

# **Guidelines and minimum standards for Good Pharmacy Practice (GPP) in UAE Pharmacies**

Version 1, July 2003

## **Introduction**

There are almost 1000 pharmacies across the UAE and they are staffed by pharmacists and assistants from over 20 countries. Minimum standards of practice vary across the globe for all professions and pharmacy is no exception. The people of the UAE have access to a high standard of medical care and this has been applauded by the World Health Organisation. The WHO, together with the International Pharmacy Federation (FIP) have published *Good Pharmacy Practice* guidelines and have called for all countries to develop minimum standards of pharmacy practice. This document is the first step to stating publicly what the minimum requirements are for Good Pharmacy Practice.

These guidelines and standards are used as the basis for inspection by Ministry of Health inspectors.

## **1. Legal and Ethical framework**

- 1.1. Pharmacy law and code of practice: pharmacists and assistant pharmacists must comply with the UAE Pharmacy law (No.4 of 1983) and the Ministry of Health (MOH) Code of Conduct for Pharmacists. Copies of these should be available in the pharmacy<sup>1</sup>.
- 1.2. Continuing professional development is essential and pharmacists and assistants must keep their knowledge and skills up to date. A record of professional development activities should be maintained

## **2. Personnel**

- 2.1. The list of staff on duty must agree with that registered at the MOH. Students can only be trained after MOH approval
- 2.2. Assistants and any unlicensed staff, including pharmacists or students, must be under the supervision of a licensed pharmacist when dispensing medicines.
- 2.3. All staff must wear clean, white coats
- 2.4. All staff must wear a name badge stating their name, position and license number.
- 2.5. The staff must project a clean, tidy & professional appearance

## **3. Environment and Equipment**

- 3.1. The pharmacy must be structurally unchanged from when the license was last issued or renewed. Any structural changes must be approved by the ministry.

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<sup>1</sup> Available via the MOH web-page URL: [http://www.moh.gov.ae/moh\\_site/phar\\_med/moh\\_p\\_m.htm](http://www.moh.gov.ae/moh_site/phar_med/moh_p_m.htm)

- 3.2. The pharmacy must be clean and tidy. Floors, walls and ceiling must be in good repair. Shelves must be neat and logically arranged with no visible dust.
- 3.3. Air conditioning must be working efficiently and a thermometer should be used to record the temperature in the pharmacy. Records must be kept to show that the temperature does not exceed 30°C at any point during the day or night.
- 3.4. Lighting must be strong and well maintained throughout the pharmacy, especially in any dedicated dispensing areas.
- 3.5. Electrical wires must not present a danger for staff or customers e.g. must not trail across the floor.
- 3.6. Work surfaces should be impervious, clean and well maintained
- 3.7. Running water must be available for washing, cleaning and preparation of medicines. Drainage must be adequate.
- 3.8. A medicines refrigerator must be available for storage of any medicines that require refrigeration. The temperature must be monitored and recorded to demonstrate that it remains between 2 and 8°C at all times.
- 3.9. All pharmacies should have a computer that can be used for record keeping and correspondence. Electronic-point-of-sale (EPOS) systems, computerised stock control and ordering systems are strongly encouraged. Where possible these systems should support the production of typed labels for dispensed medicines.
- 3.10. Internet access and email access from the pharmacy is strongly recommended.
- 3.11. All pharmacies must have a working telephone line. A fax machine is recommended.
- 3.12. The pharmacy must enforce a strict "No smoking" policy within the pharmacy.
- 3.13. The pharmacist is responsible for the security of the medicines. Precautions must be in place to minimise the risk of a person stealing medicines.
- 3.14. Fire prevention and fire fighting equipment must be working and in accordance with the civil defence requirements.
- 3.15. Pest control must be in place to prevent and eliminate infestations and should be in accordance with municipality requirements.
- 3.16. Pharmaceutical waste must be disposed of in accordance with UAE laws and regulations. It must not be disposed of via the routine garbage collection system. Disposal of pharmaceutical waste via the approved companies must be recorded and these records must be available *see also 5.11 below* .

## 4. Documents

- 4.1. Pharmacy license and the in-charge pharmacist's license must be available and on display to the public.
- 4.2. All pharmacies must display their opening hours to the public and the contact details for late-night pharmacies and local hospital emergency departments.
- 4.3. Each pharmacy must keep a file of MOH circulars or have access to the MOH drug control web-page<sup>1</sup>
- 4.4. The register requirements for controlled drugs must be followed. These are summarised below. More information and advice is available direct from the inspection section. The pharmacist in charge shall record the data and description of the controlled medicines dispensed daily as follows:
  - 4.4.1. **Psychotropic drugs register** (also known as the "Registered Prescription", R.P, "group 4" medicines or "CD-A"). The register is obtained from the Ministry of Health after payment of the specified fees, and it shall be labelled "CD-A" / "R.P" / Group 4.
  - 4.4.2. **Semi-Controlled drugs register**, also known as "Controlled Prescription", C.P, or "group 5" medicines. For each item, the register should record the date and quantity dispensed. It must be labelled "CD-B" / "C.P" / Group 5

### 4.5. Prescription file system

In addition to the controlled drugs registers, the following files shall be kept and presented to the inspector on request:

- 4.5.1. **General file**, to be divided into two parts:
  - First part, the reports and circulars issued by Ministry of Health (unless there is access to these via the internet).
  - Second part, Copies of staff licences, MOH approval of staff leave & training positions, pharmacy operating procedures etc
- 4.5.2. **Price file**: For filing the MOH price list and updates (electronic version is acceptable).
- 4.5.3. **Controlled medicines prescriptions**, to be divided as follows:
  - *First part*: "CD-A" / "RP" / group 4 prescriptions, arranged by prescribing doctor and date.
  - *Second part*: "CD-B" / "CP" / group 5 prescriptions, arranged by prescribing doctor and date.
- 4.6. Delivery notes for controlled medicines must be filed (according to agent) and kept for at least 12 months after delivery. Controlled medicine prescriptions must be kept for 5 years from the date of dispensing (Minimum of 2 years in the pharmacy, remaining 3 years can be in secure storage). Computerised records may be acceptable after careful consideration by the Ministry of Health inspection section.

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- 4.7. All pharmacists must have access to at least one international pharmacopoeia such as *Martindale: The complete drug reference*. An electronic subscription is acceptable. The latest editions should be available and must not be more than one edition out of date.

## **5. Dispensary**

- 5.1. Medicines and healthcare products must be approved for sale in the UAE by the MOH.
- 5.2. Prescription medicines should not be included in pharmacy-window displays or otherwise advertised to the public.
- 5.3. Prescription medicines must not be available for self-selection by the customers.
- 5.4. All medicines must be clearly marked with the latest MOH approved retail price.
- 5.5. Medicines, must be sold as original packs. If part packs are required then they must carry the medicine name, batch number and expiry date and the patient must receive (free of charge) a copy of the original package insert or patient leaflet from the pharmacy.
- 5.6. Controlled medicines must be stored in a lockable cupboard
- 5.7. Prescriptions for controlled items should only be dispensed if they are valid according to UAE law number 4 (article11) and regulations
- 5.8. Prescription medicines can only be sold in accordance with a prescription written by a UAE licensed doctor within the last 6 months. The prescription must state the doctors name and UAE license number and have the clinic stamp. It must have the patient's name, the medicine name and dose instructions must be clear.
- 5.9. Essential medicines must be available including at least one generic alternative if approved in the UAE
- 5.10. Shelf-life of stock must be long enough to cover a reasonable period of use. Stock rotation is essential and existing stock must be sold before new stock.
- 5.11. Quarantine of rejected and expired stock is essential and should be clearly labelled in a lockable cupboard. This material should be returned to the distributor (see also 3.16 above).

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