सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

OPERATIONAL GUIDELINES

FREE DRUGS SERVICE INITIATIVE

Ministry of Health and Family Welfare
Government of India

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राष्ट्रीय स्वास्थ्य मिशन
जगत प्रकाश नड्डा
Jagat Prakash Nadda

सत्यमेव जयते

स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India

Message

Ensuring uninterrupted availability of drugs in the public health system is one of the key parameters of a well functioning health system. Spending on drugs constitutes a substantial proportion of out- of-pocket (OOP) expenditure on health care. Free provision of essential drugs in public health facilities brings huge savings to the patients without much burden on the government, since bulk procurement of generics costs only a small fraction of cost of branded drugs. This is, thus, one of the easiest and quickest options to improve access to essential medicines and reduce OOP expenses. We have noticed that those states that have effectively rolled out a scheme to provide free essential medicines of quality in public health facilities have seen a tremendous surge in the footfalls in public health facilities. Thus, Government intervention for better access to essential medicines is urgently required. It is indeed a sad travesty of justice that the country that leads the world in producing pharmaceuticals, particularly generics, has not been able to make available free drugs to its citizens.

This Free Essential Drugs Initiative is aimed at expanding the availability of free drug provision in all public health facilities. The initiative will not only support states for the purchase of drugs, but enable states to put in place transparent systems of procurement and quality assurance, IT backed supply chain management system and logistics that would ensure the highest possible levels of safety and quality of drugs. I urge states to make the best use of this investment, so that the vision of the initiative is fully realised.

It gives me pleasure to introduce the Operational Guidelines, including the RFP, and it is my earnest hope that states are able to make meaningful use of these, to ensure rapid rollout and scaling up of the initiative throughout the country, so that the benefits of these investments reach those who need them the most and Out of Pocket Expenses come down. I urge states to publicize the initiative widely so that people are aware and can hold the system accountable to its commitments. I am optimistic that with the implementation of this Initiative, the effectiveness and credibility of our public health system will improve and I am confident that states will rise to the challenge.

(Jagat Prakash Nadda)

348, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011
348, A-Wing, Nirman Bhawan, New Delhi-110011
Tele: (O) +91-11-23061647, 23061661, 23061751, Telefax: 23062358, 23061648
E-mail: hfwminister@gov.in

भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Foreword

As India moves on the path towards providing universal health coverage, the provision of essential drugs free of cost, especially for the poor, becomes a non-negotiable factor. The Ministry of Health and Family Welfare has for several years supported states for drugs under several national programmes. Notwithstanding this, there is much evidence to suggest that the high cost of drugs account for significant out of pocket expenditures on health care, which can be catastrophic for the poor.

The Free Essential Drugs Initiative is an endeavour to enable such provision. Enabling free essential drugs at all public health facilities is a challenging task. It involves both streamlining of existing processes and establishing newer mechanisms so that there is a seamless and uninterrupted system from procurement to supplying the end user in the health facility. States would be supported under the NHM not only for procurements of essential drugs but also for setting up and strengthening the systems of procurement, quality assurance, IT backed supply chain management, modern warehousing, prescription audits, standard treatment guidelines and grievance redressal. Effective roll out of such an initiative would also earn states incentives over and above their resource envelope.

The Operational guidelines layout mechanisms for tendering and procurement of drugs through Model Tender documents, for states to adapt to their context, but keeping in mind that transparency and quality are fundamental to the system. One area of concern is the rational use of drugs, particularly the prevention of Antimicrobial Resistance. I urge states to put in place systems that are defined in the guidelines to establish prescription audits and institute systems of monitoring and accountability that will, while ensuring continuous drug availability, prevent waste and mismanagement and ensure patient safety.

The guidelines are designed on the principle of serving as a broad framework for states to use, as appropriate to their context. I hope states find them useful as they embark on this initiative as a way of enabling access to essential drugs.

(B.P. Sharma)

कमरा नं 156, ए-स्कंध, निर्माण भवन, निर्माण भवन, नई दिल्ली-110011
Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110011
Tele: (O) 011-23061863, Fax: 011-23061252
E-mail: secyhfw@gov.in

C.K. Mishra, IAS
Additional Secretary &
Mission Director, NHM
Telefax: 23061066, 23063809
E-mail : asmd-mohfw@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

Foreword

Over the years, as part of the National Health Mission's effort at strengthening the health system to enable increased access and coverage, states have been supported to enable free drug provision. The introduction of the Free Essential Drugs Initiative builds on the learning from these states, and is aimed at universalizing and scaling up the availability of free drugs in public health facilities in all the States/ UTs. The key goal of the initiative is to eliminate cost barriers to drug availability for the poor and improve quality in public health facilities.

Making a set of essential drugs available free of cost within public health facilities at all levels is no small challenge. Nonetheless it is a challenge to be addressed if we are to build on the gains of the NHM which has resulted in increasing confidence of the people in services delivered through the public health system. Such confidence would soon suffer a loss if drug prescriptions cannot be honoured within health care facilities.

Arranging for free drugs implies the institution of transparent systems of procurement, made more efficient by technological tools and IT systems, setting in place adequate infrastructure and mechanisms for effective supply chains, quality assurance, monitoring and grievance redressal, and above all, good governance structures. The NHM will fund states for the establishment/ strengthening of these systems so as to make the availability of free essential drugs an objective, that should be realized soon.

These Operational Guidelines layout guiding principles for states to follow as they begin implementing the initiative. The model tender documents are intended to support states in strengthening their procurement systems to make them more robust, transparent and accountable.

The NHM is committed to providing states with any form of technical assistance needed to implement the initiative. Many states have already rolled out such initiatives either with the support under NHM or with state budget or both. It is my hope that all the states will now expeditiously implement this initiative so as to ensure free supply of essential drugs at all levels of health care in the public system as a step towards universal health coverage.

(C.K. Mishra)

Manoj Jhalani, IAS
Joint Secretary
Telefax: 23063687
E-mail : manoj.jhalani@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली – 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

Foreword

The impoverishing effects of health care costs on account of private spending are well known, as is the fact that drugs contribute over 70% of Out of Pocket Expenditure (OOPE) at the point of care. Making free drugs available in public health facilities therefore becomes an imperative. The Free Essential Drugs Initiative is expected to address this. Procurement of generics in bulk quantities costs only a small fraction of the cost of branded drugs. Thus, while it brings huge relief to the patients in reducing high OOPE, it does not cost the government so much.

Some states have successfully implemented free drugs programmes in the states and thus the roadmap for successful implementation is well known. However, many states are struggling to provide quality free essential drugs despite their keenness and access to resources. These Operational Guidelines are an attempt to address this gap. The Guidelines lay out a broad framework that encompasses the various institutional systems, structures and processes required in order to implement such an initiative. These define the standards for the processes and structures needed to implement this programme. Setting in place governance and management practices and processes of procurement that are transparent and efficient will play a crucial role in the success of the initiative. The Model Tender documents are included as part of the Operational Guidelines to enable this.

The Free Drugs initiative is not about drug procurement and provisioning alone but is also expected to ensure a responsive supply of quality drugs to facilities and promote rational drug use. States/ UTs would be supported under the NHM not only for procurement of essential drugs, but also for setting up robust systems of procurement, quality assurance, IT backed supply chain management, warehousing, HR & training, prescription audit, IEC & BCC, monitoring and grievance redressal.

As a concomitant measure to the free essential drugs initiative, states are expected to notify the use of Standard Treatment Guidelines in all facilities. This will improve patient care, safety and efficiency.

I hope that states are able to utilize the resources provided for this initiative and that the guidelines help in rolling it out successfully. I expect all the states to prioritize such an initiative so that impoverishment on account of expenditure on, drugs is avoided and public health facilities get strengthened.

(Manoj Jhalani)

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LIST OF CONTRIBUTORS

Operational Guidelines for Free Essential Drugs Service Initiative Guidelines

1)	Mr. C. K. Mishra	AS & MD (National Health Mission), MoHFW
2)	Mr. Manoj Jhalani	JS, Policy, MoHFW
3)	Dr.J. Radha Krishnan	Principal Secretary, DoHFW, Tamil Nadu
4)	Dr. Samit Sharma	Commissioner, Bureau of Investment Promotion
5)	Mr. Gautam Guha	Ex. AS & FA, MoHFW
6)	Ms. Limatula Yaden	Director, NHM
7)	Dr. Rajani Ved	Advisor, NHSRC
8)	Dr. Shahab Ali Siddiqui	Senior Consultant, NHM, MoHFW
9)	Mr. Ritesh Aeron	Programme Manager, EPMU
10)	Dr. Salima Bhatia	Senior Consultant, NHM, MoHFW
11)	Dr. Nikhil Utture	Senior Consultant, NHM, MoHFW
12)	Dr. Anil Kashyap	Senior Consultant, NHM, MoHFW

1. INTRODUCTION

India is among the countries with the highest Out Of Pocket (OOP) expenses on health care. Expenditure on drugs constitutes over 67% of out of pocket expenditure on health care (NSSO 68th Round 2011-12). High Level Expert Group Report (HLEG) on Universal Health Coverage (UHC) for India recommended that an increase in the public procurement of medicines from around 0.1% to 0.5% of GDP would ensure universal access to essential drugs, greatly reduce the burden of out-of-pocket expenditures and increase the financial protection for households. As per WHO study estimates, about 65% of the Indian population lacks regular access to essential medicines. This is a paradox given that India is one of the largest manufacturers and suppliers of generic drugs to the world.

Government procurement of generic drugs in bulk, substantially lowers the cost compared to the price paid for a branded drug by an individual consumer. It can be as low as 2% of the retail price of a branded drug. If quality essential drugs are provided free of cost to all patients visiting public health facilities, it would bring significant savings to the patients. Provision of free drugs is therefore one of the most important interventions towards mitigating the burden of health care costs. One of the targets of the proposed Sustainable Development Goals is to "achieve universal health coverage, including financial risk protections, access to quality essential health care services, *and access to safe, effective, quality and affordable, essential medicines and vaccines for all*", testifying to the importance of this initiative.

Under the National Health Mission (NHM), the Ministry of Health & Family Welfare (MoHFW) has been supplementing the efforts of the States to improve access to free/affordable and quality healthcare. This support includes provision for strengthening/setting up robust systems of procurement, quality assurance, IT backed supply chain management systems like Drugs and Vaccines Distribution Management Systems (DVDMS), warehousing, prescription audit, grievance redressal, Information, Education and Communication (IEC), training, dissemination of Standard Treatment Guidelines, etc. NHM continues to provide incentives to those States that notify a policy to provide free essential drugs in public health facilities.

While beginnings have been made in many states, only a few states have been able to successfully implement such a scheme at scale. In order to support the other states to rollout/implement the provision of free drugs, NHM has developed this set of Operational Guidelines for the Free Drugs Service Initiative. NHM will support States to ensure that a set of quality essential drugs are available free of cost to all those who access public health facilities, irrespective of economic status. States are free to select those essential drugs that which they would wish to provide in their states.

These Operational Guidelines lay out the key features of the Initiative including operational steps on establishing systems for effective roll out and implementation such as procurement, quality assurance, supply chain management and monitoring mechanisms. The guidelines also include a model tender document to support states in adopting transparent tendering processes. These guidelines build on state experiences, in rolling out such initiatives. The guidelines provide a flexible framework for state adaptation based on context without compromising the benchmarks for transparent procurement, distribution, quality assurance, adherence to Standard Treatment Guidelines (STGs), and an effective grievance redressal mechanism. This Initiative needs to be accorded the highest priority so that accessibility of free essential drugs to the beneficiaries is assured.

2. KEY FEATURES

(i) The initiative would ensure that a set of essential drugs based on the level of public health facilities is made available free of cost to all who access these facilities. All states are expected to implement this Initiative and seek NHM funding wherever needed.

(ii) For the purposes of this document, the term drugs shall mean medicines.

(iii) The model tender document is based on state learning, and states could adapt this document in consonance with state level Procurement Act and Rules/Policy.

(iv) States should notify the policy for universal provision of essential drugs, which should be widely publicized as an entitlement, and disseminated through posters, wall writing and hoardings in all public health facilities and other vantage points and also through different media. States should also undertake orientation workshops for doctors to promote prescription of generics and rational drug use.

(v) It seeks to meet drug requirements for primary and secondary healthcare through Primary Health Centres (PHCs), Community Health Centres (CHCs), Sub Divisional Hospitals (SDH) and District Hospitals (DHs).

(vi) Quality Assurance in public procurement for this Initiative would be extremely critical. All these drugs must be sourced from Good Manufacturing Practices (GMP) compliant manufacturers through robust procurement mechanisms, and post supply testing of every batch before distribution.

(vii) States would be assisted to set up robust IT backed procurement, quality assurance, warehouses, and supply chain systems that are benchmarked for key management processes with the best practices in this field. Adherence to such practices of procurement, supply chain management, quality assurance and prevention of wastage, and sound monitoring mechanisms for these would be essential pre-requisites for continued central funding under this initiative. Moreover, all drugs procured, distributed and prescribed under this initiative shall be generic drugs.

(viii) Ensuring rational use of drugs and preventing all forms of wastage is important. States could either develop their own Standard Treatment Guidelines (STGs) or adapt the STGs published by the MoHFW that would be shared with all the States. A system of prescription audits would be required to be put in place to ensure prescription of generics and rational use of drugs.

(ix) States must have a facility wise Essential Drug List (EDLs) and display them prominently at each facility.

(x) A Grievance Redressal System, including a toll free call centre and using various social and electronic media, other than facility level written complaints box, and /or Help Desk may be set up as required. This should be monitored by the Rogi Kalyan Samiti (RKS).

(xi) Facilities such as like the Mother and Child Tracking Facilitation Center (MCTFC) systems may also be used to obtain telephonic feedback from beneficiaries about this initiative.

(xii) This Initiative would be dovetailed with existing schemes/programs under NHM, Revised National TB Control Programme (RNTCP) and other disease control programmes, National Programmes for Control of Non-Communicable diseases and the Rashtriya Swasthya Bima Yojana (RSBY).

3. FINANCING

(i) Funding under the scheme would be available for procurement of drugs and also to set up/strengthen systems of procurement, quality assurance, supply chain and warehousing, prescription audit, Grievance Redressal, IEC, training and orientation programmes for service providers for rational prescriptions, etc. After the establishment of the basic structures for the initiative, it is envisaged that the funding to the States, in future years, would be essentially based on actual utilization and the extent to which patients are getting the essential drugs free of cost through public health facilities.

(ii) Procurement of drugs whether through NHM or state fund should be by a single agency for improved effectiveness and efficiency.

(iii) It is desirable that the department / health corporation and individual facilities maintain a double entry system, i.e. transactions are recorded in terms of debits and credits. Thus a debit in one account of drugs in the district warehouse would be offset by a credit of drugs in another facility. For managing accounts in each facility, a Passbook of supplies may also be countersigned by the district warehouse.

4. INSTITUTIONAL MECHANISMS

4.1 Centralized Procurement Body (CPB) at State Level

Several states have already established an autonomous body such as a Corporation at State level for centralized procurement of drugs/ procurement locally through rate contracts finalized by the corporation. In States where decentralized procurement is the key modality for procurement, the first step for effective rollout of free essential drugs initiative would be the constitution/identification of a State level body to undertake centralized procurement. The HLEG recommended the adoption of centralized national and state procurement systems to realize economies of scale and create the conditions necessary to drive down the prices of drugs, vaccines, and medical devices. Such procurement entities may be formed on the lines of State Public sector enterprise/ corporation/ company owned by the State government and registered under Companies Act, 1956 or the Societies Registration Act.

A board of directors, headed preferably by the Principal Secretary Health & Family Welfare of the State, would function as Governing Body. The members of the Board may include representatives from NHM, the Departments of Health, AYUSH, Finance, Commerce and Industry, and any other department necessary for effective and efficient functioning of the body. For effective implementation of the initiative in States it is suggested that a dedicated manager be appointed for the functions of procurement, supply chain, quality control and finance.

The main source of working finances for the corporation could be an appropriate service charge on the value of the procurement and "handling and testing charges" on the value of supplies. The Corporation should, in the long run, meet the recurring expenditure from its own income source as a self-sustained entity. The functions of the CPB would be to:

- Procure and distribute essential generic drugs
- Strengthen the process of quality control of drugs
- Ensure uninterrupted availability of drugs in facilities.
- Promote rational use of drugs

4.2 Constitution of Sub-Committees

The constitution of a State level body as proposed in the above paragraph will further constitute a Technical Committee (TC) and a Purchase committee (PC). The Technical Committee would provide recommendations on various technical issues regarding the drugs (name, formulation and dosage) and their procurement. These committees would advise on the facility wise essential drug lists, tender specifications, drug substitutes, inventory management, annual forecasting, etc. The members of the committee may be nominated from Medical colleges, Finance Department apart from health department. Further multiple units may be constituted by the CPB, depending upon the specific functions for Procurement, Supplies, Logistics, Quality Control, IT, Finance, etc.

5. PROCUREMENT PROCESS

The procurement of drugs would be done by the CPB or equivalent body at the State level. Suppliers would be required to supply the tendered drugs to the district level. The flow of resources to the districts should preferably be in 'Kind'. Upto 10% preferably but not exceeding 20% of the resources may be transferred as 'Cash' to allow flexibility for Local Purchase to ensure that there are no disruptions to free drug provision.

5.1 Tendering

A model tender document is attached which the States could use to invite bids. (Appendix: Model Tender Document). The document has been drafted based on manual procurement processes, considering that several states are still using this methodology. However states are encouraged to move to e-procurement processes by incorporating appropriate changes in the biding process in consonance with state Procurement Act and Rules/Policy. States should adhere to guidelines of the Central Vigilance Commission (CVC) with respect to procurement. Moreover tender notifications would be issued to all State Drug Controllers, Pharmaceutical Manufacturing Associations and Pharmaceutical publications in order to increase the number of participation by prospective suppliers. The details of tender should also be uploaded on Central Public Procurement Portal (CPP Portal) available at eprocure.gov.in

5.2 Procurement of drugs

CPBs of the respective States must also compare the rates of the drugs being purchased by the CPBs of the States such as Rajasthan, Tamil Nadu etc. Purchase orders would be placed based on the consumption pattern for fast moving items and for slow moving items. (Such orders should anticipate the quantum of drugs required in emergency situations particularly related to seasonal variations (flood /drought /monsoon related ailments) so that these drugs are available before the onset of the season.)

The generation of demand and scheduling should be software based, verified by the appropriate authorities and put up for approval of the competent authorities. The purchase orders should be system generated and sent to the suppliers through electronic means and hard copy by courier. After receipt of Purchase Orders the suppliers would have to upload the confirmation of receipt of the Purchase order within stipulated time as per the Request for Proposal (RFP).

The supplier should ensure compliance to the delivery schedule and in case of defaults, provisions of adequate penalties and supplies from different modes should also be explored at the cost of supplier. These conditions should be clearly highlighted in the RFP.

5.3 Debarring of defaulter drug companies

A supplier / bidder may be debarred in the following conditions, (the conditions in this regard should be clearly stated in the published RFPs):

- Non execution of the terms of the contract
- Non-compliance to the rate contract
- Samples failing to meet statutory conditions of quality during shelf life.
- Furnishing incorrect information in the proposal

6. LOGISTIC SYSTEMS

To establish smooth and efficient logistic channels to ensure quality of drugs supplied, it is important to strengthen Regional/District Drug warehouses of the State. The administrative control of the warehouses would be appropriately linked with the functions of the CPB considering the existing set-ups in the State.

6.1 District Drug Warehouse (DDW)

Every district would preferably have a functional DWH. However in the case of unavailability or in smaller districts a Regional Drug Warehouse (RDW) that serves a cluster of districts may be established. The Infrastructure and HR for a DDW/RDW would be based on the quantum of drug stocks required by the facilities served by the warehouse.

Infrastructure

The infrastructure and Human resource for DWH is at Annexure I. States may adapt this to suit their requirements.

6.2 Transportation of Drugs from DDW to Health Care Facilities

All medicines must be stored and handled in accordance with the requirements of the products-drugs, vaccines, serum, etc. in order to maintain potency and effectiveness. Drugs that require to be maintained at temperatures between 2^0 to 8^0C) must be transported with proper cold chain maintenance. Storage outside the recommended temperature range can result in chemical and/ or physical changes to the product which may lead to a loss of efficacy and/or altered patient response with potential to cause harm. When medicines are transported between Drug Warehouse and health institutions, the following points should be taken into account:

- Drugs and vaccines should be kept in proper boxes and delivered to the facility in appropriate vehicle.
- Drugs and vaccines should only be handed over to an authorized representative of the facility
- Drugs and vaccines containers must not be left unattended during transit
- On arrival in the facility, the supply should be rechecked with respect to the delivery challan. Any discrepancy must be reported to Officer In-charge of DDW/ RDW immediately

- If there is any difficulty in handing over the drugs, it must be reported to the DDW and the State Head Quarter with justification.
- The transport process should be designed to maintain the integrity and quality of the drug products.
- Wherever stipulated all the controlled storage conditions required during transit must be followed.
- Loading and unloading activities should be done in a manner that preserves the quality of the drugs.

Transportation of medicines requiring cold storage conditions

All concerned DDW / RDW staff needs to ensure the following:

- During transportation of such medicines, it must be ensured that the temperature range is maintained between 2°C and 8°C
- Handling and transportation time to the destination should be kept to a minimum to ensure that the medicines retain optimal efficacy.
- If portable fridges/ILRs are used for transportation of such medicines it is essential that temperature range is maintained between 2°C and 8°C and a power supply is available to access in an emergency.
- A temperature monitoring device should be used to record the minimum and maximum temperature range of the refrigerated medicine during the transportation process. The temperature monitoring device should be placed in the middle of the package.
- Temperatures during transportation should be recorded in a Log Book
- The temperature monitoring device must be checked on arrival at the destination.
- If transport is within a single building, and transit time is less than 15 minutes, then the products should be transported in an insulated container (cool bag).

6.3 Storage

Facility level storage and distribution

- This would involve storage in the main store of the facility as well as at the Drug Distribution Centre/Pharmacy. Therefore strengthening of these sites would be required. States can develop facility specific requirements in the PIPs. The infrastructural and HR strengthening would be done on the need basis.
- An IT enabled e-inventory management System should be put in place to track the inward and outward movement of drugs as also to ensure that drugs, nearing expiry dates are distributed first.
- Storage space shall consist of cool storage (2-8 degree Celsius) and ambient storage (room temperature). States shall be supported for costs of infrastructure and storage space.
- The drug distribution centre would be managed by a pharmacist and assisted by an IT support staff / Data Entry Operator to enter and retrieve the requisite information.
- Prescription audit should be performed by random sampling.

- Facilities can be provided with 10% flexibility for local purchase of the drugs which would not be available in the Drug distribution centers. However, this flexibility should not exceed 20% of the total annual worth fixed in the passbook of the facility. The local purchase drugs should also be distributed through the IT system and payment to the vendor should also be made through the system.
- States would need to formulate mechanisms for validating the receipt book records and actual consumption of medicines in order to prevent pilferage of any kind.
- At the facility, an analysis of short expiry drugs would be conducted on a fortnightly basis, based on consumption patterns. The facility would utilize such drugs on priority. Such a review mechanism if conducted at the warehouse level, such drugs could be redistributed to nearby facilities in need.

7. QUALITY ASSURANCE

There is often a common perception in many states that government procured low cost drugs are of poor efficacy. Quality Assurance of drugs is extremely critical in making this initiative successful. Such quality assurance would be ensured through effective implementation of a series of measures. The foremost responsibility for providing quality drugs would rest with the drug manufacturers. The quality would be ensured through drug regulatory departments of Centre and State governments under the provision of the Drugs and Cosmetics Act and Rules.

When drugs are received in district warehouses from the suppliers drugs will be quarantined in clearly demarcated & segregated Quarantine Area of warehouse, the boxes would be numbered. Samples drawn should be double the minimum quantity of drugs required for testing and should be from randomly selected cartons, containers, packings from the supplies of each batch. These should then be sent to the Quality Control wing of the CPB. In the Quality Control wing samples received will be sorted, common batch number drugs would be mixed and sample be drawn from pooled quantity. Labels details viz. Manufacturer's name, manufacturing license number, logo or monogram of the company will be concealed by indelible ink, coded with a secret number and would be sent to one of NABL accredited Empanelled Laboratories for analysis. The analysis will be based on specifications of standards of drugs as specfied under second schaedule to the Drugs & Cosmetics Act, 1940 and will be tested in respect of all parameters whichever may be prescribed in respective monograph of the drug formulations.

Drug samples will be tested by the empanelled laboratories within a reasonable time frame say 30 days. After receipt of test reports from empanelled laboratories they will be scrutinized by quality control wing officials to ensure that the sample have been tested for all specified parameters. The batches which **'Pass'** the testing will get a **'Release'** confirmation by the software programs or where such specific IT systems are not available the concerned warehouse in-charges should be informed through email to shift stock of such batches from quarantine area to distribution area for release. In case of reports indicating Non Conformation to quality standards such report will also be scrutinized by Quality Control (QC) officials through further testing by an empanelled laboratory. Moreover, statutory testing through Drug Regulatory officials may also be done in case of serious failure. All failed batches will be rejected and such stock would be returned to the supplier. After 30 days of the issue of the letter for return of stocks, if the Supplier fails to take back the stock and it remains lying in the warehouses, penalty of 2% per week would be levied on the value of stocks in the warehouse till it is destroyed by CPB (90 days).

Such quality control would also be conducted in health facilities on a random basis. In case of any failure reported after the testing, a letter would be issued immediately to the Warehouse in-charges to stop the issue of the product and also request them to retrieve the drug supplied to the hospitals. The Warehouse in-charge will in turn issue letters to every facility where the batch has been supplied for retrieval of the drugs, to collect the stocks from the wards and sub stores inform the Warehouse in-charge about the quantity available and return the stocks within two days from the date of receipt of the letter. Such drugs will be isolated from the supply stocks and kept separately and suitably marked. All laboratories shall be identified in the state with NABL accreditation as minimum eligibility criteria.

The value of the quantity returned to the supplier would be deducted from their bills depending upon the nature of failures of the product, the product/Company would be blacklisted after following due procedures. The Director of Drugs Control would also be requested that in case of any "Not of Standard" Quality report of any drug, on the sample drawn from the Hospital / Institution by the Drug Inspectors, additional samples would be drawn from the same drug (different batch Nos.) or other drugs supplied by the same company from different locations in the State, to verify the quality of the drugs during storage. Suitable action as prescribed in the law shall also be initiated against the offender. Suggestive tables containing Quality Indicators for CPB/State level, warehouses, facility is at Annexure II. Sample Adverse drug reaction reporting format is at Annexure-II A.

8. IEC, TRAINING AND ORIENTATION

There is a need to sensitize the public about rational drug use, the dangers of unnecessary and excessive use of drugs, and the mis-perception about the efficacy of generic drugs/or those provided in government facilities. Targeted IEC efforts using interpersonal communication, mass media and social media will be undertaken for this purpose. In addition, orientation and training workshops for doctors would be organized to educate them and motivate prescription of generic drugs, rational use, and avoidance of over- prescription.

The Orientation workshops for doctors to promote the Rational Use of Drugs (RUD) and generic prescription should be organized at district level. The role of orientation program is very important to success such interventions. The state should monitor the level of sensitization in the Doctors and schedule the programmes as per need.

9. MONITORING & EVALUATION OF THE INITIATIVE

The initiative would be monitored with respect to effectiveness of procurement and supply systems, IT backed logistics, Quality Assurance, and Grievance Redressal mechanisms. A monitoring cell should be set up at the CPB headquarters. A team of experts in the field would be constituted for the purpose. The teams would conduct both physical and on-line monitoring of the Initiative. Sub teams would also be constituted at all district drug warehouses which would conduct the facility level monitoring.

10. STANDARD TREATMENT GUIDELINES (STGs)

Standard Treatment Guidelines are designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical conditions. STGs reflect expert consensus based on a review of current published scientific evidence of approaches to diagnosis, management or prevention of specific conditions. In addition to supporting rational decision making for patient care, other important uses of STGs are:

- Provide standardized guidance to practitioners
- Guiding allocation of resources for health care; and estimating cost of health services
- Making specific decisions evaluating decisions and performance of the primary users of guidelines

While many States have already developed and disseminated STGs to the health facilities, several still do not have them in place. States which do not have STGs in place would have to develop or adopt existing STGs in other States as per their needs. States would notify such STGs at the earliest. States can also adopt STGs developed by MoHFW which can be accessed through the following link: http://nrhm.gov.in/nhm/nrhm/guidelines/nrhm-guidelines/standard-treatment-guidelines.html

11. PRESCRIPTION AUDIT

Prescription audit is an important mechanism to improve the quality of care provided by the health facilities. Data generated on the morbidity pattern together with current treatment practices provide an objective basis for preparing an Essential Drug List. Comparing the current usage of drugs with the standard treatment guidelines will enhance the efficacy of treatment and improve cost-effectiveness. Prescription audits would throw light on rational use of drugs in the facilities. The prescriptions followed in the outpatient and inpatient departments would be analyzed to improve the quality of care. In order to improve drug prescribing the following points should be adhered to:

- As far as possible, the diagnosis, or at least provisional diagnosis would be written in the prescriptions issued in the OPD or IPD.
- The prescription would be written only in Generic/ salt name.
- Prescribed drugs would be selected on the basis of efficacy, safety, suitability & scientific evidence.
- Prescription would be based on credible evidence from well conducted clinical studies which would inter alia mean, adherence to STGs.
- In the event that a drug not on the NLEM is prescribed, a brief justification would be provided by the prescribing doctor.
- Two copies of a self carbonized prescription slip would be used. One slip would be retained in the facility (OPD/IPD), one would be given to the pharmacy and the other would be given to the patient. The facility slip would be used to conduct prescription audits.
- The prescription slip would be considered as valid only when it is signed and dated by treating doctor.
- Prescription audits would be undertaken at regular intervals by a Drug and Therapeutic Committees, which would be constituted at least at the level of the DH.
- A suggested format for conducting a prescription audit is at Annexure III.
- Corrective action taken on the audits would be uploaded on the CPB website.

12. GRIEVANCE REDRESSAL SYSTEM

Each state would establish a grievance redressal system which would have the authority to not only immediately redress the grievance but also recommend action to be undertaken within a stipulated time period. The basic architecture of the grievance redressal system would have the following features:

- Help desks would be established at facilities so as to facilitate prompt registration of grievances related to availability of free essential drugs.
- Grievances would be registered through multiple routes - which shall include in the least a call centre with a well publicized toll free number like 104. Besides this, grievances could be sent through sms, email, web post, post, or social media. Civil society organizations could also play a role in registering grievances and enabling redressal.
- Grievances would be registered at the facility or at the district level office. Though registration at the facility is preferable, it is not mandatory and a complainant could go directly to the grievance officer. States would be encouraged to partner with credible civil society organizations to undertake the role of grievance redressal cells
- All grievances would be recorded and registered and allotted a registration number.
- Grievance could include denial of care that is part of the entitlement or inappropriate care or complaints regarding quality of care. This implies that every facility must prominently display the set of free assured services provided.
- The grievance could be related to the systemic issues or denial of drugs. The grievance system must be able to address the grievances such as those relating to denial of drugs at the point of care itself
- If the grievance is not settled to the satisfaction of the complainant she/he could appeal to an appellate authority.

13. SUPPLY CHAIN MANAGEMENT SYSTEM FOR DRUGS AND VACCINES

States would be supported to strengthen the supply chain and logistics management of drugs and vaccines for effectively manage the scheme. Use of IT enabled systems for the management of procurement and distribution of drugs and vaccines offers enormous benefits over the manual system. For example, an IT enabled Drugs and Vaccines Distribution Management System (DVDMS) can provide real-time status of drugs and vaccines in different health facilities to help in better planning, execution and control on demand and supply at all the levels. The utilization of funds from different sources can also be monitored more effectively.

Keeping in view the potential benefits of an IT enabled DVDMS, MoHFW plans to support the roll-out of DVDMS throughout the country. States which already have software based inventory management systems may continue to do so with required upgradation. States that are still operating on manual mechanisms of inventory and storage management would be provided technical support to upgrade to IT backed systems.

13.1 Stakeholders and Benefits

This IT enabled Supply Chain application integrates multiple entities at various levels. They include (but need not be limited to) the following:

- State/UT Head Quarter
- Finance, Procurement, Logistic & Quality department
- Central Drug Warehouse (CMSS etc.)
- Regional / District Warehouse
- Sub-Stores (Facilities) that receive drugs from Main Drug warehouse / District Warehouse
- Drugs Distribution Counter (to track consumption at lowest possible level)
- Testing laboratories for certification

The system enables adaptation of technology to improve and automate drug supply in the Regional/ District Warehouse, Sub Stores and Drug Distribution Centers (DDC). The application should therefore integrate finance, procurement, quality control and management of drugs, vaccines, sutures and surgical items required in the state. DVDMS have the potential to improve availability, reduce costs, improve inventory management, planning and forecasting, expiry management, epidemic management, and better management of existing resources and plan for future needs.

13.2 Drugs and Vaccines Distribution Management System by CDAC

MoHFW in consultation with CDAC has issued advisory for implementation of such a Drugs and Vaccines Distribution Management System (DVDMS) with a provision for State-specific customization. DVDMS is a customized application with multiple modules for automating the workflow of the Procurement, Supply Chain, Quality Control and Finance Department at Center / States/ UTs level. It would also have the facility to generate actionable dashboards with detailed statistical and analytical reports regarding the functioning of the Regional / District Drug Warehouse, its sub-stores and their Drug Distribution Centers (DDC).

The customization of the application will be done by CDAC in consultation with the State Department (and State Program Management Units) through a systematic Gap Analysis Process. Since the deployment of the application would also require infrastructure that would be deployed by the State Department, this would also be analyzed by CDAC through a systematic Finalized System Document (FSD). DVDMS application is on open source platform in compliance to the guidelines of Department of Information & Technology (Deity), GoI. States are also suggested to deploy IT solutions on cloud provided by DeitY to optimize the cost. DVDMS will also have the customized modules integrated in a single framework for Equipment Maintenance and Management and Human Resource & Finance Management to optimist the cost.

Enabling automation of inventory in the Center / States / UTs will allow obtaining the complete detail of stock in-hand at various levels, supplies in pipeline, and consumption pattern in the state. The system would allow for obtaining information on materials and finances across the supply chain as they move from manufacturer to warehouse to beneficiaries. This would involve coordinating and integrating flows of information both within the system and with other stakeholders. Data could be obtained "upstream" (say GoI), "downstream" (within State) and "vertically" (with other initiatives like MCTS, Hospital Management Information Systems (HMIS), etc.

Quality Control (QC) plays a major role in providing high quality drugs to the patients. QC module will ensure real time linkage between quality laboratory and the District Drug Warehouse to ensure drug quality before the actual distribution of the drug to the beneficiaries. Supplier performance and payment will also link with QC and can be viewed by the health facilities, suppliers and paying authorities. An application like DVDMS, that manages the various components on a real time basis, streamlines the overall supply of drugs in the State and empowers the workforce to perform assigned tasks in an optimal and efficient manner. The application should be modeled on the unique combination of 'Administration Centric and Pharmacy staff centric' paradigm, providing benefits to the beneficiaries and the health care providers. This would enable significant improvement in the health service delivery by bringing efficiency and reducing out of pocket expenditure.

Annexure -I: DDWH Suggested Infrastructure and HR

Sl. No.	INFRASTRUCTURE
1.	Adequate facilities for storage of drugs based on the quantum required
2.	Seating space for staff with office infrastructure
3.	Quarantine area for storing of medicines waiting for quality check approval
4.	Area for "Not of Standard Quality Drugs"(NOSQ)/rejected/date expired drugs
5.	Space for loading and unloading of supplies
6.	Fire extinguishers
7.	Adequate facilities for storage of medicines
8.	Seating space for staff with office infrastructure
9.	Quarantine area for storing of medicines waiting for quality check approval
10.	Area for "Not of Standard Quality Drugs"(NOSQ)/rejected/date expired drugs
11.	Space for loading and unloading of supplies
12.	Fire extinguishers
13.	Adequate facilities for storage of medicines
14.	Heavy Duty Racking System 8' feet
15.	Heavy Duty Racking System 14' feet,
16.	Hydraulic Hand pallet trucks
17.	Pallets
18.	Side Racks
19.	Desktop Computer
20.	DMP Column Printer
21.	Laser Printer
22.	Bar Code Reader
23.	Cold place(20-80 C)- Walk-in-Coolers constructed at all DDWs, ILRs
24.	Cool place(80 – 250 C) - Refrigerators/Air Conditioners in Rooms
25.	Normal temperature - Enclosed ventilated places with sufficient cupboards (preferably wood-en) protected from water seepage, moisture, dust, insect, rodents etc.

Sl. No.	INFRASTRUCTURE
26.	UPS for power backup
27.	Steel Cupboard
28.	Office Table
29.	Chairs
Human Resources (DDW/RWD for smaller districts)	
1.	Officer in-charge – DDW
2.	Warehouse Storage Manager
3.	Hospital Supply Manager
4.	Informatics Assistant

Annexure - II: Quality Indicators for Procurement & Supply Chain

Facility level indicators

Sl.No.	Indicator	Explanation
1	% age of Antibiotic Drugs available.	No of Antibiotics drugs available during the month/total number of Antibiotics in essential drugs List x100
2	% age of Analgesics and Antipyretics Available	No. of Analgesics and Antipyretics Available/total no. of Analgesics and antipyretics in the EDL x 100
3	% age of Antihypertensive and Antidiabetic drugs Available	No. of Antihypertensive and Antidiabetic Available/total no. of Antihypertensive and Antidiabetic in the EDL x 100
4	%age of Drugs expired	Units of drugs expired/total units received x100
5	No of stock out days of essential drugs.	A stock out is non availability of a particular drug for one day. Stock out of all categories of drugs will be calculated.
6	Lead time for drug procurement from the warehouse	Time lag between indenting by the facility and actual receipt of drugs from warehouse.
7	No. of Adverse events reported and follow up action taken.	All adverse reactions should be reported in the "Suspected Adverse Drug Reaction Form" distributed by Pharmacovigilance centres and submitted to CDSO.
8	No. of prescriptions Audited in the month.	Sample size should be drawn with a confidence limit of at least 90%. (a Minimum of at least 30 prescriptions should be audited/ month).

Warehouse Indicators

Sl.No.	Indicators	Explanation.
1	%age of Drugs expired	Units of drugs expired/total units received x100
2	Lead time for drug procure-ment.	Time lag between placing the order by the warehouse and actual receipt of drugs from Manufacturer/Importer/Distributor.
3	No. of instances of, breakage and pilferage.	The wastage will be automatically updated in the software.
4	Facility requirements not met by the ware house	No. of units requested by facility-No. of drugs issued by ware house

CPB/State Indicators

Sl.No.	Indicators	Explanation.
1	%age of Antibiotics available in the state	No. of Antibiotics available in state/total no. of Antibiotics in the EDL x 100
2	%age of Analgesics and antipyretics available in the state	No. of Analgesics and antipyretics available in state/total no. of Analgesics and antipyretics in the EDL x 100
3	%age of Antihypertensive and antidiabetic drugs available in the state	No. of Antihypertensive and anti-diabetic drugs available in state/total no. of Antihypertensive and anti-diabetic drugs in the EDL x 100
4	Cycle time for testing.	Time taken from taking the sample and receipt of Quality test report.
5	%age of batches failed in Quality testing.	No. of batches failing Quality testing/total no. of batches of drugs received x 100
6	%age of drugs expired in last one year.	Total units of drugs expired/total units of drugs procured x 100
7	Per capita expenditure on 50 Essential drugs	Total expenditure on 50 Essential drugs /Population of state
8	Per capita expenditure on State EDL drugs.	Total expenditure on State EDL drugs /Population of state.

Annexure - II-A: Adverse Drug Reaction Reporting Form

Sr. No.....

PATIENTS DETAILS

Name..... Age/Sex .....

Weight .....

Pregnancy ..... (Yes/ No/ Not applicable)

Relevant Medical .....

History .....

.....

.....

ADVERSE DRUG EVENT (Reasons for reporting)

a) Requires hospitalization

b) Extension of hospitalization period

c) Disability (Partial/Permanent)

d) congenital anomaly

e) Life threatening

f) Death

g) Congenital anomaly

h) Overdose

i) Others (Details).....

.....

.....

.....

DRUG SUSPECTED IN ADVERSE DRUG REACTION

Name of suspected drug .....

(SALT NAME).....

Name of manufacturer .....

Name of supplier .....

Date of Occurrence.....

Duration of Event .....

Medication Started on.....

Date of discontinuation of treatment because of ADR .....

REPORTING OFFICER

Name..... Signature .....

Institution..... Date .....

Annexure - III: Suggested format for Prescription Audit

Sl. No.	Item	Yes / No		Remarks
1	Complete Name of the client			
2	Age in years (≥ 5 in years) in case of < 5 years (in months)			
3	Date of consultation - day / month / year			
4	Sex of the client			
5	Legible handwriting			
6	OPD Registration Number			
7	**Medical component**			
i.	Presumptive / definitive diagnosis written			
ii.	Brief history Written			
iii.	Salient features of Clinical Examination recorded			
iv.	Investigations advised			
v.	Medicines advised mostly available in the dispensary			
vi.	Medicines advised partially available in the dispensary / Medicines advised not available in the dispensary			
vii.	Dosage Schedule / doses clearly written			
viii.	Duration of treatment written			
ix.	Drugs prescribed by generic names			
X	Antibiotics prescribed			
xi.	Date of next visit (review) written			
xii.	In case of referral, the relevant clinical details and reason for referral given			
xiii.	The required precaution / do's and don'ts recorded			
xiv.	Prescription duly signed (legibly)			

ANNEXURE

MODEL TENDER DOCUMENT

Issued to M/s. .....

Serial Number

NOT TRANSFERABLE

Reference Number: 001 with <Date>

NOTICE INVITING TENDER FOR THE SUPPLY OF DRUGS

TO

<Name of the Procurement Agency>

LAST DATE FOR RECEIPT OF TENDER : <Date> at <Time>

SCHEDULE

Tender Reference	
Date of commencement of Sale of Tender documents	
Last date for sale of Tender documents	
Last date and time for Receipt of Tender	
Time and date of opening of Tender	
Place of opening of Tender	
Address For Communication	
Cost of the Tender Documents	
[All times shown are as per the Indian Standard Time (IST)]	

1.0 NOTICE INVITING TENDER

<Name of the Procuring Agency>, hereinafter referred to as Procurement Agency(PA), hereby invites Bids from Suppliers eligible as per the terms and conditions described in this Notice for supply of Drugs to Procuring Agency for the period from <month, year> to <month, year>.

1.1 The selected Bidders would be required to sign agreement with the Procurement Agency as per Clauses 11.1 to 11.4 in this document and deliver drugs according to the Purchase Orders (POs) placed on them to designated offices/depots/ warehouses /other specific places mentioned in the POs. These supply points will be within the geographical boundaries of the State of < Name of the State>.

1.2 Bids are invited in two separate sealed envelopes - Cover A containing Technical Bids and Cover B containing Price Bids. These will be received till 10.30 A.M. on <date> by <Name of the Procuring Agency>. Bids without either the Technical Bids or the Price Bids will be treated as incomplete and will not be considered.

1.3 The Bids shall be valid for a period of 180 days or in consonance with the state's Procurement Act and Rules/ policy, from the scheduled date of opening of Cover A. Prior to the expiry of the Bid validity, the Tender inviting Authority may ask the Bidder in writing to extend the validity for any further period. The Bidder shall within three days of issue of such request will intimate his acceptance or otherwise to extend the validity of the Tender.

1.4 Bidders should quote for a minimum of 50% of the tendered quantity of each drug and commit the quantity as exclusively earmarked for the Procurement Agency in this tender irrespective of any other tender that may be floated by any other agency for any drug in which the same Bidder becomes eligible or is selected. The Bidder would be permitted only upward revision of the quantity of any drug(s) earmarked. Downward revision of the quoted quantity or of production capacity after submission of bid will not be permitted. Any such downward revision after the Tender is submitted, may result in the Tender not being considered. It will be the prerogative of the Procurement Agency to accept the upward revision of quantity proposed by the Bidder.

1.5 Procurement Agency reserves the right to place Purchase Orders at the quoted rate during the validity of the Bid and the Bidder(s). Pending finalization of the tender and execution of agreement, the supplier will accept orders at the rates quoted for such quantity as within his production capacity. Such a supply order, however, will not convey any commitment of the Tender issuing Authority (TIA) to finalise the contract in favour of the supplier nor it will confer any right on the supplier for his bid to be accepted. Bids will be processed and accepted in accordance with the extant rules of the Government and terms and conditions of this tender." However such orders would be based on the terms and conditions of the tender.

1.6 Standard terminology has been adopted in this document. In certain areas, there may be two or more widely used terminologies bearing the same meaning as mentioned below:

(1.6.a) Tender, Bid, Quotation. (Meaning: offer received from a supplier)

(1.6.b) Tenderer, Bidder. (Meaning: an entity who seeks to supply goods by sending tender/ bid)

(1.6.c) Tender Enquiry Document, Tender Document, Bidding Document. (Meaning: a detailed document issued by the purchaser specifying his needs and the requirements that a potential tenderer/bidder must meet).

(1.6.d) Notice Inviting Tenders, Invitation for Bids (Meaning: Documents containing brief details of the requirement and other terms and conditions).

(1.6.e) Earnest Money Deposit, Bid Security. (Meaning: monetary guarantee furnished by a tenderer along with its tender)

(1.6.f) Security Deposit, Performance Se curitty. (Meaning: monetary guarantee furnished by the successful tenderer for due performance of the contract concluded with it.)

2.0 ELIGIBILITY CRITERIA

2.1 Bidders shall be manufacturers of drugs that they wish to offer, having valid manufacturing license in its own name or direct importers of drugs that they wish to offer holding valid import license. Distributors/Suppliers/Agents/Loan licensees are not eligible to participate in this tender.

2.2 Annual turnover for the units in any of the last three years i.e. <Year 1>, <Year 2> and <Year3> shall not be less than 60% of the total Tender value quoted by the Bidder. The turnover should be at least of INR <amount> Crore in any one of the above mentioned years.

2.3 For each drug quoted in the present tender, the manufacturer should have marketed the drug in India without interruption for at least 1095 days preceding the date on which the tender is submitted. In case of Importer, their principal manufacturer should have marketed the drug without interruption for at least 1095 days preceding the date on which the tender is submitted.

2.4 Bidders must possess requisite license /permission from the competent authority as on the date of the Tender to manufacture the drug quoted as per specification in the tender. Bidders for imported product must possess valid import license by the competent authority as on the date of the Tender for the drug quoted as per specification in the tender.

2.6 Bids for any drug for which the Bidder has been blacklisted by any State/UT Government / Central Government / its Drug procurement agencies due to quality failure or fraudulent/ illegal practices of the drugs supplied will not be considered.

2.7 Bidders who have been blacklisted by the State/UT Government / Central Government / its Drug procurement agencies on any grounds should not participate in the tender during the period of blacklisting. Such Bids will not be considered.

2.8 Bidders who have been blacklisted by any State Government/Central Government / its Drug procurement agencies on account of fraudulent/ illegal practices should not participate in the tender during the period of blacklisting. Such Bids will not be considered.

2.9 Bidders must provide notarized affidavit that they have not been black listed due to quality failure and /or fraudulent/illegal practices for the quoted product/firm by any State Government / Central Government / its Drug procurement agencies or by any other authority as per the affidavit form at Annexure III to this document. Bids unaccompanied by such affidavit will not be considered.

2.10 During the validity of the Tender if the Bidder is blacklisted by any of the authorities mentioned at Paragraph 2.9 above, it shall be intimated to the Authority inviting this Bid without any delay.

3.0 GENERAL CONDITIONS

3.1 Complete set of Tender documents may be purchased from the office of Bid Inviting Authority between 10.00 A.M. to 5.00 P.M. on or before <date> on all working days either in person or by post by making an application in writing and upon payment of a non-refundable fee of INR 500 in the form of Demand draft drawn in favour of Procurement Agency payable at <place>. The Procurement Agency will not be responsible for any delay in transmission by post.

3.2 The Tender documents can be downloaded from the website <website> free of cost.

3.3 The complete set of Tender documents (Cover A and Cover B) should be submitted latest by 10.30 A.M. on <date>. The date and time of pre-Bid meeting will be intimated to each purchaser of Tender documents separately. It will be displayed on the website also.

3.4 All Bids must be accompanied with Earnest Money Deposit as specified against each drug in Annexure VIII of the Bid document. Bids not accompanied by Earnest Money Deposit will not be considered.

3.5 Bids will be opened in the presence of Bidders/authorized representatives of the Bidders who choose to attend on the specified date and time.

3.6 At any time prior to the date of submission of the Bid, Tender Inviting Authority may either on own initiative or in response to a clarification requested by a prospective Bidder, may modify any of the conditions in the Tender documents by issuing an amendment in writing. All the prospective Bidders who have purchased the Bid document will be notified of the amendment and such amendments will be binding on them. In order to provide reasonable time to take the amendment into account in preparing their Bid, Bid Inviting Authority may at its discretion, extend the date and time for submission of Tender.

3.7 Bidders who have downloaded the Bid document should watch for such amendments on the website <website>. No separate intimation will be issued to them.

3.8 CONDITIONAL BIDS WILL NOT BE CONSIDERED.

4.0 TECHNICAL BID - COVER "A"

4.1. The Bidder should furnish the Technical documents in a separate cover hereafter called "Cover A". Cover A should be sealed with the following written on the cover of the envelop:

"TECHNICAL BID - COVER "A" – BID FOR THE SUPPLY

OF DRUGS TO <Name of Procurement Agency**> DUE**

ON <date**> AT 10.30 A.M"** addressed to the

<Tender Inviting Authority> <address>

4.2 All the documents submitted should be signed with seal by the Bidder on each page. Photocopies of the documents should be self-attested by the Bidder. Failure on the part of the Bidder to produce original document on demand at any point of time may result in rejection of the Tender documents in toto.

4.3 Earnest Money Deposit, shall be as indicated in Annexure VIII of the Bid document against each drug quoted for by the Bidder. The total amount of the EMD must be furnished in the form of Banker's Cheque or Demand Draft and/or irrevocable Bank Guarantee favouring <Name of Procurement Agency>, payable at <place>. The Bidder should attach a statement showing amount of EMD against each drug and the total of this statement should tally with the amount of EMD provided. EMD in any other form like cheque /cash /postal order etc. will not be accepted and the Tender will not be considered.

4.4 COVER A must contain the following documents. Bids without any of these documents without valid reasons will be rejected. The Bid document should be signed only by the authorized official of the Bidder in all pages with office seal. All the documents enclosed with the Bid document should also be signed by the authorized official of the Bidder

(A.1) Documentary evidence for the constitution of the Company/Firm such as Memorandum and Articles of Association, Partnership deed, Permanent Registration Number.

(A.2) Names, Addresses, Telephone Numbers, Fax Numbers, e-mail address of the firm and of the Managing Director / Partners / Proprietors.

(A.3) The list of present Directors in the Board of the Company duly certified by the Company Secretary of the Company/Practicing Company Secretary / Charted Accountant.

(A.4) Photocopy of valid Manufacturing License duly approved by the Licensing Authority for each and every product quoted as per specification in the Bid. The drugs for which Bids are submitted shall be clearly highlighted in the license.

(A.5) Photocopy of import license (in Form 10 with Form 41), as per Rule 122A of the Drugs and Cosmetics Act 1940. The license must be renewed up to date.

(A.6) Copy of a valid license for the sale of Drugs imported by the firms issued by the State Licensing Authority.

(A.7) Instruments such as power of attorney, resolution of board etc., authorizing the officer signing the Tender documents to sign these documents.

(A.8) Letter authorising a person with photograph to interact with the Procurement Agency during the bidding process if the officer is different from the officer (A.7) above. Such nominated person shall not represent more than one Bidder.

(A.9) Market Standing Certificate issued by the Licensing Authority as a Manufacturer for each drug quoted for the last 3 years (Certificate should be enclosed with list of items). In case of direct importer, evidence of import of the said items for the last three years such as bill of landing, bill of entry for last three years and certificate of analysis are to be produced (irrespective of the Importer).

(A.10) Performance statement of manufacture/import to establish required marketing credentials as per format in Annexure VI.

(A.11) Non-conviction Certificate issued by the Drugs Controller of the State certifying that the firm/company has not been convicted and the product quoted have not been cancelled during last three years (along with list of items) to be submitted.

(A.12) Certificate of GMP as per schedule M or WHO-GMP where applicable issued by the competent authority.

(A.13) An affidavit in the format given in Annexure II declaring that the Bidder complies with the requirements of WHO-GMP or GMP as per Schedule M.

(A.14) In case of Imported drugs, labels and product literature of all quoted product(s) must be submitted with WHO-GMP or certificate which is at par with WHO-GMP issued by the authorities of exporting countries like U.S. FDA etc or COPP certificate of their Principal Manufacturing company or firm.

(A.15) Annual turnover statement for last three financial years in the format given in Annexure-VII duly certified by the Charted Accountant.

(A.16) Printed Annual reports including the Balance Sheet and Profit and Loss Account for the last three years duly certified by the Chartered Accountant.

(A.17) VAT Clearance certificate issued by the competent authority in the prescribed format

(A.18) Undertaking (as in the proforma given in Annexure I) for embossment of logo on tablets, capsule shell, on labels of vials, Ampoules, bottles, tubes etc. as the case may be, and for supply of tablets/capsules on the strips as per the conditions specified under Clause 14 herein.,

(A.19) Undertaking (as in the proforma given in Annexure IA) for affixing the logo on the Secondary/Primary packing for the imported items along with Brand/Trade names.

(A.20) The details containing the name and address of the manufacturing premises / importing unit where the items quoted are actually manufactured / imported should be given as per the format in Annexure XII along with exact address of the registered/ Corporate office.

(A.21) Details of technical personnel employed in the manufacturing and testing of drugs (Employee Name, Qualification, and Experience) as endorsed in license.

(A.22) List of items quoted (The name & Drug code of the Items quoted, monthly production capacity of individual drug earmarked exclusively for the Bid of Procurement Agency and the amount of EMD for each drug alone should be furnished and the rate of those items should not be indicated in this list), as shown in the Annexure XIII.

(A.23) A Checklist (Annexure XVII) indicating the documents submitted with the Bid document and their respective page number. The documents should be serially arranged as per Annexure XVII and should be securely tied or bound. If a company/ firm has two or more separate manufacturing units at different sites / States, which are not separate entities then the company will be allowed to submit only one Tender for all units but necessary document regarding separate manufacturing units will have to be submitted as a separate set with the same Tender. But a Bidder will be allowed to submit only one offer for one product.

5. 0 PRICE BID - COVER "B"

5.1 Bidders shall submit Annexure-XVIIIA and Annexure XVIIIB duly filled in and signed on each page by authorized signatory and this will be considered as Price Bid. The list of drugs in these annexures is not intended to provide a complete list. They are only illustrative in nature and meant to denote the format in which the annexure is to be completed. The list will reflect the nature and number of drugs to be procured by the state. The Price Bid that is filled in and signed Annexure XVIIIA and Annexure XVIIIB will be sealed in an envelop by the Bidder which will be COVER B. The following will be written on the cover of the envelop:

"PRICE BID - COVER "B" – BID FOR THE SUPPLY OF DRUGS TO <Name of

Procurement Agency> **DUE ON** <date> **AT 10.30 A.M"**

addressed to the <Bid Inviting Authority> <address>

5.2 Both COVER A and COVER B shall be placed by the Bidder in a cover which shall be sealed by him. The following would be written on the cover of the envelop:

BID FOR THE SUPPLY OF DRUGS TO <Name of

Procurement Agency/ Body> **DUE ON** <date> **AT 10.30 A.M"**

addressed to the <Bid Inviting Authority>

<address>

5.3 The Bidder must adhere to the following conditions while submitting the Price Bid. Failure to adhere to these conditions without valid reasons may result in the rejection of the Tender submitted by the Bidder.

(B.1) Bid should be typewritten.

(B.2) No handmade correction would be allowed. No correction would be made by using correcting fluid or any other chemical or substance.

(B.3) Each page of the Price Bid should be duly signed by the Bidder or authorized signatory affixing the office seal.

(B.4) In addition to Price Bid submitted Bidder in the Annexure-XVIII A & B for the items quoted, the Bidder should also submit the information on a Compact Disc (CD) (supplied with Bid document). The Bidders who have downloaded Bid document, shall also download Excel file <filename>, copy the same file on a Compact Disc (CD) and submit the CD duly filled in. In case there is a difference in any figure between hard copies of Annexure XVIII A & B and data entered in the CD file, the figures on the hard copies of Annexure XVIIIA and Annexure XVIIIB will be considered for Bid valuation.

(B.5) The rate quoted in column 8 of Annexure XVIIIA and Annexure XVIIIB should be for a unit and for the given specification. The Bidder is not permitted to change/alter specification or unit size given in the same Annexures.

(B.6) The details of rates and manufacturing capacity earmarked for the Procurement Agency (for each item individually) given in Annexure XVIIIA and XVIIIB should be

entered clearly. The production capacity earmarked for the Procurement Agency as indicted in these Annexure in column 13 alone will be considered for placement of Purchase Orders.

(B.7) The Bidder shall necessarily quote the excise duty or customs duty applicable when the item is excisable or imported as the case may be. The tariff applicable and relevant chapters should be indicated for each item.

(B.8) The Bidder shall specifically mention " EXEMPTED " when the item is excisable but exempted for the time being, based on turn over or for any other grounds by the notification issued by the Government of India.

(B.9) The Bidder once quoted the excise rate is not permitted to change the rate/amount unless such change is supported by the notification issued by the Government of India, after submission of Tender.

(B.10) The Bidder, who has quoted excise duty as "NIL" in Annexure XVIIIA and XVIIIB and the item is excisable, at award of contract, will be eligible for payment of excise duty only on production of invoices drawn as per Central Excise Rules.

6.0 OPENING OF BIDS

6.1 Only authorized representatives of the Bidders are entitled to be present at the time of opening of Technical Tender – Cover "A" of the Bid submitted by them. None else will be permitted.

6.2 Price Bids of only those Bidders who are technically qualified on criteria for technical evaluation and inspection will be opened.

7.0 EARNEST MONEY DEPOSIT

7.1 The Earnest Money Deposit referred to under Clause 4.3, shall be for the amount as indicated against each drug in Annexure-VIII of the Bid documents. In case a Bidder is quoting for more than one drug, the Earnest Money Deposit payable by such Bidders shall be the aggregate total of the Earnest Money Deposit for all the drugs quoted by such Bidder. The Bidders are required to furnish the breakup of the Earnest Money Deposit for the items quoted along with the Bankers Cheque or Demand Draft or irrevocable Bank Guarantee in the format favoring <Name of Procurement Agency/ Body). However, if the total EMD payable is less than INR 50,000 it should be paid only by way of Bankers Cheque / Demand Draft. In other cases a minimum of INR 50,000/- to be paid only by Bankers Cheque / Demand Draft and the balance may be paid by irrevocable Bank Guarantee/Demand Draft/Bankers Cheque. EMD furnished in the form of a Bank Guarantee should remain valid for a minimum period of 60 days beyond the validity period of Tender. The format of Bank Guarantee for EMD is enclosed in the Annexure-XVI. This should be enclosed with the Bid in Cover "A". For the matter of clarity, if the due date for receiving the tenders is extended, the validity period of the Bid will automatically stand extended and it is the responsibility of Bidders to ensure that the EMD is valid at the time of Cover-A opening. Earnest Money Deposit in the form of Cheque/Cash/Postal order will not be accepted. Earnest Money Deposit will not earn any interest.

7.2 In case the EMD submitted by the Bidder is not sufficient to meet the EMD requirement of all the items quoted, the available EMD will be adjusted for the drug items in the ascending order

of the drug codes of the items quoted by the Bidder, till the EMD is exhausted. Further, the Tender of such Bidder for the remaining items, out of the quoted items, will be treated as non-responsive for want of the EMD. Any part value of EMD remaining unadjusted will be treated as an excess value furnished.

7.3 Earnest Money Deposit for those Bidders who are found to be not technically qualified will be returned.

8.0 OTHER CONDITIONS

8.1 The details of the required drugs are shown in Annexure-VIII. The Bid quantity is only a tentative indicative requirement and may be increased or decreased by the Procurement Agency at its discretion, depending on the actual need. The Bidders shall supply the drugs only on the basis of the Purchase Order issued by the Procurement Agency. Any supply without a valid Purchase Order will not be accepted and no liability will be accepted by the Procurement Agency for any payment on this account.

8.2 The Bidders should not renege from the commitment of supplying the quantity mentioned in the agreement / undertaking once the Purchase Order is issued.

8.3 The rates quoted will remain firm irrespective of the quantity ordered or destination.

8.4 Bids have been called for in the generic name of drugs. The Bidders should quote the rates for the generic products only. The composition and strength of each product should be as per specifications given in Annexure VIII. Any variation will result in rejection of the Tender for the. However the imported/combination drugs are allowed to be quoted in trade / brand name.

8.5 Rates quoted should be inclusive of Excise Duty, Customs duty, transportation, insurance, and any incidental charges, but exclusive of VAT (Sales Tax)) for each of the required drugs on door delivery basis according to the unit prescribed in Annexure VIII.

8.6 Bids for the supply of drugs etc. with cross conditions like "AT CURRENT MARKET RATES" shall not be accepted. Handling, clearing, transport charges etc., will not be paid separately. The delivery should be made as stipulated in the Purchase Order placed on the Bidders.

8.7 The price quoted by the Bidders shall in any case not exceed the controlled price, if any, fixed by the Central/State Government, the Maximum Retail Price (MRP).

8.8 Bid Inviting Authority will exercise the right to revise the price at any stage so as to conform to the controlled price or MRP or the lowest selling price of the Bidder as the case may be. This discretion will be exercised without prejudice to any other action that may be taken against the Bidder.

8.9 To ensure sustained supply without any interruption, the Procurement Agency reserves the right to split orders for supplying the requirements among more than one Bidders, pursuant to the provisions laid under the State Transparency Acts and Rules (if any).

8.10 The rates quoted and accepted will be binding on all the Bidder for the full contract period of one year and any increase in the price for any reason will not be entertained till the completion of this contract period.

8.11 No Bidder shall be allowed at any time and on any ground to claim revision or modification in the rates quoted by him. Representation to make correction in the Bid documents on the

ground of Clerical error, typographical error, etc., committed by the Bidders in the Bids shall not be entertained after submission of the tenders. Cross Conditions such as "SUBJECT TO AVAILABILITY", "SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED" etc., will not be entertained under any circumstances and the Bids with such conditions shall be treated as incomplete and accordingly the Tender will not be considered.

8.12 For the drug formulation like Injections, Liquid orals, Tablets and Capsules, rates should be quoted only for the composition stated in the Bid. Blood products should be supplied along with HIV and Hepatitis-B screening certificate, failing which the items will not be accepted. A copy of these Certificates duly attested should be sent with every consignment and every invoice.

8.13 Supplies should be made directly by the Supplier and not through any Agency / Dealer / Distributors.

8.14 The Bidder shall allow inspection of the factory premises at any time during the validity of the Tender by a team of Experts/Officials nominated by the Procurement Agency for the purpose. The Bidder shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If Company/Firm does not allow such inspection, their Bids will be rejected during the currency of the contract.

8.15 The Bidder should not influence the Inspection team in any manner including by providing conveyance, accommodation, food etc. Any effort may result in rejection of the Tender/ contract.

9.0 PRICE BID EVALUATION AND DETERMINATION OF SUCCESSFUL BIDDER

9.1 Bids will be evaluated in accordance to the provisions of the State Transparency in Tenders Act and Rules, where applicable and the criteria and conditions mentioned in this document. Rate per unit inclusive of various taxes and charges (landed price) as mentioned in Annexure XVIIIA and Annexure XVIIIB shall be worked out for determining the L1 rate (Lowest rate).

9.2 The Procurement Agency reserves the right to accept or reject the Bid for the supply of all or any one or more items of the drugs tendered for in the Bid without assigning any reason.

9.3 Procurement Agency or its authorized representative(s) has the right to inspect the factories of any of the Bidders any time before, accepting the rate quoted by them or before releasing any Purchase Order. The Procurement Agency has the right to reject the Bid or terminate/ cancel any Purchase Order issued and/or to decide not to place further order based on adverse reports brought out during such inspections or by any statutory authorities without prejudice to other action being taken.

9.4 The acceptance of the Bids will be communicated to the lowest / matched Bidders in writing. In determining the lowest evaluated price, (the rate quoted per unit or landed price in Annexure-XIX) the evaluation shall include all taxes and duties such as customs duty, excise duty, etc. subjected to the following:

(9.4.i) In Bids where all the Bidders are from within the State of ……., or where all the Bidders are from outside the State of ……., the Sales Tax shall be included for the evaluation of the price; and

(9.4.ii) In Bids where the Bidders are both from the State of ……. as well as from outside the State of ……., the sales tax under the State act……shall be excluded for the evaluation of the price.

9.5 After the conclusion of Price Bid opening (Cover B), the lowest offer of the Bidder will be considered for negotiation and rate arrived after negotiation will be declared as the lowest rate and that Bidder is the lowest evaluated for the item (s) for which the Bid has been invited.

9.6 The Bidder, who has been declared as lowest Bidder for certain item(s), shall execute necessary agreement for the supply of the tendered quantity of such item(s) as specified in the Bid Document on depositing the required amount as Performance Security deposit. On execution of the agreement such Bidder will become is eligible for the placement of Purchase Orders.

9.7 If two or more Bidders are declared lowest Suppliers for the same item(s), such Bidders shall execute necessary agreements as specified in the Bid Document. On depositing the required amount as Performance Security and on execution of the agreement, such Bidders will become eligible for the placement of Purchase Orders.

9.8 Procurement Agency will inform the lowest rate to other Bidders who had qualified for Price Bid (Cover B) opening, inviting their consent to match with the lowest rate for the item(s). The Bidders who agree to match lowest rate, will be considered as Matched lowest Bidders.

9.10 The Bidders, who agree to match the lowest rate, shall furnish the revised breakup details of Price (Lowest Rate) in Format in Annexures- XVIII A & B clearly indicating that it is revised and matched with the lowest rate. The revised details will be signed with seal by the authorized official.

9.11 The Matched lowest supplier, on placement of Purchase Order, will be deemed as lowest rate supplier for the purpose of the Bid and all provisions of the Bid documents applicable to L1 rate Bidder will apply mutatis mutandis to the Matched L1 supplier also.

9.12 In the case of purchase of item(s) where the total quantity earmarked by the lowest / matched Bidders, is less than the total quantity required, the Procurement Agency may, after placing orders with the lowest evaluated / matched Bidders for the entire quantity earmarked by such Bidders subject to the Bidders' ability to supply, request all the other eligible Bidders to submit revised price and quantity they would be willing to supply. Such Bidders will not be allowed to change any other parameters like rates of taxes etc. They will also not be allowed to revise the production capacity from what had been mentioned earlier in the original Tender. The revised offer in other words will be restricted to rate and quantity offered. The Procurement Agency may place order for the remaining required quantity at the revised rates offered in strict ascending orders of offered rates subject to provisions of State Tender Rules.

10.0 SECURITY DEPOSIT

10.1 On being informed about the acceptance of the Bid and at the time of signing the Agreement, the lowest/matched Bidders shall pay the Security Deposit as indicated below in the form of Demand Draft or irrevocable Bank Guarantee in favor of Procurement Agency. In case the Security Deposit is paid in form of Bank Guarantee, the bank guarantee shall be valid for a period of 2 years from the date of communication of the acceptance letter from the Bid inviting Authority. The format of Bank Guarantee is at Annexure-XI. Failure to deposit the performance security will attract Clause No. 21.2.

10.2 The amount of Performance Security Deposit will be 3% of the contract value (subject to a minimum of INR 5,000/-) where the total value of contract does not exceed INR1.00 Crore.

10.3 Where the contract value exceeds INR 1.00 Crore, the amount of Performance Security Deposit will be INR3.00 Lakhs Plus @ 2% of the contract value over and above INR1.00 Crore.

11.0 AGREEMENT

11.1 The successful Bidders shall execute an agreement on a non- judicial stamp paper of value of INR100/- (stamp duty to be paid by the Bidder) within 15 days from the date of the intimation from Procurement Agency of the decision to award the contract to the Bidder. The Specimen form of agreement is available in Annexure-X.

11.2 The Bidder shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or persons whatsoever.

11.3 All notices or communications relating to and arising out of the agreement or any of the terms thereof shall be considered duly served on or given to the Bidder if delivered to him or left at the premises, places of business or abode as provided by the Bidder.

11.4 If the Bidder fails to execute the agreement and/or to deposit the required security deposit within the time specified or withdraws the Bid, after the intimation of the acceptance of the Bid or owing to any other reasons to undertake the contract, the contract will be cancelled and the Earnest Money Deposit deposited by the Bidder along with the Bid shall stand forfeited. The firm will also be liable to make up for the damages/losses suffered by the Procurement Agency apart from blacklisting and other penal actions.

12.0 METHODOLOGY FOR PLACING ORDERS

12.1 After the agreement is signed, Procurement Agency may authorize other officials under his control to place Purchase Orders on the selected Suppliers. Procuring Agency will provide the Suppliers with a list of such officials. Purchase Orders issued by these officials will be treated as having been issued in terms of the agreement.

12.2 In cases of emergency, orders for supply of drugs may be communicated over telephone to enable the Suppliers to prepare consignments. Such telephonic orders will be followed by issue of Purchase Orders within 24 hours and the total value of such a Purchase Order (PO) should not exceed INR 1 lakh.

12.3 Where Procurement Agency has chosen to place Purchase Orders with the Matched lowest supplier and there are more than one such Matched lowest supplier, the Purchase Orders for the requirement of item(s) will be placed among them in equal proportion provided that no Matched lowest supplier is entitled to be placed Purchase Orders exceeding the production capacity.

12.4 If the supplier on receipt of the Purchase Order discovers that the Purchase Order exceeds the production capacity declared by him in the Tender document and agreement, he shall inform the Procurement Agency immediately without loss of time and the Purchase Order shall be returned within 7 days from the date of the order, failing which the supplier is stopped from disputing the imposition of liquidated damages, fine for the delayed supply etc.

12.5 If any supplier fails to supply the required item(s) within the stipulated time or within the extended time, as the case may be, the Procurement Agency will cancel such Purchase Orders. The Procurement Agency will then place order at the risk and cost of the defaulted supplier, on the supplier available for supply on rates which are equal or immediately higher satisfying other conditions.

12.6 If the supplier fails to supply the item(s) either fully or partly within the stipulated time for any of the three Purchase Orders placed for the same item(s) at any point of time and no Matched Suppliers are available, the Procurement Agency is at liberty to place Purchase Orders either with other Suppliers (in ascending order, viz., L2,L3 and so on) at the price offered by them or with alternate sources at the risk and cost of the defaulted supplier.

12.7 Notwithstanding anything contained in para 12.5 or 12.6 above, the supplier after committing the default in supply either partly or fully, can inform the Procurement Agency about his willingness to supply further quantities during the contract period. The Procurement Agency may at his discretion consider his request and may place fresh Purchase Order.

12.8 The supplier shall supply of the Drugs required by Procurement Agency at the destination mentioned in the schedule within the period stipulated in the Purchase Order.

12.9 The Drugs supplied in excess of the ordered quantity shall not be accepted and the supplier shall take back the excess at their cost. Procurement Agency will not be responsible for the loss to the supplier and will not entertain any claim on this account.

12.10 The supplier shall supply the Item(s) at the specified destination along with original excise invoice, Test reports of raw materials procured and finished products for every batch, Delivery Challans and other relevant documents. Any supply without the above documents will not be accepted and the said supply will be accepted only on the date of submission of the required documents

12.11 The supplier shall take utmost care in supplying the quality Drugs and ensure that the batch number mentioned in the packages of the Drugs tally with the batch number mentioned in the Invoices submitted to the Procurement Agency for payment.

12.12 The supplier shall ensure the quantity relevant to the Batch Number of the Drugs is mentioned in the invoice. Any variation will be examined seriously and the payment for the supply will be released only after confirmation of the batch number by the supplier and reconciliation of the same. While at the discretion of the Procurement Agency, minor normal variations in the batch numbers in the invoices and actual supply may be accepted, any abnormal variation may lead to Blacklisting of the product(s) by the Procurement Agency.

12.13 It will be the responsibility of the supplier to supply Drugs at the destinations mentioned in the Purchase Order and supply shall conform to the conditions mentioned in the provisions of tender documents, viz., logo, nomenclature in regional language etc.,

12.14 Procurement Agency will all efforts to process the invoices submitted by the supplier and to make payments against supply within 30 days from the date the Drugs supplied has been declared of STANDARD QUALITY, by the Empanelled laboratory.

12.15 Subject to the conditions mentioned in the Purchase Order, Bid Document, Agreement executed by the supplier and here under, the Supplier is entitled for the payment against supply. Any case of discrepancy in levy of LD, Penalty, Unexecuted Fine, Short Passing of Bills

will be intimated to the Procurement Agency in writing within 45 days from the date of receipt of payment. Procurement Agency may not entertain any claim thereafter.

13.0 SCHEDULE OF PURCHASE ORDERS AND OTHER SUPPLY CONDITIONS

13.1 Purchase Orders along with the place of supply (destinations) will be issued to the Suppliers by the Procurement Agency preferably once in a month.

13.2 The supplier should confirm receipt of the Purchase Order immediately on receipt of the same.

13.3 The supplier will inform the Procurement Agency and the agency receiving the supply at the destination the details of supply schedule within 7 days from the receipt of the Purchase Order.

13.4 For Category 'A' drugs, the supplier shall supply at least 50% of the ordered quantity within 30 days from the date of Purchase Order and the balance quantity within 45 days from the date of Purchase Order at the destinations mentioned in the Purchase Order. If the 30th day or 45th day, as the case may be, happens to be non-working day, the supply should be completed on the next working day. In case the supply is not completed within the stipulated time, the Procurement Agency will have the liberty to make alternative procurement arrangements for these drugs without any notice/information to the supplier. This will be treated as default in supply.

13.5 For Category 'B' drugs, the supplier shall supply at least 50% of the ordered quantity within 45 days from the date of Purchase Order and the balance quantity within 60 days from the date of Purchase Order at the destinations mentioned in the Purchase Order. If the 45th day or 60th day, as the case may be happens to be non-working day, the supply should be completed on the next working day. In case the supply is not completed within the stipulated time, the Procurement Agency will have the liberty to make alternative procurement arrangements for these drugs without any notice/information to the supplier. This will be treated as default in supply.

13.6 The Procurement Agency may at its discretion after considering the reasonableness of any appeal made by the supplier within the stipulated supply period for extension of the time limit of supply may accept the offer. Such supply must be completed within 80 days of the Purchase Order in case of Category 'A' drugs and 95 days from the date of the Purchase Order in case of Category 'B' drugs. The Purchase Order will automatically stand cancelled on the 81st day from the date of issue of Purchase Order in case of Category 'A' drugs and on the 96th day from the date of Purchase Order in case of Category 'B' drugs.

13.7 The supplier is entitled to receive a bonus payment @ 0.25% flat on the order value provided the entire order is completed within 30 days and 45 days for Category "A" and "B" drugs respectively.

13.8 Supplier shall complete the earliest pending purchase order before commencing the supply of subsequent Purchase Orders.

13.9 In addition to any other condition laid down in these Tender documents and in the Purchase Orders, the supplied Drugs (covered in SCHEDULE "P" of Drugs and Cosmetics Act) should have the prescribed potency throughout the shelf life period as prescribed in the Drugs and Cosmetics Act 1940 and rules there under and in relevant Pharmacopoeias. All other items of drugs should have shelf life period of minimum 24/18/12 months from the date of manufacture as prescribed in official compendiums. Each batch of product (s) supplied should have ingredients at the lower limit of 95% at the entry level to the destination supply point including warehouses. The upper limits should be as prescribed in the official Pharmacopoeias

throughout its shelf life. The Procurement Agency will reserve the right to reject the supplies not fulfilling these conditions.

13.10 The supplier must submit an Analysis report from a Government approved Laboratory for every batch of drug along with invoice. In case of failure on part of the supplier to furnish such report, the batch of drugs will be returned back to the Suppliers and he is bound to replenish the same with Govt. approved lab test report. The Drugs supplied by the successful Bidder shall be of the best quality and shall comply with the specifications, stipulations and conditions specified in the tender.

13.11 Supplier should supply the product within 30 days from the date of manufacture of that product. In case, the product is received after 30 days from date of manufacture and the product is not consumed before its expiry date, the supplier should replace the short expiry/ expired quantity with fresh stock of longer shelf life. The expired product if not replaced will be returned to the supplier and the value equal to the cost of expired quantity will be recovered from any dues payable or by any other method.

13.12 The supplier is responsible for any shortages/damage at the time of receipt in Warehouse. The Procurement Agency is not responsible for the stock of drug received, for which no order is placed.

13.13 If at any time the supplier has, in the opinion of the Procurement Agency, delayed the supply of drugs due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest or other exceptional events at the manufacturing premises, the time for supplying the drugs may be extended by the Procurement Agency at the discretion for such period as may be considered reasonable. Such extension shall be considered only if a written request is made by the supplier within 10 days from the date of occurrence of such event with necessary documentary evidence. The exceptional events will not include the scarcity of raw material, increase in the cost of raw material, Electricity failure, breakdown of machineries, labour disputes/strikes, insolvency, and Closure of the Factory/Manufacturing unit on any grounds etc.

13.14 The supplier shall not be liable to pay LD/penalty and forfeiture of performance security for the delay in executing the contract on account of the extension of supply period granted on the ground of force majeure events.

14.0 LOGOGRAMS

14.1 Logogram means, wherever the context occurs, the design as specified in Annexure-II & IIA. The name of the drug shall be mentioned in State's official language and English only.

14.2 Bids for the supply for Drugs shall be considered only if the Bidder gives an undertaking that the product(s) will be prepared as per the specifications such as strength, minimum size and packed with appropriate size of the strips/blisters and with the logogram of proportionate size either printed or embossed on tablets and capsules, bottles etc., as per the design enclosed as per Annexure-II and IIA.

14.3 All tablets and capsules have to be supplied in standard packing of 10 x 10 in strip or blister packing with printed logogram of proportionate size and shall also conform to Schedule P1 of the Drugs & Cosmetics Act & Rules wherever it applies. Affixing of stickers and rubber stamps shall not be accepted.

14.4 Vials, Ampoules and Bottles containing the items tendered for should also carry the printed logogram of proportionate size.

14.5 The Procurement Agency will reserve the right to reject such supplies which are in violation of conditions laid down in Clauses 14.1 to 14.4. Failure to supply Drugs etc., with the printed logogram of proportionate size will be treated as breach of the terms of agreement / violation of Tender conditions and action may be taken to blacklist the product and/or fine will be deducted from the amount payable as per condition in Clause 18.5

15.0 PACKING

15.1 The drugs shall be supplied in the package specified in Annexure-VIII and Annexure-IX and the package shall carry the logograms of proportionate size specified in Annexure-II. Affixing of labels in smaller size will be treated as violation of Bid conditions and fine will be deducted from the amount payable.

15.2 2D Bar coding as per GS1 standard should be done on tertiary packing of the supplies as per the specifications given in Annexure-XIV.

15.3 The minimum size of each tablet should be 6.4 mm in diameter. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties as per clause 18.5.

15.4 The packing in each carton shall be strictly as per the specification mentioned in Annexure-IX. The outer carton should be of white board with a minimum of 300 gsm with laminated packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with white board of 450 gsm. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties as per clause 18.5. However in case of poor / damaged packing, necessary replacement should be provided for damaged goods.

15.5 The caps of bottle preparations should not carry the name of the supplier.

15.6 The labels in the case of Injectable preparations should clearly indicate whether the preparations are meant for Intravenous (IV), Intra Muscular (IM), Intra Dermal (ID), Subcutaneous (SC) administration etc.

15.7 The capsule shell should have the name of the drug, in addition to the logo.

15.8 It should be ensured that only first-hand fresh packaging material of uniform size, including bottle and vial, is used for packing.

15.9 All primary packing containers should be strictly conforming to the specification included in the relevant pharmacopoeia.

15.10 Packing should be able to prevent damage or deterioration during transit.

15.11 In the event of items of drugs supplied found to be not as per specifications in respect of their packing and logogram, the Procurement Agency, is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Bidder who might have quoted higher rates, at the risk and the cost of the supplier. In such cases the Procurement Agency has every right to recover the cost and impose penalty.

16.0 QUALITY TESTING

16.1 Samples of supplies in each batch will be chosen at the point of supply or distribution/storage points for testing. The samples will be collected from each batch of supply of the same drugs and after eliminating the common batch, samples shall be taken in random, decoded and will be sent to the empanelled testing laboratories for testing. Such samples will be sent to different laboratories including Government Drugs Testing Laboratory/ Kings Institute as decided by the Procurement Agency.

16.2 Even if samples of a particular batch have passed quality tests, if drugs of the same batch are supplied subsequently, the same will be again subjected to testing and the latest report of that particular batch will prevail and be binding on the entire quantity of the batch supplied.

16.3 If the sample fails in quality test and report is received certifying that sample is "NOT OF STANDARD QUALITY", one more sample shall be drawn from the same batch and to be sent to Government Laboratory for quality testing. If such sample passes the quality test as per the report of Government Laboratory, the drugs representing the sample shall be qualified for issue to various Institutions.

16.4 If such sample fails in the quality test, as per the report of the Government Laboratory, the drugs of the batch are not qualified for issue and the supplier shall take back the drugs supplied in that batch. The Procurement Agency will reserve the right to take such other action as are envisaged in this document and in the agreement.

16.5 The Drugs shall have the active ingredients at the prescribed level as indicated in official compendiums throughout the shelf life period of the drug. The samples will be drawn periodically throughout the shelf life period and if found "Not of Standard Quality", the cost of entire batch paid will be recovered whether consumed fully/partially.

16.6 Action may be initiated for blacklisting the supplier irrespective of the period of supply. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirement shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.

16.7 In the event of the samples of Drugs supplied failing in quality tests or found to be not as per specifications, the Procurement Agency will be at liberty to arrange alternative procurement of the items which would include procurement from any other supplier at the same rate or from the open market or from any other supplier who might have quoted higher rates. Such alternative procurement will be at the risk and the cost of the supplier and in such cases the Procurement Agency will reserve the right to recover the additional cost and impose penalty, if deemed fit.

16.8 The supplier shall furnish to the Procurement Agency, the evidence of bio- availability and/or bio-equivalence reports for certain critical drugs upon demand.

16.9 The supplier shall furnish evidence of the basis for expiration dating and other stability data concerning the commercial final package on request by the Procurement Agency. In case of any adverse report in the field, the B.M.R/B.P.R for the particular batch of the product(s) supplied shall be produced when demanded.

16.10 The products should conform to the standards of IP/BP/USP/EP/JP as the case may be. In case the product is not included in the said compendiums, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing. For imported drugs, respective Country's Pharmacoepial standards shall be acceptable (even if the product is official in IP).

16.11 The case of admixture of drugs / mixing of various batches in the Primary / Secondary and/or Tertiary packing, such case will be treated as a violation of tender conditions and fine will be levied as per clause 19. If such lapses happens more than twice in a tender period such cases will be treated as "Misbranded Drugs".

16.12 On complaint from Drug Inspector(s) during their test of field sample that the particular drug has been reported to be of "NOT OF STANDARD QUALITY", the issue of available stock of the particular item will be stopped. Further, the available stock of the product in hospitals will be retrieved. If the sample is reported to have less than 50% of content, the particular product will be blacklisted for 2 years from the date of intimation of blacklisting.

16.13 The Procurement Agency if and when is required to determine whether a drug is "Not of Standard Quality" will be guided by the guidelines of Central Drug Control Standards Organization.

17.0 QUALITY FAILURE

17.1 If the samples do not conform to statutory standards, the Bidder will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Bidder at his expense within a period of 30 days of the receipt of the letter from the Procurement Agency. The Procurement Agency will reserve the right to destroy these drugs after the expiry of 30 days mentioned above without further notice, and may also collect demurrage charges calculated at the rate of 2% per week on the value of the drugs rejected till its destruction by the Procurement Agency.

17.2 If any items of Drugs supplied by the supplier have been partially or wholly used or consumed after supply and are subsequently found to be in bad odor, unsound, inferior in quality or description or otherwise faulty or unfit for consumption, then the contract prices of such articles will be recovered from the supplier, if payment had already been made to him. In other words the supplier will not be entitled to any payment whatsoever for items of drugs found to be of "NOT OF STANDARD QUALITY" whether consumed or not consumed and the Procurement Agency is entitled to deduct the cost of such batch of drugs from any amount payable to the Bidder.

17.3 Notwithstanding the provisions in Clauses 17.1 and 17.2, the Procurement Agency may initiate other action as deemed fit on the basis of the nature of failure.

17.4 In case of supply of "NOT OF STANDARD QUALITY" drug, the product shall be blacklisted by the Procurement Agency and no further supplies shall be accepted for the particular drug(s). The supplier shall not be eligible to participate in tenders of the Procurement Agency for supply of such Drugs for a period of 2 years from the date of blacklisting. Security deposit will also be forfeited without any intimation.

17.5 In addition, the Director of Drugs Control of concerned State will be informed to initiate necessary action on the supplier in their state.

17.6 If it is established that the supplier has supplied Adulterated/Spurious/ Misbranded drugs to the Procurement Agency, he shall be blacklisted by the Procurement Agency immediately and no further supplies shall be accepted from the supplier. Any agreement entered by the Procurement Agency with the supplier and any Purchase Order against which supplies are still outstanding will stand automatically cancelled. The supplier will also not be eligible to participate in tenders of the Procurement Agency for supply of Drugs for a period of 5 years from the date of blacklisting.

17.7 The supplier shall furnish the source of procurement of raw material utilized in the formulations, if required by the Procurement Agency who reserves the right to cancel the Purchase Order, if the source of supply is not furnished.

17.8 The decision of the Procurement Agency or any officer authorized by him on the quality of the supplied drugs shall be final and binding.

18.0 PAYMENT PROVISIONS

18.1 No advance payments towards costs of drugs will be made to the supplier.

18.2 Payments towards the supply of drugs will be made by means of Cheque or through RTGS (Real Time Gross Settlement System) /Core Banking/NEFT. The supplier shall furnish the relevant details in original (Annexure-XVI) at the time of submission of the Tender documents and any change of Bank Account during the validity of the Bid will not be entertained without valid reasons.

18.3 All bills/Invoices should be raised in triplicate and in the case of excisable Drugs, the bills should be drawn as per Central Excise Rules in the name of Procurement Agency or in the name of any other authority as may be designated.

18.4 It would be the endeavor of the Procurement Agency to make payment without delay for supplies accepted and all other formalities completed. Any outstanding against the supplier will be adjusted from the payment due to the supplier. In case of last invoice from a supplier, payment will be made only after expiry of sixty days from the date of submission of the invoice.

18.5 If at any time during the period of contract, the price of tendered items is reduced by any law or Act of the Central or State Government or by the supplier himself, the supplier shall be bound to inform the Procurement Agency without any delay. Procurement Agency will unilaterally effect such reduction as is necessary in rates in case the supplier fails to notify or fails to agree for such reduction of rates. The amount of reduction will be recovered from any payment due to the supplier.

18.6 Without altering the basic price structure of the drugs tendered and approved, any increase/ decrease in the tax/ statutory levies after the submission of the Tender document and not reflected in the price structure in the agreement would be added/ deducted. For claiming any additional payment on account of increased taxes/ statutory levies, the supplier should produce relevant notification and proof of payment. Similarly, the Procurement Agency will unilaterally reduce from the payment due, an amount equivalent to reduced tax/ statutory levies.

19.0 LIQUIDATED DAMAGES AND OTHER PENALTIES

19.1 For Category 'A' drugs, delay in supply of 50% of the drugs beyond 30 days as envisaged in Clause 13.4 will attract liquidated damages at the rate of 0.5% per day subject to a maximum

of 7.5% of the value of the delayed supply. Similarly supply beyond 45th day as envisaged in Clause 13.4 for the remaining 50% of the supply, will attract liquidated damages at the same rate subject to a maximum of 7.5% of the value of the delayed supply. Beyond 45 days and 60 days as the case may be, additional liquidated damages will be imposed at the rate of 0.75% per day subject to a maximum of 11.25%. Imposition of liquidated damages is irrespective of the fact whether the Procurement Agency has suffered any damage / loss on account of delay in effecting supply or not. If any of the cut off day happens to be a holiday the supply will be accepted on the next working day without any liquidated damages.

19.2 For Category 'B' drugs, Liquidated damages for delay in supply of 50% of the drugs beyond 45 days as envisaged in Clause 13.5 will attract liquidated damages at the rate of 0.5% per day subject to a maximum of 7.5% of the value of the delayed supply. Similarly supply beyond 60th day as envisaged in Clause 13.5 for the remaining 50% of the supply will attract liquidated damages at the same rate subject to a maximum of 7.5% of the value of the delayed supply. Beyond 60 days and 75 days as the case may be, additional liquidated damages will be imposed at the rate of 0.75% per day subject to a maximum of 11.25%. Imposition of liquidated damages is irrespective of the fact whether the Procurement Agency has suffered any damage / loss on account of delay in effecting supply or not. If any of the cut off day happens to be a holiday the supply will be accepted on the next working day without any liquidated damages.

19.3 Against a specific request of the supplier, the Procurement Agency may at its discretion provide an extension of another 5 days beyond 75th day in case of Category 'A' drugs and beyond 90th day in case of Category 'B' drugs with additional liquidated damages at the rate of 1% per day.

19.4 If there are any unexecuted orders after 80th day in case of Category 'A' drugs and 95th day in case of Category 'B' drugs or the date of delivery extension granted whichever is later from the date of Purchase Order, the order shall stand cancelled and a penalty @ 30% on the value of unexecuted order will become due. Such penalty will be recoverable from any amount payable to the supplier. This will be in addition to additional liability of the supplier on account of alternate procurement carried out at his risk and cost.

19.5 All the days mentioned in Clauses 18.1 to 18.4 will be counted from the date of the Purchase Order.

19.6 If the supply is received in damaged condition it shall not be accepted. In case of damage in the packing, the supply will be accepted only after levying penalty to the extent of damaged value of supply received at the destination place.

20.0 OTHER GENERAL CONDITIONS

20.1 The Procurement Agency will be at liberty to terminate, without assigning any reasons thereof, the contract either wholly or in part after giving notice to the supplier at least 30 days before the proposed date of termination. The supplier shall not be entitled for any compensation whatsoever in respect of such termination.

20.2 If the Procurement Agency suffers any monetary loss on account of any infringement of the conditions of the contract on the part of the supplier, the Procurement Agency would have the right to recover such losses from the supplier besides forfeiture of Security deposit.

20.3 In the event of making Alternative Purchase the excess expenditure over and above contracted prices incurred by the Procurement Agency in making such purchases from any other sources or in the open market or from any other Bidder who has quoted higher rates and other losses sustained in the process, shall be recovered from the Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.

20.4 In all the above conditions, the decision of the Procurement Agency shall be final and binding.

21.0 BLACK LISTING

21.1 Blacklisting is an administrative penalty disqualifying a Bidder to participate in any tender process for a given period.

21.2 If a Bidder after having been notified of the award of the contract in his favour on the basis of his response to this notice inviting Tender, fails to execute the agreement and/or fails to deposit performance security deposit, the Bidder will be blacklisted for a minimum period of two years by the Procurement Agency from the date following the date by which he was required to execute the agreement or deposit performance security.

21.3 After participating in the Bid either fully or partially, if a Bidder withdraws from the tender process without assigning any valid reason, he will be blacklisted for a minimum period of two years from the date of intimation by the Procurement Agency.

21.4 On receipt of report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Item/Drug is "NOT OF STANDARD QUALITY/ ADULTERATED/ SPURIOUS/ MIS- BRANDED (as the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the Procurement Agency shall take appropriate action on merits of the case and will be entitled to impose such penalty including the blacklisting of the particular item of the product /supplier as deemed fit besides forfeiture of performance security deposit.

21.5 In case of any sample in any batch supplied by the supplier being declared as Adulterated/ spurious/ Misbranded by the Government Authorities, the Supplier shall be blacklisted for a period of 5 years from the date of intimation besides forfeiture of security deposit in full.

21.6 If the supplier supplied more than one item and 50% of such items are blacklisted, the supplier is liable to be blacklisted for a period of 2 years from the date of intimation.

21.7 Failure to execute at least 70% of the ordered quantity in any three Purchase orders of the same drug will result in the same drug by the supplier being blacklisted for a minimum period of two years.

21.8 Purchase orders, if any, already issued before taking any blacklisting action or orders given in past will not be affected in view of action taken as per above guidelines but all strict quality checks shall be observed for each supply of products.

21.9 The blacklisting of particular product or a supplier will be done without prejudice to other penalties which may be imposed as per the conditions of Bid documents and also to other actions which may be initiated under Drugs and Cosmetics Act 1940 or any other law of Land. The Procurement Agency will display names of such blacklisted product(s) and supplier on its

website and also circulate the same among other state Governments / Central Government and its Drug procurement agencies including respective State Drugs Control Department where the supplier is located.

22.0 SAVING CLAUSE

22.1 No suit, prosecution or any legal proceedings shall lie against the Bid Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of the tender.

23.0 ARBITRATION

23.1 If dispute or difference of any kind shall arise between the Procurement Agency and the supplier, the parties shall make every effort to resolve the same amicably by mutual consultations.

23.2 If the parties fail to resolve their dispute or difference by such mutual consultations within thirty days of commencement of consultations, then either of the parties may give notice to the other party of its intention to commence arbitration, as hereinafter provided. The applicable arbitration procedure will be as per the Arbitration and Conciliation Act, 1996 of India. In that event, the dispute or difference shall be referred to the sole arbitration of an officer to be appointed by the Procurement Agency as the arbitrator. If the arbitrator to whom the matter is initially referred is transferred or vacates his office or is unable to act for any reason, he / she shall be replaced by another person appointed by the Procurement Agency to act as Arbitrator.

23.3 Reference to arbitration shall be a condition precedent to any other action at law or in terms of the conditions of this document.

23.4 The venue of arbitration shall be the place where the Procurement Agency is located..

24.0 SPECIAL INSTRUCTIONS TO BIDDERS

24.1 No Bidder or any official connected to the Bidder or any person on behalf of the Bidder shall contact any official in the Tender Inviting Authority on any matter relating to its Tender from the time of Tender opening to the time the contract is awarded.

24.2 Any effort by a Bidder through any official connected to him or any person on behalf of him to influence the processes of Tender evaluation, Tender comparison or contract award decisions may result in rejection of the Bidder's Tender.

24.3 The Bidder through any official connected to him or any person on behalf of him shall not make any attempt to establish unsolicited and unauthorized contact with the Tender Accepting Authority, Tender Inviting Authority or Tender Scrutiny Committee after opening of the Bids and prior to the notification of award. Any attempt by any Bidder to bring to bear extraneous pressures on the Tender Accepting Authority, Tender Inviting Authority or Tender Scrutiny Committee, shall be sufficient reason to disqualify the Bidder.

24.4 Notwithstanding anything contained in clauses 24.1 to 24.3 above, the Tender Inviting Authority or the Tender Accepting Authority, may seek bona fide clarifications from Bidders relating to the Bids submitted by them during the evaluation of Bids.

24.5 The Tender Accepting Authority may waive minor infirmity and/or non-conformity in a Bid, provided it does not constitute any material deviation. The decision of the Tender Accepting

Authority as to whether the deviation is material or not, shall be final and binding on the Bidders.

25.0 FRAUDULENT AND CORRUPT PRACTICES: FOR BIDDERS

25.1 It is the policy of the Procurement Agency to require that the Bidders, Suppliers and contractors and their authorized representatives/agents observe the highest standard of ethics during the procurement and execution of such contracts. Any action taken by a Bidder, Supplier, Contractor, or by their authorized representatives/agent, to influence the procurement process or contract execution for undue advantage is improper. In pursuance of this policy, the purchaser defines for the purposes of this provision, the terms set forth below as follows:

(25.1.i) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party ("another party" refers to a public official acting in relation to the procurement process or contract execution]. In this context, "public official" includes staff and employees of other organizations taking or reviewing procurement decisions.

(25.1.ii) "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation (a "party" refers to a public official; the terms "benefit" and "obligation" relate to the procurement process or contract execution; and the "act or omission" is intended to influence the procurement process or contract execution).

(25.1.iii) "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party ["parties" refers to participants in the procurement process (including public officials) attempting to establish Tender prices at artificial, non competitive level].

(25.1.iv) "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party (a "party" refers to a participant in the procurement process or contract execution).

(25.1.v) "Obstructive practice" is deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede an investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation and includes acts intended to materially impede the exercise of the rights of the Procurement Agency of inspection and audit provided for under sub-clause (e) below.

25.2 The Procurement Agency will reject a Tender and cancel a contract if he determines that the Bidder considered for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question.

25.3 The Procurement Agency will debar a Bidder either indefinitely or for a stated period of time from being awarded any contract if it at any time he determines that the firm has, directly or

through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract.

25.4 The Procurement Agency will have the right to inspect the accounts and records of the Bidders, Supplier, and Contractors and their sub-contractors/authorized representatives and to have them audited by auditors appointed by the purchaser.

26.0 JURISDICTION

26.1 In the event of any dispute arising out of the tender such dispute would subject to the jurisdiction of the Civil Court within the city of <Name of the City>.

ANNEXURE - IA

DECLARATION

I / We do hereby declare that I will supply the Drugs by affixing the logo for Secondary / Primary packing for the imported items along with Brand / trade Names as per the designs (Procurement Agency to enclose designs) and as per the instructions given in this regard.

Signature of the Tenderer

Name in capital letters with Designation

ANNEXURE - II: REFER CLAUSE 4.4 A.13

I/We M/s. .....represented by its Proprietor / Managing Partner / Managing Director having its Registered Office at..... ..... and its Factory Premises at ..... do declare that I/We possess the valid license and GMP Certificate as per WHO-GMP/ GMP as per Schedule M which ever applicable, issued by the Competent Authority. I/We furnish the particulars in this regard in enclosure to this declaration.

I am/we are aware of the Tender Inviting Authority's right to forfeit the Earnest Money Deposit and/or Security Deposit and blacklisting me/us for a period of 5 years if, any information furnished by us proved to be false at the time of inspection and not complying the conditions as per WHO GMP/ GMP as per Schedule M, whichever applicable, for a period of 5 years.

Signature :
Seal

Name & Address :

To be attested by the Notary.

ANNEXURE - III: REFERENCE CLAUSE NO. 2.9

DECLARATION

I.....Managing Director/ Director/ Partner/ Proprietor of M/s. .....having registered office at .....do hereby declare that we have not blacklisted either by Bid Inviting Authority or by any State Government or Central Government Organization for the following products quoted in the Bid. We are eligible to participate in the Tender ref. no..... Dated..... for the following products.

Sl. No.	Drug Code	Name of the Drug

M/s.

Company seal

To be attested by the Notary

ENCLOSURE TO ANNEXURE - III: CLAUSE 4 (1) (J)

DECLARATION FOR COMPLIANCE OF WHO-GMP/ GMP AS PER SCHEDULE M (Whichever Applicable)

01. Name and Address of The Firm :

02. Name of Proprietor / Partner / Director :

03. Name and Designation of Person Present :

04. GMP Certificate : As per WHO GMP/ GMP as per Schedule M whichever applicable

05. Details of Licenses Held With Validity :

06. Number of Workers Employed : Ladies : Gents :

07. Whether Workers Provided with Uniform : Yes / No

08. Whether Medical Examination done for the Workers : Yes / No

09. Hygienic Condition

(I) Surrounding : Satisfactory / Not Satisfactory

(II) Production Areas : Satisfactory / Not Satisfactory

(III) Other Areas : Satisfactory / Not Satisfactory

10. Provision For Disposal of Waste : Yes / No

11. Heating System : Yes / No

Working Area

12. Whether Benches Provided in all Working Area

13. Water Supply

(A) Source

(B) Storage Condition : Satisfactory / Not Satisfactory

(C) Testing
(With reference to Pathogenic Organization) : Yes / No

(D) Cleaning Schedule In Water Supply System With Proper Records : Yes / No

(E) Type of Machinery installed as to Semiautomatic or Fully Automatic plant for water purification system along with cost and whether this is working, and if so he flow rate of Pharmaceutical water to must the requires preparation :

14. Air handling system along with list of machine and cost of the unit. Separately for sterile and non sterile preparation :

15. Whether the pollution control clearance is valid for Air and Water and if so the period upto which valid (copy of the certificate to be enclosed) :

16. Raw Material Storage Area

(Storage Facilities / Hygienic Condition) :

(I) Quarantine : Provided / Not Provided

(II) Passed Materials : Provided / Not Provided

(III) Rejected Materials : Provided / Not Provided

17. Finished Product Storage Area (Hygienic / Storage) :

(I) Quarantine : Provided / Not Provided

(II) Released Material : Provided / Not Provided

18. Details of Technical Staff Name Qualification Experience

(B) For Manufacturing : For Testing :

19. Testing Facilities (List of Equipments to be furnished separately in the format to meet the bench mark vide Annexure)

Chemical Method : Yes / No

Instrumental (Type of Instrument Provided as indicated in Annexure) : Yes / No

Biological : Yes / No

Micro Biological : Yes/No

Animal Testing : Yes/ No

20. Remarks

(A) Whether Products Quoted to ..... (Name of Procurement Agency/ Body). are Endorsed in the Licence : Yes / No

(B) Whether the drugs Quoted to..... (Name of Procurement Agency/ Body). have been Manufactured Earlier (Last 3 Years) : Yes / No

If Yes, Details Like

Sl.No	Date of Manufacturer	Name of the Drug	Batch No.	Batch Size	Date of Release

(C) Production Capacity (Section Wise)

PRODUCTION CAPACITY

Tablet Section

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	Production Capacity allotted for... (Name of Procurement Agency/ Body).
(1)	(2)	(3)	(4)	(5)
Planatery mixer				
Fluidized bed drier				
Tray drier				
Mechanical shifter				
Multi mill				
Tablet compression machine				
1) With ..... number of station				
2) With ..... number of station				
3) With number of station				
4) With ..... number of station				
Coating pan.				
Blister Packing machine				
Strip packing machine				

Capsule Section

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	Production Capacity allotted for...(Name of Procurement Agency/ Body).
(1)	(2)	(3)	(4)	(5)
Double cone blender				
Automatic capsule filling machine				

Parenteral Section

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	Production Capacity allotted for...(Name of Procurement Agency/ Body).
(1)	(2)	(3)	(4)	(5)
Small volume Parenteral				
Mixing Vessel				
Laminar Flow unit				
Filtration unit				
Ampoule filling machine (with No of head)				
Vial filling Machine (with No of head)				
Vial sealing machine				
Powder filling machine				
Autoclave for terminal Sterilization				
Ampoule labeling machine				
Vials labeling machine				

Large Volume Parenterals

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	Production Capacity allotted for...(Name of Procurement Agency/ Body).
(1)	(2)	(3)	(4)	(5)
Mixing vessel				
Filtration Unit.				
Filling Machine Autoclave for terminal Sterilization				
Labeling Machine				

Ointment/ Cream

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	Production Capacity allotted for... (Name of Procurement Agency/ Body).
(1)	(2)	(3)	(4)	(5)
Stream jacket vessel for mixing				
Ointment/cream filling machine				

Liquid Section

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	Production Capacity allotted for... (Name of Procurement Agency/ Body).
(1)	(2)	(3)	(4)	(5)
Bottle washing machine				
SS tank with capacity				
Filter press				
Colloidal mill				
Bottle Filling Machine				
Labeling Machine				

External Preparation

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	Production Capacity allotted for...(Name of Procurement Agency/ Body)
(1)	(2)	(3)	(4)	(5)
Mixing Vessel				
Filling machine				
Labeling machine				

(D) Any, Not Of Standard Quality : Yes / No

Reports of Product Quoted/
Approved By .....(Name of Procurement Agency/ Body).

(If Not, Nil Statement)

(E) Any Prosecution After : Yes / No

Submission of Tender Documents.
(If Not, Nil Statement)

(F) Chances Of Cross Contamination : Yes / No
at Raw Materials/In Process/ Finished
Product Stages and Steps/Facilities

(G) Validation of Equipments done : Yes / No

(H) Cleaning Schedule

(I) For Premises :

(II) For Equipments

(I) Adverse Reaction, If Any and Reported :

Sl.No.	Description	Remarks
1	Whether any drug(s) manufactured by the tenderer has / have been recalled during last five years? If yes given details	
Sl.No.	**Description**	**Remarks**
2	What are the results of investigations on the recalled drug(s)?	
3	What action have been taken to prevent recurrence of recall of drug(s) on that particular account?	

(J) Complaints Received If Any and Steps taken. :

Sl.No.	Description	Remarks
1	Whether any drug(s) manufactured by the tenderer has / have been recalled during last five years? If yes given details	
2	What are the results of investigations on the recalled drug(s)?	
3	What action have been taken to prevent recurrence of recall of drug(s) on that particular account?	

Signature and seal of Proprietor/Partner/Director

To be attested by the Notary

INSTRUMENT INVENTORY

Sl. No.	Name of the Instruments	No. of Instruments	Cost of Instruments	Whether it is in working condition
1	Analytical Balance			
2	Infra Red Spectrometer			
3	Karl Fisher Tritator			
4	Melting Point			
5	Brookfield Viscometer			
6	Polarimeter			
7	Autoclave			
8	Refractometer			
9	Sampling Booth			
10	UV-Vis Spectrometer			
11	HPLC			
12	Muffle Furnace			
13	Fuming Cupboard			
14	Micrometer			
15	Dissolution Tester			
16	Disintegration Tester			
17	Friability Tester			
18	Vernier Calipers			
19	IR Balance			
20	Hardness Tester			
21	Leak Test Apparatus			
22	Laminar Air Flow			
23	BOD Incubator			
24	Vacuum oven			
25	Bulk Density Apparatus			
26	Water Activity Meter			
27	Anaerobic System			
28	Gas Chromatograph			
29	LAL Kit			
30	Sterility Test Kit			
31	Particle Counter			
32	Air Sampler			
33	Flame Photometer			
34	Tap Density Tester			

ANNEXURE - IV : REF. CLAUSE NO.7.1 (A)

DETAILS OF E.M.D. SUBMITTED

We herewith submit the E.M.D. of Rs. .....in the form of Demand Draft bearing No. ..... Dated: ..... Drawn On. .... Bank ..... Branch in favour of ..... (Name of Procurement Agency/ Body) for the following items of drugs.

Sl. No.	Drug code*	Name of the Drug	Amount of E.M.D.
		Total	

* in ascending order as in Annexure-VIII.

Signature & Seal

ANNEXURE - V

NOTORISED UNDERTAKING

(In 20- Rupees stamp paper)

I ....., S/o ....., Proprietor / Partner / Managing Director of ..... (Proprietary Concern / Firm / Company Ltd.) execute this Undertaking for myself and on behalf of (Proprietary Concern / Firm / Company Ltd.).

2. Where as ..... (Name of Procurement Agency/ Body) (Tender Inviting Authority) has invited Tender for supply of drugs and medicines for the year 2014-2015 and in pursuant to the conditions in the tender documents. M/s ..... (Proprietary Concern/ Firm / Company Ltd.), having its Office at..... .... is exempted from payment of Earnest Money Deposit as indicated in the Annexure-VIII of tender document.

3. and where as, in pursuant to the conditions in Clause Nos. 7.2 & 7.3(viii) of the tender, the Earnest Money Deposit can be forfeited by the Tender Inviting Authority in case of violation of any of the conditions and for non-performance of the obligation under tender document.

4. In consideration of exempting M/s. ..... (Proprietary Concern/ Firm / Company Ltd.) from payment of Earnest Money Deposit as indicated in the Annexure-VIII of tender document, I undertake to pay the said sum without any demur on receipt of demand issued by the tender inviting authority.

M/s. .....

for Self and Firm / Company Ltd.

Signature and Seal

Witness:

(1)

(2)

ANNEXURE - VI: REF. CLAUSE NO. 4.4 (A.10)

PROFORMA FOR PERFORMANCE

STATEMENT

Name of firm .....

Sl.	Name of the product	Year	No. of batches manufactured / imported & supplied	Batch No.	Name and full address of the purchaser
	(1)	(2)	(3)	(4)	(5)
1					
2					
3					
…					

Note : Proof for the manufacturing (BMR) / importing and supply for marketing of the drug quoted to be attached

Signature and seal of the Tenderer

ANNEXURE - VII

Annual Turn Over Statement

The annual Turnover of M/s. ..... for the past three years are given below and certified that the statement is true and correct.

Sl.No.	Financial Year	Turnover in Lakhs (Rs)	
1.	–<Year>		
2.	–<Year>		
3.	–<Year>		

Total - Rs. ..... Lakhs.

Average turnover per annual - Rs.....Lakhs.

Signature of Auditor/ Chartered Accountant

(Name in Capital)

Date

Seal

ANNEXURE - VIII

TENDER FOR THE SUPPLY OF DRUGS FOR THE YEAR…

CATEGORY "A" DRUGS

1. Every Consignment of Blood and related products should be certified to be

   (a) AIDS Free (b) Hepatitis B Free

2. Strips of Aluminium foils refer to gauge (Specifications…….)
3. Aluminium foils as back material for blisters refer to gauge (Specifications…….).
4. The rigid PVC used in blister packing should be of not less than (Specifications…….).
5. All glass bottles should be new neutral glass.
6. Ointments should be packed in liquidized Aluminium Tubes.
7. Small Tablets packed in blisters should be packed to facilitate easy removal of the tablet without breaking / crushing.
8. Specification of outer cartons are as given in the Schedule (Annexure-IX)
9. In case of any conflict between Carton specifications and packets per carton specification (Last column of this table), the specification of the packets / carton shall prevail.
10. All tablets should have a score line.
11. All plastic containers should be made of virgin grade plastics.
12. All plastic jars above 450Gms / ml should carry an inner plastic lid.
13. Injection in vials should have a flip of seals.
14. The strips shall be aluminium strip / blisters with aluminium foil back.
15. The minimum diameters of each tablets should be of (Specifications…….).
16. The outer carton should be of white board with a minimum of (Specifications…….). with laminated packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with white board of (Specifications…….)..

TENDER FOR THE SUPPLY OF DRUGS FOR THE YEAR…

CATEGORY "A" DRUGS

(LIST OF DRUGS IS MEANT TO BE ILLUSTRATIVE ONLY)

Sl. No.	Drug Code	Drug Name / Specification	Unit	Approx Tender Qty in Units	Packing Per Carton Specification	EMD Value (`)
1	2	Paracetamol Tab. IP Strength : 500 mg Packing : Blister with Aluminium Back	10X10 tabs		100X10X10	
2	3	Paracetamol Syrup. IP Strength : 125mg/5ml Packing : Pet / Glass Bottle with Dosage Cap	60 ml Bottle		100X 60 ml Bottles/ Carton	
3	4	Co-Trimoxazole Oral suspension IP Strength : Bottles of 50 ml Each 5ml contains Trimethoprim - 40 mg and Sulphamethoxazole - 200 mg acking : Pet / Glass Bottle with Dosage Cap	50 ml Bottle		100X 50 ml Bottles/ Carton	

ANNEXURE - IX

I. SCHEDULE FOR PACKAGING OF DRUGS GENERAL PECIFICATIONS

1. No corrugate package should weigh more than 15 kgs (ie., product inner carton+ corrugated box).
2. All Corrugated boxes should be of `A' grade paper ie., Virgin
3. All items should be packed only in first hand boxes only.

FLUTE:

4. The corrugated boxes should be of narrow flute.

JOINT:

5. Every box should be preferably single joint and not more than two joints

STITCHING:

6. Every box should be stitched using pairs of metal pins with an interval of two inches between each pair. The boxes should be stitched and not joined using calico at the corners

FLAP:

7. The flaps should uniformly meet but should not over lap each other. The flap when turned by 45 - 60° should not crack.

TAPE:

8. Every box should be sealed with gum tape running along the top and lower opening.

CARRY STRAP:

9. Every box should be strapped with two parallel nylon carry straps (they should intersect).

LABEL:

10. Every corrugated box should carry a large outer label clearly indicating that the product is for **"……..Govt. Supply - Not For Sale"**. The lower one third of the large label should indicate in bold, the value of the product as depicted in Annexure II of this document.

11. The product label on the carton should be large at least 15cms x 10cms dimension. It should carry the correct technical name, strength or the product, date of manufacturing, date of expiry, quantity packed and net weight of the box.

OTHERS:

12. No box should contain mixed products or mixed batches of the same product.

II. SPECIFICATION FOR CORRUGATED BOXES HOLDING TABLETS / CAPSULES / PESSARIES

(1) The box should not weigh more than 7-8 kgs. The grammage of outer box should be 150 gm/m² (gsm) and inside partition / lining should be 120 gsm.

(2) The box should be of 5 ply with Bursting strength of 9 Kg/ Cm2

III. SPECIFICATIONS FOR OINTMENT / CREAM / GELS PACKED IN TUBES:

(1) No corrugate box should weigh more than 7-8 kgs.

(2) Every Ointment tube should be individually packed in carton and then packed in 20's in a grey board box, which may be packed in a corrugated box.

(3) Grammage Outer box should be 150 gsm inside partition /lining should be120 gsm.

IV. SPECIFICATIONS FOR INJECTABLE (IN VIALS AND AMPOULES)

(1) Vials may be packed in corrugated boxes weighing upto 15 Kgs. Ampoules should be packed in C.B weighing not more than 8 kgs.

(2) C.B. for vials should be of 150 gsm (outer box should be 150 gsm and inside partition / lining should be 120 gsm) and 7 ply, while C.B. for ampoules should be of 150 gsm (outer box should be 150 gsm and inside partition / lining should be 120 gsm) and 5 ply.

(3) Bursting strength for CB boxes for

a.	Vials	:	Note less than 13 Kg/Cm2
b.	Amp	:	Note less than 9 Kg/Cm2

(4) In the case of 10 ml Ampoules 100 or 50 ampoules may be packed in a grey board box. Multiples of grey board boxes packed in CB. In case of ampoules larger than 10 ml only 25 ampoules may be packed in a grey board box with partition.

(5) If the vial is packed in individual carton, there is no necessity for grey board box packing. The individual carton may be packed as such in the CB with centre pad

(6) In case of ampoules every grey board box should carry 5 amps. Cutters placed in a polythene bag.

(7) Vials of eye and ear drops should be packed in an individual carton with a dispensing device. If the vial is of FFS/BFS technology, they should be packed in 50's in a grey board box

Annexure - X

Ref. Clause No.11.1

THIS AGREEMENT made the..... day of ....., Between ……..(Name of Procurement Agency/ Body with Address. (Name of purchaser) of ..... (Country of Purchaser) (here in after "the Purchaser") of the one part and ..... (Name of Supplier) of

..... (City and Country of Supplier) (here in after called "the Supplier") of the other part :

WHEREAS the Purchaser is desirous that certain Goods and ancillary services viz;. Supply of Drugs in the tender Reference No.

..... (Brief Description of Goods and Services) and has accepted a bid by the Supplier for the supply of those goods and services for the sum of .....(Contract Price in Words and Figures) (hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to, and they shall be deemed to form and be read and construed as part of this agreement.

2. The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:

(a) The Letter of Acceptance issued by the Procurement Agency

(b) The Notice Inviting Tender

(c) The supplier's bid including enclosures, annexures, etc.

(d) The Terms and Conditions of the Contract

(e) The Schedule of Requirement

(f) The Technical Specification

(g) Any other document listed in the supplier's bid and replies to queries, clarifications issued by the purchaser, such confirmations given by the bidder which are acceptable to the purchaser and the entire Addendum issued as forming part of the contract.

3. In consideration of the payments to be made by the Procurement Agency to the Supplier as hereinafter mentioned, the Supplier hereby enters into this contract with the Procurement Agency to provide, the goods and services and to remedy defects therein in conformity in all respects with the provisions terms and conditions in the notice inviting bids .

4. The purchaser hereby agrees to pay the Supplier in consideration of the provision of the goods and services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

Brief particulars of the goods and services which shall be supplied / providedby the Supplier are as under.

Sl. No	Drug Code	Brief Description of Goods & Services	Tender Qty in Unit*	Unit Price	Sales tax in %	Total value inclusive of sales tax
Total contract value						

* Tender quantity indicated here is tentative and may vary subjected to various terms and conditions of the tender.

IN WITNESS where of the parties here to have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the said..... (For the Purchaser) in the presence of ....

Signature

Name

Address

Signed, Sealed and Delivered by the Said ..... (For the Supplier) in the presence of .....

.....
Signature

Name

Address

Annexure - XI

PERFORMANCE SECURITY BANK GUARANTEE

(UNCONDITIONAL)

To : **.....**

(Name of Procurement Agency/ Body) (Name of Purchaser) (Address of Procurement Agency/ Body)

WHEREAS ..... (Name of the Supplier) herein called "the Supplier" has undertaken, in pursuance of Tender No…**.....,** dated…**.....** to supply of **Drugs for the year .....**. (Description of Goods and Services) hereinafter called "the Contract".

AND WHEREAS it has been stipulated by you in the said Contract that the Supplier shall furnish you with a Bank Guarantee by a recognised bank for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.

AND WHEREAS we have agreed to give the Supplier a Guarantee

THEREFORE WE hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, upto a total of..... (Amount of the Guarantee in Words and Figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument, any sum or sums within the limit of ..... (Amount of the Guarantee in Words and Figures) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This guarantee is valid until the ..... day of ..... 20. . .....

Signature and Seal of Guarantors

.....

.....

.....

Date ..... 20 .....

Address .....

.....

.....

Annexure - XII

DETAILS OF MANUFACTURING /IMPORTING UNIT

Name of the Tenderer & Full Address :

PAN Number: TIN Number:

Phone Nos.

Fax: E-Mail :

Date of Inception: Licence No. & Date :

Issued by: Valid up to:

Details of installed Production Capacity:

Details of Installed Production Capacity for 30 days (In Terms of Unit Packs)

Tablets

Capsules

General

Beta-Lactum

Injections

Ampoules

Vials

I.V.Fluids

Sterile Powder

Liquids

Suspension

Syrups

Drops

Ointment

Powders

Antiseptics /

Disinfectants

Name & designation of the authorised signatory :

Specimen signature of the authorized Signatory :

* The details of manufacturing unit shall be for the premises where items quoted are actually manufactured

Annexure - XIII

List of Items quoted

1. Name of the firm and address as given in drug license:
2. Drugs Licence No. in form 25 & 28 or import Licence No:
3. Date of issue & validity:
4. Revised schedule M compliance Certificate obtained on:
5. Non-conviction Certificate Obtained on:
6. Market standing Certificate obtained on:
7. Monthly Production Capacity earmarked to ……Procurement Agency/Body

In the event of the bidder becoming L1 for more than one item, if the total annual quantity for such items is more than the capacity earmarked to Procurement Agency/Body, the procurement body reserve the rights to decide any appropriate item(s) within his production capacity.

8. Details of Endorsement for all products quoted

Sl. No	Drug Code	Drug Name	Specifications IP/BP/USP	Date of Endorsement obtained from the State Drugs Controller	Whether Endorsement is in Generic or Trade Name	Qty Earmarked for Procurement Agency	Mfg Capacity for 30 days)	Value of EMD
1.								
						EMD Total		

Authorised signatory :

Date :

Annexure - XIV

Ref. clause 15.2

BOX NO	:
PO NUMBER	:
SUPPLIER CODE	:
SUPPLIER NAME	:
DRUG CODE	:
DRUG NAME	:
BATCH NO	:
MFG DATE	:
EXPIRY DATE	:
BATCH QUANTITY	:
INVOICE NO	:
D C NO	:

Annexure - XV

01	Company Name	
02	Postal Address of the company with Telephone No., Fax No. and Mail I.D.	
03	Name of the Managing Director Director / Manager Mobile No. / Phone No. E-mail I.D.	
04	Name and Designation of the authorized company official Mobile No. E-mail ID	

Date: Company Seal Signature

Place: (Name of the person signing & designation)

01	Name of the Bank . Branch Name& address Branch Code No. Branch Manager Mobile No. Branch Telephone no. Branch E-mail ID	
02	9 digit MICR code number of the bank and branch appearing on the MICR cheque issued by the bank.	
03	IFSC code of the Branch	
04	Type of Account (Current / Savings).	
05	Account Number (as appear in cheque book)	

(in lieu of the bank certificate to be obtained, please **attach the original cancelled cheque** issued by your bank for verification of the above particulars).

I /We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all for reasons of incomplete or incorrect information, I would not hold M/s. ……. responsible. I have read the conditions of the tender/agreement entered and agree to discharge the responsibility expected of me / from the company as a tenderer /successful tenderer.

Date: Company Seal Signature

Place: (Name of the person signing & designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

Bank Seal with address. Signature of the authorized official of the bank

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Annexure - XVI

FORMAT FOR SUBMITTING BANK GUARANTEE AS EARNEST MONEY

TENDER NO.

(To be submitted in Rs. 50/- Non-Judicial Stamp Paper to be purchased in the name of the issuing bank)

To

<Tender Issuing Authority>

<Address>

WHEREAS ……...…….... (Bidder's name) (Hereinafter referred to as "Bidder"), a Corporation/ Company/ Firm having its registered office at _____ is required to deposit with you, by way of Earnest Money, Rs <amount>< amount in words> in response to abovementioned Tender issued by you for the work.

WHEREAS the Bidder as per < Tender Condition, Paragraph No > has agreed to establish a Bank Guarantee in Your favour through us valid up to <Date>, We <Bank> hereby agree and undertake to pay you on demand the said amount of <amount> <amount in words> without any protest or demur in the event the Bidder after submission of his bid, resiles from or withdraws his offer or modifies the terms and conditions thereof in a manner not acceptable to you or is rejected on the ground of making any false claim or expresses his unwillingness to accept the order placed and/ or letter of intent issued on him or fails to sign the contract within stipulated period for supply under "Notice Inviting Tender (TENDER NO. < > dated <date>) or fails to fulfill any of the conditions required of him to perform after accepting the offer.

1. Your decision as to whether the Supplier/Tenderer has resiled from or has withdrawn his offer or has modified the terms and conditions thereof in a manner not acceptable to you or has been rejected on the ground of making any false claim or has expressed his unwillingness to accept the order placed and/or Letter of Intent issued by you on the Bidder for the supply under Notice Inviting Bid <Notice Inviting Tender dated _____> in this regard or has failed to fulfill any of the conditions required of him to perform after having accepted the offer, shall be final and binding on us and we shall not be entitled to question the same.

2. Notwithstanding anything contained in the foregoing, our liability under this Guarantee shall be restricted to < amount> <amount in words>.

3. This Guarantee shall remain valid and in full force and effect up to ……..…….. (Date) and shall expire thereafter unless an intimation is given to the Bank by you earlier in writing discharging us from our obligation under this Guarantee.

4. We shall not revoke this Guarantee during its currency except by your consent in writing.

5. This Guarantee shall not be affected by any change in the constitution of the Bidder or yourselves or ourselves but shall ensure to your benefit and be enforceable against our legal successors or assignees by you or your legal successors.

6. Notwithstanding anything contained herein above unless a demand or claim under this Guarantee is made on us in writing within six months from the date of expiry of this Guarantee we shall be discharged from all liabilities under this Guarantee thereafter.

7. We have power to issue this Guarantee under our Memorandum and Articles of Association and the undersigned who is executing this Guarantee has the necessary power to do so under a duly executed Power of Attorney granted to him by the Bank.

Signed and Delivered For and on behalf of……...Bank

(Banker's Name) Name of Bank Manager ……..

Annexure - XVII

CHECK LIST

Cover-A

Sl.No	Document		Yes	No
1.	Checklist – Annexure-XVII	1		
2.	EMD in the form of DD shall be kept in an envelop as per Annexure-IV. SSI certificate for exemption			
3.	Under taking of domestic SSI units			
4.	Documentary evidence for the constitutions of the company / concern			
5.	Duly attested photocopy of License for the product duly approved by the Licensing authority for each and every product quoted.			
6.	Duly attested photocopy of Import License, if imported and whole sale Drug license			
7.	The instruments such as power of attorney, resolution of board etc.,			
8.	Authorization letter nominating a responsible person of the tenderer to transact the business with the Tender inviting Authority.			
9.	Market Standing Certificate issued by the Licensing Authority			
10.	True copy of record of manufacture to establish 3 years market standing.			
11.	Non Conviction Certificate issued by the Drugs Controller			
12.	Good Manufacturing Practices Certificate			
13.	Annual Turnover Statement for 3 Years Annexure - VII			

Sl.No	Document		Yes	No
14.	Copies of balance sheet & profit loss Account for three years			
15.	Annexure-I			
16.	Annexure-II			
17.	Declaration Form in Annexure-III along with enclosure.			
18.	Proforma for Performance Statement Annexure-VI			
19.	Details of Manufacturing/Importing Unit in Annexure-XII			
20.	WHO, UNICEF, ISO certificates if any			
21.	Details of Technical personnel employed in the manufacture and testing			
22.	List of items quoted without rates. Annexure-XIII			
23.	Mandate Form Annexure-XV			
24.	The Tender document signed by the tenderer in all pages with office seal			

Annexure - XVIIIA

TENDER FOR THE SUPPLY OF DRUGS FOR THE YEAR .....

BREAK UP OF LANDED PRICE PER UNIT

CATEGORY "A" DRUGS

(LIST OF DRUGS IS MEANT TO BE ILLUSTRATIVE ONLY)

Sl. No	Drug Code	Name of the Drug and Unit	Basic Price Inclusive of Incidental Charge (Per Unit) (Rs.P)	Packing & Forwarding Charges (Per Unit) (Rs.P)	Excise / Customs Duty (Per Unit) (Rs.P)	Freight and Insurance Charges (Per Unit) (Rs.P)	Total Landed Price (in Figure) (Per Unit) (4+5+6+7) (Rs.P)	Rate per Unit in Words	CST / VAT (% Only)	Excise / Customs Duty		Production Capacity in 30 Days
										Tariff %	Cht. No.	
1	2	3	4	5	6	7	8	(9)	10	11	12	13
1	2	Paracetamol Tab. I.P. - 500mg Unit : 10 X 10 Tabs										
2	3	Paracetamol Syrup. I.P. - 125mg/5ml Unit : 60 ml Bottle										
3	4	Co-Trimoxazole Oral Suspension I.P. Unit : 50 ml Bottle										
...	...											
...	...											

Note: The firms shall indicate the break up prices at Column 4 to 7 and 10, 11 separately and wording like "Included" shall not be substituted for the same.

Annexure - XVIIIB

Ref. Clause 5

TENDER FOR THE SUPPLY OF DRUGS FOR THE YEAR .....

BREAK UP OF LANDED PRICE PER UNIT

CATEGORY "B" DRUGS

(LIST OF DRUGS IS MEANT TO BE ILLUSTRATIVE ONLY)

Sl. No	Drug Code	Name of the Drug and Unit	Basic Price Inclusive of Incidental Charge (Per Unit) (Rs.P)	Packing & Forwarding Charges (Per Unit) (Rs.P)	Excise / Customs Duty (Per Unit) (Rs.P)	Freight and Insurance Charges (Per Unit) (Rs.P)	Total Landed Price (in Figure) (Per Unit) (4+5+6+7) (Rs.P)	Rate per Unit in Words	CST / VAT (% Only)	Excise / Customs Duty		Production Capacity in 30 Days
										Tariff %	Chpt. No.	
1	2	3	4	5	6	7	8	(9)	10	11	12	13
1	12	Theophylline and Etofylline Inj. Unit : 2 ml Amp										
2	17	Cyanocobalamine Inj. I.P. - 100mcg/ml Unit : 2 ml Amp										
3	23	Methyl Ergometrine Inj. I.P. - 0.2mg/ml Unit : 1 ml Amp										
.....	.....											
....	.....											

Ministry of Health and Family Welfare
Government of India