二零零五年六月二十八日
討論文件

立法會衞生事務委員會

醫藥分家

目的

本文件向委員闡述當局對醫藥分家所持的意見。

詞義闡釋

2. 對於「醫藥分家」一詞，各界人士的詮釋不盡相同。在本文件內，該詞意指把診症和配藥這兩項原本可由醫生兼顧的職責分開；換言之，醫生只負責診斷病症和開出處方的工作，另由獨立人士(藥劑師或經過訓練的配藥員)根據醫生在處方寫明的指示配發藥物。

先前就此事所進行的討論

3. 醫藥分家在一九七九年首次被提出討論。在一九八零年十月，政府設立了工作小組[1]研究藥劑業事宜，當中包括醫藥分家。工作小組於一九八二年六月發表報告，建議當局在處方和配發藥物方面維持現狀。

4. 其後，前立法局／立法會先後於一九九五年和一九九九年兩度討論此事。當局曾經發表以下意見：

- 現時做法多年來在香港行之有效；
- 病人可按其意願，要求醫生開出處方，然後自行向藥

[1] 在 1980 年 10 月，當時的總督委任了「藥劑業及有關事宜研究小組」專責檢討關於藥劑師僱用、職責、學歷、訓練等事項的法例。

劑師配藥；

- 新加坡及日本等若干國家的醫生兼顧配藥工作；
- 英美等實行醫藥分家的國家，設有醫療保險制度向投保人發還藥費；
- 未知有國家立例禁止醫生配發藥物；
- 實行醫藥分家所需要的藥劑師人數，遠超過現有藥劑師的數目。

目前情況

5. 多年來，政府醫院／診所和私家醫院一向實行醫藥分家，而全港大部分配藥工作亦在這兩類醫護機構進行。而私家診所醫生則可以配發藥物或者開出處方予病人到社區藥房購買。

6. 在私家診所實行醫藥分家，可以鼓勵醫生分配更多時間在診病上，而藥房藥劑師則能夠在防止配藥失誤方面爲病人提供較佳保障，兼且可以向病人提供較多藥物資訊和用藥建議，改善病人服藥的依從性以至治療效果。

7. 和其他專業一樣，本地西醫的規管乃依循「專業自我規管」的原則。《醫生註冊條例》爲本港醫生的註冊，以及規管其專業執業和操守提供了法律架構。香港醫務委員會(下稱“醫委會”)是根據該條例成立的法定組織，負責醫生的規管。

8. 醫委會對配藥安全十分關注。其公布的《香港註冊醫生專業守則》提到，在註冊醫生的臨床執業過程中，其對病人的專業責任包括藥物的使用，而妄顧專業責任則可被視作專業上失當行爲。政府亦注意到，守則列明醫生不適當地將其職責轉授予他人，有可能面對紀律處分程序。而醫生可以依循適當途徑僱用受過訓練的人士執行專責職務，但該醫生必須有效地督導該等僱員，並維持診治病人的個人責任。

9. 醫院轄下藥房已設有相關機制，務求盡量減低錯配藥物的危險。醫院管理局在 2000 年制訂了一份《藥物管理程序及

守則》，該守則爲醫院員工提供了處方、藥房配發和病房分派藥物的指引，以確保病人使用藥物的安全及有關系統的效率和品質控制。

10. 市面的藥房屬於在藥劑業及毒藥管理局註冊的「獲授權毒藥銷售商」。現時有多條法例訂明關乎銷售藥物的規定，而「獲授權毒藥銷售商」的執業守則亦就按照處方配發藥物等事宜載明相關指引。在沒有處方的情況下銷售處方藥物、在沒有藥劑師監督的情況下銷售咳藥水以及銷售未經註冊藥劑製品均屬刑事罪行，可遭受檢控以及面對藥劑業及毒藥管理局的紀律行動。

最近的事態發展

11. 就日前引起社會關注的一宗私家醫生錯配藥物事件，醫委會設立了工作小組，負責檢討私家醫生診所配發藥物的工作。工作小組會在適當時間向醫委會報告檢討結果和作出建議。

12. 香港醫學會[2](下稱“學會”)亦設立了專責小組，負責檢討私家醫生診所配發藥物的方法。該專責小組現正擬定一份給醫生的指引，學會並已預先向會員透過電子傳訊方式發出指引的草稿。指引強調建立有效的安全配藥程序的重要性，包括一再覆核所有發出藥物，以及由醫生主理整個程序並確保所有員工遵守。學會並已將指引交與醫委會作參考(見附件[3])。指引即將定稿，學會冀望在下月正式向會員派發。

13. 另外，目前有數個針對診所助理和其他參與配藥程序人員的訓練課程正在籌備當中。課程包括不同科目以配合診所僱員的不同需要，開辦課程的機構包括香港專業教育學院、香港護理學院和香港公開大學。

當局的意見

14. 目前，病人有權選擇持私家診所醫生開出的處方由藥

[2] 香港醫學會是本港最具規模的註冊醫生專業團體， 成員約 6 500 人。

[3] 此指引尚未有中文版本。

劑師配發藥物。鑑於醫藥分家對於現時作個人執業的醫生的角色、藥劑師的人力需求和市民的醫療開支等問題有深遠影響，同時亦關乎市民求醫習慣的重大改變，該問題須經由社會各界廣泛和深入討論。在作出任何重大轉變前，社會須先就該問題取得共識。政府會繼續聆聽多方意見，並與相關各界進行討論。

衞生福利及食物局
二零零五年六月

附件

THE HONG KONG MEDICAL ASSOCIATION

GOOD DISPENSING PRACTICE MANUAL

1 PREFACE

The Hong Kong Medical Association has formed a working group to review the process of dispensing and to make recommendations on safety in dispensing. We have come to the conclusion that an effective system of safe dispensing with checking and double-checking of all dispensed medicine is very important. The doctor should be in charge of the system and be able to supervise all clinic staff to adhere to the system. It is the doctor's responsibility to ensure that the drugs are properly dispensed to the patient. The system should be updated regularly and the importance of adherence be monitored and stressed regularly.

One of the important steps we emphasize is that medications be double-checked by doctors before dispensing. We also try to identify each and every step which could go wrong in the process. Some of them might seem trivial. However a chain would break in its weakest link. The presumption is that human error cannot be eliminated completely. So what can be done is to pick up errors by cross-checking and to prevent the result of mishaps from happening. To identify more steps which could go wrong and to take precautions would help to minimize the burden of wrongful events flowing to the more important steps.

The following serves to provide some general guidance and each user should review his own system according to individual setting with his staff.

2 THE PREMISES

The premises on which a dispensing service is provided would reflect the quality of service and inspire confidence in the nature of the health care that is delivered. Every dispensing staff is recommended to maintain the premises in a clean and tidy manner.

1. Safety

Working conditions are recommended to be so arranged as to take into consideration the safety and health of the public and people working on the premises. Guidelines on the Occupational Safety and Health Ordinance should be adhered to.

2. Condition

The walls, floors, windows, ceiling, woodwork, drainage and all other parts of the premises are recommended to be kept clean and hygienic by regular cleansing with appropriate agent to prevent, as far as is reasonably practicable, any risk of infestation and contamination. Waste should be properly kept and timely disposed of. Walls are recommended to be finished in a smooth impervious material.

3. Tidiness

All parts of the premises are recommended to be maintained in an orderly and tidy condition.

4. Environment

Pharmaceutical products are recommended to be protected from the adverse effects of light, freezing or other temperature extremes and dampness. Levels of light, heat, noise, ventilation, etc., are recommended not to exert adverse effects on personnel.

5. Size

Dispensaries in clinics would be designed to accommodate the anticipated increase in workload. In dispensaries with space constraints, maximization and effective use of available space by good planning could be explored.

6. Security

Careful consideration is to be given to the overall security of the dispensary and the stores. Special attention must be paid to the Dangerous Drugs Stores, which must be kept separately from other drugs and be locked properly.

3 DISPENSARY DESIGN AND EQUIPMENT

The dispensary, its fittings and equipment should be adequate for the purpose of dispensing.

Working surface and shelves

Working surfaces, cupboards and shelves need to be in a good state of repair and in a clean and tidy condition. They are recommended to be smooth, washable and impervious to moisture. A clear area of bench space is recommended to be set aside for dispensing. Food and drinks are recommended to be kept away from the working area.

Water supply

The dispensary is recommended to be provided with distilled and/or purified water.

Dispensing equipment

All dispensing equipment is recommended to be of suitable material, clean and in a good state of repair. Below is a suggested list and can be extended according to the requirements of individual dispensaries:

1. Tablets and capsules counting devices. They should be cleaned regularly so that cross contamination between products is avoided.

2. A range of graduated, stamped/or plastic measures.

3. A refrigerator equipped with a maximum/minimum thermometer and capable of storing products at temperatures between 2ºC and 8ºC. The refrigerator needs to be cleaned and checked periodically to ensure efficient running.

4. A suitable range of dispensing containers for pharmaceutical products with separate sets for internal and external use

4 STORES PROCUREMENT AND STOCK MANAGEMENT

Stores procurement

The Doctors or Dispensers in-charge are responsible for the requisition of pharmaceutical stores. Orders for drugs are recommended to be made in writing via post or fax by the doctor. All drugs should be checked and receipts signed by the doctor upon delivery of the drugs. (A sample order form is attached on P. 12 for reference)

Stock management

The purpose of good stock management is to bring about a safe and effective dispensing service. Over-stocking of stores should be avoided and optimum stock quantities should be maintained to ensure a continuous supply. To ensure proper stock management, the following measures are recommended:

1. To ensure that the correct medicine is received:
   a. The medicine label, including the expiry date, should be checked before receiving stores.
   b. Unlabelled medicines should be rejected and the supplier should be informed of it.

2. To avoid mixing-up of medicines:
   a. The label of a medicine should be checked before putting it on the shelf.
   b. Similar looking medicines should be stored separately from each other.
   c. Internal medicines should be stored separately from external medicines.
   d. Staff should be notified if the shape and/or colour of any medicine has been changed.
   e. Expired medicines should be labeled properly and put aside for proper disposal as chemical waste according to the guidelines of the Environmental Protection Department.

3. To avoid product deterioration:
   a. Medicines should be stored in a clean and good condition.
   b. The temperature of the store and the refrigerator should be regularly checked.

4. To ensure effective use of stock:
   a. Stock rotation should be carried out right after stores receiving.
   b. The expiry dates of medicines should be regularly monitored.

5. To ensure safe custody of Dangerous Drugs:
   a. Dangerous Drugs should be stored separately under lock and key.

5 THE DISPENSING OF MEDICINE

Dispensing includes all of the activities, which occur from the time the prescription is received in the dispensary until the medicine or other prescribed items have been collected by the patients. It therefore includes: the review of the prescription; any action taken to address concerns so identified; the correct dispensing of the medicine in an appropriate container with a correct label; and the provision of information and advice as appropriate.

Supervision of dispensing

Doctor in clinic is responsible for supervising drug dispensing.

The doctor should ensure that a dispensed product will still be within the expiry date at the end of the treatment period, where this is predictable.

Counselling/information and advice

When a medicine is supplied to a patient, information should be given to the patient or his/her agent to enable the correct and effective use of the medicine. Most importantly, is recommended to make sure that the directions on the label of the dispensed medicines are understood. Relevant information pamphlets may be provided to the patient as appropriate.

Dispensing containers

1. All containers intended for medicinal products should be properly stored and free from contamination.

2. All stock bottles should be regularly cleansed or replaced when necessary.

Labelling of dispensed medicines

Labelling of dispensed medicines should be clear and legible. All medicines should normally be labeled with the following particulars:

a. name of doctor or means of identifying the doctor who prescribes the medication;

b. a name that properly identifies the patient;

c. the date of dispensing;

d. the trade name or pharmacological name of the drug;
[If a generic drug is used, a doctor may add the term "generic substitute for (name of patent drug)" on the label to further facilitate identification of the generic drug. Reference could be made to the "Compendium of Pharmaceutical Products" which lists all the drugs registered in Hong Kong and is published by the Department of Health.]

e. the dosages, where appropriate;

f. the method and dosage of administration; and

g. precautions where applicable.

Storage

1. Medicines are recommended to be stored in the manufacturer's original containers. If, in exceptional cases, the contents need to be transferred to other containers, care must be taken to avoid contamination and all relevant information should be clearly marked on the new containers. Furthermore, cross checking should be undertaken by another staff whenever possible, or double-checked by the staff himself/herself. Care should be taken to avoid mixing up products of different batches.

2. All medicines should be stored under suitable conditions, appropriate to the nature and stability of the material concerned. They should be protected from contamination, sunlight, moisture and adverse temperatures.

3. Any substances which have deteriorated, or which have reached their expiry dates should be segregated for proper disposal as chemical waste.

Reuse of medicine

Under no circumstances should medicines brought in by patients be accepted for reissue to other patients.

Defective medicines

1. Doctors are recommended to inform the drug companies of hazards, which come to their attention, in particular suspected defective or counterfeit medicines for return.

2. Examples of defective medicines are: foreign bodies embedded in tablets, mould or glass visually seen in vials of injections, abnormal odour and colour variation detected in tablets, etc.

Dispensing procedure

The dispensing of prescriptions involves both interpretation of the prescriber's instructions and the technical knowledge required to carry out these instructions with accuracy and safety to the patient. There is a considerable variety of factors that require close attention in dispensing, and proficiency requires the establishment of a routine system which can be followed safely even under stress. The following is a useful basis for the development of a satisfactory routine:

1. Filling of prescription
    a. Match the labels with the prescription.
    b. Select the appropriate containers or envelopes.
    c. Read the label on the drug bottle when selecting the drug. Ensure that the drug to be dispensed will not expire within the period of treatment.
    d. When dispensing capsules or tablets, count out the correct number of the capsules or tablets.

e. The labels of all containers of stock drugs, should be checked when selected from and replaced in stock, as well as at the time of actual dispensing, making three checks in all.

f. Attach the label neatly, rechecking the directions against the prescription as you do so.

g. Decide whether any additional labelling is required.

h. It is important that the prescription must be filled not against the generated labels, but against the prescription.

i. Always handle one prescription at one time.

2. Issuing of drugs

a. Ask the patient to give his/her name and check his/her name with that on the prescription. If in doubt, ask for HK Identity Card or proof of identify for identification.

b. Check drug labelling details against the prescription.
- Correct patient's name
- Drug name
- Dose
- Route
- Frequency

c. Check the right drug and right quantity against the prescription.

d. Counsel patient or his/her guardian on proper use and storage of prescribed drugs.

e. Issue drug information pamphlets, if required.

f. effects where appropriate.

The principle of three checks and seven rights

In dispensing, the following principle of "three checks and seven rights" should always be observed. These are:

1. First check of the container label before taking container from the shelf.
2. Second check of the container label against the prescription during actual dispensing.
3. Third check of the container label before putting the container away.
4. Right patient
5. Right drug
6. Right dose
7. Right route
8. Right frequency
9. Right container
10. Right Date

6 INCIDENT REPORTING

Complaints made against the dispensary service

When there is a complaint made against the dispensing service, the doctor is recommended to investigate and find out the nature and cause of the complaint. Prompt feedback to the patient and apologise as appropriate are recommended.

Medication errors

Medication error is defined as any deviation from the physician's intended prescription. It can occur in any step from prescriptions to the actual administration of drugs to patients.

The contributing factors to medication errors include illegible handwriting, misinterpretation of abbreviations, misreading of label, carelessness, distraction, failure to follow procedures, mathematical errors in dosage calculations and lack of drug knowledge.

Medication errors associated with prescribing could be due to:

a. Sloppy, illegible handwriting of the physician.

b. Ambiguity or abbreviations resulting in misinterpretation.

c. Prescribing the wrong or inappropriate drugs, dosage, frequency or route of administration.

Medication errors associated with dispensing could be due to:

a. Labelling errors where the label does not match the content of the drug product.

b. Misreading prescription leading to dispensing of a wrong drug or a correct drug in wrong strength, dosage form or quantity.

c. Dispensing to one patient the drugs intended for another patient.

Medication errors can have damaging effects on patients. The magnitude of risk will depend on the potential toxicity of the drug, the route of administration, the amount administered and the clinical status of the patient. Instead of the desired therapeutic effect, it can have fatal effects on the patient. The liability implications can be high and the widespread public attention will have negative impact on the Doctor. Needless to say, unnecessary suffering and loss of patients' lives cannot be measured in monetary terms.

Dispensing errors

Dispensing error includes any of the following: dispensing of wrong drug, wrong dosage form, wrong strength, wrong quantity, wrong label information, drug omission, double dispensing and dispensing the drug to the wrong patient.

Incident management

When a major incident of dispensing error occurs, it is vital that staff follow an established procedure for responding. The Doctor is judged not only by the details of the incident, but also by the response to it. The first priority must be an appropriate clinical response to the incident. The well being of the patient is the most important, and mistakes must be immediately acknowledged and the appropriate clinical intervention initiated.

All staff must be aware of their responsibilities to respond both clinically and administratively.

Attitude towards patient

When a patient has to be contacted for correcting a dispensing error, he/she should be provided with information about what has occurred and an apology given. Even though the full details may be uncertain, it is still important to assure the patient that Doctor will be thorough in its investigation, and open and honest in its communications. Always be frank with the patient and remember that their well-being is the most important.

If the patient has taken the medicine, inform the Doctor for medical assessment of the patient. Ensure that all patients whom may be affected are contacted.

Dispensing error reported by patient

1. In the event that the dispensing error is reported by the patient, find out the nature of the error and ask whether the patient has taken the medicine.

2. If the patient has not taken the medicine, apologise to the patient and change the medicine for the patient if necessary.

3. If the medicine has been given to other patients, pick out the prescriptions of the affected patients and follow step 2 above.

4. All incidents must be recorded and reported to the Doctor.

Dispensing error detected by dispensing staff

1. In the event that the dispensing error is detected by dispensing staff, investigate on the extent and nature of the error and find out whether the medicine has been given out to patients.

2. If the medicine has been given out to patient, find out if it has been given out to one or more patients. Pick out the prescription(s) of the patient(s) affected. Report to the doctor in order to contact the patient(s).

3. If a patient has taken the medicine, he/she should be referred to the doctor for medical assessment if necessary.

4. If the patient has not taken the medicine, apologise to the patient and change the medicine for him/her.

5. All incidents must be recorded and reported to the Doctor.

Monitoring of dispensing errors

It is important to take measures in the prevention of dispensing errors by improving control systems and following procedural guidelines. It is also beneficial to learn from mistakes that have been committed. In this regard, a voluntary medication incident reporting mechanism is recommended in all clinics to collect information on episodes of dispensing errors and to identify the causes and trends in order to prevent future occurrences. The information collected would be forwarded to the doctors' respective membership association for attention and analysis. Members of the Hong Kong Medical Association can do it on an anonymous basis to the Association Secretariat via e-mail to hkma@hkma.org or via fax to 2865 0943.

Please fill in the attached form (See P. 13) and fax or mail to the Hong Kong Medical Association. Incidences would be collected, analyzed and reported to members on an anonymous basis. You can report to us without giving the names of patients or doctors involved. However it would be more helpful if we could contact the supplier **of** information.

It is important to take prompt action for any dispensing error so as to limit the damage done to the patient involved, the doctor and the public. Assistance would be provided by the Hong Kong Medical Association and the Medical Protection Society.

The Hong Kong Medical Association
Tel : (852) 2527 8285
Fax : (852) 2865 0943
E-mail : hkma@hkma.org
Address : 5/F Duke of Windsor Social Service Building
15 Hennessy Road
Wanchai
Hong Kong

Medical Protection Society
Tel : (44) 0845 605 4000
Fax : (44) 0113 241 0500
E-mail : querydoc@mps.org.uk
Address : Granary Wharf House
Leeds LS11 5PY
United Kingdom

7 EDUCATION, TRAINING AND DEVELOPMENT

All dispensing staff are recommended to avail themselves of all opportunities to undergo continuing education and training. This is necessary to enable them to provide competently the professional services being offered. Members of staff involved in the dispensing process need to be adequately trained for the purpose.

The following courses are being organized:

Course name/duration	Fee/hours	Organized by	Enquiry
Basics in Dispensing & Pharmacy Practice	$5,000 150 hours	Hong Kong Institute of Vocational Education	2595 8242
Certificate Course on Introduction to Drug Dispensing in Office Clinic	$800 4 sessions	Federation of Medical Societies of Hong Kong	2821 3511 2821 3512
診所助理深造課程（藥物學）	$1,500 30 hours	College of Nursing, Hong Kong	2572 9255
Certificate Course for Medical Clinic Assistants	$8,000 112 hours	Hong Kong Doctors Union & Open University of Hong Kong	3120 9988

8 RELATIONSHIP WITH PATIENTS, PUBLIC AND OTHER HEALTH CARE PROFESSIONALS

Health care advice to the public should be accurate and appropriate. Dispensing staff are recommended to be prepared and be available to give advice on health related matters and answer enquiries. Try to be patient and courteous at all times. Supervisors should coach staff on courtesy and means to resolving difficulties.

9 ADMINISTRATION AND MANAGEMENT

A sound management structure should be established to ensure the efficient operation of the clinic dispensary. Doctors should adopt an open attitude in management. They should be ready to listen to staff concerns and make improvement as appropriate. Good and effective communication within the clinic is also essential to bring about overall service improvement.

10 ACKNOWLEDGEMENT

The Association is deeply indebted to the following members of the Task Force on Drug Dispensing for their advice and guidance, without which the timely publication of this manual would not have been possible:

Dr. Cheng Chi Man
Dr. Cheng Man Yung
Dr. Cheung Hon Ming
Dr. Choi Kin
Dr. Li Sum Wo
Dr. Tse Hung Hing
Ms. Anna Wong

Medical Products Order Form

From : Dr _____

To : _____

Date : _____

This is to place an order for the following medical product(s):

1. _____
2. _____
3. _____
4. _____

Please confirm by replying to Dr / Ms _____ at _____

Tel : _____ or _____

Fax : _____

_____

(Signature / Chop)

Dr _____

The Hong Kong Medical Association
Dispensing Error Incident Report

(Doctor's name not required)

Incident Date .....

A. Incident for patient type: General Practice ☐ Specialty Practice ☐

Description of the incident (What, when, where, how, why - without mentioning names)

.....

.....

.....

.....

.....

B. Incident Reported By Doctor ☐ Clinic Assistant ☐ Patient ☐ Others ☐
Incident Detected By Doctor ☐ Clinic Assistant ☐ Patient ☐ Others ☐

C. Type of Error

Prescribing

Unclear/Wrong Drug Name	☐
Wrong Dosage Form	☐
Wrong Strength/Dosage	☐
Wrong Duration	☐
Wrong Frequency	☐
Wrong Route	☐
Wrong Abbreviation	☐
Unclear/Wrong Instruction	☐
Wrong Patient	☐
Double Entry	☐
Others _____	☐

Incomplete Prescription

Missing Drug Strength	☐
Missing Dosage Form	☐
Missing Duration/Qty	☐
Missing Frequency	☐
Missing Dose	☐
Missing whole item claimed by patient and confirmed with doctor	☐
Incomplete or missing name of patient	☐
Missing Date	☐
Others _____	☐

Dispensing

Wrong Drug	☐
Wrong Dosage Form	☐
Wrong Strength/Dosage	☐
Wrong Quantity	☐
Wrong Patient	☐
Wrong Label Information	☐
Double Dispensing	☐
Drug Omission	☐
Expired Drug Issued	☐
Others _____	☐

Administration

Wrong Drug	☐
Wrong Dosage Form	☐
Wrong Dose	☐
Wrong Patient	☐
Wrong Route	☐
Wrong Time	☐
Extra Dose	☐
Dose Omission	☐
Others _____	☐

The Hong Kong Medical Association
Dispensing Error Incident Report (Continued)

D. Contributing factors to error

Inadequate Knowledge or Skills	☐	Stock Management	☐
Failure to comply with policies or procedures	☐	Not familiar with Item Code of Drug Miscalculation	☐
Failure in communication/ Misinterpretation of order	☐	Wrong Dose Mislabelling	☐
Distraction	☐	Lack of Supervision	☐
Stress	☐	Illegible Handwriting	☐
Similar Drug Name/Appearance	☐	Unclear Prescription	☐
Transcription	☐	Commercial Packaging/ Product Labelling	☐
Incorrect Computer Entry	☐	Deterioration of Drug/Storage Problem	☐
		Others _____	☐

E. Patient Outcome

Incident discovered before medication reaches patients ☐

Incident discovered after medication reaches patient ☐

Patient condition prior to incident: Satisfactory ☐ Fair ☐ Critical ☐

Action Taken:

F. Incident Reported to: HKMA ☐ Department of Health ☐

G. Remarks: