Legal Requirements Relating to Drug Management in Clinics

Lot Chan

Department of Health

Relevant Regulations (1)

- **Pharmacy and Poisons Ordinance (Cap. 138)**
- **Antibiotics Ordinance (Cap. 137)**
- **Dangerous Drugs Ordinance (Cap. 134)**
- **Public Health and Municipal Services Ordinance (Cap. 132)**
- **Waste Disposal (Chemical Waste) (General) Regulation (Cap. 354C)**

Relevant Regulations (2)

- **Import and Export Ordinance (Cap. 60)**
- **Undesirable Medical Advertisements Ordinance (Cap. 231)**

Section 28 of PPO (1)

- **Requirements on sale (retail) of poisons not apply to-**
  - **A medicine supplied by a registered medical practitioner for the purposes of medical treatment/ supplied by a registered dentist for the purposes of dental treatment**
  - **The medicine must be labelled with the name and address of the supplier**

Section 28 of PPO (2)

- **Record** on the day of supply (or following day if not practicable) –
  - Date of supply
  - Name and address of the person to whom the medicine was supplied
  - Ingredients of the medicine and the quantity, dosage and duration of supply
- **Contravention –**
  - Subject to level 6 ($100,000) fine and 2-year imprisonment upon conviction

Other Requirements under PPR

- **Wholesale of pharmaceutical products**
- **Registration of pharmaceutical products**
- **Conducting clinical studies**

Private Healthcare Facilities Ordinance (Cap. 633)

- **Institution:**
  - **Any private healthcare facility within the meaning of the Private Healthcare Facilities Ordinance (Cap. 633) for which a licence under that Ordinance is in force**

Special Provisions with Respect to Institutions

- **Regulation 22 of PPR**
  - **Supply of medicines to out-patients from certain institutions, etc.**
- **Regulation 23 of PPR**
  - **Supply of medicines for use in institutions, etc.**
- **Regulation 24 of PPR**
  - **Storage of poisons in institutions**
- **Contravention –**
  - **Subject to level 6 ($100,000) fine and 2-year imprisonment upon conviction**

Regulation 22 of PPR (1)

- **Nothing in the PPO or PPR, except regulation 16 and this Part, shall apply to –**
  - **Any medicine dispensed in an institution where the dispensing is under the supervision of a registered pharmacist**

if the requirements of this regulation are satisfied

Regulation 22 of PPR (2)

- **The medicine shall not be supplied except by, or on and in accordance with a prescription of, a duly registered medical practitioner for the purposes of medical treatment/ registered dentist for the purposes of dental treatment**

Regulation 22 of PPR (3)

- **If substance in the Schedule 1 supplied, keep records for 2 years after the date of supply:**
  - **Name and quantity of the poison supplied**
  - **Date of supply**
  - **Name and address of the patient**
  - **Name and address of the supplier or the person who give the prescription**

Regulation 22 of PPR (4)

- The container of the medicine shall be labelled with a designation sufficient to identify the institution
- The medicine shall be clearly labelled with instructions for use in either English or Chinese
- Fulfil regulation 16

Regulation 16 of PPR

- **In the case of embrocation, liniment, lotion, liquid antiseptic, or other liquid medicine for external application:**
  - **Labelled with the words "For external use only 抵供外用"**

Regulation 23 of PPR

- In any institution in which medicines are dispensed in a dispensing or pharmaceutical department in charge of a registered pharmacist
  - No medicine containing a poison shall be supplied from that department for use in the institution
  - Except upon a written order signed by a registered practitioner, registered dentist or in charge of a ward of the institution
- The container of medicine shall be labelled with words describing its contents

Regulation 24 of PPR (1)

- **In any institutions in which medicines are dispensed in a dispensing or pharmaceutical department, all poisons other than those issued for use within the institution shall be stored in that department**

Regulation 24 of PPR (2)

- If no dispensing or pharmaceutical department, all poisons (other than those for use within the institution) poisons shall be stored –
  - In the charge of a person appointed for the purpose by the governing body or person in control of the institution;
  - For substances in the Schedule 1, either in a cupboard or drawer, or on a shelf, reserved for the storage of poisons

Regulation 24 of PPR (3)

- All storage places for poisons shall be **inspected** at regular intervals of time **not exceeding 3 months** by a registered pharmacist or registered medical practitioner appointed for the purpose and a **record of all inspections** shall be made in a book kept at the institution

Section 4 & 5 of AO

- A registered medical practitioner/dentist may supply an antibiotic for the purpose of treatment
- A medical practitioner/dentist may administer by way of treatment any antibiotic
- A registered medical practitioner/dentist may possess any antibiotic

Section 7 of AO

- A registered medical practitioner/dentist shall **maintain written records** including –
  - Name and address of the person from whom received and if received from an antibiotic permit holder the serial number of such permit
  - Quantity received
  - Date received
- Entries made in records shall be supported by invoice or other voucher
- Contravention: subject to a maximum fine of $5,000

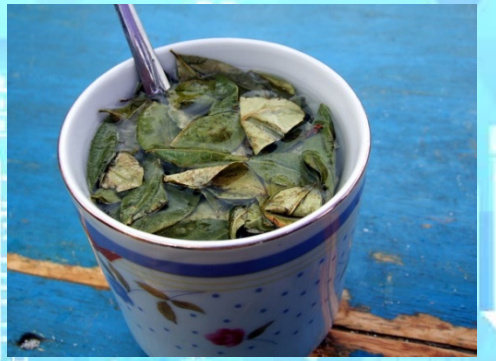
Section 22 of DDO

- A **registered medical practitioner** or a **registered dentist** is authorized, so far as may be necessary for the practice or exercise of his profession, function or employment, and in his capacity as such, to be in possession of and to supply a dangerous drug (but…)

Section 22 of DDO



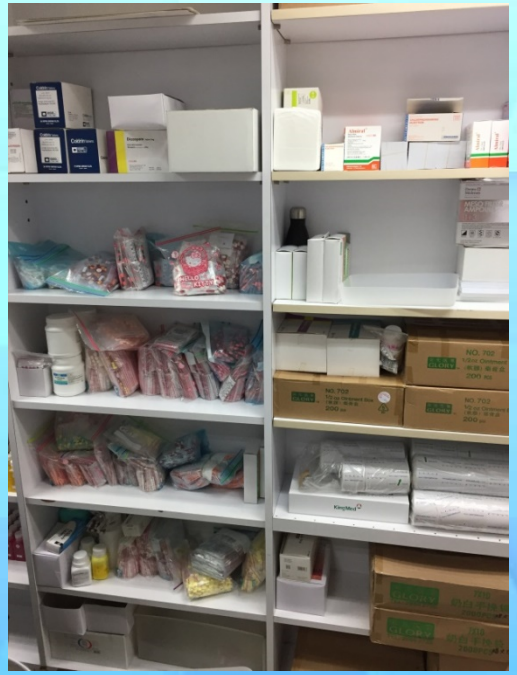


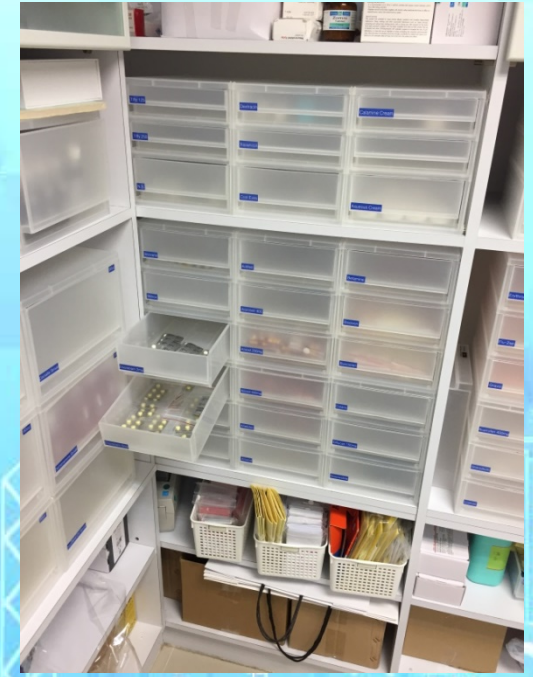



Section 23 of DDO

- Section 22 does not authorize a registered dentist to supply a dangerous drug unless the drug is administered by him, or under his direct supervision and in his presence, to a person receiving treatment by him
- Except when the necessities of the practice of the profession require, all dangerous drugs must be kept in a locked receptacle which can be opened only by a person authorized under section 22 (maximum fine: $5,000)

Storage of DD





Trafficking in dangerous drug

- **Maximum fine of $5,000,000 and life imprisonment**

Regulations 5 & 6 of DDR (1)

- A medical practitioner/dentist shall keep, in accordance with regulations 5 & 6, a register
- Enter in the register in chronological sequence in the form specified in the Schedule 1 true particulars with respect to every quantity of a dangerous drug obtained and supplied by him

Regulations 5 & 6 of DDR (2)

- A **separate** register or separate part of the register for entries made with respect to **each** of the dangerous drugs
  - Each dangerous drug includes its salts, preparations and isomers
- A separate page within the register or separate part of the register for entries made with respect to different dangerous drugs and different strengths of preparations within the class of dangerous drugs mentioned above

Regulations 5 & 6 of DDR (3)

- **Specify at the head of any page of the register –**
  - **The class of dangerous drugs**
  - **The particular dangerous drug and the particular strength of the preparation, if applicable**
- **Every entry shall be made on the day the dangerous drugs is received or supplied. If not reasonably practicable, on the following day**

Regulations 5 & 6 of DDR (4)

- **No cancellation, obliteration or alteration of any entry shall be made. Every correction of an entry shall be made only by way of a marginal note or footnote which shall specify the date on which the correction is made**
- **Every entry and correction shall be made in ink or otherwise so as to be indelible**

Regulations 5 & 6 of DDR (5)

- The register shall not be used for any purpose other than the purposes of the DDO
- A separate register shall be kept in respect of each set of premises, but save as aforesaid not more than one register shall be kept at one time in respect of each class of dangerous drug
- Every register shall be kept at the premises to which it relates and at all times available for inspection

Regulations 5 & 6 of DDR (6)

- **Shall furnish the register, documents, particulars in respect to the obtaining and supplying of any dangerous drugs as well as the stock of the dangerous drugs to any public officer authorized by the Director of Health**
- **Contravention: subject to a maximum fine of $450,000 and 3 years imprisonment**

DD Register

SCHEDULE 1

[reg. 5]

FORM OF REGISTER

Date of receipt/ supply	Name and address of person* or firm from whom received/to whom supplied	Patient's identity card number+	Amount		Invoice No.	Balance
			received	supplied		

* Cross reference of the person to whom supplied may be made in which case only the reference number of the person's treatment record needs to be given.

\+ For a patient who is not resident in Hong Kong, the reference number of any proof of identity, other than an identity card, specified in section 17B(1) of the Immigration Ordinance (Cap. 115) shall be inserted.

Regulation 7 of DDR

- All registers and records shall be preserved for a period of **two years** from the date on which the last entry therein is made
- Other documents shall be preserved for a period of two years from the date on which it is issued or made
- Contravention: subject to a maximum fine of $10,000 and 12 months imprisonment

Section 52 of PHMSO

- Any person sells to the prejudice of a purchaser any drug which is not of the nature, or not of the substance, or not of the quality, of drug demanded by the purchaser, he shall be guilty of an offence
- Maximum fine of $10,000 and 3 months imprisonment

Section 61 of PHMSO

- Any person gives with any drug sold by him a label, which –
  - Falsely describes the drug; or
  - Is calculated to mislead as to its nature, substance or quality,
  - He shall be guilty of an offence
- Maximum fine of $50,000 and 6 months imprisonment

Chemical Waste (1)

- **Antibiotics, poisons and dangerous drugs are Part A chemical waste**
- **Other pharmaceutical products are Part B chemical waste**

Chemical Waste (2)

- Register as chemical waste producers (Maximum penalty: $200,000 fine and 6 months imprisonment)
- Part A chemical waste require prior notification to EPD (Maximum penalty: 1st offence - $100,000; 2nd offence - $200,000 + $500 per day)

Chemical Waste (3)

- **Proper labelling and packaging of chemical waste (various offences)**
- **Proper disposal of chemical waste (Maximum penalty: $200,000 fine and 6 months imprisonment)**
- **Information and records supporting proper disposal (Maximum penalty: $100,000 fine and 6 months imprisonment)**

Chemical Waste (4)

- **Engage licensed waste collector (Maximum penalty: $200,000 fine and 6 months imprisonment)**
- **Follow trip-ticket system (various offences)**
- **Furnishing false information (Maximum penalty: $200,000 fine and 6 months imprisonment)**

Thank You