

Licence No: MOH//PHARM P 2560



SPECIMAN

EXPORT CLEARANCE CERTIFICATE

(In accordance with the provisions of Sections 4(1); 5 and 6 of the Dangerous Medicines Act OF 1973)

The Ministry of Health and Social Welfare in the capacity as licensing authority, hereby licence:

Name of Applicant (Pharmacist)of
.....

LMPD Council Registration Certificate
No

To export to.....of.....
.....the undermentioned pharmaceutical products
(medicines, herbal medicines and allied substances) for sale: (documents attached on the back of the
form) subject to due compliance with the requirements of the medicines regulations.

This licence remains valid until the

Granted on this day

Signature of licensing authority

Designation

Date Stamp



Medicines Regulatory Unit, Pharmaceuticals Department, Ministry of Health and Social Welfare, P.O.Box
514,Maseru 100, Lesotho GPL 1204/07 – 100 Bks

Overleaf notes

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Conditions of issue/renewal for export licence

Consideration for application for issue/renewal may take advantage to impose any new conditions or insist on any aspects that have been previously overlooked or are brought to a new or legislation or policy.

Conditions for Premises

- Compliance with minimum requirements
- Valid local trader's licence
- No adverse report/s since the previous issue regarding e.g. wrongful dealing in medicines, lack of proper management and control of pharmaceutical business, etc
- Appropriately registered pharmacist with practicing licence from the pharmacy council and without any recorded acts of professional misconduct over the previous years (acts that may or may not warrant revocation of practicing licence)
- Appropriate renewal forms submitted well before previous licence lapsed
- No changes to the previous conditions under which the licence was issued.

Conditions for Amendments

All amendments to conditions under which an export licence was issued must be formally applied for and approved.

An applicant must not affect any changes without prior approval except for situations where e.g. a registered pharmacist leaves without notice and a locum tenens is in attendance for a period less than four weeks, changes of directorship in a company without changes in the effective supervision of the business.

Changes of ownership, effective directorship of a company, structural changes to the premises, changes in effective supervision of business, relocation to another premise require prior and written approval.

Validity

Certificates are valid for 6 months from time to time or until formally cancelled by the issuing authority. An annual renewal must be applied for each time an applicant wishes its licence to be renewed.

Once a licence has elapsed due to failure to renew by the licensee, there should not be a requirement for formal notification of intent by the authorizing authority to consider the licence invalid.

Suspension or cancellation of licence

A licence may be cancelled under the following situations:

- Failure to comply with specific conditions of licensing

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- Wrongful dealing in medicines, herbal medicines and allied substances
- Unauthorized change of premises
- Failure to comply with other legislature e.g local authority licensing, health requirements that were part of the initial approval.

A formal and legislated process must be conducted prior to cancellation of a licence.

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