Proper Handling of Clinical Waste & Chemical Waste

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Introduction
Various clinical waste and chemical waste are generated by the dental practice every day, such as used sharps, syringes, blood samples, spent organic solvents and expired drugs. This article introduces the relevant ordinances and regulations governing proper clinical and chemical wastes handling. It will also touch on other wastes generated in minute quantities in dental clinics, such as expired X-ray film, spent fixer and developer, and used dental amalgam. The phasing down of the use of dental amalgam under the Minamata Convention on Mercury will also be covered.

Clinical Waste Control Scheme
Clinical waste control scheme has been in place since August 2011 to provide for the control and regulation of the whole path of handling clinical waste from its production through to disposal as well as for the protection and safety of the public in relation to any such activity. Waste Disposal Ordinance (Cap.354) defines clinical waste as waste that is generated from healthcare or medical-related laboratory practice, and belongs to any one of the six groups specified in the Schedule 8 of the Ordinance:

(i) Group 1 – Used or contaminated sharps, including needleless syringes
(ii) Group 2 – Laboratory waste
(iii) Group 3 – Human & animal tissues but exclude human teeth from dental practice and dead animals/ animal tissues, etc. from veterinary or Chinese medicine practice;
(iv) Group 4 – Infectious materials from patients with 16 specific pathogens such as SARS, Ebola, etc.
(v) Group 5 – Dressings, referring to materials caked with blood/ dripping with blood/ containing free-flowing blood
(vi) Group 6 – Other wastes, currently none in this group

Meanwhile, Waste Disposal (Clinical Waste) (General) Regulation (Cap. 3540) stipulates proper ways to handle clinical waste. Code of Practice for the Management of Clinical Waste was issued for both major and small clinical waste producers to follow. For example, waste producers should safely handle clinical waste with proper segregation, packaging, sealing, labeling and storage. After applying for a premises code, which is location and operator specific, waste producers can then engage a licensed clinical waste collector to collect the clinical waste from the point of generation. It is an offence to mix any clinical waste with general waste for disposal and offenders are liable to a maximum fine of $200,000.
Alternatively, healthcare professional can choose to self-deliver the clinical waste (not more than 5kg) to Chemical Waste Treatment Centre (CWTC) at Tsing Yi by using a private car. In this case, the healthcare professional is required to bring his/her own ID card, proof of professional registration and a filled trip ticket. A disposal fee of $2.7/kg (in cash) will be charged. Apart from CWTC, it is illegal for a healthcare professional to deliver clinical waste from the point of generation to another place such as another clinic or hospital. Again, offenders are liable to a maximum fine of $200,000.

**Chemical Waste Control Scheme**

Clinics, hospitals and institutes (including dental clinics), etc. regularly generate chemical waste, i.e. unwanted pharmaceutical waste, spent fixer and developer solutions, acid, alkali, organic solvent, etc. The storage, collection and disposal of chemical waste have to comply with the requirements of the Waste Disposal Ordinance (Cap. 354) and the Waste Disposal (Chemical Waste) (General) Regulation (Cap. 354C). Waste producer must be registered with the Environmental Protection Department (EPD) as a chemical waste producer. Chemical waste producers shall engage the services of licensed chemical waste collectors to transport their chemical waste to licensed waste disposal facilities for proper disposal. For the details, please refer to the below links.

- A Guide to the Chemical Waste Control Scheme

- A Guide to the Registration of Chemical Waste Producers

- Code of Practice on the Packaging, Labelling and Storage of Chemical Wastes

- List of chemical waste collectors (Please refer to the categories of "Dangerous Drugs, Poisons, Antibiotics, Pharmaceutical Products and Medicines", and "General Chemical Waste")
Phasing Down the Use of Dental Amalgam under the Minamata Convention on Mercury

The Minamata Convention on Mercury aims to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. The Convention entered into force in the People’s Republic of China on 16 August 2017, and applies also to the Hong Kong Special Administrative Region. Although studies conducted by international authorities (including the WHO, World Dental Federation, etc.) have confirmed the safety and effectiveness in dental amalgam used as a restorative material, its impacts on the environment cannot be neglected. Mercury from dental amalgam will be released to the environment through its production and application, discharge of dental wastewater, landfilling or incineration of municipal sewage sludge contaminated with amalgam, cremation of the deceased with amalgam restorations, etc. The Convention requires all Parties to undertake at least two of the nine measures listed below:-

(i) Setting national objectives aiming at dental caries prevention and health promotion;
(ii) Setting national objectives aiming at minimising its use;
(iii) Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;
(iv) Promoting research and development of quality mercury-free materials for dental restoration;
(v) Encouraging professional organisations and dental schools to train on use of mercury-free dental restoration alternatives;
(vi) Discouraging insurance policies that favour dental amalgam use;
(vii) Encouraging insurance policies that favour use of quality alternatives;
(viii) Restricting the use of dental amalgam to its encapsulated form; and
(ix) Promoting use of best environmental practices to reduce releases of mercury and mercury compounds to the environment.

In October 2018, a "Consensus Statement on the Minamata Convention on Mercury and Phase Down of Dental Amalgam in Hong Kong" was jointly issued by the Hong Kong Dental Association, Department of Health, et al. The Consensus Statement supports phasing down the use of dental amalgam in Hong Kong while reaffirms its safety as a restorative material. The Consensus Statement recommended all dental professionals in Hong Kong to undertake the following five measures:-

(i) Non-mercury containing filling materials should be considered as far as practicable;
(ii) Dental amalgam must only be used in pre-dosed encapsulated form;
(iii) Amalgam separators are strongly recommended to be installed;
(iv) Amalgam waste must be properly stored, handled and disposed of in accordance with the provisions of the Waste Disposal (Chemical Waste) (General) Regulation; and
(v) Dental amalgam restorations should not be removed and replaced with alternative materials without clear clinical indications.

The Government is preparing a new ordinance to implement those requirements in the Convention that cannot be effectively fulfilled under the existing regulatory or administrative frameworks, which shall come into effect by end 2020. Although the phasing down of the use of dental amalgam will not be stipulated in the new ordinance, EPD wishes to appeal to all dental professionals to undertake the five measures recommended in the Consensus Statement with a view to discharging the obligation of the Convention and fostering a better environment.
Drug Regulatory System in Hong Kong

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In Hong Kong, pharmaceutical products are mainly regulated under the Pharmacy and Poisons Ordinance (Cap. 138). However, other Ordinances such as the Antibiotics Ordinance (Cap. 137), Dangerous Drugs Ordinance (Cap. 134), Public Health and Municipal Services Ordinance (Cap. 132), Import and Export Ordinance (Cap. 60) and Undesirable Medical Advertisements Ordinance (Cap. 231) may also be relevant.

Legal Requirements Relating to Handling of Drugs by Dental Professionals

According to the Pharmacy and Poisons Ordinance, a registered dentist may supply a medicine for the purposes of dental treatment (section 28 of Cap. 138). In this case, the medicine shall be labelled with the name and address of the dentist. The dentist is also required to make a record with the following particulars –

(a) the date on which the medicine was supplied;
(b) the name and address of the patient;
(c) the ingredients of the medicine and the quantity, dosage and duration of supply.

The above section does not authorize a registered dentist to deal with medicines by way of wholesale dealing (supplying of goods to a person who would resupply such goods) or manufacturing (except dispensing) unless relevant licence is obtained in accordance with Cap. 138.

If the medicine contains a substance regulated under the Antibiotics Ordinance, the dentist also needs to maintain a record (section 7(3) of Cap. 137) with the following particulars –

(a) name and address of the supplier;
(b) quantity of antibiotics received;
(c) date received.

According to section 22 of Dangerous Drugs Ordinance, a registered dentist is authorized, so far as may be necessary for the practice or exercise of his profession, and in his capacity as such, to be in possession of and to supply a dangerous drug. However, 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 (section 23(1) of Cap. 134) although a registered dentist may issue a prescription for his patient to obtain a dangerous drug from pharmacy.

Every dangerous drug possessed by a registered dentist shall, except when the necessities of the practice or exercise of the profession, be kept in a locked receptacle which can be opened only by him or by some other person authorized by section 22 to be in possession of the dangerous drug (section 23(4) of Cap. 134).

In addition, regulations 5, 6 and 7 of the Dangerous Drugs Regulations (Cap. 134A) also provide the requirements of keeping of register or other records in relation to the dangerous drugs obtained and supplied by a registered dentist. For details, please refer to Cap. 134A accordingly.

Section 52 of the Public Health and Municipal Services Ordinance provides a general protection for purchasers of drugs. Under this section, it is an offence for a person supplying 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 the drug demanded by the purchaser. Section 61 of Cap. 132 also provides that false labelling of drugs is an offence.

Apart from the procurement, supply, storage, labelling and record keeping of medicines, healthcare professionals should note that the disposal of medicines, which are classified as chemical waste, should comply with the Waste Disposal (Chemical Waste) (General) Regulations (Cap. 354C). For details, please refer to the guidelines provided by the Environmental Protection Department (https://www.epd.gov.hk/epd/english/environmentinhk/waste/guide_ref/guide_cwc_sub1.html).
Proposed Regulation for Advanced Therapy Products

Advanced therapy products (ATP) are innovative medical products based on cell, tissue or gene therapy. The rapid scientific advancement in the research and development of ATP offers great medical potential for benefiting patients. At the same time, due to their complicated nature and our limited knowledge and experience, the risks and long-term side effects of ATP need to be carefully managed.

Having studied the regulation of ATP in overseas jurisdictions, the Government proposed to regulate ATP under the existing regulatory framework for pharmaceutical products. Amendments to the Pharmacy and Poisons Ordinance are required. A public consultation was conducted between April and June 2018. During the consultation a total of 28 written submissions were received and the proposed regulation was broadly supported. A consultation report was also published in October 2018.

In the proposal, ATP includes gene therapy products and products with cells or tissues that have been substantially manipulated or intended for non-homologous use (somatic cell therapy products and tissue-engineered products). ATP would be classified as pharmaceutical products and current requirements for pharmaceutical products would be applicable (i.e. products must be registered before market, clinical trials require prior authorization, manufacturers and wholesalers require relevant licence, import/ export must under valid import or export licence, etc). In addition, extra requirements will be imposed for ATP that include additional record-keeping and labelling requirements, transaction records are required to be kept for at least 30 years, all premises including hospitals require a licence to produce ATP.

The Government plans to introduce the legislative proposal to the Legislative Council within 2019.

Adverse Drug Reaction Reporting

Adverse drug reaction (ADR) is a response to drug which is noxious and unintended which occurs at doses normally used in human. Very rare or even uncommon ADR may not be detected during the course of drug development prior to marketing. As such, post market surveillance including an ADR reporting system is essential to monitor the safety of medicines.

Drug Office of the Department of Health has set up a surveillance system to capture and evaluate ADR reports. The system includes a spontaneous ADR reporting platform for healthcare professionals. Healthcare professionals are encouraged to report any suspected serious ADR, unexpected ADR, drug interaction and medically significant cases. After receiving the report, officers of the Drug Office would acknowledge receipt and may contact the reporter for more information. All information would be analysed based on WHO principles. For more information, please refer to the Drug Office’s website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html.