Assessment Criteria for State Drug Procurement and Distribution System

National Health Systems Resource Centre, New Delhi

Standards

Standard 1	• State has efficient and transparent drug procurement mechanism
Standard 2	• State ensures quality of drugs procured and dispensed
Standard 3	• State has efficient system for storage and distribution of drugs and consumables
Standard 4	• State ensures rational prescription practices
Standard 5	• State ensures accessibility and affordability of drugs to end user

Measurable Elements	
Standard 1	**State has efficient and transparent drug procurement mechanism**
ME 1.1	State has a functional central procurement agency for drugs/consumables and Equipment
ME 1.2	State has an established procedure for selecting suppliers for drugs/consumables and equipment
ME 1.3	State has system for maintaining transparency and credibility in drug procurement system
ME 1.4	State ensures optimal estimation of requirements and purchasing of drugs
Standard 2	**State ensures quality of drugs procured and dispensed**
ME 2.1	State has adequate structure for quality control of drugs
ME 2.2	There is a system for reporting Adverse drug reaction
ME 2.3	State has established system for quality assurance of drugs
Standard 3	**State has efficient system for storage and distribution of drugs and consumables**
ME 3.1	State ensures adequate structural arrangements for storage of drugs
ME 3.2	State ensures safe and scientific storage of drugs
ME 3.3	State has adequate arrangement for transportation of drugs
ME 3.4	State has scientific inventory management system in place
ME 3.5	State has an efficient and responsive distribution system that ensures no stock outs under all circumstances.
Standard 4	**State ensures rational prescription practices**
ME 4.1	State has formulated and disseminated essential drug list
ME 4.2	State has developed and established Standard treatment guidelines
ME 4.3	State ensures rational prescription and use of drugs
Standard 5	**State ensures accessibility and affordability of drugs to end user**
ME 5.1	State ensures adequate allocation and optimal utilization of financial resources
ME 5.2	Facility ensures availability of essential drugs free of cost at the public health facilities
ME 5.4	State informs community/patients of free drug entitlements
ME 5.5	State measures drug availability and accessibility indicators and tries to improve it to reach national benchmarks.

Checklist for Drug Procurement and Distribution System

S. No	Checkpoint	Compliance	Benchmark
Standard 1	**State has efficient and transparent drug procurement mechanism**		
ME 1.1	**State has a functional central procurement agency for drugs/consumables and Equipment**		
CP 1.1.1	A Central Procurement Agency is established in the state and having autonomy in its functioning.		Board of directors Cells Procurement, supplies, logistics, finance, IT,
CP 1.1.2	The Procurement Agency has mandate for procurement of full range for drugs, consumables, reagents and equipment.		Drugs, consumables, surgical supplies, equipment and instruments including diagnosticequipment and reagents
CP 1.1.3	The system of the procurement, its quality control procedure, punitive action methodology in case of non-compliance, and internal system & processes are documented and are available on the public domain.		Procurement, Quality control, distribution and ensuring rational use of drugs
CP 1.1.4	Agency has dedicated technical advisory committee constituted and it has representation from independent domain experts.		senior doctors from medical colleges, in-service/retired pharmacology experts, State healthofficials Procurement, Logistic and Quality section,
CP 1.1.5	Internal organisational structure of the procurement organisation is delineated and well - defined. There is no-conflict of interest like situation internally between functional departments and externally as well.		with competent technical experts like biomedical engineer
CP 1.1.6	Procurement agency has valid registration under requisite law		Indian companies Act 1956
ME 1.2	**State has an established procedure for selecting suppliers for drugs/consumables and equipment**		
CP 1.2 .1	Procurement of drugs is done through a two-bid system		Technical and Financial Bids
CP 1.2 .2	Tender evaluation/ purchase committees and purchase committee are formed, the committees are broad based and have subject matter expert on board.		Drug controller, state health officials and finance department
CP 1.2 .3	Procurement is done though a transparent 'e-tendering' process		
CP 1.2 .4	Criteria for technical evaluation are defined, in the tender document and had been communicated to all bidders, before hand		
CP 1.2 .5	Only manufacturer of the items or direct importers are qualified		No intermediary companies
CP 1.2 .6	Minimum turn-over is defined in the selection criteria		Defined for different categories of products
CP 1.2 .7	Minimum experience for production of the item is defined		3 years
CP 1.2 .8	GMP certification is mandatory for manufacturer		GMP Certificate
CP 1.2 .9	Shelf life of product is defined		
CP 1.2 .10	Labelling and Packaging of product is defined in criteria		
CP 1.2 .11	Cycle time for supplying the products is defined		45 days for general 60 days for imported items
CP 1.2 .12	Supplier are selected on L1 bases		
CP 1.2.13	L2 and L3 are identified and listed, if they agree to match the L-1 rate		
CP 1.2.14	State has documented and approved standard operating procedures for selecting suppliers		
ME 1. 3	**State has system for maintain transparency and credibility in drug procurement system**		
CP 1.3.1	State has criteria and system for blacklisting defaulter drug companies		

S. No	Checkpoint	Compliance	Benchmark
CP 1.3.2	Name of the blacklisted companies are displayed in the Public Domain.		
CP 1.3.3	Procedure for re-listing of drug companies is defined in charter / TOR of the Procurement Organisation		
CP 1.3.4	Payment of drugs is made in defined cycle time		
CP 1.3.5	Payment is done through e-banking/CBS		CBS / NEFT /RTGS No Physical Cheques
CP 1.3.6	Centralized payment to all stakeholders		suppliers, labs, other service providers
ME 1.4	**State ensures optimal estimation of requirements and purchasing of drugs**		
CP 1.4.1	Estimation of quantity of drugs to be procured is done based on consumption data for the previous year using scientific methods		
CP 1.4.2	Stock outs, change in morbidity/epidemiological / demographical profile is factored in while doing estimation		
CP 1.4.3	Drugs are procured only in generic name		
CP 1.4.4	Drugs/consumables are not procured at any condition higher than market price		
CP 1.4.5	Rational preferential allocation is given to public sector units and small-scale industries		Not more than 25% 10% PSU 15% SSU
CP 1.4.6	Purchase order is given on centrally		
CP 1.4.7	Purchase order is based minimum required stock (Buffer Stock), consumption pattern and lead time		At least for one quarter
CP 1.4.8	Buffer stock is defined at state level		At least for two months
CP 1.4.9	Budget allocation for different level of facilities is defined according to level of care and bed strength		
CP 1.4.10	State has documented and approved standard operating procedures for purchasing process		
Standard 2	**State ensures quality of drugs procured and dispensed**		
ME 2.1	**State has adequate structure for quality control of drugs**		
CP 2.1.1	Dedicated quality control cell		
CP 2.1.2	State empanelled competent laboratories for quality testing of drugs		
CP 2.1.3	Selection of empanelled laboratories is done on rotation basis		
CP 2.1.4	Empanelled testing labs has quality management system in place		Preferably NABL certified / Other quality certification
CP 2.1.5	Parameters for quality control at lab are defined		stability, bio-availability, chemical/biological composition and any other parameter deemed necessary such as sterility in case of sterile products
ME 2.2	**There is a system for reporting Adverse drug reaction**		
CP 2.2.1	There is an enabling government order for reporting of adverse drug events to authorities		
CP 2.2.2	Adverse drug reactions are being reported to authorities as per law		Check no of drug reactions reported in last one year
CP 2.2.3	Time frame for reporting adverse drug reaction is determined and monitored		
CP 2.2.4	Service providers has been sensitized how to report adverse drug reactions		
CP 2.2.5	State has analyse ADR data taken action on adverse drug reactions reported to it		In case of sever drug reaction there is system for prohibition of further distribution and recall of such drugs
ME 2.3	**State has established system for quality assurance of drugs**		

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CP 2.3.1	Each batch of the drug is subjected to quality control test before releasing the drugs to health facilities for general usage.		
CP 2.3.2	There is provision of sharing Quality Control pass report of each batch of drug with the central agency (procurement organisation)		
CP 2.3.3	Bills are cleared only after a valid Quality Control report for each batch has been obtained by the procurement organisation		
CP 2.3.4	Drugs failed in quality tests are called back and are stored separately, with a procedure being in place to ensure that such failed drugs do not get issued inadvertently		
CP 2.3.5	There is system for physical verification of product packaging, labels and external appearances in while receiving the drug in warehouse		Periodic check for contamination of any kind in the product or unexpected dilution/concentration in product mass
CP 2.3.6	There is system for periodic and random physical check of drug for any inconsistency during storage		
CP 2.3.7	Criteria for physical verification at receiving and subsequent verification at storage is defined		
CP 2.3.8	Random retesting of batches of drugs at storage in ware house/ facility level drug store, in event of reporting of adverse reactions.		
CP 2.3.9	In case of any complaint there is provision for inspection of such drugs by central agency		
CP 2.3.10	Quality samples for a batch are pooled from all warehouses before sending to lab		
CP 2.3.11	One part of samples are kept as control samples and for further retesting		
CP 2.3.12	Anonymity of the sample are maintained		System for concealing the identity by stickers/ink etc
CP 2.3.13	There is s system for codification of samples		Each sample is codified before sending it to lab
CP 2.3.14	Cycle time for sending samples to lab is defined and adhered		3 days
CP 2.3.15	Cycle time for sending samples for pre release testing to quality cell is defined and adhered		5 days for collecting the sample
Standard 3	**State has adequate infrastructure and credible management system for storage and distribution of drugs and consumables**		
ME 3.1	**State ensures adequate structural arrangements for storage of drugs**		
CP 3.1.1	Drug warehouses are available at every district headquarters		
CP 3.1.2	State has defined the minimum infrastructure and storage equipments should be available at district warehouses / Facility Level drug stores		
CP 3.1.3	There has been planned resource allocation for up gradation / maintenance of district warehouses		
CP 3.1.4	Storage equipments are provide adequately at district ware houses		• Heavy Duty Racking System 8' feet • Heavy Duty Racking System 14' feet, • Hydraulic Hand pallet trucks • Pallets • Side Racks
CP 3.1.5	Physical infrastructure of the warehouses is in sound condition		No Cracks, seepage, chipping of plaster, broken window panes etc.
CP 3.1.6	There is established procedure and adequate financial resource for periodic maintenance of warehouses		
CP 3.1.7	IT equipments and software are provided adequately		Desktop Computers Printer Bar Code Reader & Printer
CP 3.1.8	Cold storage equipments are provide adequately		• Cold place(2O-80 C)- Walk-in-Coolers ILRs • Cool place(80 - 280 C) - Air Conditioners in Rooms

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CP 3.1.9	Adequate power back-up is available		Generator and UPS/Inverter as per load
CP 3.1.10	Fire safety equipment are available at key locations, and have been serviced periodically. Staff is aware of their usage.		
CP 3.1.11	Rodent and pest control measures are in place		
CP 3.1.12	Work space for the staff with office infrastructure is available		
CP 3.1.13	Adequate facilities for storage of medicines		
CP 3.1.14	Quarantine area for storing of medicines waiting for quality check approval		
CP 3.1.15	Walk-in-Cooler		
CP 3.1.16	Area for "Not of Standard Quality Drugs"(NOSQ)		
CP 3.1.17	Space for loading and unloading of supplies		
CP 3.1.18	Drug warehouses have administrative linkages /control with central procurement agency		
CP 3.1.19	District drug ware houses are adequately staffed		• Officer in-charge • Pharmacist 1(Warehouse Storage Manager) • Pharmacist 2 (Hospital Supply Manager) • Data Entry Operators (2) • Helpers(need based) • Security man(need based)
CP 3.1.20	Adequate security measures to avoid pilferages		
CP 3.1.21	There is system for disposal of unused/expired drugs as per pollution control board		
CP 3.1.22	There is established procedure for safe storage, retention and disposal of records		
ME 3.2	**State ensures safe and scientific storage of drugs**		
CP 3.2.1	District ware houses ensures that drugs are kept at optimum temperature		
CP 3.2.2	State has adequate arrangement for drug stocks for disaster/disease out break		
CP 3.2.3	Storage temperature is monitored in cold room and for those items, which require storage a low temperature.		
CP 3.2.4	Expiry and near expiry drug list are maintained at drug stores/ dispensaries		
CP 3.2.5	There is a system for using the near expiry drugs before end of its shelf life		There is system of sharing of near expiry/slow moving drugs to other warehouses
CP 3.2.6	There is system for periodic cleaning of storage area		
CP 3.2.7	There is established procure for identification and segregation of damaged/ not for fit/Expiry drugs for use drugs		
CP 3.2.8	The entry and exit of personnel inside the facility is monitored		
CP 3.2.9	The facility is classified into areas clearly demarcating areas with restricted entry		
CP 3.2.10	There are documented standard operating procedures for optimal and safe storage of drugs		
CP 3.2.11	Drugs are arranged and labelled in store in a systemic way		Alphabetical , Type and category of drugs
ME 3.3	**State has adequate arrangement for transportation of drugs**		
CP 3.3.1	Adequate special vehicles are available for transportation of vaccines and others drugs requires controlled temperature		
CP 3.3.2	Drugs are directly supplied to District warehouses from manufacture		
CP 3.3.3	Dedicated budget has been allotted for transportation of drugs to facilities		
CP 3.3.4	Route chart is prepared at district level for smooth distribution of medicine form District Drug Ware House		
CP 3.3.5	Pooled vehicles are used for distribution of drugs		
CP 3.3.6	Delivery schedule log book are maintained for drug transportation vehicle		Time and quantity of drugs received are entered by each facility in vehicle log book

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CP 3.3.7	Efficiency of transportation system is monitored regularly		Timeliness is monitored
ME 3.4	**State has scientific inventory management system in place**		
CP 3.4.1	State has developed a inventory management software for logistic management of drug		
CP 3.4.2	Stock registers are maintained and daily updated at drug stores		
CP 3.4.3	Training has been provided to pharmacist/store in charges for estimation of requirements and inventory management		
CP 3.4.4	Stores has defined minimum stock category of drug as per there consumption pattern		
CP 3.4.5	Reorder level is defined for each category of drugs		
CP 3.4.6	Look alike and sound alike drugs are stored in separate area		
CP 3.4.7	All the facility level stores connected with inventory management software		
CP 3.4.8	Software has a module for indenting		Indent generation and issuance of drugs to hospitals/institutions
CP 3.4.9	Software has module quality control		Sample register desk for recording the receipt of sample, return of sample and disposing of sample
CP 3.4.10	Software has module Drug locator and transfer of drugs		helps to locate drugs in various warehouses and facilitate transfer of drugs between drug warehouses whenever needed
CP 3.4.11	Software has module for Processing of bills and supplier payment		
CP 3.4.12	First expiry first out policy is established and ensured at drug stores		
CP 3.4.13	Psychotropic and Narcotic Drugs are kept at secure place as per law		
ME 3.5	**State has an efficient and responsive distribution system that ensures no stock outs under all circumstances**		
CP 3.5.1	Drugs are supplied for indented quantity only		No dumping of drugs at facility
CP 3.5.2	Passbook system is used for indenting the drugs		
CP 3.5.3	Pharmacists at facility level have been trained for estimation of drug requirement by scientific methods		
CP 3.5.4	District ware houses and facility level stores calculate and maintain buffer stocks		
CP 3.5.5	Bin Cards are maintained at drug stores /dispensaries		
CP 3.5.6	Physical verification of inventory is done periodically		
CP 3.5.7	Verification of quality and quantity is done before dispatch of drugs to the facilities by authorized person		
CP 3.5.8	There is established procure for delivering the drugs in on urgent basis in case of stock out/emergency		
CP 3.5.9	Drug stock outs are recorded and analysed		There is system for recording and informing the incidences when warehouse unable to provide indented quantity in time
CP 3.5.10	Cycle time for resolving stock out situation at each level of facility		
Standard 4	**State ensures rational prescription practices**		
ME 4.1	**State has formulated and disseminated essential drug list**		
CP 4.1.1	State has formulated Essential drug list		Establishment of EDL with enabling government order
CP 4.1.2	Updated versions of EDL are periodically disseminated and are available for different level of facilities		EDL for Sub centre, PHC, CHC, SDH, DH and Tertiary care hospitals
CP 4.1.3	EDL are revised at periodic intervals		Every two year
CP 4.1.4	EDL developed taking in consideration national and international documents		Compliance with NLEM, WHO etc

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CP 4.1.5	Cost and cost effectiveness is considered while formulating EDL		
CP 4.1.6	Drugs being provided by GoI for various National Health Programs and Janani Shishu Suraksha Yojna have also been included in the list.		Disease control program, JSSK etc
CP 4.1.7	EDL includes consumables , surgical items and supplies		
CP 4.1.8	EDL is developed taking in consideration the specific local disease burden/ morbidity profile		Drugs for local endemics are included
CP 4.1.9	EDL contains strength and packing size of the drugs/consumable		
CP 4.1.10	State prepares drug formulary based on EDL		Includes indication, dosages and formulations , side effects, contraindication and interaction of drugs
CP 4.1.11	Drug Formulary is available at the facility level		
ME 4.2	**State has developed and established Standard treatment guidelines**		
CP 4.2.1	State has developed standard treatment guidelines		Published standard treatment guidelines with enabling orders
CP 4.2.2	Standard treatment guidelines are disseminated effectively		Distribution of STGs to health care providers free of cost
CP 4.2.3	Training has been provided on STGs		
CP 4.2.4	Evidence based regular updating of STGs is done		At least in three years
CP 4.2.5	Initiatives are taken for dissemination and ensuing compliance to STG in private sector also		
CP 4.2.6	STGs are available at point of use		
CP 4.2.7	Standard Treatment Guidelines are formulated taking in consideration the level of care		Separate guidelines for Primary and Secondary care
CP 4.2.8	Standard treatment Guidelines are integrated with national disease control program		
CP 4.2.9	Standard Treatment Guidelines are developed in participatory way involving end user		
CP 4.2.10	Standard treatment guidelines are user friendly and easy to read		
ME 4.3	**State ensures rational prescription and use of drugs**		
CP 4.3.1	Drugs and therapeutic committees are constituted at district hospital and above level of facilities		
CP 4.3.2	Drug and therapeutic committees have representation of all concerned department and also independent experts		Representatives of clinical departments, Clinical microbiologist/ lab technician , Nursing staff, Hospital administration, pharmacist and medical record department
CP 4.3.3	State conduct regular training / sensitization workshops for rational use of drugs		
CP 4.3.4	State has developed and published guidelines for rational use of drugs		
CP 4.3.5	There is prevision of keeping one copy of prescription with the health care facility		Provision of duplicate copy of prescription Self carbonated copy
CP 4.3.6	Diagnosis is written on the prescription		
CP 4.3.7	There is a enabling order from state administration regarding writing prescription in generic name only		
CP 4.3.8	State has defined criteria for prescription audit		Formats for Prescription audits available
CP 4.3.9	Prescription audit is done at regular interval		Monthly
CP 4.3.10	Third party /independent pres prescription audits are conducted at regular interval		
CP 4.3.11	Finding of Prescription audit are collated and analysed		

S. No	Checkpoint	Compliance	Benchmark
CP 4.3.12	Corrective actions are taken based on findings of Prescription audits		Step 1- Counselling by Unit head and DTC members has to be done Step 2 -Written advice to the concerned doctor by Supdt../PMO/CM*HO/MO I/C with copy to the department Step 3-Case may be referred to Principal Secretary Health & FW /Med. Education for disciplinary action
CP 4.3.13	State provides training for prescription audit to DTC members		
CP 4.3.14	Adequate sample is taken for prescription audit		At least 1%
CP 4.3.15	Only drugs from essential drug list are prescribed except when it is unavoidable		Use of non-essential drugs be justified by the concerned doctor,
CP 4.3.16	Drug Dispensing quantity is defined and adhered for regular patients		routinely medicines are to be prescribed for 3 days but can be extended up to 7 days in special cases; however for
CP 4.3.17	Drug Dispensing quantity is defined and adhered for chronic patients		chronic cases medicines may be prescribed for up to 1 month
Standard 5	**State ensures accessibility and affordability of drugs to end user**		
ME 5.1	**State ensures adequate allocation and optimal utilization of financial resources**		
CP 5.1.1	Calculation for financial resources has been done in a scientific		Per capita, factoring in the burden of disease
CP 5.1.2	Sufficient budget has been provided for procurement of the		
CP 5.1.3	There is provision for reserve budget for exigencies		10% reserve
CP 5.1.4	There is provision of local purchase in condition of exigencies and		10 % of total budget
ME 5.2	**Facility ensures availability of essential drugs free of cost at the public health facilities**		
CP 5.2.1	Free drug scheme has been implemented at state		Formally decreased with enabling government order
CP 5.2.2	Free Drug scheme is universal in nature		Includes all categories of patients BPL/or Non BPL
CP 5.2.3	No document /administrative procedure is required for access to free drugs		Drugs are given based on valid prescription without requirement of any BPL, Adhaaar, ration card etc
CP 5.2.4	Free drug scheme includes Blood and Blood components		At least for BPL and JSSK entitlements For Thalassemia and Haemophilia Patients
CP 5.2.5	Free drug Scheme includes consumables and surgical supplies		Syringes, IV Sets, Suture and dressing materials etc are included
CP 5.2.6	There is system for ensuring drug availability at IPD, Emergency after normal working house of store		Drug Stores are accessible after routine hours
CP 5.2.7	State monitors stock out situations at different level		
CP 5.2.8	State provides adequate drug dispensing counters as per load of the patients to reduce the waiting time		Waiting time should not be more than 30 minutes
ME 5.3	**State informs community/patients of free drug entitlements**		
CP 5.3.1	Drug availability status is displayed at the dispensary/indoors		In local language , Updated daily
CP 5.3.2	Free drug entitlements are displayed at the facility in local language		Information about scheme is displayed at the public health facilities and other public places like railway station etc .
CP 5.3.3	Drugs are arranged at the dispensary so visible to patients		Transparent glass panes at dispensary
CP 5.3.4	A person is responsible at every facility of ensuring availability of		MS, MO I/C , BMO as per level of facility
CP 5.3.5	There is a grievance redressal system in case of non availability of essential drugs		help-line. Patients are free to call this number if they do not get medicines from the facilities.
CP 5.3.6	Provision of low cost generic drug store for drugs not covered in		Jan Aushadhalaya
CP 5.3.7	Patients are counselled for use of drugs		By Pharmacist / Doctored
CP 5.3.8	State has program for Public education on drugs and its rational use		Through mass media, NGOs, Print Media, Workshops etc
ME 5.4	**State measures drug availability and accessibility indicators and tries to improve it to reach national benchmarks.**		
CP 5.4.1	Per Capita drug expenditure		
CP 5.4.2	Per patient drug expenditure		
CP 5.4.3	Drug coverage against NLEM		
CP 5.4.4	% of drugs available against EDL		
CP 5.4.5	Cycle time for Quality Testing		
CP 5.4.6	% of drugs expired in last one year		

S. No	Checkpoint	Compliance	Benchmark
CP 5.4.7	No of stock out incidences reported in last quarter		
CP 5.4.8	Lead time for drug receipt at facility after indenting to warehouse		
CP 5.4.9	Lead time for receipt of drug at district drug ware houses		
CP 5.4.10	No. of Batches failed in quality testing		