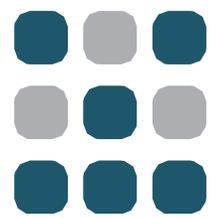




COMMUNITY
PHARMACY
BENCHMARKING GUIDELINE
PHARMACEUTICAL SERVICES DIVISION
MINISTRY OF HEALTH MALAYSIA



2nd EDITION

2015

FOREWORD



The Ministry of Health's Vision: "A Nation Working Together for Better Health" regards all stakeholders as partners in fulfilling its commitment towards improving the health status of the population and providing access to quality healthcare. Community pharmacists play major roles in reaching out to the population as they are among the healthcare professionals who are most accessible to the community. Besides, the standard and practice in the community pharmacies reflects the pharmacy profession as a whole.

This benchmarking guideline serves as a set of standards that needs to be complied with for the purpose of community pharmacy practice set up, training activities (under-graduate / pre-registration), audits and complementing the licensing requirement. The facilities should project a professional image befitting the roles of community pharmacists without compromising the occupational and safety requirements.

A checklist on benchmarking audit of community pharmacies is also included in this edition to allow community pharmacies to conduct self-audits in order to ensure adherence to proper practice and requirements. The criteria for general pharmacy and pharmacy in a facility are also highlighted under zoning.

I would like to extend my heartfelt appreciation to everyone involved for their tremendous support and invaluable contributions towards developing this guideline. It is also my fervent hope that this guideline will serve its purpose well in meeting our challenge to provide quality healthcare to the public.

Thank you.

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COMMUNITY PHARMACY BENCHMARKING GUIDELINE

1.0 INTRODUCTION

This benchmarking guideline serves as a set of standards that needs to be complied with for the purpose of community pharmacy practice set up, training activities (under-graduate / pre-registration), audits and complementing the licensing requirement.

The purpose of this guideline is to ensure the quality of the community pharmacy practice for the benefit of consumer/ patients.

For the purpose of this guideline, the community pharmacy is defined as a premise with at least one pharmacist holding a Type A license issued under the Poisons Act 1952 who can supply/sell poison either by retail only or by both retail and wholesale.

2.0 OWNERSHIP

A community pharmacy should be legally incorporated, complying with current government policy and relevant legislations.

The community pharmacist should:

- have full management control of the pharmacy practice
- have significant representation in executive board and possess share equity
- inform any changes in shareholding to the Licensing Officer and/or any other relevant authorities

3.0 PREMISES

3.1 Location

The premises are located within the management of the Local Council, where appropriate.

Pharmacies need to comply with the Local Authority laws.

The pharmacy premise cannot be shared with any other businesses (including Multi-Level Marketing business)

Under certain circumstances where sharing of premise is unavoidable, the following conditions must be complied with:

- Full separation with no access allowed between the different businesses in the same premises
- Should have different access points and clear signages
- Different business entities
- Each premise has its own staff

For a pharmacy in a shop lot:

- A new pharmacy should be located at least 300 meter radius from an existing pharmacy outlet.

For a pharmacy within a facility/shopping complex/ business center/ multi-storey building:

- 1 outlet for every 200,000 square feet rentable space and below

A new pharmacy should be located at least 150meters in a linear measurement distance (shortest legal travelling route) to the main entrance of the facility from nearest pharmacy.

(Please refer to Appendix I)

3.2 Medicine Dispensing Area (MDA)

The MDA should:

- be a minimum of 18 square meter (193 sq. ft)
- consist of :
 - Prescription counter
 - Counseling area
 - Medicines preparation area (dry and wet compounding)
- Screening tests area

3.3 Signboard & Advertisement

Pharmacy signboard must project the professional image of a pharmacy.

No advertisement is permitted in any pharmacy signboard. This applies to signboards of both existing and new pharmacy businesses.

Any posters or products advertisements displayed to public must be in accordance with the relevant legislations/guidelines.

The types of services offered should be displayed clearly inside the premises.

Examples of services are:

- Blood Glucose Test
 - Certified Smoking Cessation Service Provider Program (CSCSP)
 - Urine Pregnancy Test
 - Electronic blood pressure monitoring
- (Other service(s) displayed is subjected to the relevant legislations)

Notice of the pharmacist(s) on duty to be displayed must include:

- Name of pharmacist(s)
- Time and date/day of duty
- Photo (optional)

Certificates of Registration and Annual Retention for the pharmacist in-charge should also be displayed clearly.

“No Smoking” signs must be displayed prominently to promote healthy lifestyle.

Designated areas are indicated clearly, such as “Prescription Counter” or “Pharmacy”.

3.4 Facilities

Drugs and merchandises should be displayed in a neat and tidy manner thus projecting a professional image.

Pharmacist office (optional).

Medicine Dispensing Area/ Prescription Counter

- Preferably without any barrier to facilitate patient counseling and for more effective communication.
- Enable safe and efficient workflow.
- Pharmacist should be able to maintain a direct supervision of the pharmacy and staff from this area.
- Size and organization of this area should be adequate for the volume of work.

Counseling area must be a properly designated area, private and comfortable.

- If it is a room, the door should be made of half glass

Waiting area

- Comfortable with adequate space for customers.

Lighting and ventilation

- Ensure adequate lighting to reduce risk of medication errors.
- Bright white fluorescent lights are preferred to filament.

Noise level

- Acceptable noise level - may have soft background music.

Air-conditioner with scheduled maintenance to ensure the stability of medicines and for the comfort of staff and customers.

Refrigerator

- Should be maintained at temperature between 2 – 8°C.
- Daily temperature reading must be recorded and verified.
- Appropriate action should be taken to rectify any problems identified.
- Do not store food or drinks in the refrigerator used for the storage of medicines.

Cleanliness

- There should be appropriate pest control measure.
- Daily cleaning to maintain the pharmacy in a tidy and dust free state.
- Regular cleaning of merchandise.

- Written cleaning procedures and schedules should be set out and made available.

Medicines Preparation Area

- A washbasin with water supply should be available, other than in the toilet.

a) “Wet Compounding Area”

(for the purpose of extemporaneous preparations only)

- A designated area with sink and water supply.
- Should be away from food and drinks.
- All working surfaces and shelves should have a smooth impervious surface and washable material finishing.
- Wet compounding area must be equipped with the following, if applicable:
 - i. Weighing scale
 - Regular verification and calibration by relevant bodies are required to ensure reliability and efficiency
 - ii. Mortar and pestle
 - Must be maintained in good condition.
 - iii. Tile/glass slabs with spatula
 - Must be maintained in good condition.
 - iv. Measuring appliances
 - Must be maintained in good condition.

b) “Dry Compounding Area”

- A designated area for counting tablets/ capsules, filling and packing of medicines. Also for labeling the prepared medicines.
- Should be away from food and drinks.
- Provide suitable and hygienic means of counting tablets/capsules (e.g. counting tray).

Health Screening Area

- Equipped with appropriate equipment and devices.
- Equipment and devices in reliable conditions at all times.

Water closet (optional)

Equipment

- a) Computerized system (where available) preferably with the following functions:
 - Pharmacy Information Software
 - Inventory/Stock keeping
 - Printing of labels
 - Printing of customer information leaflet
 - Keeping of patient medication record
 - Itemised billing with GST function
 - Appropriate drug naming system
- b) Printer (where available) preferably with the following functions:
 - For the production of labels, leaflets or any printed materials.
- c) Cabinets
 - For the storage of documents/ records.
- d) Labels
 - Appropriate sizes and shapes
 - Preferably printed to prevent/ minimize errors due to illegible handwriting

Other Requirements (optional)

- Entrance should be accessible to wheelchairs and pushchairs.
- Pantry area for staff.
- Adequate toilet facilities, clean and in good condition.
- Arrangement must be made for the regular collection and safe disposal of pharmaceutical waste and other refuse.

3.5 Occupational and safety requirements:

The premises should be safe for the public and staff working in the pharmacy. Must comply with all statutory requirements where appropriate:

- Appropriate fire escape way
- Fire alarm
- Fire extinguisher
- Occupier's indemnity

3.6 References

The following references should be available:

- British National Formulary or Australian Formulary
- Code of Conduct for Pharmacist and Bodies Corporate
- All relevant pharmacy legislations.

Optional:

- Martindale
- MIMS
- References for herbal medicines

4.0 PRACTICE

4.1 Service

Essential services

- Screening of prescription(s)
- Dispensing of medicines
- Compounding of medicines (patient specific)
- Counseling and advisory
- Monitoring and screening tests
- Pharmacy management in drug procurement
- Proper documentation

Optional Services

Medication review and accredited pharmacy services including:

- Home Medication Review (HMR)
- Medication Therapy Adherence Clinic (MTAC)
- Certified Smoking Cessation Service Provider (CSCSP)
- Weight management
- Health screening
- Any other certified pharmaceutical care services

4.2 Type of products

70% of the merchandise in a community pharmacy should consist of registered pharmaceutical products, health and nutritional products, surgical and medical devices, personal care and rehabilitation aids.

Sale of goods and food which is harmful to health is strictly prohibited. Non-pharmacy products, e.g gift items, cards and drinks, should be minimized.

4.2 Personnel

a) Pharmacists

- Registered with the Pharmacy Board of Malaysia
- Observe the Code of Conduct for Pharmacists and Bodies Corporate
- Comply with all the pharmacy legislations of Malaysia
- Dress code
 - i. Pharmacist Tunic (White Coat)
 - ii. Must project a professional image
- Name tag must have the word “Pharmacist”
- Ratio of pharmacist to prescription should not exceed 80 to 100 prescriptions per pharmacist per day
- Notice and photograph of the pharmacist on duty must be displayed with the duty hours
- The pharmacist in a new community pharmacy has to possess at least 4 years working experience as a pharmacist or 2 years as a community pharmacist

b) Pharmacy Assistants

- Diploma in Pharmacy are preferred
 - Structured training
 - Suitable number
- The role of the pharmacy assistants are to help in the preparation of medicines to be dispensed. They are not allowed to dispense scheduled poisons without a pharmacist.

4.3 Storage of medicines

All medicines must comply with labeling requirements and should be kept in the original packaging or properly labeled containers.

Different categories of items should be systematically arranged.

Separate storage should be provided for internal and external medicines. Medicines with similar names and packaging should be distinctively separated to prevent dispensing errors.

All scheduled poisons under the Poisons Act 1952 must be stored in accordance with the legislations.

Poison B and Poison C items as listed in Part I of the Poison List should be kept in a locked cabinet to prevent access to customers and unauthorised personnel.

Psychotropic drugs/ dangerous drugs must be kept according to Regulations 24, Poison (Psychotropic Substances) Regulations 1989 whereas Dangerous Drugs should be kept according to Regulations 9(2) Dangerous Drugs Regulations 1952. A separate, safe and locked cabinet should be used for storage of psychotropic substances and dangerous drugs away from other goods/medicines.

All keys must be kept by the pharmacist.

Storage conditions must comply with manufacturer instructions and cold chain requirements where relevant.

4.4 Safety and Quality Improvement Activities

Secure locks on main door and grille/gate.

Secure locks on back doors and grille/gate if applicable.

Electronically controlled locks may be utilised.

Additional safety control such as video cameras and alarm system are advisable.

Policy for appropriate security should be arranged.

To comply with relevant statutory requirements.

To comply with Good Dispensing Practice. (Please refer to GDsP Guideline)

4.5 Record

Records and documentations should be kept and updated systematically as stipulated by the law.

4.6 Operating Hours

Minimum 40 hours/week with pharmacist

5.0 STANDARD OPERATING PROCEDURE

5.1 Counseling and Dispensing Medicines

Refer to GDSP Guidelines

5.2 Response to Minor Health Problems/ Sales of Pharmacy Medicines (Self-care)

This SOP applies to situations where the customer/patient comes to the pharmacy to consult the pharmacist on a minor health problem or request to purchase a pharmacy medicine or an over-the-counter medicine by name.

All pharmacy staff must be adequately trained. They should also know when to refer the customer to the pharmacist.

Pharmacists and their staff must be aware of the potential of misuse for certain non-prescription medicines and should not supply when there are reasonable grounds for suspecting misuse/wrongful use.

Pharmacy should have an area for confidential conversation with the patient/customer.

Pharmacists should counsel/ assess the health problem after obtaining sufficient information on the following:

- Who has the problem: if a child, the age of the child is required
- What are the problems
- How long has the condition existed
- Action already taken
- Medicines already used for the problem
- Medical history: allergies, other existing health problems and medication history
- To rule out possible underlying serious acute diseases
- When to refer to a medical practitioner or other health professionals, with a referral note(refer to Appendix iv).

After the assessment, the pharmacist should:

- Differentiate minor ailments from major diseases
- Minimize risk factors and complications
- Offer appropriate advice (non-pharmacological and/or pharmacological)
- Counsel patient/customer on the efficacy and safety of the medicine(s) recommended
- Refer patient/customer to a medical practitioner or other Health care professionals when appropriate.

When counseling patient:

- Make sure the patient knows/understands the objective of the treatment.
- Go through the treatment as to why, what, when and how to use The medicine(s).
- Advise on non-pharmacological treatment when appropriate.
- Advise on possible side-effects and contraindications.
- If symptoms persist, the patient should be advised to see a Medical practitioner with a referral note.

Documentation

Proper documentation should be maintained to fulfill legal and professional requirements.

Preferably, the pharmacy should maintain patient medication record:

- To check the progress of the treatment and provide information on the medical history of the patient.
- To be kept in pharmacy computer systems or in manual records.
- Should be pertinent, accurate, up-to-date, stored securely and treated as confidential and used only for the purpose for which it is obtained.

Labeling

Refer to Guide to Good Dispensing Practice

5.3 Self-monitoring Devices

Pharmacist should give full information to the patients on the use of the self-monitoring devices and the frequency of measurement.

Patients may be asked to perform self-monitoring under the guidance of the pharmacist to ensure effective learning of the technique.

Encourage patients to document their own results. Help them to understand the results.

5.4 Health Screening

All staff involved in providing the above service should be trained in the use of the monitoring devices and the procedures. They should also be aware of the limits of the tests provided.

The pharmacy must have a suitable area with facilities to perform the tests and provide counseling.

Ensure that the devices used are in good order.

Keep up to date with the latest development and know when to refer patients to medical practitioners.

Before conducting the test, explain the procedure to the patient.

Communicate test results to the patient in a manner in which he/she can understand and provide appropriate counseling.

5.5 Extemporaneous Dispensing

Ensure that the formula and intended method of preparation is correct.

Requisite facilities and equipment for the preparation are available and maintained in good order.

Ingredients must be sourced from reliable pharmaceutical supplier and be of a quality accepted for use in the preparation of the extemporaneous products.

All calculations, ingredients and quantities should be checked by a second person who is a pharmacist.

Pharmacists must pay particular attention to substances that may be hazardous and require special handling techniques.

The product must be suitably labeled with the necessary information, including special requirements for the safe handling and storage of the product including an expiry date.

Document the preparation and keep the records for at least 2 years. The records must include the formula, the ingredients and the quantities used, their source, batch number, expiry date, date of preparation and personnel involved in the preparation.

All documentations should be certified and duly stamped by a registered pharmacist with his/her registration number indicated.

Labeling

Refer to Guide to Good Dispensing Practice

5.6 Awareness of Original and Counterfeit drugs, OTC and herbal supplements

Pharmacist should only buy medicines from legitimate sources

Pharmacies must be equipped with the Meditag reader in order to ascertain if a product is genuine and registered with the competent authority.

Pharmacists must educate customers on how to identify counterfeit medicines.

Pharmacists must be able to check the registration of a product through the National Pharmaceutical Control Bureau (NPCB) website.

Pharmacists must be aware of the latest information on de-registered products, products found containing adulterated ingredients, changes to product information and safety issues.

6.0 OPTIONAL PROFESSIONAL SERVICES

6.1 Patient Medication Review (PM Review)

Patient Selection

Patient selection must have the following criteria:

- A PM Review can be conducted with patients on multiple medications and those with long-term conditions.
- These regular PM Reviews, initiated by the pharmacist, shall only be provided for patients who have been patronizing the pharmacy for the dispensing of prescriptions for at least the past three months.
- PM Review can be conducted every 3 months after the last PM Review.
- Self-referral by patients.
- Referral by medical practitioners.
- Referral by other health care professionals, e.g. nurses, key workers and social services.
- Identified by the pharmacist as having problems with medicine e.g. poor compliance, problems with administration and complicated medicine regimen.

Appointment

Schedule the appointments for the PM Review to be carried out.

Give the patient an appointment card with the date and time.

Give patient an option for care giver to be present.

Inform the patient that the appointment will last for about 30 minutes.

Inform the patient to bring their medicines including any complementary medicines, vitamins or any medicines they are taking regularly.

A day before the review, remind the patient about his/her appointment.

Review

Prior to the review:

- Prepare the pharmaceutical care plan.
- The pharmacist should be fully aware of the appropriate use/ dose/ administration time/ side effects and major drug interactions of each medicine the patient is taking.
- The pharmacist may need to refer to treatment guidelines as needed.

During the review:

- Welcome patient and make the patient comfortable in the consultation area.
- Explain the aims of the review.
- Explain the patient's consent.
- Explain that the information will be shared with their GP and a record will be kept in the pharmacy.
- Confirm and complete patient details on a PM Review form (refer Appendix iv).
- Record the basic health data section of the form.
- For each medicine the pharmacist should consider the following interventions:
 - i. Advice on medicines usage (prescribed and OTC), aiming to develop compliance;

- ii. Effective use of 'when required' medicines;
- iii. Ensuring appropriate use of different medicine dosage forms (e.g. inhaler and soluble tablets);
- iv. Advice on possible side effects;
- v. Identification of items without adequate or correct dosage instructions;
- vi. Identification of unwanted medicines (if patient is no longer taking their medicines);
- vii. Identification of the need for a change of dosage form to facilitate effective usage;
- viii. Suggestions of appropriate substitutes, if required;
- ix. Proposals for dose optimization;
- x. Suggestions to improve patient's clinical outcome;
- xi. Advice on the use of any vitamins, complementary medicines or self purchased OTC medicines.

During the review, other health-related issues should be discussed such as:

- Practical problems in ordering, and obtaining their medicines.
- General problems in taking and using medicines, e.g. compliance charts.
- Health promotion advice where appropriate.
- Referral to other health care providers.

Complete the action plan

- The action plan will probably contain no more than 4 key points.
- Discuss the action plan with the patient and get patient's consent
- Discuss with the patient information that requires follow-up.

The PM review form shall be completed and a copy will be given to the patient at the end of the review.

Thank the patient and see him/her out.

Post review:

- Send a copy of the review form to the patient's GP
- Update the patient medication record.
- File all documents systematically and securely.
- Follow up on any actions you have agreed to do with the patient.
- Record number of PM Reviews performed.

6.2 Health Promotion

Health promotion is the process of enabling people to have increased control over, and to improve their health. Community pharmacists can play a very important role in promoting, maintaining and improving the health of communities that they serve.

6.2.1 Smoking Cessation

- Before providing this service, the pharmacists should have undergone the Certified Smoking Cessation Service Provider Program (CSCSP).
- Pharmacists should apply the 5 A's in the screening and assessment of customers:

Ask	:	Pharmacists should systematically identify all tobacco users among the customers who visit the pharmacy.
Advise	:	Pharmacists should strongly urge all tobacco users to quit.
Assess	:	Pharmacists must determine the willingness of the customers to make the quit attempt.
Assist	:	If the customer is willing to quit, the pharmacist must help to devise an effective quit plan – provide practical counseling and recommend the use of approved pharmacotherapy.
Arrange	:	Pharmacists must also devise a follow-up plan to ensure the success of the quitting process.
- For customers who have no intention to quit smoking, pharmacists should advise them of the possible health hazards of smoking. Pharmacists should provide them with leaflets and materials that they can take home to read. Customers should be assured of the pharmacist's readiness to help them quit smoking.
- If the customer is an ex-smoker (has not smoked for 6 months), the pharmacist should advise the customer on the dangers of relapse and offer solutions to overcome any potential problems.

- If the patient is an ex-smoker (has not smoked for 12 months), the pharmacist should reinforce the benefits of cessation and help the customer to maintain smoke free.
- Pharmacists should document the service provided and keep a record of the follow-ups for the individual customer in a prepared format to enable the service to be audited.

6.2.2 Weight Management

- Pharmacists intending to provide a weight management program should have a good understanding about obesity and the multi-disciplinary approach to weight management, which includes dieting, exercise, behavior modifications and recommendation of approved and suitable pharmacotherapy and/or evidence-based natural therapies.
- Pharmacists and staff should offer to do a Body Mass Index (BMI) screening and a waist circumference measurement on potential customers.
- If a more sophisticated weighing apparatus is available, measurements of total body fats, visceral fats and muscle mass would be more useful.
- Pharmacists and staff should be able to interpret the results and explain the risks involved if one is overweight or obese.
- Pharmacists should be able to recommend a weight reduction program suitable for the customer and design the proper follow-up visits in order to monitor the customer's progress.
- Customers who are overweight/ obese and who also have other co-morbidities such as diabetes, hypertension, hyperlipidemia, fatty liver, arthritis and gout should be encouraged to lose at least 5 to 10% of their body weight in order to reduce the risks associated with their weight. These customers may have to be referred to a physician if the need arises.

ZONING**Establishing a new pharmacy****A. For general pharmacy****Criteria:**

1. National Population ratio : 1 pharmacy outlet in 5,000 population → 5,800 outlets
2. District ratio 1 in 5,000 (urban) and 1 in 10,000 (rural)
*urban & rural as defined in National Population Census
3. Distance from nearest pharmacy 300 meters in a linear measurement (shortest legal travelling route) → official surveyor's report must be submitted if the distance is very close to the 300 meters limit (measuring from the centre of the main entrance of the proposed premise to the centre of the main entrance of the nearest existing pharmacy)
4. As near to existing clinics as possible

B. For pharmacy in a facility

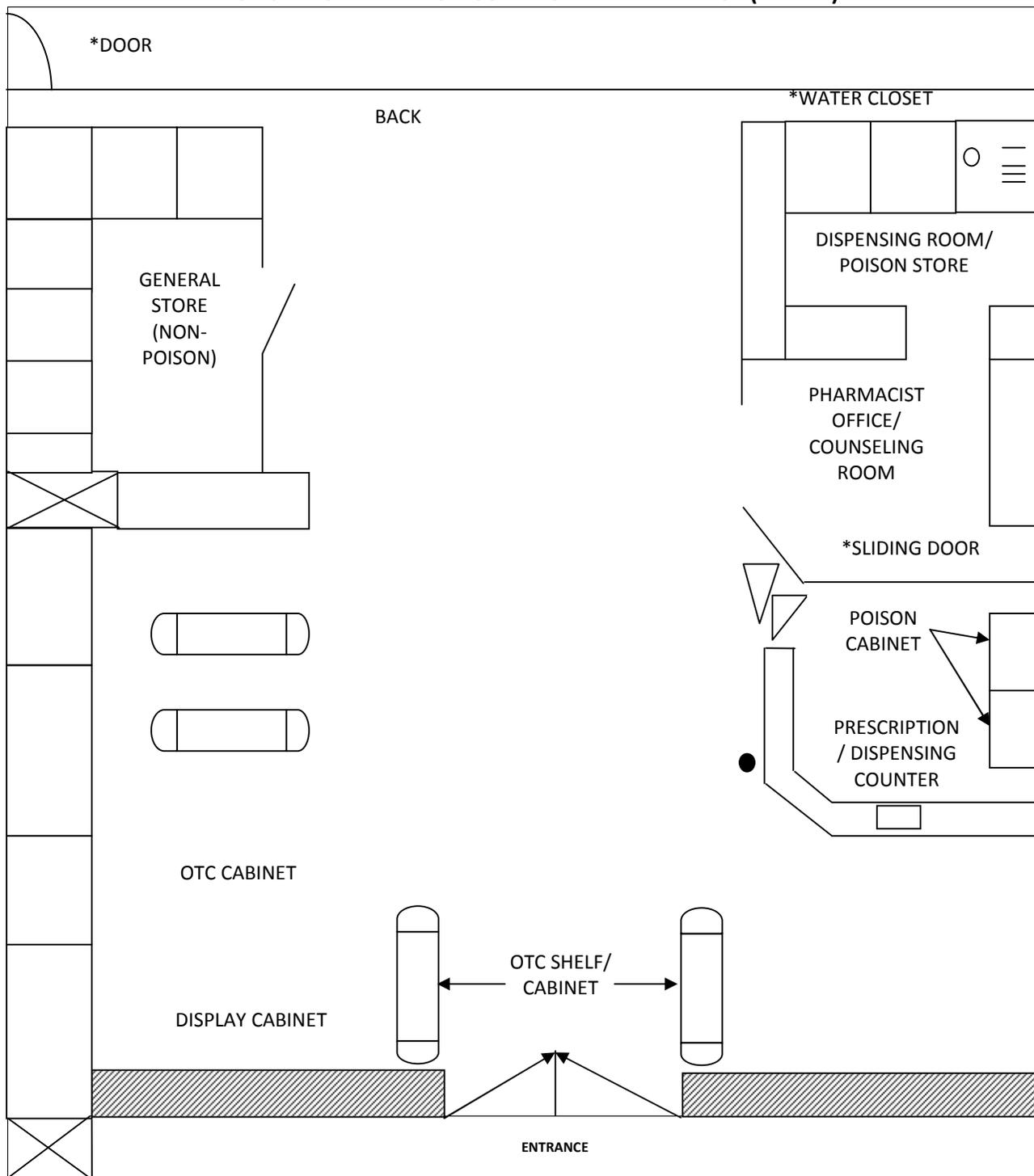
1. District ratio 1 in 5,000 (urban) and 1 in 10,000 (rural)
*urban & rural as defined in National Population Census
2. 1 outlet for every 200,000 square feet rentable space and below
3. Distance from nearest general pharmacy 150 meters in a linear measurement (shortest legal travelling route) to the main entrance of the facility

Number of outlets allowed in facility

Distance between general pharmacy & facility / complex	≤ 150 meters	≥ 150 meters
Rentable retail space		
≤ 200,000 square feet	0	1
200,000 – 400,000 square feet	1	2
400,000 – 600,000 square feet	2	3

Appendix II

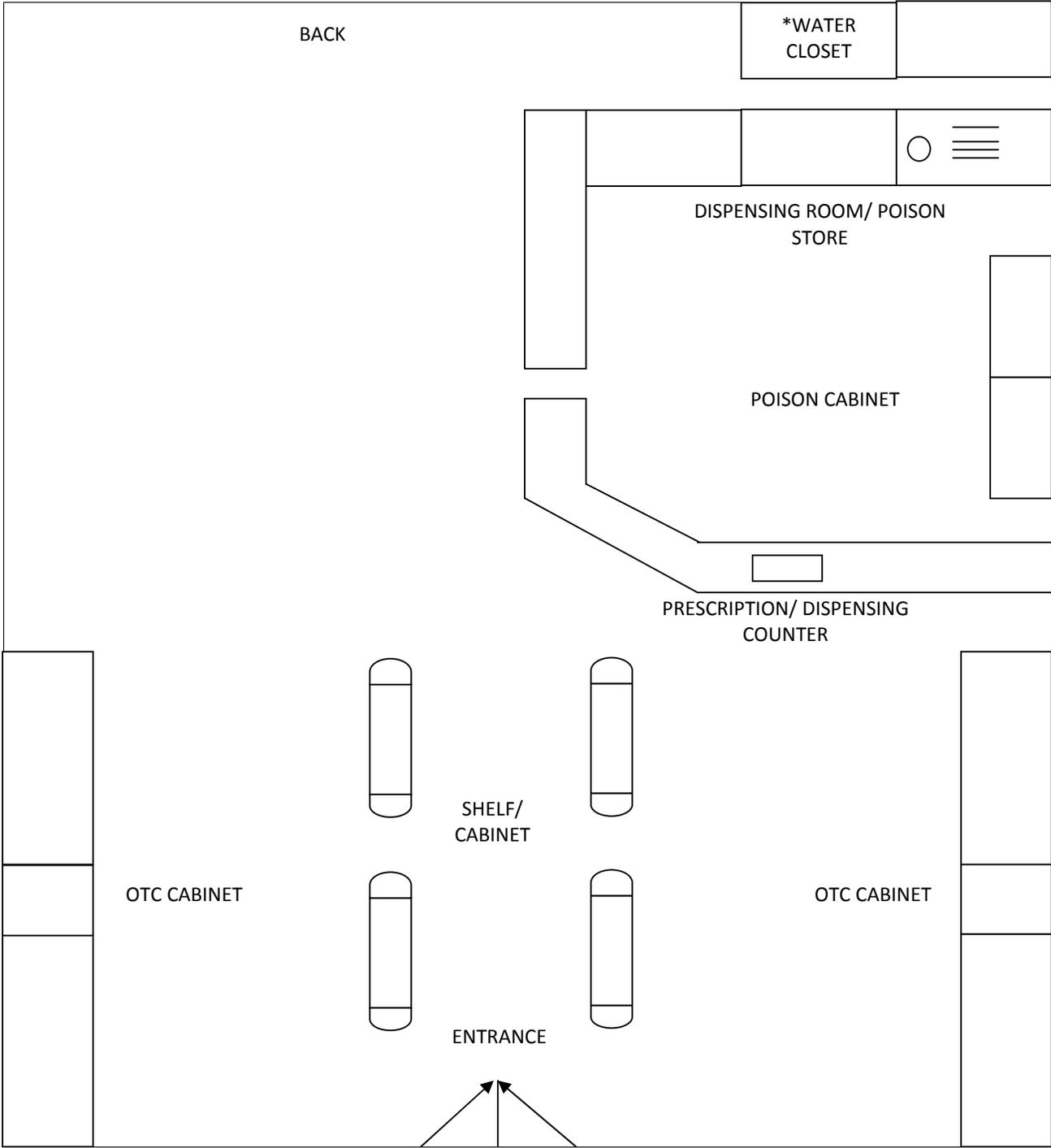
EXAMPLE OF SKETCH-PLAN FOR COMMUNITY PHARMACY (TYPE A)



- Notes:**
1. The sketch is not scale based.
 2. The estimated width for each premise is according to appropriateness.
 3. *Optional
- This document is for guidance purpose and subjected to amendments.*

Appendix III

EXAMPLE OF SKETCH-PLAN FOR COMMUNITY PHARMACY (TYPE B)



Notes:

- 1. The sketch is not scale based.
- 2. The estimated width for each premise is according to appropriateness.
- 3. * Optional

This document is for guidance purpose and subjected to amendments.

Appendix IV

TEMPLATE OF REFERRAL NOTE

FROM	
Pharmacist : _____	Phone : _____
Address : _____	Fax : _____
_____	Email : _____
TO	
Doctor : _____	Phone : _____
Address : _____	Fax : _____
_____	Email : _____
Name of patient : _____	
NRIC : _____	
Phone : _____	
<p>The above named patient is being referred to you for the following:-</p> <ol style="list-style-type: none"> 1) Presented with signs and symptoms which require further investigation by a medical practitioner 2) Review of the patient's medications 3) Management of drug related problem(s) 	
<p>Please contact me if required, so that we can provide the best care possible to the patient. Thank you.</p>	
Date: _____	Pharmacist's signature and official stamp:

This document is for guidance purpose and subjected to amendments.

Appendix V

TEMPLATE OF PATIENT MEDICATION REVIEW FORM

Patient Name : _____

File Number : _____

Date of Review : _____

NO.	MEDICATION (including strength & frequency prescribed)	ACTUAL DOSE/ FREQUENCY TAKEN BY PATIENT	INDICATION	MEDICATION ISSUE (e.g. none, duplication, compliance, adverse events, polypharmacy, etc.)	PLAN OF ACTION (e.g. reduce/increase dose, cease medication, counsel patient, etc.)	OUTCOME
1						
2						
3						
4						

This document is for guidance purpose and subjected to amendments.

Appendix VI



Pharmacy Board of Malaysia
Ministry of Health Malaysia
Lot 36, JalanUniversiti,
46350, Petaling Jaya, Selangor

COMMUNITY PHARMACY BENCHMARKING
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Community Pharmacy			
Premise Name			
Address			
State			
Contact Number		Postal Code	
Email		Fax Number	

Pharmacist Details		
Name	Type A License Number	Validity

*Panel			
Date		Time	
Chief Panel			
Panel 1			
Panel 2			
Panel 3			

**Minimum of 2 members*

Signature	_____	Name	_____
	Pharmacist on Duty		
	_____	Name	_____
	Chief Panel		

SECTION 1: COMPULSORY

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
1. OWNERSHIP			
Full management control of pharmacy practice by pharmacist.			
TOTAL (1 mark)			
2. PREMISES			
Location (1 mark)			
No sharing with other Business.			
Medicine Dispensing Area (MDA) (3 marks)			
MDA consists of: <ul style="list-style-type: none"> • Prescription counter • Counseling area 			
Should be clean and tidy			
Signboard and Advertisement (5 marks)			
Pharmacy signboard project the professional image of a pharmacy			
Notice of the pharmacist(s) on duty is displayed which include: <ul style="list-style-type: none"> • Name of pharmacist(s) • Time and date/day of duty 			
Certificates of Registration and Annual Retention for the pharmacist in-charge are clearly displayed.			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
Designated areas are clearly indicated, e.g “Prescription Counter” or “Pharmacy”.			
Facilities (16 marks)			
<p>Medicine Dispensing Area/ Prescription Counter</p> <ul style="list-style-type: none"> • Without any barrier (to facilitate patient counseling and for more effective communication). • Enable safe and efficient workflow. • Pharmacist is able to maintain a direct supervision of the pharmacy and staff from this area. • Size and organization of this area is adequate for the volume of work 			
Counseling area is a properly designated area, private and comfortable			
Air-conditioner with scheduled maintenance			
<p>Refrigerator</p> <ul style="list-style-type: none"> • Temperature is maintained between 2 – 8°C. • Records of temperature is available and verified • Does not store food or drinks 			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
Cleanliness <ul style="list-style-type: none"> • Appropriate pest control measure is made available. 			
Dry Compounding Area (Medicines Preparation / Filling Area) <ul style="list-style-type: none"> • A designated area for counting tablets/ capsules, filling, packing of medicines and for labeling the prepared medicines. • Located away from food and drinks. • Provide suitable and hygienic means of counting tablets/capsules (e.g. counting tray). 			
Equipment <p>a) Cabinets</p> <ul style="list-style-type: none"> • For the storage of documents/ records. <p>b) Labels</p> <ul style="list-style-type: none"> • Appropriate sizes and shapes • Legible 			
Occupational and safety requirements (1 mark)			
<ul style="list-style-type: none"> • Fire extinguisher 			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
References (2 marks)			
<ul style="list-style-type: none"> • Drug Information Handbook/ British National Formulary (or any other reliable references – hardcopy or online) • Code of Conduct for Pharmacist and Bodies Corporate (hardcopy or online) 			
TOTAL (27 marks)			
3. PRACTICE AND SERVICES			
Services (5 marks)			
Essential Services <ul style="list-style-type: none"> • screening prescriptions • medicines dispensing • dispensing instruction • medication counseling • pharmacy management in drug procurement and documentation 			
Type of Products (2 marks)			
<ul style="list-style-type: none"> • 70% of the merchandise in a community pharmacy consists of registered pharmaceutical products, health 			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
<p>and nutritional products, surgical and medical devices, personal care and rehabilitation aids.</p> <ul style="list-style-type: none"> • Sale of goods and food which is harmful to health is strictly prohibited. Non-pharmacy products, e.g gift items, cards and drinks, should be minimized. 			
Personnel (9 marks)			
<p>a) Pharmacists</p> <ul style="list-style-type: none"> • Registered with the Pharmacy Board of Malaysia • Observe the Code of Conduct for Pharmacists and Bodies Corporate • Comply with all the pharmacy legislations of Malaysia • Dress code <ul style="list-style-type: none"> i. Pharmacist Tunic (White Coat) ii. Project a professional image • Name tag with the word “Pharmacist” • Suitable number of pharmacists 			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
<ul style="list-style-type: none"> i. in line with the workload of the pharmacy ii. workload preferably should not exceed 150 prescriptions/pharmacist/day • Minimum distraction when filling prescriptions or carrying out pharmacy services 			
Storage and Security of Medicines (8 marks)			
All medicines comply with labeling requirements and kept in the original packaging or properly labeled containers.			
Different categories of items are systematically arranged.			
Separate storage is provided for internal and external medicines.			
Medicines with similar names and packaging are distinctively separated.			
Poison B and Poison C items as listed in Part I of the Poison List are kept in a locked cabinet.			
All keys are kept by the pharmacist.			
Storage conditions complied with manufacturer instructions and cold chain requirements.			
Secure locks on main door and grille/gate			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
Medication Safety and Quality Improvement Activities (4 marks)			
ADR reporting			
ME reporting			
Product Recall			
Regular collection and safe disposal of pharmaceutical waste and other refuse.			
Record and Documentation (4 marks)			
Records and documentations are kept and updated systematically			
Necessary documentation are completed by pharmacy staff: <ul style="list-style-type: none"> • Prescription details are entered into record book(s)/computer. • Patient medication record (PMR) are kept appropriately 			
<ul style="list-style-type: none"> • • Legal and professional requirements for record keeping and record management are adhered to at all times – (confidentiality and			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
security of patient data should be considered)			
Operating Hours (1 mark)			
<ul style="list-style-type: none"> Minimum 40 hours/week with pharmacist 			
TOTAL (33 marks)			
4. STANDARD OPERATING PROCEDURE			
Handling Minor Ailments (4 marks)			
<ul style="list-style-type: none"> All pharmacy staffs are adequately trained and know when to refer the customer to the pharmacist. Pharmacists and their staff are aware of the potential of misuse for certain non-prescription medicines and do not supply when there are reasonable grounds for suspecting a misuse. Area for confidential conversation with the patient/customer is available. Proper documentation is maintained to fulfill legal and professional requirements. 			
Identification of Registered and Counterfeit Drugs (4 marks)			
<ul style="list-style-type: none"> Meditag reader is available. 			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
<ul style="list-style-type: none"> • Pharmacists educate customers on how to identify counterfeit medicines. • Pharmacists are able to check the registration of a product through the competent authority. • Pharmacists are aware of the latest information on de-registered products, products found containing adulterated ingredients, changes to product information and safety issues. 			
TOTAL (8 marks)			

SECTION 2: OPTIONAL

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
1. PREMISES			
Medicine Dispensing Area (MDA) (2 marks)			
MDA consists of: <ul style="list-style-type: none"> Medicines preparation area (dry and wet compounding) Screening tests area 			
Signboard and Advertisement (2 marks)			
Types of services offered are clearly displayed inside the premise			
Photo of the pharmacist(s) on duty is displayed			
Facilities (16 marks)			
Pharmacist office is available			
Waiting area is comfortable with adequate space for customers			
Adequate lighting and ventilation			
Acceptable noise level			
Health Screening Area <ul style="list-style-type: none"> Provide appropriate equipment and devices Equipment and devices in are properly maintained 			
Equipment <p>a) Computerized system are available with the</p>			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
<p>following functions:</p> <ul style="list-style-type: none"> • Pharmacy Information Software • Inventory/Stock keeping • Printing of labels • Printing of customer information leaflet • Keeping of patient medication record • Itemized billing with GST function • Appropriate drug naming system <p>b) Printer is available for the production of labels, leaflets or any printed materials.</p>			
<p>Other Requirements</p> <ul style="list-style-type: none"> • Entrance is accessible to wheelchairs and pushchairs. • Pantry area for staff. 			
References (1 mark)			
<p>Other references e.g:</p> <p>Malaysian Laws on Poisons and Sale of Drugs</p>			
TOTAL (21 marks)			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
2. PRACTICE AND SERVICES			
Services (5 marks)			
Optional Services Medication review and accredited pharmacy services including: <ul style="list-style-type: none"> • Home Medication Review (HMR) • Medication Therapy Adherence Centre (MTAC) • Certified Smoking Cessation Service Provider (CSCSP) • Weight management • Health screening 			
Personnel (3 marks)			
Pharmacy Assistants <ul style="list-style-type: none"> • Diploma in Pharmacy (preferred) • Structured training • Suitable number 			
Storage and Security of Medicines (1 mark)			
Additional safety control such as video cameras and alarm system			
Medication Safety and Quality Improvement Activities (1 mark)			
Know Your Medicine activities			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
TOTAL (10 marks)			
3. STANDARD OPERATING PROCEDURE			
Self-monitoring Devices (3 marks)			
<ul style="list-style-type: none"> Pharmacist provides general advice on health matters. Pharmacists have undergone appropriate training on the usage of self-monitoring devices. Patients are encouraged to document their own results (help them to understand the results). 			
Health Screening (6 marks)			
<ul style="list-style-type: none"> All staffs involved in providing the above service are trained in the use of the monitoring devices and the procedures. They also are aware of the limits of the tests provided. Suitable area with facilities to perform the tests and provide counseling is available. Devices used are in good order. Keep up to date with the latest development and know when to refer patients to medical practitioners. 			

DESCRIPTION	COMPLIANCE		NOTES/COMMENTS
	0	1	
<ul style="list-style-type: none">• The related procedure has been explained to the patient before test is conducted.• Test results are communicated to the patient in a manner in which he/she can understand and appropriate counseling is provided.			
TOTAL (9 marks)			

**SECTION 3: COMPULSORY
(if service/product(s) available)**

DESCRIPTION	COMPLIANCE		COMMENTS
	0	1	
1. PREMISES			
Facilities (6 marks)			
A washbasin with water supply is available in the medicines preparation area			
<p>“Wet Compounding Area”</p> <p>(for the purpose of extemporaneous preparations only)</p> <ul style="list-style-type: none"> • A designated area with sink and water supply. • Located away from food and drinks. • All working surfaces are made of smooth impervious surface and washable material finishing. • Equipped with the following (if applicable): <ul style="list-style-type: none"> i. Weighing scale – with regular verification and calibration by relevant bodies ii. Mortar and pestle, tile/glass slabs with spatula and measuring appliances – all are maintained in good condition 			
TOTAL (6 marks)			

DESCRIPTION	COMPLIANCE		COMMENTS
	0	1	
2. PRACTICE AND SERVICES			
Storage and Security of Medicines (2 marks)			
Psychotropic drugs are kept according to Regulations 24, Poison (Psychotropic Substances) Regulations 1989.			
Dangerous Drugs are kept according to Regulations 9(2) Dangerous Drugs Regulations 1952.			
TOTAL (2 marks)			
3. STANDARD OPERATING PROCEDURE			
Extemporaneous Dispensing (8 marks)			
<ul style="list-style-type: none"> • Formula and method of preparation are correct. • Requisite facilities and equipment for the preparation are available and maintained in good order. • Ingredients are sourced from reliable pharmaceutical supplier and be of a quality accepted for use in the preparation of the extemporaneous products. • All calculations, ingredients and quantities are checked by a second person who is a pharmacist. • Pharmacists paid particular attention to substances that may be hazardous and require special handling techniques. 			

DESCRIPTION	COMPLIANCE		COMMENTS
	0	1	
<ul style="list-style-type: none"> The products are suitably labeled with the necessary information, including special requirements for the safe handling and storage of the product including an expiry date. All preparations are documented and the records are kept for at least 2 years. The records included the formula, the ingredients and the quantities used their source, batch number, expiry date, date of preparation and personnel involved in the preparation. All documentations are certified and duly stamped by a registered pharmacist with his/her registration number indicated. 			
TOTAL (8 marks)			

AUDIT DESCRIPTION

NO	AUDIT COMPONENTS	MARKS		
		Full Marks	Obtained Marks	Percentage (%)
SECTION 1 (Compulsory)				
1.	Ownership	1		/ 80
2.	Premises	28		
3.	Practice and Services	33		
4.	Standard Operating Procedures	8		
TOTAL		70		
SECTION 2 (Optional)				
1.	Premises	21		/ 20
2.	Practice and Services	10		
3.	Standard Operating Procedures	9		
TOTAL		40		
GRAND TOTAL				

SECTION 3 (Compulsory if service/product(s) available)				
1.	Premises	6		
2.	Practice and Services	2		
3.	Standard Operating Procedures	8		
TOTAL		16		

AUDIT DESCRIPTION

NO	AUDIT COMPONENTS	COMMENT / OBSERVATION	STATUS (O/R)
1.	SECTION 1 <ul style="list-style-type: none"> • Ownership • Premises • Practice and Services • Standard Operating Procedures 		
2.	SECTION 2 <ul style="list-style-type: none"> • Premises • Practice and Services • Standard Operating Procedures 		
3.	SECTION 3 <ul style="list-style-type: none"> • Premises • Practice and Services • Standard Operating Procedures 		

Note: *O* : Observation

R : Remedial Action Required

Auditor's Comment

Remedial Action/s Required

CONFIDENTIAL

PHARMACY BOARD OF MALAYSIA	SUMMARY OF COMMUNITY PHARMACY BENCHMARKING AUDIT	REF. NO:
Community Pharmacy:		Address:
<input type="checkbox"/>	Recommended	
<input type="checkbox"/>	Recommended after remedial action taken	
<input type="checkbox"/>	Re-audit	
Reported by :		Verified by:
Name :	Name :	
Signature :	Signature :	
Date :	Date :	



PHARMACY BOARD OF MALAYSIA
Ministry of Health

**Lot 36, JalanUniversiti,
46350 Petaling Jaya, Selangor**

**Tel : 03-7841 3200
Faks : 03-7841 3658**