



health

Department of Health
NORTHERN CAPE

Policy on Distribution and Handling Schedule 5, Specified Schedule 5 and Schedule 6 Medicines

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Policy Aim

1. The aim of this policy is to provide a standard framework for the assurance of safe and effective handling of Schedule 5, Specified Schedule 5 and Schedule 6 medicines.

Policy Scope

2. This policy is applicable to all pharmacists and pharmacy support personnel as well as all other Health Care Professionals who render pharmaceutical related service.

Policy Statement

3. It is the policy of the Northern Cape Department of Health that Schedule 5, Specified Schedule 5 and Schedule 6 medicines are handled in accordance with the following principles:

3.1. Introduction to the Procurement of Medicines

- 3.1.1. The Northern Cape Department of Health participates in the National Tender process. This process consists of the following:

- 3.1.1.1 Price negotiations for the procurement of medicines for the public sector are carried out on a national level.

- 3.1.1.2 After tenders have been decided upon and awarded, medicines is purchased directly from the supplier via the Provincial Medical Depot, except Large Volume Parenteral and Stoma-therapy products, which are bought directly at District level.

- 3.1.1.3 Medicines which can be procured must be included in the Provincial Formulary¹. These medicines form mostly part of the Essential Medicines List.

¹ "Provincial Formulary means A list of medicines that is approved for the use in the health care system by authorised prescribers and dispensers"

3.1.1.4 Exception to the aforementioned, are items approved by the Provincial Pharmaceutical and Therapeutic Committee for a specific Patient.

3.1.1.5 The award of tenders shall always be a transparent process, which is conducted in the terms recommended by the National Tender Board.

3.2. Ordering of Schedule 5, Specified 5 and Schedule 6 Medicines.

3.2.1. Orders for medicines must be placed on behalf of by the district or hospital from the Provincial Medical Depot (PMD) by Supply Chain Management (SCM) personnel to the relevant suppliers.

3.2.2. Medicines sourced from the depot are ordered and procured from the suppliers specified in the National Tender.

3.2.3. Suppliers must be of a reputable nature and recorded with the Medicines Control Council (MCC).

3.2.4. SCM personnel at the PMD must capture the orders on the Stock Management System after which the orders must be authorised by the relevant authorised Pharmacist supervising the Supply Chain Management unit.

3.2.5. Orders must be faxed to the appropriate supplier.

3.2.6. One copy of the order must be sent to the department and the other copy must be filed for record and audit purposes.

3.2.7. In the event of a buy-out², of the supplier as indicated in the National tender document, the PMD may approach suppliers that can provide the required products and request quotations as per the Public Management Finance Act.

3.2.8. If the buy-out is necessitated by the failure of the supplier on tender not being able to fulfil their obligations; the supplier will be held accountable for differences between the tender price and the price of the supplier who is able to supply the medicines.

² "Buy –Out means: Purchase of pharmaceuticals not on the National Tender"

3.3. Receiving Schedule 5, Specified Schedule 5 and Schedule 6 medicines from the Supplier

3.3.1. Medicines for each hospital and district of the Northern Cape Department of Health must be received at the Provincial Medical Depot.

3.3.2. The responsible pharmacist, receiving the stock, must ensure that the dispatch voucher from the delivery company matches the order number, name and quantity of medicines delivered.

3.3.3. The dispatch voucher must be signed by the pharmacist in charge after the invoice and medicines have been checked for:

- Items ordered compare to items received
- Quantity received compared to quantity ordered
- Expiry date of said medicines
- Purchase order number on the invoice compared to the Purchase order number
- Quality of the items

3.3.4. The invoice of the medicines is logged in the Stock Management System and moved to the Schedule Medicines Unit which is locked.

3.3.5. Upon the receipt of new schedule medicines in the schedule medicines unit, the assigned pharmacist must enter the medicines into the schedule register with the following information documented in full:

- The date on which the medicines was received
- The name, business address of the person from whom the medicines was received
- The quantity, in words and figures, of medicines received

3.4. Storage and Safekeeping of Schedule 5, Specified Schedule 5 and Schedule 6 medicines in the Provincial Medical Depot

3.4.1. All Schedule 5, specified Schedule 5 and Schedule 6 medicines must be stored separately from Schedule 1 to 4 medicines.

3.4.2. All Schedules 5, specified Schedule 5 and Schedule 6 medicines must be kept in a locked cupboard or lockable room.

- 3.4.3. Medicines must be stored according to FEFO principles.
- 3.4.4. Storage conditions must adhere to the manufacturer's instructions.
- 3.4.5. Only the pharmacist who is responsible for the schedule room and pharmacist assistants, under direct supervision of a pharmacist, should have access to the room.

3.5. Issuing of Schedule 5, Specified Schedule 5 and Schedule 6 medicines from the Medical Depot

- 3.5.1. Hospital and District pharmacists must place order on behalf of Health Care facilities for medication on a weekly basis via the stock management system. Orders are placed according to pre-approved roster for all the hospitals and facilities in each district.
- 3.5.2. Issuing of medication follows the FEFO principle.
- 3.5.3. The list of medicines that each facility requires must be printed at the Provincial Medical Depot and the medicines must be picked by a pharmacist/ pharmacist assistant.
- 3.5.4. The picked medicines must be checked by another pharmacist/ pharmacist assistant. The list must be signed by both parties.
- 3.5.5. The medicines picked for each facility must be logged in the register book.
- 3.5.6. After verification a stock adjustment must be done on the Stock Management System to record this action.
- 3.5.7. The medicines must be boxed and securely sealed with the facility name and invoice number clearly written on the top of the box.
- 3.5.8. In the case of Schedule 6 medicines, a sticker saying "ATTENTION PHARMACIST" is placed on the box.

3.6. Distribution of Scheduled 5, Specified Schedule 5 and Schedule 6 Medicines from the Provincial Medical Depot to Health Care Facilities

- 3.6.1. It is the responsibility of the Provincial Medical Depot to ensure that arrangements are made for the safe and secure distribution of medicines to

health care facilities, including environmental control and cold chain management³ throughout the distribution process.

3.6.2. The clearly marked sealed boxes must be sent to the Dispatch Unit within the Provincial Medical Depot where they must be loaded onto closed delivery vehicles. Vehicles must be large enough to accommodate the medicines and need to follow the specifications for delivery vehicles for transportation of medicines.

3.6.3. The driver responsible for the delivery of the medicines to the health care facilities must carry identification as well as a signed copy of the form authorising him/her to transport medicines.

3.6.4. All deliveries must be accompanied by a trip sheet and the relevant issue vouchers.

3.7. Maintenance and Ordering of Schedule 5, Specified Schedule 5 and Schedule 6 medicines from the Provincial Medical Depot by Health Care facilities.

3.7.1. The proposed stock levels of Scheduled 5, Specified Schedule 5 and Schedule 6 medicines must be verified by the pharmacist responsible for the specific hospital or facility in a specific district.

3.7.2. The pharmacist or facility manager must ensure that the stock levels of medicines remains above the minimum required quantity.

3.7.3. If the stock on hand is less than the required minimum quantity, the pharmacist or facility manager must order the medicines through the Hospital or District pharmacist.

3.7.4. Orders for Schedule 5, Specified Schedule 5 and Schedule 6 items submitted to the Hospital or District pharmacist must be accompanied by an Institutional Requisition Form and Scheduled and Substance Order form (original copies).

3.7.5. All orders for Schedule 5 specified Schedule 5 or Schedule 6 items must be supported by the original order form for Schedule substances NCPD2 and kept

³Refer to Policy of The Distribution and Handling of Thermolabile Medicines

by the district pharmacist/hospital pharmacy manager. NCPD2 forms must be directed to the responsible pharmacist at the Provincial Medical Depot.

3.7.6. After the orders are placed on the Stock Management System, the NCPD2 form with the order number and facility name indicated on it, will be faxed to mail to the schedule unit of the Provincial Medical Depot.

3.7.7. Orders will be cancelled automatically by the provincial medical depot if the applicable faxed NCPD2 form is not received by the depot by 08:00 on the due date. The demander shall be informed in writing by the depot of the cancellation of the order.

3.8. Receiving Schedule 5, Specified Schedule 5 and Schedule 6 medicines from the Provincial Medical Depot

3.8.1. Medicines are delivered to the health care facilities by drivers employed by the Provincial Medical depot.

3.8.2. The trip sheet must be checked, completed and signed with the following details being recorded:

- Full name in printed letters of the health care professional/ official receiving the stock
- Signature of the health care professional/official receiving stock
- Designation of the health care professional/official
- Date stamp of the institution

3.8.3. The original signed copy of the trip sheet must be returned with the driver to the PMD and the designated pharmacist/ pharmacy assistant must keep the copy.

3.8.4 The authorised person responsible for the acceptance of the delivered stock must ensure that:

- The item ordered is the same as the item delivered
- The quantity sent by the PMD corresponds to the quantity delivered
- The medicines delivered has not expired
- The medicines as well as the box that the medicines has been delivered in have not been tampered with

3.8.5 Thorough checking of the order must be completed within 2 working days of receipt of an order and any discrepancies must be reported to the Provincial Medical Depot via the Hospital or District Pharmacist.

3.8.6. Medicines received must be recorded on medicines stock cards to ensure correct stock levels are reflected.

3.8.7. Medicines must be received in a secure, designated delivery area.

3.8.8. Medicines must be entered into the schedule register with the following information documented in full:

- The date on which the medicines was received
- The name and business address of the person from whom the medicines was received
- The quantity, in words and figures, of such medicines received
- Invoice and purchase order number
- The name of the person who checked and verified the medicines

3.9. Storage and Safekeeping of Schedule 5, Specified Schedule 5 and Schedule 6 medicines in the Health Care Facilities

3.9.1. Schedule 5, Specified Schedule 5 and Schedule 6 medicines must be stored separately from Schedule 1 to 4 medicines.

3.9.2. All medication must be stored according to the FEFO method.

3.9.3. All Schedule 5 specified Schedule 5 and Schedule 6 medicines must be kept in a locked cupboard or lockable room.

3.9.4. Storage conditions must be according to the manufacturer's instructions. The medicines must be stored in a lock up cupboard that is attached to a permanent fixture.

3.9.5. The key of the cupboard must be in the personal possession of the Responsible Pharmacist or an authorised person responsible for the control of scheduled medicines.

3.9.6. Cupboards must be clearly marked and locked at all times.

- 3.9.7. Keys to the pharmacy and cupboard must be kept separate and must never be left unattended.

3.10. Issuing of Schedule 5, Specified Schedule 5 and Schedule 6 medicines in Health Care Facilities

- 3.10.1. When a medical practitioner requires Schedule 5, specified Schedule 5 and Schedule 6 medicines in a health care facility for a patient, he/she must complete and hand in a prescription for the said patient to the pharmacy.
- 3.10.2. Medication issued follows the FEFO principle.
- 3.10.3. In the case of a ward, the professional nurse must bring the balance of the relevant schedule medicines in the ward and the ward schedule medicines register to the pharmacy on times set by the pharmacist.
- 3.10.4. The pharmacist must issue ~~the~~ new order after the balance is checked against the schedule medicines register.
- 3.10.5. The pharmacist must check for any discrepancies. If the balance on hand corresponds with the balance in the register, the new medicines requisition must be entered as a receipt into the register.
- 3.10.6. The balance in the register must be updated and the pharmacist with the nurse must both sign.
- 3.10.7. If the balance on hand does not correspond with the balance in the register; the matter must be investigated and reported. The matter must be resolved before the medication is issued; exceptions can be made if the situation permits it.
- 3.10.8. In the case of Schedule 5, Specified Schedule 5 and Schedule 6 medicines required in non-ward settings, the schedule medicines must be prescribed by a health care practitioner on the prescription card.

3.11. Returns of Medicines from the Health Care Facility to the Provincial Medical Depot

- 3.11.1. Medicines issued to health care facilities may not be returned to the PMD without prior approval by the responsible pharmacist of the PMD.

3.11.2. The collection of returned stock must be done to coincide with the next delivery to the facility.

3.12. Patient Prescription for Schedule 5 Specified Schedule 5 and 6 Medicines.

3.12.1. Prescriptions for Schedule 5 specified Schedule 5 and Schedule 6 medicines require the following particulars on the script:

- The name, qualification, practice number and address of the prescriber
- The name and address of the patient
- The date of issue of the prescription
- The approved name/proprietary name of the medicines
- The quantity of the medicines prescribe in words and numbers
- Instructions for the administration and frequency of the dosage
- Signature of the prescriber

3.12. Schedule Medicines Register

3.12.1. Separate register books must be kept for Specified Schedule 5 and Schedule 6 medicines.

3.12.2. All registers must be stored in a locked cupboard that only the pharmacist or other person in charge of the schedule medicines has access to.

3.12.3. The first page of the register must show an index of all of the medicines logged in the register.

3.12.4. It is imperative that the register be kept up to date at all times with the following circumstances documented each time that they occur:

- When medicines are received from the supplier/medical depot/other health care facility
- When medicines are issued in a ward setting
- When medicines are issued to a patient
- When errors, breakages or losses of medicines occurs
- When medicines expires
- When the register is balanced

3.12.5. Errors in the register must be corrected by:

- A red line drawn through the entry
- "Incorrect Entry" must be written in red pen above the entry
- The correction must be signed by the pharmacist or person responsible for the upkeep of the registers

3.12.6. Registers must be balanced at the end of March, June, September and December or within fourteen days of the last day of the mentioned dates.

3.12.7. When the register is full, a new register must be obtained and the balances of the medicines carried to the new book. Full register books must be retained in the pharmacy for a period of 5 years.

3.13. Medicines Errors

3.13.1. Broken Ampoules of Schedule 6 Medicines.

3.13.2. If a breakage of an ampoule of Schedule 6 medicines occurs, the ward must immediately notify the manager of said ward.

3.13.3. The breakage must not be cleaned until the manager has verified that the breakage is a Schedule 6 medicine.

3.13.4. Once verified, the ampoule must be placed in an envelope where it is sealed, labelled with the name of the Schedule 6 medicine and dated.

3.13.5. Statements from witnesses and any involved health care professionals must be obtained.

3.13.6. The breakage must be logged in the medicines register and signed by the pharmacist, manager and any other health care professionals involved in the incident.

3.13.7. The broken ampoule along with any collected statements must be kept in a locked cupboard.

3.14. Expired Schedule Medicines

3.14.1. The expired medicines must be returned to the pharmacy where the expired medicines are logged in the scheduled medicines register.

3.14.2. The entry must be signed by the pharmacist and the sister who returned the stock, and the medicines must be stored in a locked cupboard until disposed of.

- 3.14.3. The expired medicines must not be kept in the same place as other schedule medicines to ensure that no expired medicines are accidentally dispensed.

3.15. Missing Schedule Medicines

- 3.15.1. A comprehensive investigation must be carried out as soon as missing stock is identified, where the ward/pharmacy is completely searched as well as checking all prescription sheets and patient notes.
- 3.15.2. If the loss occurred in a ward the person who discovered the loss must inform the sister in charge, otherwise the pharmacist in charge must be notified. The person who discovered the loss must write a statement.
- 3.15.3. In the case a missing Schedule 6 medicines, if the medicines cannot be located the police must be contacted and statements taken before the loss can be logged in the scheduled medicines register.

3.16. Disposal of Scheduled 5, Specified Scheduled 5 and Scheduled 6 Medicines

- 3.16.1. The medicines shall be disposed inline to the Policy on Disposal of Medicines and Scheduled Substances (Pharmaceutical Waste).

4. Roles and Responsibilities

- 4.1. It is the responsibility of the designated pharmacist to ensure the safe keeping of the medicines as well as ensuring the pharmacy and all pharmaceutical staff adheres to all necessary legislation and guidelines stipulated in the Good Pharmacy Practice Manual.
- 4.2. It is the responsibility of all pharmacists and pharmacist's assistants to adhere to all necessary legislation and guidelines stipulated in the Good Pharmacy Practice Manual while practicing pharmacy.
- 4.3. It is the responsibility of the responsible pharmacist to ensure the maintenance of the schedule register.
- 4.4. It is the role of the Hospital and district pharmacists to place medicines orders with the Provincial Medical Depot
- 4.5. It is the responsibility of the drivers of the depot to ensure that the same number of boxes of medicines dispatched from the PMD and the boxes of medicines which

reach the hospital or intended facility and that none of the boxes are tampered with while in transit.

4.6. It is the responsibility of the drivers to ensure that the relevant issue vouchers are signed and returned to the PMD.

4.7. It is the role of the medical practitioner to prescribe schedule 5, specified schedule 5 and schedule 6 medicines.

5. Review and Distribution

5.1. The Director for Pharmaceutical Services is the responsible manager for this policy and for ensuring it is reviewed and updated.

6. This Policy will be reviewed after 3 years but not later than 5 years of the last publishing date. If necessary an updated version will be issued, if not a formal cover letter will be issued to supplement the cover of this Policy (identifying a revised publication date).

7. The Director for Policy & Planning will distribute updated versions to:

- Member of the Executive Council for Health
- Head of Department of Health
- All Chief Directors, Directors and Deputy Directors (who will in turn distribute to their staff as appropriate.)
- The Chairperson(s) of all Hospital Boards and Clinic/Community Health Centre Committees.

8. Acknowledgements and Sources

8.1. Pharmacy Act (Act no 53 of 1974)

8.2. Medicines and Related Substances Control Act (101 of 1965) as amended

8.3. National Drug Policy

8.4. Good Pharmacy Practice