings & labels
    - Reports & evaluations of relevant studies
    - Activities (sell, supply, export, procure)
    - Use (human, animal, ingredient, animal feed)
    - Contemplated sale/supply method in Fiji
    - Manufacturer/assembler name & address
    - Manufacturing/assembling operations in Fiji & elsewhere
    - Address of each manufacturing/assembling place in Fiji
    - Third-party involvement details (if applicable)
    - Sample of the medicine
    - Copies of relevant licenses/certificates from other countries
        - Good Manufacturing Practicing Certificate
        - Letter of authorization from the manufacturer
        - Quality standards of products (USP.BP or International Pharmacopeia)

Application Submission:

- Submit 6 English copies of the application & details.
- Include an original copy of any translated documents.
- State reasons for any omitted information.
- Sign the application (applicant & proposed licensee, if applicable).
- Sign a statutory declaration confirming that all particulars, data and reports submitted are true and all documents supplied are true copies.