GUIDE TO GOOD DISPENSING PRACTICE

This guide has been developed based on the Poisons Act 1952 (Revised 1989), Poisons Regulations 1952, Poisons (Psychotropic Substances) Regulations 1989 and other related acts, guidelines and standards which are currently being used in Malaysia.

The purpose of this guide is to ensure that medicines are dispensed in accordance with the laws and guidelines mentioned above in government and private healthcare facilities and that patients receive the correct medicines with appropriate labelling, accurate instructions and adequate information through which adherence can be improved and occurrence of adverse reactions minimised.

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A. Introduction

Dispensing refers to the process of supplying medicines based on a prescription for a named person together with clear instructions and advice on the use of those medicines[1]. It involves the correct interpretation of the wishes of the prescriber and accurate preparation and labelling of medicines for use by the patient. The dispensing process includes all activities that occur between the time the prescription is presented up to the time the medicines or other prescribed items are issued to the patient.

Good Dispensing Practice ensures that medicine of desired quality is delivered correctly to the right patient i.e. right dose, strength, frequency, dosage form and quantity together with clear instructions, both written and verbal and with appropriate packaging suitable for maintaining the potency of the medicine.

A safe, clean and organised working environment provides the basis for good dispensing practice. The dispensing environment includes[1]:

- Physical surrounding
- Shelving and storage areas
- Work surfaces
- Equipment
- Packaging materials

Responsibility for the accuracy and quality of the medicines supplied lies on the persons overseeing the dispensing process. It is important that the staff who dispense medicines are trained and equipped with technical knowledge and skills necessary to dispense the range of medicines prescribed together with soft skills to communicate effectively with patients.

Dispensing of scheduled poisons; Only a registered pharmacist/medical practitioner/ registered dentist or a person working under their immediate personal supervision; or a person employed in a public hospital or dispensary can dispense, compound or mix any poison with any other substance, whether a poison or not, for the purpose of it being used for medical treatment[2].

Dispensing of psychotropic substances; No person shall sell, supply or administer any psychotropic substance unless he is a registered medical practitioner/ registered dentist/ licensed pharmacist (upon a prescription) or a person acting in accordance with the direction of a registered medical practitioner/ registered dentist. The psychotropic substance is administered for the purpose of medical or dental treatment of a particular patient[4].

In licensed private healthcare facility that has 49 beds or less, the facilities' pharmaceutical services may be headed by a registered medical practitioners (or a registered dental practitioner, wherever relevant). The head then, is

responsible to direct, coordinate and supervise all activities relating to the pharmaceutical services within the establishment[6, 7], including the training of the staff assigned to handle the dispensing of medicines.

B. Dispensing Process

Adherence to good dispensing procedures is vital in ensuring that medicines are dispensed correctly and any errors which may occur during the dispensing process are detected and rectified before medicines reach the patient.

1 Screening and Processing the Prescription

a. <u>Receiving and Validating the Prescription</u>

- On receiving a prescription, it should be checked and validated to ensure that it is for the correct patient. The prescription should have the following information[2]:

Patient Details	**Prescription Details**
1. Name 2. Address and contact number 3. Identification number (IC/Passport No)	1. Drug regimen (name of drug, dose, frequency, administration and duration) 2. Doctor's signature and stamp 3. Doctor's name and address 4. Date of prescribing

- The prescription should be written legibly or printed.

- Names of medicines prescribed should be written in generic name and abbreviations avoided.
- Age of the patient should be stated and for children under 12 years of age, body weight of the patient should also be stated.

b. Understanding and Interpreting the Prescription

Check for the following:

- Dose, frequency and duration
- Drug interactions, known allergies, medicine duplication, polypharmacy, inappropriate drug therapy, contra-indications.
- Unusual usage and suspected drug misuse or abuse.
- For partial medicine supply, ensure that the second or subsequent supply does not exceed the quantity for the duration prescribed.
- In situations where clarification is required which may require intervention, refer to section B.1(c).

c. Handling Prescriptions which Require Queries

- If an incomplete prescription or one which requires further clarification is received, attempt must always be made to contact the prescriber:
    i. If the prescriber can be contacted and is available on site, arrange for the incomplete/missing details to be inserted in the prescription by the prescriber.

Remedial action for such prescriptions should be discussed with the prescriber prior to sending the prescription back to him/her.

ii. If the prescriber is not available to amend the prescription himself/herself, authorisation to make the change may be obtained verbally through the phone. The amendments to the prescription should be repeated back to the prescriber to ensure accuracy. The amendments should be documented on the prescription and endorsed with "PRESCRIBER CONTACTED" (PC), dated and initialled by the pharmacist (or head of the pharmacy services for private healthcare facility)

iii. If the prescriber cannot be contacted, the prescription must be sent back to the prescriber with information on the clarification/action needed.

d. <u>Handling Prescriptions In A Stock-Out Situation</u>

- Stock-out medicine is defined as a situation where the prescribed medicine is not available at the pharmacy when a prescription is being processed. This may be due to the medicine being temporary out-of stock at that time or the pharmacy does not keep it in stock.
- If such a situation occurs:

i. Inform the patient that the medicine is not available. If the patient agrees for it to be supplied at a later time, arrange for the medicine to be stocked and supplied to the patient promptly or;

ii. If the patient requires the medicine urgently, the pharmacist or head of pharmacy services must communicate with the prescriber to discuss if the prescribed medicine can be substituted with another medicine which is readily available.

iii. Any substitution of medicines must be approved by the prescriber and documented on the prescription.

2 Preparing the Medicines

a) Filling

I. Selection of Medicines

- When selecting the medicine to be dispensed, minimise the possibility of medication errors by establishing an appropriate system to ensure that the correct medicine is selected, especially if there are medicines with similar names and packaging. Select the item by reading the label at least twice and cross-checking the medicine name and strength against the prescription.
- Medicines should be dispensed in its original packaging as far as possible.
- Selection of medicines supplied in blister or strip packing is strongly encouraged for solid oral dosage forms (e.g. tablets and capsules). Tablets/capsules should not be removed from the strip when dispensing. Bulk loose packs for supply are not encouraged. However, if loose packs are to be used, make sure the dispenser's hands must not be in direct contact with the medicine.
- Medicines which need to be packed such as

capsules/tablets should be packed into a clean, dry container, such as a bottle or plastic envelope which will not compromise the quality of the product after dispensing.

- Check the expiry date of dispensed medicines to ensure they will remain unexpired for the duration of the treatment course.

II. Extemporaneous Preparation/ Compounding

Extemporaneous preparations should only be prepared if there is no such product available in the commercial market or unsuitable for patient.

- Ensure that the preparation is prepared according to formulation from a reputable reference.
- All calculations done must be double-checked by the pharmacist or counter-checked by another staff member knowledgeable in compounding.
- Staff involved in compounding should be trained and competent to perform this task.
- Availability of requisite facilities and equipment is maintained in good order.
- Ingredients are sourced from recognised pharmaceutical suppliers.
- Once the preparation are ready, label the product with necessary particulars including expiry date/ special requirements for safe handling and storage.

- Keep work sheet records for a minimum of two years. The work sheet should contain information as below:
    - Formula
    - Ingredients and quantity used
    - Manufacturer, batch number, expiry date of ingredients used
    - Patient & prescription details
    - Name of person who prepared the product and the counter-checker
    - Date of compounding

Note: The MOH Extemporaneous Formulary[10] and *Garis Panduan Pembancuhan* (Compounding) *Sediaan Ekstemporanus*[11] can be used as references.

b) Labelling

Every medicine containing any poison sold or supplied must be prepared and labelled by or under the immediate personal supervision of the medical practitioner[3].

All dispensed medicines should be labelled appropriately. It is advisable for labels to be printed. If handwritten, it should be neat and legible.

Do not clutter the label. Only include the most relevant information & check:

- Name, address, and contact number of clinic/pharmacy

- Patient's name
- Name of medicines (generic and/or trade names)
- Dosage form with the strength and quantity per unit dosage form: mg/ml of liquid, mg/g for semi-solid preparations
- Directions for use: dose, frequency and duration
- Date of supply
- Date of expiry (especially if dispensed medicine is not in its original packaging)
- The serial number of the entry (for the sale or supply of medicines entered into the Prescription Book)
- The word "Controlled Medicine" or "*Ubat Terkawal*" should be labelled for all controlled medicines
- Medicines for external use should be dispensed in suitable containers and should be labelled conspicuously with the words "Not to be Taken" or "For External Use Only" in *Bahasa Malaysia* and/or English printed in red OR on a red background
- Special precautionary labels should be used where necessary (e.g., "Complete the course" for antibiotics, "May cause drowsiness" for sedating drugs, etc)

Whenever possible, always dispense the medicine in its original packaging so that patients will have access to the product information.

If a medicine is not dispensed in its original packaging and it is not possible to include all the necessary information on the

label, it should be written separately and dispensed together with the medicine. **Patient information leaflet (PIL) should be provided where available.** Approved PILs can be downloaded from the National Pharmaceutical Control Bureau (NPCB) website at http://portal.bpfk.gov.my/ under Consumers - *Risalah Maklumat Ubat Pengguna (RiMUP).*

3 Final Check

Check the prescription and the filled medicines by ensuring that:

- Filled medicines match the prescription
- Name of the patient is correctly written
- Medicines are filled and labelled with the correct name and strength
- Directions for use on the label matches the prescriber's instructions
- Date of expiry is stated on the label (or on the separate paper with all information pertaining to the dispensed medicine)

Counter-Checking

- Counter-checking should be done by a second person, other than the staff who did the previous tasks.
- Check all the medicines prepared for dispensing against the prescription.
- Separate each patient's medicines that have been counter - checked to prevent mix-up by using an individualised

container.

- Once the counter-checking is done, the person performing this task should initial on the prescription.
- Separate finished prescriptions to prevent mix-ups, by keeping it elsewhere after the medicines has been dispensed to the patient

4 Recording

Proper record keeping is are an essential part of dispensing as it facilitates good management and monitoring of services provided. Such records can be used to verify the stocks used in dispensing, and will be required if a need arises to trace any problems with the medicines issued to patients.

- **All sale or supply of poisons must be recorded in a "Prescription Book" on the day of the sale or supply[2].** The following particulars need to be recorded:

  1. Date of sale or supply and the serial number of the entry of the prescription
  2. Name of the poison and the active ingredients of the medicine or in the case of a proprietary medicine, the name of the medicine and the quantity supplied
  3. Name and address of the patient

- **All sale or supply of psychotropic substances must be recorded in a "Prescription Register for Psychotropic**

Substances" on the day of the sale or supply[4].
The following particulars need to be recorded:

1. Date of sale or supply
2. Name and strength of the psychotropic substance and the quantity sold/supplied/administered
3. Name and address of the patient
4. The total stock of the psychotropic substance. Entry of quantity received also should be made for every purchase of psychotropic substance.
5. Each strength or type of psychotropic substance must be recorded in a separate register or a separate part of the register

Note: All **record books must be in the form of a bound book[4]**. Records kept as soft copy must be printed weekly (if there is a transaction) and form a bound book.

5 Issuing Medicines to the Patient

Dispensing of medicine should only be done by a registered medical practitioner or a licensed pharmacist *[Definition of "dispensed medicine" [2]].*

No poisons shall be sold or supplied to any person under the 18 years of age, otherwise than for the purposes of the medical treatment of such person *[Section 17:"Prohibition of Sale to persons under 18" [2]].*

- Check the name and ID to confirm the correct prescription

items are being received by the correct patient/ representative.

- Give **clear instructions** and **proper advice** on how to take/ use the medicines dispensed.
- When necessary, demonstrate the correct use of device involved.
- Ensure the patient is made aware of the transportation, storage conditions and usage requirements for the medicines.
- Compliance aids (measuring spoon or syringe) for the appropriate dose should be provided, if required.
- Every effort must be made to ensure that the recipient understands the information/instructions and advice provided.

When dispensing the medicines, ensure the **5Rs**:

1. **Right Patient**
2. **Right Medicine**
3. **Right Dose**
4. **Right Route**
5. **Right Time**

- Advise patients to inform the clinic/pharmacy should they encounter any adverse drug reactions (ADRs) when taking the dispensed medicines.
- For the supply of Group B poisons, the name of the person who dispensed the medicines, address and the date of supply should be written on the prescription above the

doctor's signature as a form of endorsement[2].

C. Medication Counselling

- If necessary, provide medication counselling to patients dispensed with medicines.
- It is encouraged to counsel patients with chronic diseases on multiple medications.
- Maintain records of the counselling done.

D. Maintaining Pharmaceutical Stocks

Store all medicines in the original containers as supplied by the manufacturer. If the contents need to be transferred to other containers (pre-packing), care must be taken to avoid contamination and mix up. The new containers of the pre-packed medicines should be labelled appropriately with:

- Name, address, and contact number of clinic/pharmacy
- Name of medicines (generic and/or trade names)
- Dosage form with the medicine strength (mg of tablet, mg/ml of liquid, mg/g for semi-solid preparations)
- Manufacturer batch number
- Manufacturer expiry details

All psychotropic substances must be stored in a locked cabinet, safe or receptacle and can only be locked or unlocked by the registered medical practitioner or licensed pharmacist[4].

- Store medicines under suitable conditions, taking into consideration the general usage of the medicine (internal/ external item should be segregated/ store separately), stability of the drug and manufacturer recommendations.
- Protect medications from contamination, sunlight, moisture and adverse temperatures.
- Application of Tallman Lettering, Handling of Look Alike, Sound Alike Guideline and High Alert Medications Guideline in arranging medication stocks is encouraged in order to prevent medication error.
- Segregate deteriorated/ recalled/ expired/ returned medicines for proper disposal and store in an appropriate bin/ container to prevent unauthorised access.
- Management of disposal of expired/ returned medicines should follow as below:
    a) Poisons (Psychotropic Substances) Regulations 1989[4] for disposal of psychotropic substance – needs to be witnessed by a Pharmacy Enforcement Officer, Ministry of Health.
    b) The Guidelines on the Management and Handling of Clinical Waste in Malaysia[14] by the Department of Environment, Ministry of Natural Resources & Environment for disposal of medicines.

E. Repeat Prescriptions

- Repeat prescription is a prescription that involves multiple supplies of medicines on a periodically, based on the validity of the prescription and duration for supply.

- If a prescription is not supplied in full, ensure that a copy of the original prescription is made and kept for recording purposes. Also, ensure that the quantity supplied by the pharmacy is recorded on the original prescription as reference for the next supply.
- The original prescription should be returned to the patient as it will be required for the next supply.

F. Delivery of Part-Supply Medicines by Post

- A delivery service should **ONLY** be provided for **repeat prescription.** The delivery service is applicable when it has been established that the patient/caregiver understands the use of the medicines and direct face-to-face contact with the patient or caregiver is deemed not necessary for subsequent refills of the prescription.

Criteria for eligibility:

1. Only stable and compliant patients should be eligible to receive medicines through the delivery service.
2. Only part supply medicines for chronic diseases should be considered for delivery services. First time supply must always be dispensed at the pharmacy counter.
3. Only medicines that do not require specific storage conditions can be delivered through post.
4. Psychotropic drugs and medicines containing pseudoephedrine, ephedrine, codeine and tramadol **should not** be delivered by post.

- Consent from the patient must be obtained prior to providing the delivery service and appropriate records of requests for the service must be kept.
- The delivery mechanism used must be secure and medicines delivered promptly to the patient so as not to compromise on the quality of the medicines and to ensure continuity of their medicines.

Note: The *Garis Panduan Perkhidmatan Ubat Melalui Pos 1Malaysia (UMP 1Malaysia)*[15] should be referred for further information.

Glossary

a) **Registered Pharmacist**: A pharmacist registered under any written law relating to the registration of pharmacists, and includes, in Sabah or Sarawak, a person holding a qualification recognised by the Director of Medical Services in Sabah or Sarawak, as the case may be, as a sufficient guarantee of the possession of the requisite knowledge and skill for the efficient practice of the profession of a pharmacist[2].

b) **Licensed pharmacist**: a registered pharmacist who is the holder of a Type A Licence issued to him under section 26 of Poison Act 1952[2]

c) **Registered medical practitioner**: A medical practitioner registered under the Medical Act 1971 [Act 50][5]

d) **Private healthcare facility**: Any premises, other than a

Government healthcare facility, used or intended to be used for the provision of healthcare services or health-related services, such as a private hospital, hospice, ambulatory care centre, nursing home, maternity home, psychiatric hospital, psychiatric nursing home, community mental health centre, haemodialysis centre, medical clinic, dental clinic and such other healthcare or health-related premises as the Minister may from time to time, by notification in the Gazette[5]

e) **Healthcare professional**: includes a medical practitioner, dental practitioner, pharmacist, clinical psychologist, nurse, midwife, medical assistant, physiotherapist, occupational therapist and other allied healthcare professional and any other person involved in the giving of medical, health, dental, pharmaceutical or any other healthcare services under the jurisdiction of the Ministry of Health[5]

Acknowledgement

- Private Medical Practice Control Section (CKAPS), Medical Practice Division, Ministry of Health Malaysia
- Oral Health Division, Ministry of Health Malaysia

References

1. WHO. Chapter 30: Ensuring good dispensing practices). Management Science for Health - Part II: Pharmaceutical Management. 2012

2. Poisons Act 1952 (Revised 1989)
3. Poisons Regulations 1952
4. Poisons (Psychotropic Substances) Regulations 1989
5. Private Healthcare Facilities and Services Act 1998
6. *Private* Healthcare Facilities and Services (Private Medical Clinics or Private Dental Clinics) Regulations. 2006 [P.U.(A) 137/2006]
7. *Private* Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations [P.U.(A) 138/2006]
8. *Bahagian Perkhidmatan Farmasi & Bahagian Pembangunan Kesihatan Keluarga, Kementerian Kesihatan Malaysia*. *Prosedur Operasi Piawai Farmasi Kesihatan.* 2005
9. *Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia. Polisi Operasi Farmasi Ambulatori (Hospital & Klinik Kesihatan) Edisi 1.* 2011
10. Pharmaceutical Services Division, Ministry of Health Malaysia. MOH Extemporaneous Formulary. 2012
11. *Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia. Garis Panduan Pembancuhan* (Compounding) *Sediaan Ekstemporanus. 2015*
12. Pharmaceutical Services Division, Ministry of Health Malaysia. Guide On Handling Look Alike, Sound Alike Medications, 1st Edition. 2012
13. Pharmaceutical Services Division, Ministry of Health Malaysia. *Guideline on Safe Use of High Alert Medications,* 1st Edition. 2011
14. Department of Environment, Ministry of Natural

Resources and Environment. Guidelines on the handling and management of clinical waste in Malaysia, 3rd Edition. 2009

15. *Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia. Garis Panduan Perkhidmatan Ubat Melalui Pos 1Malaysia (UMP 1Malaysia). 2011*