GUIDELINE OF
THE MALAYSIAN MEDICAL COUNCIL

GOOD DISPENSING PRACTICE
VERSION 2/2025

CONTENT

PREAMBLE

This Guideline is based on relevant existing provisions, regulations and recommendations, including:

- The Poison's Act 1952
- Private Healthcare Facilities and Services Act 1998 & Regulations P.U.[A]137
- Dangerous Drugs Act 1952
- Drug Dependent (Treatment Rehabilitation) Act
- Sale of Drugs Act 1952 (Revised 1989) P.U. [A] 223/84 Control of drugs and cosmetic regulations 1984
- Poisons (Psychotropic substances) Regulations 1989/and all amendments
- Medicines (Advertisement and Sale) Act 1956 Revised 1983), Amendment-Act A778/1990
- MMC Code of Professional Conduct
- MMC Guidelines on Good Medical Practice
- Guide to legislations on the recording, labelling, storage and disposal of poisons and psychotropic substances applicable to private clinics/2012
- Draft Good Dispensing Practice Guidelines (PSD)/2015

1 Definition

"Dispense" or "dispensing" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labelling, or packaging necessary to prepare that prescription or order for delivery or administration.

"Drug" includes and poisons, narcotic preparations and products for medicinal purposes.

2 Duty to Dispense

In Malaysia, the duty to dispensing medication/drugs in a registered private medical clinic is part and parcel of the continuity of care expected of doctors attending to patients.

3 Notice of Clinic with Pharmaceutical Services

In all registered medical clinics with dispensing facilities, it is recommended that a notice be displayed in a prominent area of the registration counter to inform patient that the clinic has a pharmaceutical service and that patients have the choice to have their medication/drugs dispensed at the clinics or at any pharmacy.

Patients who do not wish to have their medication/drugs dispensed in the clinic can indicate so at any time before the prescription and dispensing is made.

4 Guidelines

It is a requirement in standard medical care to patients, to prescribe/dispense drugs only after consulting the patient and/or after review of patient's medical records and making relevant notes in the patient records.

In the event when a repeat dispensing of medication/drugs is requested it should be made after review of patient records.

Any medication/drugs prescribed and dispensed to the patient should be based on the independent professional judgment of the RMP and in accordance with the indications based on his patient's medical conditions.

At all times, the RMP in charge is responsible for maintaining a stock inventory of relevant medication/drugs in the clinic.

It is required by legislation to maintain proper records of the prescription of dangerous and controlled drugs, and a stock inventory.

The practitioner is strongly advised to avoid prescribing/dispensing habit-formatting medication/drugs, particularly sedatives and tranquilizers in large quantities to patients as this may lead to substance abuse. There is also the risk of overdose by patients.

5 Written Orders for Medication or Treatment

Medication/drugs dispensed or administered shall only be given on the written order of an RMP.

The orders shall be written legibly in ink by the RMP in the patient's medical record and/or the prescription slip

The generic or registered trade names of medication/drugs should be written in full before the usage of any abbreviations in the patient's medical record.

The manner of taking the drug should be stated in relation to meals, and number of times a day, etc.

6 Medical Errors and Adverse Drug Reactions

The patient must be counselled or advised about any medication errors and adverse drug reactions that may have occurred.

Any medication errors and adverse drug reactions shall be recorded in the patient's medical record.

The practitioner shall routinely reconfirm the correct medication/drugs dispensed for the patient and to reconfirm the history of any previous allergies with the patient.

The practitioner shall ensure that dispensing of medication by the staff is strictly according to his instruction and as prescribed by him.

7 Clinics with Computerized Patient Record

In clinics using computerized medical records RMP shall enter all orders for medication/drugs or treatment in the patient's medical records by technologically appropriate medium as may be determined by RMP.

8 Head of pharmaceutical Services

The head of pharmaceutical services in the clinic is preferably a registered pharmacist, or in his absence, or if none is available, the RMP in charge of the clinic.

He/She shall be responsible for all activities relating to pharmaceutical services including the compounding of medications/drugs.

He/She should have sufficient number of appropriately trained staff.

9 Location of pharmaceutical services

The pharmaceutical/ dispensing services should be located in a suitable clean room or area within the clinic, and easily accessible to the patient.

There must be adequate space and relevant equipment for all pharmacy operations including storage, safeguarding, compounding, preparation and dispensing of medications/drugs with proper lighting, temperature control, ventilation and sanitation facilities.

For safety, storage of alcohol and other inflammable substances shall be in separate room or area.

10 Dispensing and Compounding Unit

The following are good practice requirements:

i. Dispensing counter
ii. Work counter with impermeable surface;
iii. Corrosion-resistant sink;
iv. Storage unit;
v. Pharmaceutical refrigerator with thermometer for the proper storage of thermo-labile products and vaccines;
vi. Locked storage for storage of narcotics, psychotropic, poisons and other controlled drugs.

11 Labelling of medications/drugs

It is good dispensing practice to ensure that all drug containers from which medication/drugs are to be dispensed or administered be properly filled and labeled with:

a. Name and address of the clinic;

b. Name of the patient;

c. Name of the medication/drugs;

d. Adequate directions for the use of such medication/drugs;

e. Date of dispensing/delivery;

f. Container for dispensed medication/drugs shall be labelled with the words “Controlled Medicine” or *“Ubat Terkawal”;*

g. For Dispensed medication/drugs for external use, the container shall be labelled conspicuously and distinctly with the words “Not to be taken” or “For External Use Only” in English, Malay, Chinese and Tamil printed in red or on a red background/or in a language appropriate to the patient’s understanding;

h. Labelling of poisons and narcotics shall be in compliance with the relevant written laws.

12 Prescription Book

The Poisons Act stipulates conditions for the prescription book as follows:

"Prescription book

24. (1) Where any poison is sold or supplied as a dispensed medicine or as an ingredient in a dispensed medicine, the seller or supplier shall, on the day on which such poison or medicine is sold or Laws of Malaysia 24 ACT 366 supplied, enter or cause to be entered in a book, kept for such purpose (in this Act referred to as the "Prescription Book")

a) The date on which the medicine was sold or supplied and the serial number of the entry in such book of the prescription (if any);

b) The name of the poison and the ingredients of the medicine or, in the case of a proprietary medicine, the name of the medicine and the quantity supplied;

c) In the case of a sale or supply by a retailer on a prescription, the name of the patient or when the prescriber is a veterinary officer, or the prescription relates to animal treatment, the name of the recipient, and

d) In the case of a sale or supply as a dispensed medicine otherwise than on a prescription, the name and address of the person to whom it was sold or supplied: Provided that when a prescription is repeated it shall be sufficient to enter in the prescription book the date, the serial number of the sale, supply and prescription (if any) originally entered and the name of the patient or recipient. "

Details of dispensed medicines/drugs shall be properly recorded. This will also apply to any other methods of dispensing, including electronic.

This record may be in physical or in electronic form, and should be accessible when needed for inspection.

13 Storage and Containers for Stored Medicine

All medications/drugs should be in properly labelled container(s).

Medication containers having soiled, damaged, incomplete, illegal or makeshift labels shall be relabeled or disposed of.

Relabeling of containers may be allowed only if the identity of its contents is certain.

Containers with no labels and its contents should be destroyed and disposed-off accordingly.

14 Contaminated, expired or discontinued medications/drugs

Expired or discontinued medication/drugs should be properly disposed of in accordance with the private medical clinic's policy and with any written law governing the disposal of medication/drugs.

Medication/drugs that have been subjected to contamination should not be dispensed and should be disposed of immediately.

15 Cold Chain

It is good medical practice to maintain the cold chain for all thermolabile pharmaceutical products stored in the clinic.

16 Written Policies

The written policies and procedures must specify control and accountability, drug distribution, storage and assurance of quality of all drugs and biological products throughout a registered private medical clinic.

It is good medical practice to have written policies and procedures for control and accountability, drug distribution, storage and assurance of quality of all drugs and biological products throughout a registered private medical clinic.

All written policies should be consistent with any written laws relating to advertisement, sale and use of medicines and poisons.

The Guideline is also in line with the Code of Professional Conduct and Good Medical Practice of the Malaysian Medical Council, adopted in 2019. The relevant sections are reproduced in the Appendix below:

APPENDIX

"Code of Professional Conduct:

2. ABUSE OF PROFESSIONAL PRIVILEGES AND SKILLS

2.1 Abuse of Privileges Conferred by Law

2.1.1 Prescribing of Drugs

The prescription of controlled drugs is reserved to members of themedical profession and of certain other professions, and the prescribing of such drugs is subject to statutory restrictions.

The Council regards as serious professional misconduct the prescription or supply of drugs including drugs of dependence otherwise than in the course of bona fide treatment. A practitioner may be convicted of offences against the laws which control drugs. A practitioner must not prescribe such drugs in order to gratify hisown addiction or the addiction of other persons.

2.1.2. Dangerous Drugs

The contravention by a registered practitioner of the provisions ofthe Dangerous Drugs Act 1952 and the Regulations made thereunder may be the subject of criminal proceedings, and any conviction resulting therefrom may be dealt with as such by the Council in exercise of their powers under the Medical Act 1971 (Amended 2012). But any contravention of the Act or Regulations, involving an abuse of the privileges conferred thereunder upon registered practitioners, whether such contravention has been thesubject of criminal proceedings or

not, will be subjected to disciplinary punishment.

2.1.3 Sale of Poisons

The employment for his own profit and under cover of his own qualifications, by any registered practitioner who keeps a medicalhall, open shop, or other place in which scheduled poisons or preparations containing scheduled poisons are sold to the public,of assistants who are left in charge but are not legally qualified tosell scheduled poisons to the public, is in the opinion of the Council a practice professionally discreditable and fraught with danger to the public, and any registered practitioner who is provedto the satisfaction of the Council to have so offended will be liableto disciplinary punishment.

3.2.1. *<u>Personal Misuse or Abuse of Alcohol or Drugs</u>*

A practitioner's conviction for drunkenness or drug abuse or other offences (driving a vehicle when under the influence of alcohol or drugs) indicate habits which are discreditable to the profession and may lead to an inquiry by the Council.

A practitioner who treats patients or performs other professional duties while he is under the influence of alcohol or drugs, or who is unable to perform his professional duties because he is under the influence of alcohol or drugs is liable to disciplinary proceedings."

Relevant sections in the Good Medical Practice of the MMC are reproduces below:

4. "The Doctor and his Practice (Adopted by MMC on 16/06/2019)

4.1. <u>Prescribing</u>

4.1.1. A doctor should not issue a prescription without examining the patient, unless the doctor is already familiar with the patient and his illness and his medications

through previous consultation.

4.1.2. A doctor must not prescribe medications to a caller, who has notyet established a personal doctor-patient contract, merely on listening to a complaint over the telephone or any other electronicdevice.

4.1.3. Before prescribing medication for a patient, and conforming to safe medical practice, the doctor must find out if the patient has had any adverse reactions to medications previously taken, and whether he has any allergies, asthma, skin diseases, gastro- intestinal upsets or any higher centre reactions, like giddiness, headache, or nausea. It should also be enquired if he is on treatment for any other illnesses, and, if possible, the names of medications he is already taking.

4.1.4. These simple questions will give the patient the confidence that the doctor is concerned about the current medication, so that sideeffects and adverse reactions are avoided; neither will he be receiving the same medications already prescribed by another doctor.

4.1.5. The doctor must inform the patient the purpose of the medications, and potential side effects and adverse reactions that may arise, and the steps to be taken if such occur.

4.1.6. The name of the medicine, preferably both the generic andcommercial, should be clearly labelled on the packet or containers and instructions when to take the medicine and also how to keep them safely.

4.1.7. Medications should be prescribed in most circumstances, for an appropriate convenient duration, particularly for diseases that may need close periodic monitoring. A

doctor should provide a date for review and make it clear why regular reviews are important, and explain to the patient what they should do if they suffer side effects or adverse reactions.

4.1.8. *In the case of repeat prescription for regular follow-up patients, the doctor must record the reason for repeat prescribing and also be satisfied that procedures for repeat prescribing and for generating repeat prescriptions are secure. He must ensure that the right patient is issued with the correct prescription, the correct dose is prescribed, particularly for patients whose dose varies during the course of treatment, that the patient's condition is periodically reviewed by the doctor or an appropriate healthcare professional and that any changes to the patient's medicine are quickly incorporated into their record.*

4.1.9. *At each review the doctor should confirm that the patient is taking his medicines as directed, and check that the medicines are still needed, effective and tolerated, particularly following a hospital stay, or changes to medicines following a hospital or home visit. He should also consider whether requests for repeat prescriptions received earlier or later than expected may indicate poor adherence, leading to inadequate therapy or adverse effects.*

4.1.10. *Repeat prescription without clinical review is discouraged. Disease conditions fluctuate over time; dosages and even indications need regular reappraisal. Consequently, automatic refill prescriptions are to be kept to a minimum, taking into consideration the patient's convenience, understanding of his illness and the*

availability of safety-net mechanisms. Automated refills might seem to improve patient adherence to treatment. However, inadequate supervision could result in undetected complications and ensuing medicolegal liability.

4.1.11. *Only the treatment, drugs, or appliances that serve the patient's needs, should be prescribed.*

4.1.12. *The doctor must avoid prescribing habit-forming medicines, particularly sedatives and tranquilizers in large quantities to patients since this may lead to or promote substance abuse. There is also the risk of overdose by unstable patients.*

4.1.13. *Dispensing of medication in the clinic should be on the direction and supervision of the doctor in the absence of a qualifieddispenser or pharmacist.*

4.1.14. *Patients should be warned against self-medication or purchasing controlled medication like antibiotics and sedatives without prescription.*

4.1.15. *In general, the doctor must advise the patient on the importance of keeping and maintaining a handy personal note-book in whichthe medications that he is currently on can be recorded for ease of reference by any other doctor during follow-up or in anemergency."*

"The Poison's Act 1952 (Revised 1989) regulates the import, possession, manufacture, compounding, storage, transportation, sale and use of Poisons.

The following extract refers to Group B Poisons.

21. (1) Group B Poison shall not be sold or supplied by retail to any person except-

a) *where the sale or supply of such poison, if it had been a Group A Poison, would have been authorized under section 20.;*

b) *by a registered medical practitioner, registered Dentist Division 1 or veterinary officer selling or supplying the same in accordance with section 19.*

(2) Every prescription for any Group B Poison prescribed by a registered medical practitioner, registered dentist, or registered veterinary officer shall-

a) *be in writing signed and dated by the prescriber thereof; Poisons 21*
b) *state the address of the prescriber;*
c) *state the name and address of the patient or in the case of a prescription by a veterinary officer, the name and address of the person to whom such medicine is to be delivered;*
d) *indicate the total amount of medicine to be supplied and the dose; and*
e) *specify the number of time (not exceeding three) the medicine may be dispensed and, if dispensed more than once, at what intervals.*

The PHFSA 1998 and Regulation P.U.(A) 137 confer, the registered medical practitioners (RMP) with the statutory right to prescribe and dispense medication/drugs for their patients in a registered private medical clinic.

While the current guideline may not be relevant to medical practice within hospital., institutions and other facilities where the RMP is not required to undertake, dispensing it still applies to practitioners in such establishments when they hold drug stocks and prescribe and dispense independently.

Group C Poisons:

Products containing Group C poisons include medicine for diarrhea, antihistamines and non-steroidal anti-inflammatory drugs and they are available only as dispensed medicine at pharmacies. The pharmacists are required to personally supply medicines of this category and not through the pharmacy assistants."

NOTE

1. The author of this guideline is Dato' Dr. Abdul Hamid bin Abdul Kadir.
2. This guideline was first published on 19th July 2016.
3. This updated guideline was approved by the Ethics Committee on 21st October 2024 and adopted by the Malaysian Medical Council on 18th February 2025.
4. This document will be due for review in 5 years, or earlier as necessary.