HKSTP IACUC

08 – Expired Drugs and Medical Materials Policy

Version History

Version	Effective Date
1	16/06/2023

1. Purpose

The policy aims to control and maintain the quality of anesthesia, analgesics and sedatives agents used on laboratory animals. All agents that provide anaesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely. Research teams with projects involving the use of dangerous drugs or hazardous materials must strictly comply with all relevant ordinance of Hong Kong.

For details on guidelines on the handling and disposal of expired medication issued by Hong Kong Drug Office, refer to
https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/drugdisposalguidance_eng.pdf

For details on general laboratory and research safety requirements on chemical/clinical waste disposal, refer to HKSTP Safety, Health, and Environment (SHE) Handbook.

2. General Principles

2.1 Expired drugs, fluids, foods, therapeutic, or agents must not be provided to laboratory animals as drugs and agents past their expiration date may be ineffective or unsafe to use.

2.2 Generally, drugs that are diluted or mixed may be kept up to 30 days. Drugs with published peer-reviewed evidence suggesting of a longer stability and efficacy of drug dilutions maybe submitted to HKSTP IACUC for approval of such use.

2.3 Meloxicam can stay sterile and stable for 365 days.

2.4 Buprenorphine may be diluted in glass up to 180 days but not stored in plastic syringes.

2.5 All expired drugs, agents, or dilutions waiting for properly disposal must be properly labelled and stored separately from the animal area and discarded promptly.

2.6 Use of expired medical materials for survival procedures is not permitted.

2.7 Expired medical materials may only be used if the procedures meet both criteria:

i. Non-survival, meaning that animals anaesthetized do not regain consciousness

ii. Use of expired medical materials should not affect animal welfare or compromise the validity of the scientific study

iii. All expired materials should be clearly labelled and stored separately from in-date drugs and materials.

3. Hazardous Chemicals/ Materials

3.1 Before commencement of a new research project involving the use of hazardous chemicals, the laboratory personnel should carry out a risk assessment and carefully plan for the necessary safety measures in order to minimize the risk.

3.2 The purchase, use, storage, transport and disposal of chemicals at the Science Park must comply with all applicable local legislations. Before proceeding a procurement, laboratory personnel must check and verify if the chemicals or drugs concerned require any licensing or permits for import, possession, transport or use, etc.

3.3 The quantities of the items to be purchased shall also be considered to avoid the exceedance of any applicable legal limits. Examples of some local legislations associated with hazardous chemicals are listed below for laboratory personnel's reference:

i. Import and Export Ordinance (Cap. 60)
ii. Dangerous Drugs Ordinance (Cap. 134)
iii. Antibiotics Ordinance (Cap. 137)
iv. Pharmacy and Poisons Ordinance (Cap. 138)
v. Control of Chemicals Ordinance (Cap. 145)
vi. Dangerous Goods Ordinance (Cap. 295)
vii. Waste Disposal Ordinance (Cap. 354)
viii. Water Pollution Control Ordinance (Cap. 358)
ix. Hazardous Chemicals Control Ordinance (Cap. 595)
x. Mercury Control Ordinance (Cap. 640)

3.4 Compliance with HKSTP's safety requirements, laboratory personnel at HKSTP shall also observe all applicable laboratory safety requirements and guidelines promulgated by HKSTP. For examples:

i. Laboratory personnel are not allowed to handle hazardous chemicals in those laboratories not maintained under negative pressure or not equipped with appropriate fume cupboards;

ii. Research team is required to keep DG within the exempt quantities (EQ) or licensed quantities granted by HKFSD.

3.5 Researchers shall carry out appropriate risk assessments to identify all potential hazards that may pose a risk to personnel in the laboratories. Special occasions such as working alone, unattended operations and overnight experiments, etc. should be taken into consideration.

3.6 To reduce or mitigate the associated risks, suitable safety measures should be devised and implemented to safeguard all laboratory personnel. These include engineering controls (safety facilities such as fume cupboards), administrative controls (safety procedures or standard operating procedures) and personal protective equipment (PPE).

4. Dangerous Drugs

4.1 Any activities involving dangerous drugs for the purpose of research, including but not limited to import, export, procuring, supply, dealing in or with, manufacturing, possession of Dangerous Drugs, must comply with the Dangerous Drugs Ordinance (Cap. 134). Refer to Dangerous Drugs Ordinance (Cap. 134) for more information,
https://www.elegislation.gov.hk/hk/cap134?xpid=ID_1438402700138_001

4.2 The Dangerous Drugs Ordinance (Cap. 134) confers authority on the following persons to possess, supply or use dangerous drugs in the course of their duties:

i. registered doctors, dentists and veterinary surgeons

ii. registered pharmacists or approved persons employed at prescribed hospitals (i.e., a list of hospitals specified in the Second Schedule to the Dangerous Drugs Ordinance

iii. persons in charge of certain laboratories

4.3 Dangerous drugs must be stored in a locked receptacle which can only be opened by the person authorized under the Dangerous Drugs Ordinance to possess them.

4.4 The authorized person in possession of dangerous drugs must maintain a "Dangerous Drugs Register" to record **all** transactions of dangerous drugs. The format and information included in the register must comply to the requirements stated by the Department of Health *(Refer to Table 1)*. Visit Department of Health website for more information,
https://www.dh.gov.hk/english/useful/useful_ld/useful_ld_ketamine.html

Table 1: Form of Dangerous Drugs 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.

4.5 All receipts of supply of dangerous drugs must be kept and recorded on the day of the transaction or, if this is not practicable, on the following day. No cancellation or alteration of any record is permitted. Corrections must be made by means of a marginal note or footnote and must be dated and signed.

4.6 A separate document must be maintained to record all usage of dangerous drugs. The name of the dangerous drug, strength or concentration used, name of personnel and protocol name should be recorded.

4.7 All registers must be kept in the laboratory for at least two years from the date on which the last entry was made. It is advisable that all supporting documents such as invoices should also be kept for at least two years.

5. Disposal of Pharmaceutical Product (Chemical Waste)

5.1 Research teams must ensure that disposal procedures of pharmaceutical products are in compliance with the waste disposal regulation (Cap. 345).

5.2 Research teams producing pharmaceutical waster (chemical waste) are required to register with Environmental Protection Department (EPD) as Chemical Waste Producer(s). Companies/ Applicants are required to obtain Chemical Waste Producer Number (CWPN) from EPD.

5.3 Pharmaceutical products (chemical waste) should be disposed in relevant container(s) provided by the authorized chemical waste collector. Companies/Applicants should segregate waste containers according to the chemical compatibilities.

5.4 Research teams are responsible to contact and make arrangements with the waste collector for waste collection.

For details on registration as chemical waste producer and guide to chemical waste control scheme, refer to
https://www.epd.gov.hk/epd/english/environmentinhk/waste/prob_solutions/chemical_waste.html

References

Dangerous Drugs Ordinance (Cap. 134), Part II – Part III (2019).

Mak, S. P., Letter to Doctors on Amendments to the Dangerous Drugs Ordinance (Cap 134) - Ketamine (2000). Department of Health.

Drug Office, Department of Health, The Government of the HKSAR. Guidance on Disposal of Unserviceable/ Expired Medicines for License Pharmaceutical Traders.
https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/drugdisposalguidance_eng.pdf