

License to Manufacture Medicines in Fiji
APPLICATION FORM



Application Type (Tick Relevant Box)

1. New Application
 2. Change of Ownership

3. Relocation of Warehouse
 4. Renewal of Wholesale License

Name of Applicant

Name of Manufacturing Business (as per registration/license)

Business Location

Proposed Warehouse Re-Location (only applicable for application type 3)

Schedules License Applied

Applicants Contact Details (For correspondence)

Address

Telephone #

Email ID

Ownership Status

Sole Proprietor

Partnership

Body Corporate

Others

Partnership

Name & Shares of each Partners.

Body Corporate**Name of each Director**

Proposed Opening Date/Relocation Date (only applicable for application type 1 & 3)

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Last Renewal Date (only applicable for application type 4)

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Term Wholesale License Applied (if less than 5 years)

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Declaration

I hereby declare that the information provided on this form is accurate and submitted together with the required documents as per FCCC checklist attached below of this form. I agree to notify the FCCC within 30 days of any changes to the particulars submitted.

Applicant Name

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Applicant Signature

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Date

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Witness Name

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Witness Signature

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Date

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Application with supporting documents to be emailed to yentesh.mudaliar@fcc.gov.fj and copied to vinitesh.kumar@fcc.gov.fj.

FCCC OFFICIAL USE**Application #**

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Received by Name

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Signature

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Date Received

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APPLICATION CHECKLIST				
No.	Description	Yes	No	Comments
Eligibility Verification				
	Confirm eligibility criteria (<i>Non-Pharmacists can only deal with Schedules 1 & 2 & OTC</i>)			
Applicant Details				
	Applicant details e.g. name, contact			Include proof of identification
	Provide business license			
	Provide company incorporation or business registration			
	Submit required licenses and certificates (<i>if dealing with Schedules 3 & 4</i>)			<ul style="list-style-type: none"> • Certificate of registration as a pharmacist • Valid annual practicing licence/certificate, of all directors, shareholders or partners (as applicable) • Pharmacy Licence
	Include Articles of Association or partnership agreement (as applicable)			
	Provide police clearance			
Application Details				
	Specify desired license duration			If less than 5 years
	Describe wholesale dealings			Include types of medicines/schedules and intended use
	Provide address for storage & distribution			Include lease/tenancy agreement and premises floor plan
	Outline facilities & equipment			
	Ensure secure storage arrangements			
	Specify procedures for stock turnover			
	Identify desired exclusions/modifications of standard provisions (if any)			
Qualifications & Experience				
	Provide details of registration or relevant qualifications/experience to support your applicant			
Additional Information for Imported Medicines (If applicable)				
21	Include details for each imported medicine			
22	Provide specifications and manufacturing info			

23	Include quality control procedures			
24	Describe container description and storage			
25	Outline indications, dosage, administration			
26	Include reports & evaluations of studies			
27	Provide manufacturing & assembly details			
	Include third-party involvement details			
Disclosure				
	Have you been convicted of, or are there charges pending for, an indictable offence?			
	In relation to the relevant legislation, have you: - been convicted of, or are there charges pending for, an offence? - held a licence, permit, approval, authority and/or an endorsement that was suspended or cancelled - been refused a licence, permit, approval, authority and/or an endorsement			
Application Submission Requirements				
	Submit required number of application copies			
	Clearly state reasons for any omissions			
	Ensure signatures on the application			
Consent & Declarations				
	<p>Sign statutory declaration confirming:</p> <p>I consent to Fijian Competition & Consumer Commission collecting, using and disclosing my personal information for the purpose of determining this application and any matters relevant to the related substance authority.</p> <p>I consent to Fijian Competition & Consumer Commission making enquiries of, and exchanging information with, any relevant authority of, regarding any matters relevant to this application (which may include a criminal history check). If relevant information cannot be obtained from other entities, Fijian Competition & Consumer Commission will determine the application on the information available.</p> <p>I declare that, to the best of my knowledge, all information provided in and with this form is true and correct in every detail.</p>			

	<p>I understand that if anything has been stated in this application form, or in an attachment provided with this application, that is false or misleading, any substance authority granted may be suspended or cancelled.</p>			
Additional Documents Requested				
<input type="checkbox"/> APPROVED <input type="checkbox"/> NOT APPROVED		Remarks:		
Reviewer:		Date:		
Approved by:		Date		