

### Policy on Distribution and Handling Schedule 1 To 4 **Medicines**

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Ms GE Matlaopane

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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 1 to 4 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 1 to 4 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 through the National tender process.
- 3.1.1.2. After tenders have been decided upon and awarded, medicines are 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 Formulary<sup>1</sup>. These medicines form mostly part of the Essential Medicine List.
- 3.1.1.4. Exception to the aforementioned, are items approved by the Provincial Pharmaceutical and Therapeutic Committee for a specific Patient.

<sup>&</sup>lt;sup>1</sup> A list of medicine that is approved for the use in the health care system by authorised prescribers and dispensers

3.1.2. 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 1 to 4 Medicines

- 3.2.1. Orders for medicines must be placed on behalf of the district or hospital from the Provincial Medical Depot (PMD) by Supply Chain Management (SCM) personnel.
- 3.2.2. Medicines sourced from the depot are ordered and procured from the suppliers as listed in the National Tender.
- 3.2.3. Suppliers must be of a reputable nature and recorded with the Medicine Control Council (MCC).
- 3.2.4. SCM personnel of the PMD must capture the orders on the Stock Management System after which the orders must be authorised by the relevant authorised Pharmacist supervising 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 buyout<sup>2</sup> as indicated in the National tender document, the PMD may approach suppliers that can provide the required medicines 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.

### 3.3. Receiving Schedule 1 to 4 Medicines from the Supplier

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

<sup>&</sup>lt;sup>2</sup>Purchase of pharmaceuticals not on the National Tender

- 3.3.2. The pharmacist receiving the medicines 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 the medicine,
  - Purchase order number on the invoice compared to the Purchase order number,
  - Quality of the items.

# 3.4. Storage and Safekeeping of Schedule 1 to 4 Medicines in the Provincial Medical Depot

- 3.4.1. Schedule 1 to 4 medicines which are not classified as thermo-labile<sup>3</sup> must be stored in the Ethical unit<sup>4</sup> of the Provincial Medical Depot according to FEFO (First to Expire First Out) principles<sup>5</sup>.
- 3.4.2. Thermo-labile medicines must be stored in the cold chain unit which must meet the standards and specifications as listed in the Good Pharmacy Practice<sup>6</sup>.
- 3.4.3. Medicines must be stored in locked cages in accordance with manufacturer's instructions.
- 3.4.4. No medicines should be stored on the floor.
- 3.4.5. Both the ethical and cold chain unit must be under the supervision of a registered pharmacist, with keys to the units being in possession of the responsible pharmacist at all times.

<sup>&</sup>lt;sup>3</sup>A substance which is readily destroyed or deactivated due to heat

<sup>&</sup>lt;sup>4</sup>A unit of the Dr Arthur Letele Medical Logistics Centre, which holds all Schedule 1 – Schedule 4 medicines.

<sup>&</sup>lt;sup>5</sup>Medicine which expires first must be used first

<sup>&</sup>lt;sup>6</sup>Guidelines published by the South African Pharmacy Council stating the standards to which the pharmacy profession must adhere to

### 3.5. Issuing of Schedule 1 to 4 Medicines from the Provincial Medical Depot

- 3.5.1. District and hospital pharmacists must place orders for medicines on a weekly basis via the stock management system from the PMD. Orders are placed according to pre-approved roster for all hospitals and facilities in each district.
- 3.5.2. Issuing of medicines follows the FEFO<sup>7</sup> 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. After verification a stock adjustment must be done on the Stock Management System to record this action.
- 3.5.6. The medicines must be boxed and securely sealed with the facility name and invoice number clearly written on the top of the box.

### 3.6. Distribution of Schedule 1 to 4 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 management<sup>8</sup> throughout the distribution process.
- 3.6.2. The 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 medicine and need to follow the specifications for delivery vehicles for transportation of medicine.
- 3.6.3. The driver responsible for the delivery of medicines to the health care facilities must carry identification as well as a signed copy of the form authorising him/her to transport medicine.

<sup>8</sup>Refer to Policy of The Distribution and Handling of Thermo-labile Medicines

<sup>&</sup>lt;sup>7</sup> FEFO – means First Expired, First Out

- 3.6.4. All deliveries must be accompanied by a trip sheet and the relevant issue vouchers.
- 3.7 Maintenance and Ordering of Scheduled 1 to 4 Medicines from the Provincial Medical Depot from Health Care facilities.
  - 3.7.1. The proposed stock levels of Schedule 1 to 4 medicines must be verified by the pharmacist responsible for the specific hospital or facility in the 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 medicines on hand are less than the required minimum quantity, the pharmacist or facility manager must order the medicines through the District pharmacist from the PMD.

### 3.8. Receiving Schedule 1 to 4 Medicines from the Provincial Medical Depot.

- 3.8.1. Medicines must be delivered to the Health Care Facilities by drivers employed by the Provincial Medical depot.
- 3.8.2. Medicines classified as Schedule 1 to 4 may only be received by a Health Care Official of the Department of Health at a designated delivery point.
- 3.8.3. 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 medicines,
  - Signature of the health care professional/official receiving medicines,
  - Designation of the health care professional/official,
  - Date stamp of the institution.
- 3.8.4. The original signed copy of the trip sheet must be returned with the driver to the Provincial Medical Depot and the health care facility must keep the copy.
- 3.8.5. The authorised person responsible for the acceptance of the delivered medicines must ensure that:
  - The medicines ordered are the same as the medicines delivered,
  - The quantity sent by the depot corresponds to the quantity delivered,

- The medicines delivered have not expired,
- The medicines as well as the box that the medicines have been delivered in have not been tampered with.
- 3.8.6. Thorough checking of the order must be completed within 2 working days of receipt of the order and any discrepancies must be reported to the Provincial Medical Depot via the District or Hospital Pharmacist.
- 3.8.7. Medicines received must be recorded on medicines stock cards to ensure correct stock levels are reflected.

## 3.9. Storage and Safekeeping of Schedule 1 to 4 Medicines in the Health Care Facilities

- 3.9.1. Schedule 1 to 4 medicines must be kept in a dispensary or a medicines room.
- 3.9.2. Storage areas must be large enough to ensure the organized arrangement of medicines which allows for correct stock rotation.
- 3.9.3. No medicines must be stored on the floor.
- 3.9.4. Temperature must be controlled according the guidelines in the Good Pharmacy Practise.
- 3.9.5. Only the pharmacist, pharmacist assistant or authorised health care professional may have access to the pharmacy.

#### 3.10. Issuing of Schedule 1 to 4 Medicines in Health Care Facilities

- 3.10.1. A medical practitioner or authorized prescriber can prescribe Schedule 1 to 4 medicines to a patient.
- 3.10.2. The prescription must be written on the patient's medical card/file/record and can either be dispensed directly by any authorised health care professional depending on their scope of practise and the procedure of the health care facility.
- 3.10.3. When medicine is dispensed to the patient, the medicines levels are adjusted on stock cards to reflect the new stock levels of the medicines.
- 3.10.4. Medicines must be issued according to the FEFO method.

# 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 medicines must be done to coincide with the next delivery to the facility.

### 3.12. Patient Prescription for Schedule 1 to 4 Medicines

- 3.12.1. Prescriptions for Schedule 1 to 4 medicines require the following particulars on the script:
  - The name, qualification, practice number and address of the authorized prescriber<sup>8</sup>,
  - The name and address of the patient,
  - The date of issue of the prescription,
  - The approved name/proprietary name of the medicines prescribed,
  - The quantity of the medicines prescribe,
  - Instructions for the administration and frequency of the dosage,
  - If repeatable, then specify the number of repeats (not exceeding 6 months),
  - Signature of the prescriber.

#### 3.13. Disposal of Scheduled 1 to 4 Medicines

3.13.1. Medicines shall be disposed in line the Policy on Disposal of Medicine 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 role of the district and hospital pharmacist to place medicine orders with the PMD.
- 4.4. It is the responsibility of the drivers of the PMD to ensure that the same number of boxes of medicines dispatched from the PMD and the boxes of medicines that reach the intended facility are the same and that none of the boxes are tampered with while in transit.
- 4.5. It is the responsibility of the drivers to ensure that the relevant issue vouchers are signed and returned to the PMD.
- 4.6. It is the role of the medical practitioner to prescribe schedule 1 to schedule 4 medicines.

### 5. Review and Distribution

- 5.1. The Director for Pharmaceutical Services is the responsible manager for this policy and to ensure it is reviewed and updated.
- 5.2. 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).
- 5.3. The Director for Policy & Planning will distribute updated versions to:
  - Member of the Executive Council
  - Head of Department
  - 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.

### 6. Acknowledgements and Sources

- 6.1. Pharmacy Act 53 of 1974
- 6.2. Medicine and Related Substances Control Act 101 of 1965 as amended
- 6.3. National Drug Policy
- 6.4. Good Pharmacy Practice