MMC Guidelines for Good Dispensing Practice

Preamble

These Guidelines are based on relevant provisions, regulations and recommendations of:

- The Poison's Act 1952
- Private Healthcare Facilities and Services act 1998 & Regulations P.U.[A]137
- Dangerous Drugs Act 1952
- Drug Dependant (Treatment & Rehabilitation) Act
- Sale of Drugs Act 1952 (Revised 1989) P.U.[A]223/84 Control of drugs and cosmetic regulations 1984.
- Poisons (Psychotrophic 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

This Guidelines are consistent with existing laws and regulations and also in line with the Guidelines for Good Medical Practice of the Malaysian Medical Council.

The Poison's Act 1952 and the PHFSA 1998 and Regulations P.U.(A)137 confers the registered medical practitioner (RMP) with the statutory right to prescribe and dispense medication/drugs for their patients in a registered private medical clinic.

This Guideline is not relevant to medical practice within hospitals, institutions and other facilities where the RMP is not required to undertake the duty to dispense.

1.0 Definition

1.1 "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

1.2 “Drug” includes any poisons, narcotic preparations and products for medicinal purposes

2.0 Duty to Dispense

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

3.0 Notice of Clinic with Pharmaceutical Services

3.1 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 patients that that the clinic has a dispensing facility and that patients that patients have the choice to have their medication/drugs dispensed at the clinic or at any pharmacy.

3.2 Patients who do not wish to have their medication/drugs dispensed in the clinic should requested to indicate so at the time of their registration and will be provided with a written or printed prescription when requested.

4.0 Guidelines

4.1 It is good medical practice to prescribe/ dispense a medication/drugs only after examining the patient and or after review of patient’s medical records and making relevant notes in the patient records.

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

4.3 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 indication of his patient’s medical condition.

4.4 It is good dispensing practice to maintain adequate stock inventory of relevant medication/drugs in the clinic.

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

4.6 It is good medical practice to avoid prescribing/dispensing habit-forming medication/drugs, particularly sedatives and tranquilizers in large quantities to patients as this may lead to substance abuse. There is also the risk overdose by unstable patients.

5.0 Written Orders for medication or treatment

5.1 Medication/drugs dispensed or treatment shall only be given on the written order of a RMP.

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

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

6.0 Medical Errors and Adverse Drug Reactions

6.1 It is good medical practice to counsel the patient on any medication errors and adverse drug reactions

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

6.3 It is good medical practice to routinely reconfirm at the point of dispensing, the correct medication/drugs dispensed for the patient and to re-confirm the history of any previous allergies with the patient

7.0 Clinics with Computerised Patient Record

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

8.0 Head of Pharmaceutical Services

8.1 The head of pharmaceutical services of the clinic may be a RMP or registered pharmacist

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

8.3 He shall have sufficient number of appropriately trained staff.

9.0 Location of pharmaceutical services

9.1 It is good medical practice that this service be located in a suitable clean room or area

9.2 It is good medical practice to provide 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

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

10.0 Dispensing and Compounding Unit

10.1 It is good dispensing practice to provide the following 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, psychotropics, poisons and other controlled drugs.

11.0 Labelling of medications/drugs

11.1 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 labelled with:

11.1.1 Name and address of the clinic;

11.1.2 Name of the patient;

11.1.3 Name of the medication/drugs;

11.1.4 Adequate directions for the use of such medication/drugs;

11.1.5 Date of dispensing/delivery;

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

11.1.7 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;

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

12.0 Prescription Book

12.1 Record of dispensed medicines/drugs shall be entered in a PRESCRIPTION BOOK with a reference to the serial number of the entry

12.2 For clinics with computerised record, hard copies of the entries for the PRESCRIPTION BOOK should be printed and filed accordingly.

13.0 Storage and Containers for Dispensed medicines

13.1 All medication/drugs should be in properly labelled containers

13.2 Medication containers having soiled, damaged, incomplete, illegible or makeshift labels shall be relabelled or disposed off.

13.3 Relabelling of containers may be allowed only if the identity of its contents is certain

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

14.0 Contaminated, expired or discontinued medications/drugs

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

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

15.0 Cold Chain

15.1 It is good medical practice to maintain the cold chain for all vaccines stored in the clinic.

16.0 Written Policies

16.1 It is good medical practice to have written policies developed to indicate the responsibility of the head of pharmaceutical services.

16.2 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

16.3 It is good medical practice that all written policies should be consistent with any written laws relating to advertisement, sale and use of medicines and poisons.

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