
PHARMACY, MEDICINES & POISONS BOARD

# A Guide to the Registration, Licensing and Scheduling of Medicinal Products in Malawi

Pharmacy, Medicines and Poisons Board

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## Foreword

Prior to the implementation of the Pharmacy, Medicines and Poisons Act of 1988 there was no effective means of controlling the type and availability of drugs on the Malawi market. As a result, an increasing number of harmful or useless products was being marketed and prescription-only medicines were widely available without a prescription.

In order to bring this unacceptable situation under control and to provide urgently needed protection to patients and the public from the hazards of an uncontrolled drug market a system of registration and licensing of medicinal products in Malawi was introduced. Under the provisions of the Act the Pharmacy, Medicines and Poisons Board (PMPB) was made the national drug regulatory authority and thus responsible for implementing the legislation and in particular the drug registration system.

This booklet is meant to introduce those who may be interested to the rationale behind medicinal product registration and to guide them through the registration process itself. It was prepared by the Medicines Committee (MedCom) of the PMPB with the kind assistance of the Malawi Essential Drugs Programme and subsequently approved for publication by the Board itself.

Further guidance and information together with the product registration application forms may be obtained from the PMPB to which any suggestions for improving this guide may also be sent.

*P S P Tembo*
*Registrar, Pharmacy, Medicines and Poisons Board*

# 1. Introduction

This document is meant primarily as a guide for those applying for registration and licensing of medicinal products in Malawi. It describes the legal basis and objectives of these processes and details the steps involved, giving the rationale behind specific requirements or procedures where relevant. It should be read in conjunction with the relevant parts of the Pharmacy, Medicines and Poisons Act No.15 of 1988, and the relevant product licence application form (see 2.1).

## 1.1 Definitions

In this document the terms medicinal product, medicine and product are used interchangeably to refer to a "medicinal product" defined in Part 1, section 2 of the Pharmacy, Medicines and Poisons Act No.15 of 1988 as follows:

***"medicinal product"*** *means any substance or article which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways -*

*a) use by being administered to a human being or an animal for a medicinal purpose;*
*b) use as an ingredient in the preparation of a substance or article which is to be administered to a human being or an animal for a medicinal purpose,*

*but it shall not include an instrument, apparatus or appliance"*

***"medicinal purpose"*** *means any one or more of the following purposes -*

*a) treating or preventing disease;*
*b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;*
*c) contraception;*
*d) inducing anaesthesia;*
*e) otherwise preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way"*

## 1.2 Medicinal product registration

This is a system, provided for under Parts IV to VII (sections 34-54) of the Pharmacy, Medicines and Poisons Act No.15 of 1988, whereby ***all medicinal products for human or veterinary use*** circulating in the country, whether in the public or private sectors, whether procured or donated, etc. must be duly registered and licensed with the Pharmacy, Medicines and Poisons Board and prior to any form of handling. The latter includes importation, export, manufacturing, assembly, wholesaling, retailing, dispensing, and any other type of sale or supply (see section 35).

**Notes:**

(i) Local manufacturers, wholesalers, retailers (pharmacies and drug stores), and dispensing medical practitioners must also have the appropriate manufacturing, wholesaling, or dispensing licence before they may conduct any business involving the

manufacturing, wholesaling, retailing, importation, dispensing, sale or supply of licensed medicinal products (see section 35). Handling of licensed medicinal products without the appropriate licence and the handling by anyone of unlicensed products are *serious offences* under the law and as such are subject to stiff penalties involving heavy fines and/or imprisonment.

(ii) **Exemptions** from product licence requirements (see section 36) include the following medicinal products which are:

- specially prepared or imported by a registered medical practitioner or dentist or veterinary surgeon for the *treatment of a particular patient or animal/herd* as relevant, provided the amount involved is reasonable for the treatment of the patient and is *not of commercial value*
- prepared, dispensed, assembled or procured in a registered pharmacy or hospital by or under the supervision of a pharmacist and *according to the prescription* of a registered medical practitioner or dentist
- prepared or dispensed by a pharmacist by way of *counter prescribing* (ie. at the request of the patient and in accordance with the pharmacist's judgement as to the required treatment)
- prepared as *dispensing stock* in a hospital or registered pharmacy by or under the supervision of a pharmacist
- *assembled by a nurse or midwife* in the course of that person's profession
- imported by any person for *administration to himself* or a member of his household

## 1.3 Objective of medicinal product registration

The objective is to protect patients and the general public by ensuring that all medicinal products circulating in the country are:

- safe
- efficacious
- of good quality
- suitable/appropriate to the local market
- therapeutically relevant to the health needs of the population **(**for community health diseases)

## 1.4 Registration and licensing authority

The body responsible for medicinal product registration in Malawi is the Pharmacy, Medicines and Poisons Board (PMPB). The Board is advised in this respect by its Medicines Committee which *inter alia* considers and evaluates all applications for registration. Following approval for registration of a medicinal product by the PMPB and payment of the appropriate fee, a product licence is issued by the Registrar of the Board.

## 1.5 Validity of medicinal product licences

Licences are valid for a period of *one year* from the date of the product licence after which application for renewal of the licence for

another year must be submitted together with the appropriate fee to the Board.

The licensing authority may suspend, revoke or vary the provisions of a licence if considered necessary (see sections 40 and 41). The particulars and reasons for such action will be provided to the licence holder. Examples of reasons for suspension or revocation of a licence include:

- unsuitability of premises on which the product is manufactured, assembled or stored following a CGMP inspection
- new information received by the PMPB which indicates the product is unsafe or dangerous
- procurement of registration and licensing of a product by fraud or misrepresentation
- violation of conditions attached to the licensing of a product
- misleading or exaggerated advertising and promotion of the product
- contravention of provisions of the PMP Act
- where this, for whatever reason, is determined to be in the public interest

**Note:** After a product has been licensed, any subsequent change in the particulars relating to the product (eg. change of formula, composition/ ingredients, indications, packaging and labelling, etc) may render the licence invalid, unless prior approval of such change has been obtained from the PMPB. A fee is charged to implement any such changes

## 2. The Registration Process

Following is a description of the steps which must be completed in order for a medicinal product to be registered for use in Malawi.

### 2.1 Application for registration of a medicinal product

**Notes:** i) Applicants are advised to read carefully both this document and the explanatory notes on the application forms particularly Section M before completing an application.
ii) Applicants are advised to submit applications for registration and licensing at the earliest possible opportunity to allow sufficient time for all the steps of the process to be competed.

The onus of applying for registration and licencing of a medicinal product rests with the company wishing to introduce the product onto the Malawi market.

- In the case of an imported product this would be through the foreign manufacturer's locally registered and licenced representative or sole agent
- In the case of a locally produced product this would be through the local registered and licenced manufacturer

The application must be submitted, together with the application fee and product licence fee, to the Registrar of the Board by a Registered Pharmacist who is a full-time employee of the company on whose behalf the application is being made using

the relevant application form which may be obtained free of charge from the PMPB.

There are two types of application form as provided for under the Pharmacy, Medicines and Poisons (Fees and Forms) Regulations 1991:

**a) Application for a product licence (summary sheet) (Form 8A)**

This short form may be used to apply for ***registration of any well-established product***, ie. any product which is already in widespread use and which is registered and marketed in other countries with a recognised, reputable and reliable drug regulatory authority and drug registration system.

The form has sections covering product identification and information on the supplier, product, packaging and proposed distribution and promotion. Bioequivalence data may be required for certain generic products

Any such application must be accompanied by:

- a detailed written submission supporting consideration for registration by this method, i.e. supporting a request for exemption from the need to submit a full application Form 8 (see b below)
- samples of the product, the package insert, product label, outer package label and all

proposed advertising and promotional materials as detailed in the notes on the Form.

In principle, all medicinal products appearing on the current Malawi National Drug List will be registerable by this method, although whether registration is ultimately approved or not will depend on consideration of other criteria such as quality, labelling, packaging, etc.

**b) Application for a product licence (Form 8)**

This full application form must be used for all new products and for those products not already registered/marketed in other countries as described in a). The form requires complete and detailed information on each of the following areas:

- General information
- Pharmaceutical data (formulation)
- Chemical data (active and inactive ingredients)
- Manufacturing data
- Raw materials data
- Final product data
- Container and packaging data
- Stability data
- Package insert and labelling data
- Foreign registration data
- Distribution and promotion data
- Pharmaceutical and biological availability data

- Toxicological data
- Efficacy data
- Pharmacological data
- Veterinary medicine clinical studies data (where relevant)

The form must be accompanied by sealed samples of the product and by medical literature references, package inserts, product labels, outer package labels, proposed advertising and promotional literature, the product information summary, the product formula, manufacturing records and batch data, as detailed in the Form.

**Notes:**

i) *Different product presentations:* separate applications must be made in respect of every presentation (eg. formulation) of each medicinal product.

For example, separate applications must be made:

- for each strength
- for each dose-form (eg. tablet, capsule, injection, cream, ointment, etc)
- for each type of formulation (eg. standard formulation, controlled release, injection solution, powder for reconstitution for injection, etc)

ii) *Different pack sizes:* although application may be made on one form for different pack sizes of a particular product, each pack size will be considered for registration in its own right. However, if more than one pack size is subsequently approved, only one fee will be payable.

## 2.2 Pre-checking of the registration application and product by the Registration Section of the PMPB and the National Drug Quality Control Laboratory (NDQCL).

*(a) Registration Section:* the Registrar, following receipt of an application for registration will forward it to the Registration Section of the PMPB. The Section will record the application and examine it for eligibility for consideration, completeness and accuracy. The findings of the Registration Section will be summarised in the form of a standardised report.

*(b) NDQCL:* each product, together with all supporting documentation (eg. labels, packaging, patient information inserts, advertising and promotional materials, quality analysis certificates, etc) shall be forwarded to the NDQCL for a quality pre-check.

This will involve *inter alia* quality testing of the product as appropriate and examination of supporting documentation for completeness, accuracy, etc. The results of such pre-tests will be summarised in the form of a standardised report.

**Notes:** The Registration Section and/or the NDQCL shall indicate in their reports if a particular medicine should **not** be registered, giving reasons based on the results of the pre-check.

## 2.3 Submission of applications for registration by the Medicines Committee (MedCom)

On completion of the pre-checks carried out in step 2, the relevant reports should be submitted by the Registration Section and the NDQCL to the Registrar of the PMPB to enable preparations to be made for consideration of applications by the MedCom.

The following shall be presented to the MedCom in respect of each product:

(i) the **medicinal product** in the form, presentation and packaging in which it is proposed to be marketed.
(ii) all **supporting documentation**. This will include:

- the summary or full application form as appropriate
- all labelling, packaging, patient information, promotional and advertising materials, etc. as specified in the relevant form
- copies of the pre-check reports (see 2.2)

A summary of all medicinal products to be considered for registration shall be sent to the members of MedCom at least 2 weeks before the meeting at which the applications are to be considered. This shall include the following information for each product:

a) the generic name
b) the proprietary name

c) the dose form/presentation
d) the pack size(s)
e) the active ingredients/composition
f) the indications for use
g) copies of the pre-check reports

## 2.4 Consideration of applications by the MedCom

The MedCom shall examine the medicine, pre-check reports and all supporting documentation and shall consider initially the following three ***primary criteria*** in respect of the product (see PMP Act section 38a):

(a) **Quality:** this must be according to internationally recognised standards, eg. BP, EurP, USP, etc. and shall comply (as far as may be determined by the NDQCL) with the quality control results as stated in the batch quality control certificate accompanying the product.

(b) **Safety:** *inter alia* the incidence and severity of adverse effects will be considered in relation to the expected therapeutic benefits of the product, contra-indications to and precautions for use of the product will be evaluated in the context of the anticipated administration and use of the product within the local health system environment.

(c) **Efficacy:** the objective is to maximise therapeutic potential by limiting the presence of less efficacious products on the market. Thus each product should have *proven efficacy* in treating the conditions for which it is indicated. *Comparative efficacy* related to existing products on the market will also be taken into consideration. The committee will be guided in this respect by the latest available information published in reputable medical and pharmaceutical publications including journals and reference texts such as *Martindale's Extra Pharmacopoeia, BNF, USP,* etc.

If a product satisfies these primary criteria, the following secondary criteria may also be considered, in order to complete the evaluation of the product licence application:

(d) **Therapeutic appropriateness and general suitability to the local market:** this will include *inter alia* assessment of the therapeutic appropriateness of the product in the context of any prevailing national policies related to treatment of conditions for which it is intended to be used. Where such policies are not in place, the therapeutic need for the product will be evaluated with regard to the currently prevailing conditions in the country and applicable treatment options.

General suitability of the product may also be assessed according to the required method of administration and the need for and national capability in any special monitoring of the product in use which may be required.

## 2.5 Scheduling of medicinal products

This is carried out simultaneously with registration and products which are registered for the Malawi market are scheduled into one of the following categories:

### a) POM (Prescription-only medicine)

Such a medicine may only be dispensed upon presentation of a valid prescription from a registered medical practitioner, dental practitioner, veterinary practitioner or nurse for the relevant list of prescribable medicines applicable to each practitioner. Except in the case of a registered prescriber holding a valid dispensing licence issued by the PMPB, dispensing of all POMs must be from registered pharmacy premises and under the direct supervision of a registered pharmacist.

### b) PIM (Pharmacist-initiated medicine)

This may only be dispensed by a registered pharmacist who must record details of the supply and provide special counselling to the patient. The category primarily consists of recently deregulated (ie. previously POM) medicines or other non-POM medicines requiring specialist pharmacist advice and control.

### c) P (Pharmacy-only medicine)

This may only be supplied/counter-prescribed from registered premises and the supply must be under the direct supervision of a registered pharmacist or other registered pharmacy practitioner (depending on the type of premises, eg. pharmacy or drug store).

## d) GSL (General sales list medicine)

For such medicines there is no restriction on their sale and supply which may be from shops and groceries and other licenced retail outlets.

## e) CD (Controlled drug)

This category covers drugs of abuse, narcotics, psychotropics, etc. Handling and supply of these is strictly controlled and subject to special legal requirements for prescribing, dispensing, storage, records, etc. as detailed in the Dangerous Drugs Act Cap 35:02.

## 2.6 Ratification of MedCom decisions by the PMPB

The recommendations of the MedCom regarding medicinal product registration applications are presented for ratification at quarterly meetings of the main Board of the PMPB. When the Board has confirmed these decisions, applicants are duly notified and, provided the appropriate fee has been paid, a product licence is then issued by the Registrar of the PMPB for each product which has been approved for registration.

**The PMPB Inspectorate where necessary may carry out a *Current Good Manufacturing Practices* (CGMP) Audit for a small fee of plant(s) as part of the registration process**

## 2.7 Appeals against the decisions of the PMPB

Any individual or company who is aggrieved by a decision regarding the registration and licensing of a medicinal product may appeal to the Chairperson of PMPB within 4 weeks of notification whose decision on the matter shall be final.