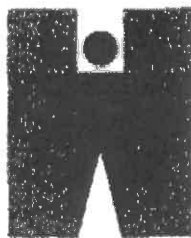


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衛生署藥物辦公室
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THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DRUG OFFICE
DEPARTMENT OF HEALTH
Room 1856, Wu Chung House,
213 Queen's Road East, Wan Chai, Hong Kong

本署編號 OUR REF: DH DO PRIE/7-30/15
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30 May 2019

Dear Healthcare Professionals,

Legal requirements on handling of pharmaceutical products by healthcare professionals

In view of the recent reports relating to suspected unregistered vaccines being supplied by local clinics, this letter serves to reiterate the legal requirements on drug handling by healthcare professionals.

Legal requirements on drug handling by registered medical practitioners and dentists

In Hong Kong, the principle Ordinance that governs pharmaceutical products is the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO") and its subsidiary regulations, in particular the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR").

According to section 28 of the PPO, a registered medical practitioner may supply a medicine for the purposes of medical treatment, and a registered dentist may supply a medicine for the purposes of dental treatment as long as the provisions in section 28 are satisfied. These include:

- The medicine shall be distinctly labeled with the name and address of the medical practitioner or dentist who supply the medicine (section 28(2)).
- The registered medical practitioner or dentist must enter in the record of treatment or other document: (a) the date on which the medicine was supplied; (b) the name and address of the patient; and (c) the ingredients of the medicine and the quantity, dosage and duration of supply (section 28(3A)).

Nevertheless, other requirements stipulated under the PPR still apply to registered medical practitioners or dentists. These include, *inter alia*, wholesale dealing of pharmaceutical products requires licence (Part 6 of the PPR), manufacture of pharmaceutical products requires licence (except dispensing of medicine for individual patient treatment) (Part 7 of the PPR), and all pharmaceutical products must be registered with the Pharmacy and Poisons Board before sale and supply (Part 8 of the PPR).

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In addition, your attention is also drawn to the fact that other Ordinances may be relevant to healthcare professionals when handling drugs. These include, but not limited to, the Antibiotics Ordinance (Cap. 137), the Dangerous Drugs Ordinance (Cap. 134), the Import and Export Ordinance (Cap. 60) and the Public Health and Municipal Services Ordinance (Cap. 132). For details of the provisions, please refer to respective Ordinances which could be downloaded at www.elegislation.gov.hk. For easy reference, a summary of offences that are relevant to registered medical practitioners and dentists is provided at the Annex.

Other advice on drug handling by healthcare professionals

To assure pharmaceutical products are supplied from legitimate source and under proper logistic management, you are advised to only procure and obtain pharmaceutical products from licensed wholesale dealers, licensed manufacturers or authorized sellers of poisons (regulation 25 of PPR). The pharmaceutical products supplied by these licensed dealers should also be registered with the Pharmacy and Poisons Board in accordance with regulation 36 of the PPR. Information on registered pharmaceutical products and licensed dealers is available at the Drug Office's website (www.drugoffice.gov.hk).

Upon receipt of the medicines from licensed suppliers, you are advised to check and verify the delivery and to keep proper storage of the medicines received, especially those require special storage conditions, e.g. vaccines at 2-8°C. For storage of vaccines, a purpose-built vaccine refrigerator is the preferred mean but domestic frost-free refrigerator may be used if proper measures and precautions are in place. For more information, please refer to Section 3.3 of the Guide: https://www.pco.gov.hk/english/resource/files/Module_on_Immunisation_Children.pdf.

Should you suspect any person supplying unregistered pharmaceutical products or supply a pharmaceutical product without licence, you may provide such information to the Drug Office of the Department of Health (Tel: 2572 2068; Email: pharmgeneral@dh.gov.hk) for further action.

Yours sincerely,


(Frank CHAN)
Assistant Director (Drug)

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Summary of drug-related offences relevant to healthcare professionals

Provision	Offence	Maximum Penalty	Remarks
Sec 28 of PPO	Improper labelling or fail to keep proper record by registered medical practitioner or registered dentist	\$100,000 fine and 2 years imprisonment	
Reg 25 of PPR	Illegal sale of pharmaceutical products by way of wholesale dealing		
Reg 29 of PPR	Manufacture pharmaceutical products without licence		Manufacture does not include individual dispensing
Reg 36 of PPR	Sale or possession for sale of unregistered pharmaceutical products		A medical practitioner or dentist may possess or use an unregistered pharmaceutical product for the purpose of treatment of a particular patient
Sec 7 of ABO	Fail to keep proper record of antibiotics	\$5,000 fine	
Sec 4 of DDO	Trafficking in dangerous drug	\$5,000,000 fine and life imprisonment	Registered medical practitioners are authorized to possess and supply certain dangerous drugs necessary for the practice of his profession Registered dentists are authorized to possess and administer certain dangerous drugs necessary for the practice of his profession
Sec 8 of DDO	Possession of dangerous drug	\$1,000,000 fine and 7 years imprisonment	
Reg 5 of DDR	Fail to keep dangerous drugs register	\$450,000 fine and 3 years imprisonment	
Reg 7 of DDR	Fail to preserve documents	\$10,000 fine and 12 months imprisonment	
Sec 52 of PHMSO	Sell to a purchaser a drug not of the nature, substance or quality demanded by the purchaser	\$10,000 fine and 3 months imprisonment	

Provision	Offence	Maximum Penalty	Remarks
Sec 61 of PHMSO	Sell a drug with a label falsely describes the drug or is calculated to mislead as to its nature, substance or quality	\$50,000 fine and 6 months imprisonment	
Sec 6C & 6D of IEO	Import or export a medicine not under and in accordance with an import licence or export licence	\$500,000 fine and 2 years imprisonment	

Notes:

- 1) The above list only highlights most common drug-related offences that are relevant to healthcare professionals and It is not an exhaustive list.
- 2) Abbreviations for the Ordinances:
 - PPO: Pharmacy and Poisons Ordinance, Cap. 138
 - PPR: Pharmacy and Poisons Regulations, Cap. 138A
 - ABO: Antibiotics Ordinance, Cap. 137
 - DDO: Dangerous Drugs Ordinance, Cap. 134
 - DDR: Dangerous Drugs Regulations, Cap. 134A
 - PHMSO: Public Health and Municipal Services Ordinance, Cap. 132
 - IEO: Import and Export Ordinance, Cap. 60

