A GUIDE TO LEGISLATIONS ON THE RECORDING, LABELLING, STORAGE AND DISPOSAL OF POISONS AND PSYCHOTROPIC SUBSTANCES APPLICABLE TO PRIVATE CLINICS

PHARMACEUTICAL SERVICES DIVISION, MINISTRY OF HEALTH MALAYSIA [JANUARI 2016]
## CONTENTS

1.0 Introduction ........................................................................................................... Page 3

2.0 Recording of poisons and psychotropic substances ............................................. Page 3

3.0 Labelling of poisons and psychotropic substances .............................................. Page 6

4.0 Storage of poisons and psychotropic substances ................................................ Page 9

5.0 Disposal psychotropic substances ................................................................... Page 10

6.0 Closing .................................................................................................................... Page 10
1.0 INTRODUCTION

Section 2 of the Poisons Act 1952 defined Poison as any substances specified by name in the First Column of the Poisons List (Schedule 1) of the Poisons Act 1952. It includes any preparation, solution, compound, mixture or natural substances containing such substances; other than an exempted preparation or an article or preparation included for the time being in the Second Schedule of the same Act. Example of poisons include antibiotics, antihistamines, most anti-inflammatory agents (NSAIDS), antihypertensive and many other medicinal preparation used in the clinic set up.

Section 30(1) of the same Act defined Psychotropic Substances as any substances specified in the Third Schedule of the Poisons Act 1952. Examples of Psychotropic Substances are minor tranquilizers such as Diazepam, Narcotic analgesic like Pentazocines, Barbiturates such as Phenobarbitone and slimming agents such as Phentermine.

2. RECORDING OF POISONS AND PSYCHOTROPIC SUBSTANCES

2.1 Prescription Book (Section 24 of Poisons Act 1952)

Any poison sold or supplied by a registered medical practitioner, registered dentist or veterinary surgeon for the purpose of medical treatment, dental treatment or animal treatment, the practitioner shall on the day which such poison or medicine is sold or supplied, enter or cause to enter in a book called the Prescription Book. This book shall contain the following particulars:

a. The date on which the medicine was sold or supplied and the serial number of the prescription (if supplied based on the prescription)

b. The name of the poison or, in the case of a proprietary medicine, the name of the medicine and the quantity supplied
c. The name and address of the patient (in the case of a sale/supply otherwise than on a prescription)  
d. The name of the patient (in the case of a sale/supply by a licensed retailer on a prescription)

Format of the Prescription Book

<table>
<thead>
<tr>
<th>Date of sale/supply</th>
<th>Serial No of Prescription</th>
<th>Name of Patient</th>
<th>Address of Patient</th>
<th>Poisons/Medicine Supplied</th>
<th>Quantity Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.2 Prescription Register for Psychotropic Substances  
(Regulation 19 of the Poisons (Psychotropic Substances) Regulations 1989)

Any person who sells or supplies or administers any psychotropic substances for the purpose of medical treatment, dental treatment or animal treatment shall keep and maintain a register called the Prescription Register for Psychotropic Substances, and shall on the day such Psychotropic Substances is sold or supplied or administered, enter or cause to be entered therein true particulars of the following:

a. The date on which the psychototropic substances was sold or supplied or administered and the serial number of the entry  
b. The name and strength of the psychotropic substances and the quantity sold, supplied or administered  
c. The name, identity card number, passport number or any other legal identification document and address of the patient, or where the prescribed is a veterinary surgeon or the prescription relates to animal treatment, the name and address of the recipient
An additional record and maintenance of the register are required as stipulated in Regulation 22 and 23 of the Poisons (Psychotropic Substances) Regulations 1989. The register shall be kept and maintained as follows:

a. A separate register or separate part of the register for each type of psychotropic substances

b. Also enter into this register the quantity of the psychotropic substances received, or administered, the name and address of the supplier or the recipient, the date on which such psychotropic substances was received, or administered, reference number of patient or client.

c. The total stock of such psychotropic substances (stock balance) in his possession

d. And shall not make any cancellation, obliteration or alteration of an entry in the register, and any correction must be made by way of marginal note or a footnote and must specify the date correction was made.

e. The entry must be made in chronological order with respect to the previous entries in the register

f. The register shall be kept on the premise to which the register relates to the sale, supply or administration of any psychotropic substances in a such premises

g. Every register shall be in the form of a bound book or in the form which has the written approval of the Licensing Officer (State Health Director)

h. Register shall be kept for a period of two years from the date of the last entry in such register.
Format of the Prescription Register for Psychotropic Substances
Name and Strength of the Medicine (Psychotropic Substances):

<table>
<thead>
<tr>
<th>Date Supplied/ Administered/ Received</th>
<th>Serial Number</th>
<th>Name and Address of Patient/ Supplier</th>
<th>Identity Card Number/ Passport Number of Patient</th>
<th>Quantity Supplied/ Administered/ Received</th>
<th>Total Stock in Possession</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronological order</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.0 LABELLING OF POISONS AND PSYCHOTROPIC SUBSTANCES

3.1 Labelling of poisons as dispensed medicine (Regulation 12 of the Poisons Regulations 1952)

Where any poison sold or supplied as dispensed medicine or as an ingredient in a dispensed medicine, the container of such medicine shall be labelled, in conspicuous and distinct manner with the following:

a. Name and address of the supplier or seller
b. Name of patient or purchaser
c. Name of the medicine
d. Adequate directions for use of such medicine
e. Date of delivery of such medicine
f. Where such medicine is sold or supplied and entered in a prescription book, with a reference to the serial number of the entry in such book relating to such sold or supply
Any poisons supplied or sold as dispensed medicine, shall be labelled on the container the words “Controlled Medicine” or “Ubat Terkawal”

When the poison or medicine containing poison is supplied or sale for external use, it shall be labelled on the container 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.

Example of dispensed medicine label:

![Example Label]

3.2 Labelling of psychotropic substances (Regulation 28 of the Poisons (Psychotropic Substances) Regulations 1989)

Where any psychotropic substances is sold or supplied for the purpose of medical or dental or of a particular patient or animal treatment of a particular animal, the
container of such psychotropic substances shall be labelled in a conspicuous and distinct manner with:

a. Full name and address of the seller or supplier
b. Full name of the patient or purchaser
c. Adequate directions for the use of such psychotropic substances
d. The date when such psychotropic substances was sold or supplied
e. The name and strength of the psychotropic substances

Example of psychotropic substances label:

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KLINIK XYZ
No 123 Jalan 456, Taman Megah,
46000, Petaling Jaya, Selangor
Tel: 03-79832987
Faks: 03-71433235

Diazepam 5mg

Name (Nama): ..Kumon bin Kumin.......
Date (Tarikh): 1.7.2012 RN: 99999

Take Tablet Times Daily After Food
Makan Tablet Kali Sehari Selepas makan
1 3
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4.0 STORAGE OF POISONS AND PSYCHOTROPIC SUBSTANCES

4.1 Storage of poisons (Regulation 6 of Poisons Regulations 1952)

Any poison stored in any dispensary, retail shop or premises used in connection therewith, shall be stored in a cupboard or drawer under lock and key reserved solely for the storage of poisons, or in a part of the premises which is partitioned off or otherwise separated from the remainder of the premises and to which customers are not permitted access.

4.2 Storage of psychotropic substances (Regulation 24 of the Poisons (Psychotropic Substances) Regulations 1989)

a. All psychotropic substances must be stored in a room, cabinet, safe or receptacle which remains locks except in so far as may necessary to have such room, cabinet, safe or receptacle opened in order to:

i. carry out the dispensing, *compounding, *mixing, sale or supply of the psychotropic substances
ii. keep other psychotropic substances in such room, cabinet, safe or receptacle or
iii. conduct a stock check of the psychotropic substances stored therein

* [Notes: Regulation 17 of the Poisons (Psychotropic Substances) Regulations 1989) – No person shall dispense, compound or mix any psychotropic substances with any other substance, whether a psychotropic substances or not, for the purpose of it being used for medical, dental or animal treatment unless he is a licensed pharmacist or a pharmacist in the public service]
b. The psychotropic substances storage must be locked and unlocked by the registered Medical Practitioner himself and the keys must be kept by him only.

c. Any room, cabinet, safe or receptacle used for storing any psychotropic substances shall be constructed and with reasonably sufficient security measures in order to prevent theft or diversion of the psychotropic substances stored therein.

5.0 Disposal of psychotropic substances (Regulation 25 of the Poisons (Psychotropic Substances) Regulations 1989)

Any disposal of psychotropic substances must be done in the presence and in accordance with the instruction of a Drug Enforcement Officer.

The date and quantity of psychotropic substances disposed must be entered into the register and shall be acknowledged by the Drug Enforcement Officer.

6.0 CLOSING

It is hope that this information will help to facilitate the practitioners in recording, labelling, storage and disposal of poison and psychotropic substances. Any questions could be directed to Pharmaceutical Services Division office at head quarter or state level.