



# **Policy on Free Distribution of Medicines at Government Hospitals**

**YEAR-2013**

**Department of Health & Family Welfare  
Government of Odisha**

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## PREFACE

This document shall be called as Policy on Free Distribution of Medicines at Government Hospitals (2013). The department of Health and Family Welfare, Government of Odisha has prepared this for its implementation in letter and spirit to improve overall public health delivery system in the state. The specific objectives under this policy are to improve availability of quality drugs at government health facilities for timely and appropriate treatment of the patient in line with accepted clinical practices.

The policy shall also provide a broad framework for production and implementation of different operational guidelines for correct and appropriate implementation of its objective at ground level. The key health care aspects that have been emphasized under this policy include, selection, procurement, storage, distribution, quality assurance, rational use and financing of drugs for treatment of patients coming to government health facility free of cost. While highlighting these aspects, due cognition has been given to available resources and socio-economic environment of the state.

This document has been developed after several consultations with different stakeholders of government healthcare system in order to ensure a coherent and multi-sectoral platform for achieving the objectives of the policy.

This policy shall remain as the official policy of the Government of Odisha to guide the department in executing its mandate of providing free medicines to patients coming to government health facility for treatment of any diseases.

I wish to express my sincere appreciation to all **including** the technical experts, health officials and administrators for their immense contribution and support towards the development of this policy

**Principal Secretary to Government of Odisha  
Department of Health & Family Welfare**

## Introduction

### 1. Purpose of this Policy

- 1.1 Improve and sustain the health of the population of the state by ensuring rational use and access to safe, effective and quality drugs (Medicines) at government health facilities.
- 1.2 To reduce financial burden with respect to out of packet expenditure on health care of the population coming to government health facility.

### 2. Policy Objectives

- 2.1 Promote rational use of drugs<sup>1</sup> (medicines) by prescribers, dispensers and patients seeking treatment at government health facilities.
- 2.2 Strengthen quality assurance to ensure that only medicines of required content, specification, description of desired therapeutic value are procured and supplied to government health facilities for dispensing.
- 2.3 Make available adequate quantity of quality drugs and medical consumables as per Essential Drug List (EDL), at all government healthcare facilities for timely and appropriate treatment of patients in conformity with the Standard Treatment Guidelines (STG<sup>2</sup>) as issued by the department from time to time.
- 2.4 Improve overall acceptability and accessibility to essential medicines<sup>3</sup> by population depending on government health facilities in the state.
- 2.5 Provide a policy framework around which procedures, guidelines and protocols can be developed with respect to procurement, storage and dispensing of medicines and medical supplies at government hospitals.

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<sup>1</sup> Patients receiving medication appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time and at lowest cost to them and their community (WHO 1985).

<sup>2</sup> Standard Treatment Guidelines (STG) represents a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances

<sup>3</sup> Essential Medicines are those that satisfy the need of majority of population, should be available in all times, in proper doses, are rational and proven therapeutic value and safety.

- 2.6 Institutionalize the procurement of quality essential medicines and supply chain management along with an accountability and oversight mechanism.

### 3. Recent Developments

- 1.1 One of the reasons of rural indebtedness in the state is due to high out of pocket expenditure on health care and treatment. The cost of medicine is one of the largest factors to this breach of human dignity as it accounts the major portion of out of pocket expenditure.
- 1.2 In recent years, government of Odisha has taken several steps to improve accessibility to quality medicine by the population depending on government health care facilities, which includes;
  - a) Declaration of “**Free Medicine Distribution Scheme**” by the government with a commitment to provide medicines covered in the Essential Drug List of the State to all coming to government health facility for treatment free of cost;
  - b) Substantial increase in budgetary allocation for drug to meet the demand;
  - c) Establishment of computerized drug distribution counters across health facilities for online monitoring;
  - d) Setting up of an independent procurement entity in the form of a company to handle the procurement and distribution function more efficiently and professionally;
  - e) Rational drug budgeting with increased allocation in the state budget for drug procurement.
- 1.3 The central procurement agency of the department in the name of “**Odisha State Medical Corporation Limited (OSMCL)**” has been set up for successful implementation of “Free Medicine Distribution Scheme” of the State Government. OSMCL shall be undertaking following activities on behalf of the department:
  - a) Centrally procure quality medicines, surgical and EIF (Equipment Instrument and Furniture) of required specification and description on behalf of the department through a transparent, fair and competitive tendering process.
  - b) Monitor the movement of medicines both at facility and warehouse level through an online inventory management system centrally to

ensure uninterrupted supply of medicines at all level of government health facilities.

- c) Online monitoring of drug dispensing at Drug Distribution Counters (DDCs) across health facilities to assess the consumption pattern, prescription practices, demand assessment and disease prevalence of particular facility or location.
- d) Procure medical equipment centrally for the health facilities of required specification and description and maintenance of existing medical equipment at facilities.

## Situation Analysis

### 4. Present Scenario in the State

#### 4.1 Policies and Procedures:

4.1.1 Department is having its Drug Policy and Essential Drug List (EDL) since 2002 and which is being revised in an interval of 2 years. Current Drug Policy (2010) and the EDL is due for a major revision in the line of recent mandate of the state government to introduce “Free Drug Distribution Scheme” in the state to make essential drugs available free of cost to the population depending on government health facility for treatment.

4.1.2 Standard Treatment Guidelines (STG) for selected diseases was published for first time in the year 2006. Department is in the process of finalizing a comprehensive STG comprising entire range of diseases likely to be treated in government health facilities.

4.1.3 Procurement practices followed by the department for procurement of medicines are in conformity of the guideline issued by finance department from time to time and provisions under Odisha General Financial Rule.

#### 4.2 Procurement, Warehousing and Distribution of Drugs

4.2.1 Presently, State Drug Management Unit (SDMU) is procuring 80% of the drug budget centrally from the essential drug list and balance 20% of the drug budget are given to the facilities for local procurement as per their requirement.

4.2.2 Tendering and selection of vendors are done centrally by SDMU and approved by the (State Level Purchase Committee) SLPC.

4.2.3 Medicines are stored in central drug warehouses and distributed to the facilities as per the indent raised by them.

4.2.4 Movement of Drugs at central warehouses and facilities are managed through an online inventory management system.

### 4.3 Quality Assurance:

- 4.3.1 As per the existing quality policy, supplier are required to furnish test certificate either form a government or NABL accredited lab for each batch of medicine along with the consignment at the time of delivery at central drug warehouses.
- 4.3.2 Medicines are issued from central warehouses to the facilities as per the test report submitted to the supplier.
- 4.3.3 After delivery of medicines at the central warehouse samples are drawn for each batch of medicine supplied and sent to SDMU for quality testing only through empanelled NABL accredited lab for further quality assurance. Payment is released to the supplier only if it qualifies in the quality testing.

## Policy Statements

### 5. Drug Selection Policy

#### 5.1 Objective

5.1.1 Ensure that drugs selected for incorporation into the Essential Drug List (EDL) are suitable for appropriate treatment of prevailing diseases and that drug needs at different level of health care facility are met.

#### 5.2 Policy Statement

5.2.1 The Department of Health and Family Welfare shall compile a selected list of drugs to be known as Essential Drug List (EDL), which shall include programme and specialist drugs.

5.2.2 Selection of drugs shall be by generic name or International Non-propriety Name (INN) only. It shall include medicines for both communicable and non-communicable diseases.

5.2.3 When several drugs are available with the same indication or when two or more drugs are therapeutically equivalent, the pharmaceutical product and dosage from that provides the most favourable benefit/risk ratio shall be selected.

5.2.4 Fixed ratio combination shall be acceptable if one or more of the following criteria are met:

- a) The clinical condition justifies the use of more than one drug;
- b) The therapeutic effect of the combination is greater than the sum of effects of the each drug;
- c) The cost of combination product is less than the total cost of the individual products;
- d) The combination form improves compliance.

5.2.5 The EDL containing all the drugs selected to be used in government health facilities shall be produced and distributed to all government health institutions and health care providers. Drugs in the EDL shall be categorized according to the level of use (facility-wise). EDL shall have clear indication of the medicines to be used for Outpatient and Inpatients.

- 5.2.6 The EDL shall be prepared or updated every year by a State Level Committee duly appointed by the department for the purpose. The members among others shall consist of eminent experts from different government health institutions and other leading specialists.
- 5.2.7 Suggestions for amendments to the EDL shall be made in writing on a prescribed form addressed to the department justifying each suggested amendment. All such suggestion shall be placed before the committee for review and consideration based on the merit of the individual case. New drugs shall only be introduced if they offer distinct advantages over existing drugs. If information on existing drugs shows they no longer have a favourable risk/benefit ratio, they shall be withdrawn and replaced with safer alternatives.

## 6. Drug Procurement Policy

### 6.1 Objective

- 6.1.1 Timely procurement of medicines and other medical consumables of required specification, description and quantity in a transparent, fair and cost effective manner.

### 6.2 Policy Statements

- 6.2.1 Department shall procure drugs centrally from EDL as per the Annual Procurement Plan utilizing 90% of the drug budget (State), whereas the balance 10% of the drug budget (State) shall be allotted to CDMOs for the health facilities under their administrative control and to the Indenting Officials of other major health institutions<sup>4</sup>.
- 6.2.2 Odisha State Medical Corporation Limited (OSMCL), a government of Odisha undertaking, shall be the central procurement agency of the department for drugs, surgical, sutures, medical consumables, medical

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<sup>4</sup> As of now the other major health institutions are Medical Colleges Hospitals (Cuttack, Burla and Berhampur), Capital Hospital (Bhubaneswar), R.G.H. Rourkela, Mental Health Institute (Cuttack), Sishu Bhawan (Cuttack), Leprosy Home & Hospital (Cuttack) T.B. Hospital (Chandpur, Nayagarh), T.B. & ID Hospital (Puri), Govt. T.B. Hospital (Kalahandi), Health & Family Welfare Centre (Cuttack), R.H.C. (Jagatsingpur), RHC (Attapura, Bargarh), R.H.C. (Gangam) and Dental Wing (SCB Medical College, Cuttack)

equipment, instruments, furniture and other health care related goods and services.

- 6.2.3 OSMCL shall be responsible for timely procurement and distribution of drugs and other medical consumables of required specification, description and quantity as per the annual procurement plan of the department.
- 6.2.4 OMSCL shall adhere to a transparent, competitive and fair system of tendering in conformity with the principle of public procurement. A detailed manual of procurement procedure along with standard bid document shall be developed and followed by the corporation with the approval of the government.
- 6.2.5 The Department shall complete **Annual Estimate** (Demand) for drugs and medical consumable in advance and which shall be considered while preparing annual budget estimates.
- 6.2.6 **Annual Estimate** (Demand) for drugs and other medical consumables shall be prepared separately for each district<sup>5</sup> and major health institutions. The Drug and Therapeutic Committee of the respective district and institutions shall be primarily responsible for preparation and submission of annual estimates.
- 6.2.8 The department shall establish a State Level Committee for consolidation, compilation and rationalization of the Annual Estimates as submitted by districts and major health institutions. In addition, the committee shall also finalise the **Annual Procurement Plan** once the budgetary allocation for drugs is confirmed along with approval of annual budget. The Annual Procurement Plan (APP) shall have details including quantity, schedule of requirement, packaging and labeling specification for each item separately.
- 6.2.9 The department shall issue relevant guidelines with detailed procedures, methods and timeline for realistic, accurate and rational assessment of demand of drugs and medical consumables by the authorities for government run health facilities.

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<sup>5</sup> District shall cover all institutions coming under its administrative control, i.e. DHH, PHCs, CHCs, SC, etc.

## 7. Storage and Distribution Policy

### 7.1 Objective

7.1.1 Ensure continuous availability of good quality, safe and effective medicines at government health facility for distribution to patients at free of cost for treatment and care.

### 7.2 Policy Statements

7.2.1 Suitably constructed and equipped storage facilities shall be made available at every facility by the department for safe storage and dispensing of medicines.

7.2.2 Adequate infrastructure shall be created by the department at different level for central warehousing including cold-chain facility for safe storage of drugs and other medical consumables.

7.2.3 Department shall ensure that at any given point of time a minimum stock level of six-month's consumption is maintained together at central warehouses and facilities.

7.2.4 Inventory management of all the drugs and medical consumables coming into the government health system from different sources<sup>6</sup> shall be done centrally through an online inventory management system.

7.2.5 Department shall set up adequate number of computerized Drug Distribution Counters (DDCs) at health facility for smooth dispensing of medicines and capturing of online data to facilitate prescription tracking and monitoring.

7.2.6 Appropriate methods and procedures for receipt, classification, storage and issue of inventory shall be adopted at different level for an efficient and effective inventory management including; (i) minimization wastages and losses due to expiry and damages (ii) improvement of drug availability at the facilities.

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<sup>6</sup> Different sources shall include pooled procurement by OSMC from state budget local procurement by the district or the facility, central government supply and supply for any other agency.

- 7.2.7 Total wastage of inventories both at warehouse and facility level in a year shall not be more than 3%<sup>7</sup> of the total value of inventory received during that year.
- 7.2.8 Medicines for a maximum of 3-7 days of requirement for general diseases and for 15 days of requirement for chronic diseases shall be dispensed to patients against OPD prescriptions at a time. However, in case of specific vertical programmes like: RNTCP, NVBDCP, NPCB, NLEP, JSSK, etc., dispensing of medicines shall be as per the respective programme guidelines. No injectable other than insulin shall be dispensed against OPD prescription to patients except in case of casualty and emergency.
- 7.2.9 Only those drugs which are registered in India and having more than three years of market standing shall be procured and supplied in government health facility. However only under special circumstances this restriction can be waived by the department for specific drug items.

## **8. Policy on Rational Drug Use**

### **8.1 Objectives**

- 8.1.1 Ensure safe, efficacious and cost effective use of medicine at government health facilities.
- 8.1.2 Ensure patient safety at government health facilities so far it relates to use of medicines for therapeutic purpose.

### **8.2 Standard Treatment Guidelines**

- 8.2.1 Department shall develop Standard Treatment Guidelines consisting of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions and which shall be applicable for all government health facilities in the state.
- 8.2.2 The State Level Committee duly appointed by the department for formulation of EDL and STG shall be responsible for finalization of the STG and review it on regular interval (i.e. every two years) in consultation

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<sup>7</sup> At warehouses maximum of 1% and at facilities a maximum of 2% of the value of drugs received.

with the Drug and Therapeutic Committees of different districts and facilities.

- 8.2.3 Department shall organize workshops and seminars on regular interval involving doctors and other clinical staff for appropriate dissemination of the STG. In addition printed STG of adequate number shall be distributed health facilities. STG flow charts as appropriate shall be displayed prominently in relevant places e.g. ICU, OT, SNCU, Labour room, casualty etc.

### **8.3 Rational Prescription Practices**

- 8.3.1 Doctors in a government health facility should, as far as possible, prescribe medicines in generic name from EDL and shall ensure that the line of treatment as prescribed by them is conforming to Standard Treatment Guidelines.
- 8.3.2 Department shall develop a prescribing format that gives adequate intimation on the patient, disease condition, the drugs and the prescriber.
- 8.3.3 The format prescribed from time to time shall be made applicable for all government health faculties uniformly and shall be used by doctors while prescribing for the patients coming to government health facility.
- 8.3.4 The Drug and Therapeutic Committee (DTC) of the respective health facility or district shall constantly monitor the prescribing practices of the doctors in government health facilities.

### **8.4 Drug and Therapeutics Committee**

- 8.4.1 Department shall ensure the establishment of Drug and Therapeutics Committees (DTCs) in all district and major government health institutions in the state in order to ensure correct, efficient and cost effective management of drugs.
- 8.4.2 The members of the DTC at medical colleges shall include specialists from all major departments and representation from pharmaceutical, nursing and other clinical services. The Superintendent of the medical college

hospital shall chair the committee and the head of pharmacology department shall be the convener.

- 8.4.3 At district level the DTC shall be chaired by the CDMO of the respective district. Specialists from all major departments shall be taken as the member of DTC. The officer who is in charge of the central drug warehouses of the district shall be the convener.
- 8.4.4 In case of major hospitals, the head of the institution shall chair the DTC. The specialists from all major departments shall be the members of the committee and the officer in-charge of the drug store shall be the convener.
- 8.4.4 The primary responsibilities of the Drug and Therapeutic Committee (DTC), either at district or institution level, shall be to ensure rational use of drugs at government health facilities which includes:
- a) Selection of cost-effective and safe medicines for use in health facilities in the district or health institutions based on Essential Drug List and STG.
  - b) Enforce the adherence to treatment guidelines by doctors and other clinical staff engaged in healthcare in government health facilities.
  - c) Provide evidence-based input to the State Level Committee (EDL & STG) for timely revision of STG and EDL.
  - d) Implement and evaluate strategies to enforce rational use of medicine at all health faculties including review of prescription practices, co-ordination with antibiotic and infection control committee)
  - e) Accurate and rational estimation of the annual requirement of drugs and other medical consumables of respective health facilities.
  - f) Consolidation and rationalization of annual requirement of drugs and other medical supplies for respective district /health institutions.
  - g) Establish measures to improve overall utilization of drugs at health facilities including enforcement of rational prescription practices; prompt and efficient dispensing of medicines at government health faculties.
  - h) Institute measures to be employed in case of shortage of drugs and other medical supplies.
  - i) Co-ordinate with OSMCL for mater relating to quality, expiry, non-availability of drugs at health facilities.
  - j) Any other matter relating to the rational use of drugs.

## 8.5 Antibiotics Policy

8.5.1 Department shall appoint a committee in the name of **Antibiotic Committee** to produce general guidelines and policy on use of Antibiotics with an objective to avoid uncontrolled misuse or abuse of antibiotics in government health facility to be followed uniformly by all healthcare professionals while treating/prescribing.

8.5.2 While appointing the Antibiotic Committee department shall consider inclusion of following members in the committee:

- a) Representatives from Odisha State Medical Corporation Ltd.: Who will report back to the committee in each meeting on the prescription pattern and item-wise drug utilization and its value;
- b) Microbiologist: Who will report on antibiotic susceptibility pattern of bacteria isolation from major infections;
- c) Clinical Doctors and Nurses: Being responsible for direct patient care shall provide a link between clinical practice and Antibiotic Committee.
- d) Representatives from State Level Committee for EDL & STG as reciprocal membership.

8.5.3 The Committee shall produce general guidelines and policy on antibiotics use after wide consultation and in agreement with clinical practitioner and microbiologists of major health institutions of the state.

8.5.4 The general guidelines on use of antibiotics in addition to other details shall include following details;

- a) Antibiotic prophylaxis i.e. with details of timing, route, duration of the therapy, dosages and frequency.
- b) Choice of antibiotics for empirical and targeted therapy of major infections.
- c) Indicate first and second line therapy for common infection.
- d) Possible drug interaction with other prescribed medicines.

## 9. Drug Financing

### 9.1 Objective

9.1.1 Institute a sustainable mechanism for adequate financing of drug budget to ensure uninterrupted supply of essential medicines at all government health facilities across the state.

## 9.2 Policy Statement

- 9.2.1 State government shall continue to make adequate provision in the state budget for procurement and free distribution of essential medicines for all diseases to patients coming to government health facilities.
- 9.2.2 State government shall also continue collaborating with central government, private sector and donor agencies for assistance to supplement state budget, if necessary, for uninterrupted availability of drugs at all government health facilities.
- 9.2.3 Ensure benefits under government sponsored Health Insurance Scheme including Rastriya Swastha Bima Yojana (RSBY) made available to patients coming to government health facilities for treatment to meet the cost of medicines which are not covered under EDL.

## 10. Quality Policy

### 10.1 Policy Objectives

- 10.1.1 Drugs procured for supply to the government health facilities by the department are safe, effective and meet approved specifications and standards.
- 10.1.2 Necessary precautions have been taken during the process of warehousing and distribution of drugs so that the efficacy and integrity of the product is retained throughout the shelf-life of the product.

### 10.2 Policy Statement

- 10.2.1 Department shall develop a system of quality control and cause its implementation to ensure that all drugs, medicines and hospital consumables moving through the drug supply-chain system for consumption by the patients coming to government health facilities are of standard (approved) quality, and no medicine of sub-standard quality are retained in the system.
- 10.2.2 The quality testing of any drug sample shall be done either through a government laboratory provided it has the testing facilities<sup>8</sup> or through

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<sup>8</sup> Includes the availability of reference salt, manpower (analyst), equipment, etc.

any laboratory accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL).

10.2.3 No drug item shall be received from the supplier having remaining shelf life of less than 15 month as on the date of receipt of consignment.

10.2.4 Department shall create appropriate warehousing and cold-chain infrastructure for safe and scientific storage of drugs and medical supplies to maintain its efficacy and integrity through out its shelf life.

10.2.5 Odisha State Medical Corporation Limited being the nodal agency for procurement, warehousing and distribution of drugs and medical consumables on behalf of the Department shall be responsible for quality testing of samples drawn from every batch of drugs supplied at central warehouses only from empaneled laboratories<sup>9</sup>.

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<sup>9</sup> OSMSL shall empanel sufficient number of NABL accredited labs for quality testing and analysis of different categories of drugs procured and supplied by it on behalf of the department.

