UiO : Universitetet i Oslo
Institutt for medisinske basalfag, Avdeling for komparativ medisin

Standard operasjonsprosedyre: Håndtering og oppbevaring av legemidler reseptgruppe A

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THE HANDLING AND STORAGE OF DRUGS IN PRESCRIPTION CLASS A

1.0 PURPOSE

1.1 To help ensure the correct handling and storage of drugs in prescription class A that are used for experiments or the training of experimental animals at KPM.

1.2 To implement a well-functioning system for registering drugs in prescription class A on arrival at KPM and for ensuring that the correct dosage is administered. The expense account for these drugs should end with a zero balance.

1.3 To provide an overview of laws and regulations governing the correct storage and distribution of drugs.

2.0 LAWS AND REGULATIONS

2.1 "Regulations governing the handling of drugs for organisations and health personnel who provide health care"

2.1.1 § 4 «The responsibility of the head of the organisation: d. To ensure that the organisation has in place a system for the handling of drugs in prescription class A and B».

2.1.2 § 9 «Drug accounts and the control of drugs in prescription class A and B: The organisation must: a. document all deliveries and withdrawals of drugs in prescription class A, including the quantity each individual patient has been given of such drugs. This information must be kept up-to-date at all times and retained for at least 5 years».

3.0 KPM DRUGS IN PRESCRIPTION CLASS A

Temgesic

3.1 Temgesic: solution for injection 0.3 mg/ml: 1 ml, contents: buprenorphine hydrochloride, equivalent to buprenorphine 0.3 mg, glucose, hydrochloric acid, water for injections.

3.2 Indications: buprenorphine is administered for the treatment of pain that is acute enough to need an opioid analgesic and when alternative treatments are insufficient.
Recommended dose of Temgesic 0.3 mg/ml for mice: 0.1 mg/kg every 6-8 hours.

Recommended dose of Temgesic 0.3 mg/ml for rats: 0.05 mg/kg every 6-8 timer.
Recommended dilution for mice: administrate 4 ml/kg of 1:9 dilution of Temgesic:NaCl, equivalent to 0.1 mg/kg
Recommended dilution for rats: administrate 1 ml/kg of 1:5 dilution of Temgesic:NaCl, equivalent to 0,05 mg/kg.

Fentanyl

3.3 Fentanyl: solution for injection 50 µg/ml: 1 ml, contents: fentanyl citrate, equivalent to fentanyl 50 µg, sodium chloride, hydrochloric acid or sodium hydroxide for pH adjustment, water for injections.

3.4 Indications: opioids are only used at KPM as a component of ZRF for 45-60 minutes of general anaesthesia.

Ketamine

3.5 Ketamine: solution for injection 50 mg/ml: 1 ml contents: Ketamine hydrochloride equivalent to ketamine 50 mg, water for injections

3.6 Indications: Induction and maintenance of general anesthesia for diagnostic and surgical procedures, as the only anesthetic in combination with other anesthetics. Before induction or as a supplement for regional anesthesia.

4.0 DIVISION OF RESPONSIBILITY

KPM's responsibilities

4.1 The Head of Department is responsible for drawing up, maintaining, distributing and revising the system for the handling and storage of drugs in prescription class A by KPM users.

4.2 The member of staff with special screening responsibility (PMSK) checks that the drugs in prescription class A correspond with FOTS.

4.3 The PMSK orders and stores drugs in prescription class A in sufficient quantities so that the drugs are always available for users.

4.4 The PMSK keeps a record of all deliveries of drugs from the chemist. Each substance is given its own number, which is entered in the «Register of incoming drugs in prescription class A». The document must include the name of the drug, its serial number, the internal ID-number, the date received, the quantity and a signature.

4.5 The PMSK records and checks drugs in prescription class A dispensed to individual users. The record «Register of dispensed drugs in prescription class A to a user group» must include the date, the name of the drug, the internal ID-number, the quantity dispensed, the number of needles/syringes and a signature.

4.6 The PMSK keeps a chronological log of all the controlled drugs, including the total quantity, the quantity taken from the vial, the quantity left in the vial and the signature of the recipient («Register of the use of drugs in prescription class A»)

4.7 The PMSK collects data for invoicing («Data for the invoicing of drugs in prescription class A»).

4.8 KPM is responsible for making sure that controlled substances are properly stored in a suitable cabinet located in an area with restricted access. Controlled substances must be kept in a place with two locks. Door locks to laboratories and offices can be regarded as one of the two locks, as long as doors to unmanned laboratories/offices are kept locked.

4.9 Drugs in prescription class A are stored in a security cabinet at KPM. The PMSK and the Head of Department have unrestricted access to drugs in prescription class A and Thai Pham may be appointed for unrestricted access in the absence of the above two persons.

4.10 The PMSK is responsible for deliveries to the chemist's or the disposal of drugs in prescription class A. Drugs past their expiry date must be returned to the chemist's. Opened vials stored in the safety cabinet must be placed in yellow waste containers within 24 hours after being opened.

Researchers' responsibilities:

4.11 All KPM users must report to and consult with the PMSK when using drugs in prescription class A in their research or teaching at KPM.

4.12 All KPM users must make sure that drugs in prescription class A are included in the approved FOTS.

4.13 Enquiries about drugs in prescription class A must be sent in writing to the PMSK/the Head of Department (or to Thai Pham if the PMSK and Head of Department are not available) at least 24 hours before the drugs in question are to be used.

4.14 The KPM user is responsible for signing the document «Register of dispensed drugs in prescription class A to a user group» and the «Register of the use of drugs in prescription class A».

4.15 The KPM user is responsible for disclosing the correct data for invoicing («Data for the invoicing of drugs in prescription class A»).

4.16 The KPM user must ensure that a sufficient quantity of diluted drugs in prescription class A are available for the animals for a maximum of 48 hours.

4.17 The KPM user must ensure that diluted drugs in prescription class A are administered to animals in the prescribed way.

4.18 The KPM user who signs the document «Register of dispensed drugs in prescription class A for a user group" is responsible for the drugs once KPM has dispensed them.

4.19 The KPM user must store drugs in prescription class A in a suitable, locked safety cabinet located in an area with restricted access.

4.20 When technical assistance in injecting a class A drug is required from a KPM employee and when class A drugs are dispensed to a KPM employee, the employee in question must contact the PMSK, the Head of Department or Pham Thai. The syringe must be used the same day and all relevant documents must be filled out.

5.0 PROCEDURE

Procedure for ordering, revising and storing drugs in prescription class A by the PMSK

5.1 The PMSK orders drugs from the chemist's by using the form «Requisition for drugs for use on animals in connection with animal experiments at IMB, Section for Comparative Medicine».

5.2 The PMSK is responsible for the receipt of all drugs from the chemist's. The PMSK can delegate to Sophia Salicath the task of fetching drugs from the chemist's and delivering them to the PMSK.

5.3 When the drugs arrive, they must be entered in the «Register of incoming drugs in prescription class A» with the following information: the name of the drug, its serial number, a unique internal drug ID-number, the date received and the quantity.

5.4 The internal drug ID-number must be written on each vial, starting with the number 1.

5.5 The drugs must be stored in the closed and locked safety cabinet located in Katarzyna Joanna Zelewska's office.

5.6 The safety cabinet must always be locked with a code lock. Only the PMSK, the Head of Department and Thai Pham know the code.

5.7 PMSK sends the «Data for the invoicing of drugs in prescription class A» and the «Register of the use of drugs in prescription class A» to Sophia Salicath who balances the account once a year (in December).

Procedure for the ordering and handling of drugs in prescription class A by the KPM user

5.8 The KPM user sends his/her order of drugs in prescription class A in writing by email to the PMSK k.j.zelewska@medisin.uio.no or to the Head of Department espeeng@medisin.uio.no, or to Thai Pham t.t.pham@medisin.uio.no if the PMSK or the Head of Department are unavailable.

5.9 The PMSK, the Head of Department or Thai Pham make an arrangement with the user for when the drug in prescription class A is to be fetched and send the form «Data for the invoicing of drugs in prescription class A» to the user in order to obtain the necessary information for the invoicing of the drug. Once filled out, the «Data for the invoicing of drugs in prescription class A» is placed in the logbook.

5.10 The KPM user will receive instructions on the use of the precise quantity of the drug in prescription class A, including a description of the correct volume for each animal.

5.11 Entire ampoules of Temgesic may be handed over to the KPM user if the user has storage facilities within applicable law and is familiar with this legislation.

5.12 For the receiving of whole ampoules, the documents must be signed by PMSK. After dispensing, the KPM user is responsible for proper storage of the product. It is recommended to document each use or loss of drug prescription group A in one form. See appendix page 9 for filling out the form.

5.13 The PMSK, the Head of Department or Thai Pham enter the use of the drug in the logbook «Register of **dispensed** drugs in prescription class A for a user group», including the date, the name of the drug, the internal drug ID-number, the quantity dispensed, the number of syringes/needles and the signatures of the dispenser and the KPM user.

5.14 The PMSK, the Head of Department or Thai Pham register the use of the drug in the «Register of the use of drugs in prescription class A», including the name of the drug, the internal drug ID-number, the date, the total quantity, the quantity taken from the vial, the quantity left in the vial and the signature.

5.15 The KPM user administrates the drug immediately to the animal/animals or stores the diluted drug in a locked refrigerator for a maximum of 48 hours.

5.16 Syringes must be treated as hazardous waste and be discarded in yellow containers once the KPM user has administrated the drug.

6.0 HEALTH, SAFETY AND ENVIRONMENT

Temgesic

6.1 Temgesic is a partial opioid receptor agonist that is used to relieve moderate to severe pain. Side effects may include respiratory depression, drowsiness, low blood pressure, irregular heartbeat, nausea, vomiting and allergic reactions. If someone with a known lung, kidney, liver or heart disease accidentally injects himself/herself with Temgesic, he/she should immediately seek advice from a doctor in case treatment is necessary.

6.2 If Temgesic comes into contact with the eyes, rinse the eyes thoroughly with plenty of eye wash solution or clean water for at least 15 minutes. If symptoms persist, consult a doctor.

6.3 If you spill a whole bottle of Temgesic, ventilate the room thoroughly. If you spill smaller amounts, these can be mopped up with paper that must then be discarded as hazardous waste. If a large amount is spilt, it should be mopped up and then placed in the container for hazardous waste. The container must then be closed and labelled with its contents and placed in a fume cupboard or directly in the hazardous waste room.

6.4 Original bottles containing residues of Temgesic must be returned to the chemist's.

6.5 Avoid storing Temgesic in temperatures over 30°C. Keep Temgesic in its original packaging and away from direct light.

Risk assessment of Temgesic:

6.6

Probability	5	1*5	2*5	3*5	4*5	5*5
	4	1*4	2*4	3*4	4*4	5*4
	3	1*3	2*3	3*3	4*3	5*3
	2	1*2	2*2	3*2	4*2	5*2
	1	1*1	2*1	3*1	4*1	5*1
		1	2	3	4	5
	Consequence					

Unwanted incident	Protective measures	C *P (consequence *probability)
Exposure by touch or injection	Always wash your hands or discard gloves after use. To clear up spillages, use nitril gloves and protective glasses and ventilate the area if possible.	1*2

The consequence index for Temgesic is *1.

- Injury after pricking with a clean needle will be minimal, but if the needle has already been used, contact the PMSK.

- Spillages will incur almost no risk if PPE is worn.
- In the case of accidental self-injection, the quantity of Temgesic will be so minimal that it will not have any effect on the human body. When Buprenorphine is injected into humans, the toxic dose is 16 mg, and for Fentanyl the toxic dose is 15µg per kg.

Exposure: no exposure is probable under normal circumstances. Probability: *2.

Fentanyl:

6.7 Fentanyl is a powerful synthetic opioid analgesic that relieves severe pain by attaching itself to the body's opioid receptors. The most common side effects may include: problems of nausea, retching/vomiting, muscle stiffness, hypotension, hypertension, bradycardia, allergic reactions and sedation and more.

6.8 If you are pregnant or breast-feeding, you should take extra preventive measures before handling Fentanyl since it is excreted in breast milk and passes through the placenta. In the case of accidental self-injection, contact a doctor.

6.9 Fentanyl must be handled in the same way as other opioids, as for example Temgesic. For information on waste disposal and risk assessment, see points 6.2-6.6 above.

7.0 EQUIPMENT AND MAINTENANCE

7.1 Yellow containers for hazardous waste
7.2 Permanent marker
7.3 Nitril gloves

8.0 HISTORY AND EDITING

8.1 27.04.2022: Added sentences for storing and retrieving whole ampoules with temgesic (H. Tandberg and K. Zelewska)
8.2 08.08.2023: Added Ketamine information. (K. Zelewaska)

9.0 REFERENCES

9.1 «Forskrift om legemiddelhåndtering for virksomheter og helsepersonell som yter helsehjelp» (Regulations governing the handling of drugs for organisations and health personnel who provide health care)
9.2 «Forskrift om apotek» (Regulations governing chemists)
9.3 The common catalogue: Fentanyl «Hameln» - Felleskatalogen
9.4 The common catalogue: Temgesic «Indivior» - Felleskatalogen
9.5 The Norwegian Encyclopaedia Fentanyl. fentanyl – Store medisinske leksikon (snl.no)

Register of incoming drugs in prescription class A

Name of drug	
Serial number	
Internal drug ID-number	
Date received	
Quantity	
Signature	

Register of dispensed drugs in prescription class A for a user group

Name of user group: ……

Date	
Name of drug	
FOTS number	
Internal drug ID-number	
Quantity dispensed	
Quantity of dispensed NaCl	
Number of syringes (1ml)	
Number of needles	
Signatures	
Dispensed by	User name

Register of the use of drugs in prescription class A

Name of drug	
Internal drug ID-number	

Date	Total quantity (ml)	Quantity taken from vial (ml)	Quantity left in vial (ml)	Signature of recipient
Date	Total quantity (ml)	Quantity taken from vial (ml)	Quantity left in vial (ml)	Signature of recipient
Date	Total quantity (ml)	Quantity taken from vial (ml)	Quantity left in vial (ml)	Signature of recipient
Date	Total quantity (ml)	Quantity taken from vial (ml)	Quantity left in vial (ml)	Signature of recipient
Date	Total quantity (ml)	Quantity taken from vial (ml)	Quantity left in vial (ml)	Signature of recipient

Data for the invoicing of drugs in prescription class A

User group name	
User in charge	
Account string	
FOTS number	