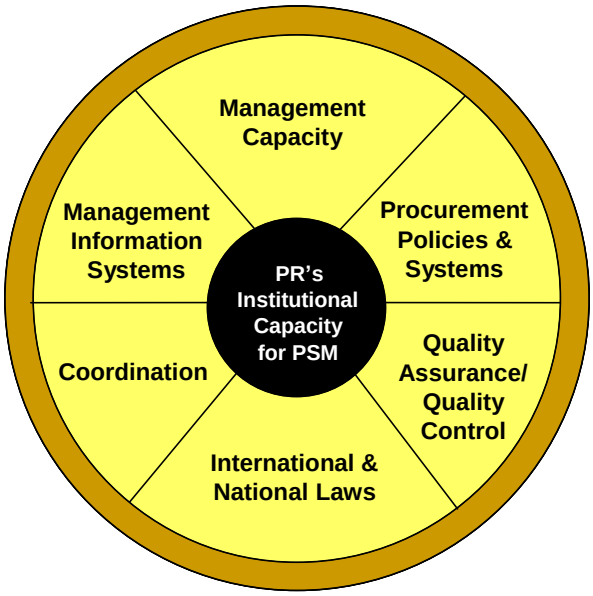
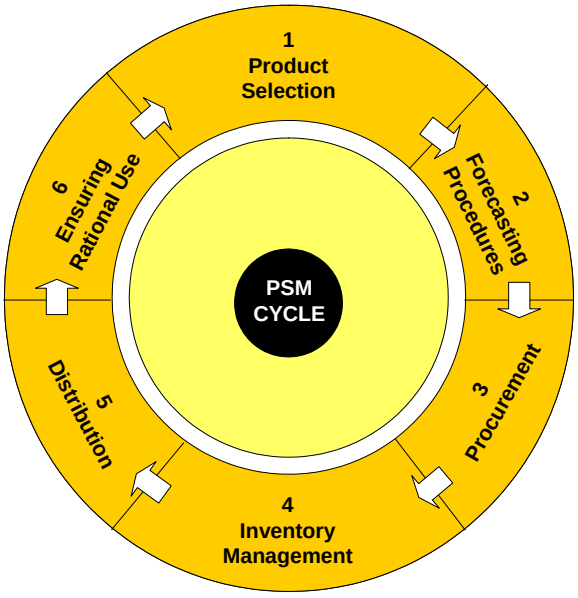
Procurement and Supply Management Plan





For Phase II (Oct.2012-Sept. 2015)

Of

Intensified Malaria Control Project-II

(Oct. 2010- Sept.2015)

Directorate of National Vector Borne Disease Control Programme
(PR-1- Malaria- Round 9)
22-Sham Nath Marg, Delhi-110054
India

Procurement and Supply Management Plan

For the period from year **October 2012** to year **Sept. 2015**

Proposal/grant title:	**Intensified Malaria Control Project – II**
Principal Recipient(PR):	Department of Economic Affairs, Ministry of Finance, Government of India (PR-1)
Country:	**India**
Component:	Malaria
Round:	IX
Phase 1 or Phase 2:	**Phase 2** (1st October 2012 to 30th September 2015)
Grant number:	**IDA-911-G23-M**

	Product category	Year 1 (US$)	Year 2 (US$)	Year 3 (US$) if applicable	Total phase (US$)
1	Pharmaceuticals	670,370	245550	600990	1516910
2	Health products & commodities (excluding pharmaceuticals & health equipment) including scaling of LLIN	15,072,463	7089699	11843251	34005413
3	Health equipment (X-rays, laboratory equipment, etc.)				
4	Services (related to PSM e.g., QA, MIS, RUD, PV, DRS, etc including handling charges.)	629714	293410	497770	1420894
5	Non-health products and services (e.g., vehicles, computers, construction, financial consultants, etc.)	342477	0	0	342477
Total		**16715024**	**7628659**	**12942011**	**37285694**
Total grant size (US$)		**24391943**	**16072311**	**20516553**	**60980807**
Total procurement as % of grant		68.52%	47.46%	63.08%	61.14%

Person (name, title, department) with overall responsibility for this grant. Provide name and contact details (tel., e-mail, etc.).	**Ministry of Health & Family Welfare, Govt. of India**
Person (name, title, department) with overall responsibility for all PSM activities. Provide name and contact details (tel., e-mail, etc.).	Dr. A. C. Dhariwal, Director, National Vector Borne Disease Control Programme 22-Sham Nath Marg, Delhi-110054 91-11-23918576, 23955510, 23994075 91-11-23968329 nvbdcp-mohfw@nic.in
Date of submission(s): Revised one	First submission: 14th Jun 2012 (with renewal proposal) **Revised on 24th December 2013**

Introduction:

PROJECT GOAL
To reduce malaria related mortality and morbidity in project areas by at least 30% by 2015 as compared to 2008.

PROJECT OBJECTIVES AND SERVICE DELIVERY AREAS (SDAs)

- To achieve near universal coverage by 2015 by effective preventive intervention (LLIN) for population living in high risk project areas from 42% (2009-10).
    - SDA: ITN (LLIN)

- To achieve at least 80% coverage by parasitological diagnosis; and prompt, effective treatment of malaria through public and private health care delivery systems in project areas by 2015.
    - SDA: Diagnosis (RDT)
    - SDA: Prompt, effective treatment (ACT, Injectable artemisinin derivatives)

- To achieve at least 80% coverage of villages in project areas by 2015 by appropriate BCC activities to improve knowledge, awareness and responsive behavior with regard to effective preventive and curative malaria control interventions.
    - SDA: Community outreach/IPC
    - SDA: Mass media

- To strengthen program planning and management, monitoring and evaluation, and coordination and partnership development to improve service delivery in project areas.
    - SDA: HSS: Human resources (technical and management assistance, planning and administration assistance, M&E assistance teams)
    - SDA: HSS: Information systems (M&E)
    - SDA: Coordination and partnership development (public-private/NGO/FBO, etc)

- To strengthen health systems through training, capacity building to improve service delivery in project areas.
    - SDA: HSS: Human resources (training/capacity building)

PROJECT AREAS
The Round 9 IMCP--II project is proposed for 86 districts in the seven NE (North-East) states in entirety. The states are: Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, and Tripura.

Project beneficiaries: 42.53 million population (2008) in 86 districts in 7 states, with particular focus on the tribal populations, other marginalized groups; and the vulnerable sections of society - women and children.

Key Implementing entity (ies):

- Principal Recipient 1(PR1) - NVBDCP (responsible for National Malaria Control Program)
    - 7 Sub Recipients, namely, the states of Assam, Arunachal Pradesh, Manipur, Mizoram, Meghalaya, Nagaland and Tripura. To carry out all the project activities.

- Principal Recipient 2 (PR2) —Caritas India led FBO/NGO/private sector consortium. [SRs - Christian Medical Association of India, Voluntary Health Association of India, Futures Group International India Pvt Ltd]. PR2 will complement activities of PR1 at community level in 49 districts in 7 project states that include remote, hard to reach areas. Major activities will include: LLIN distribution; RDT/ACT use; BCC; training of community workers/volunteers and private sector care providers].

1. PR's capacity to conduct Procurement and Supply Management – PSM

1.1 Management capacity

The entities involved in the various Pharmaceutical and Health Product Management (PHPM) related activities and the PR's capacity to manage and implement various activities are described in the following table:

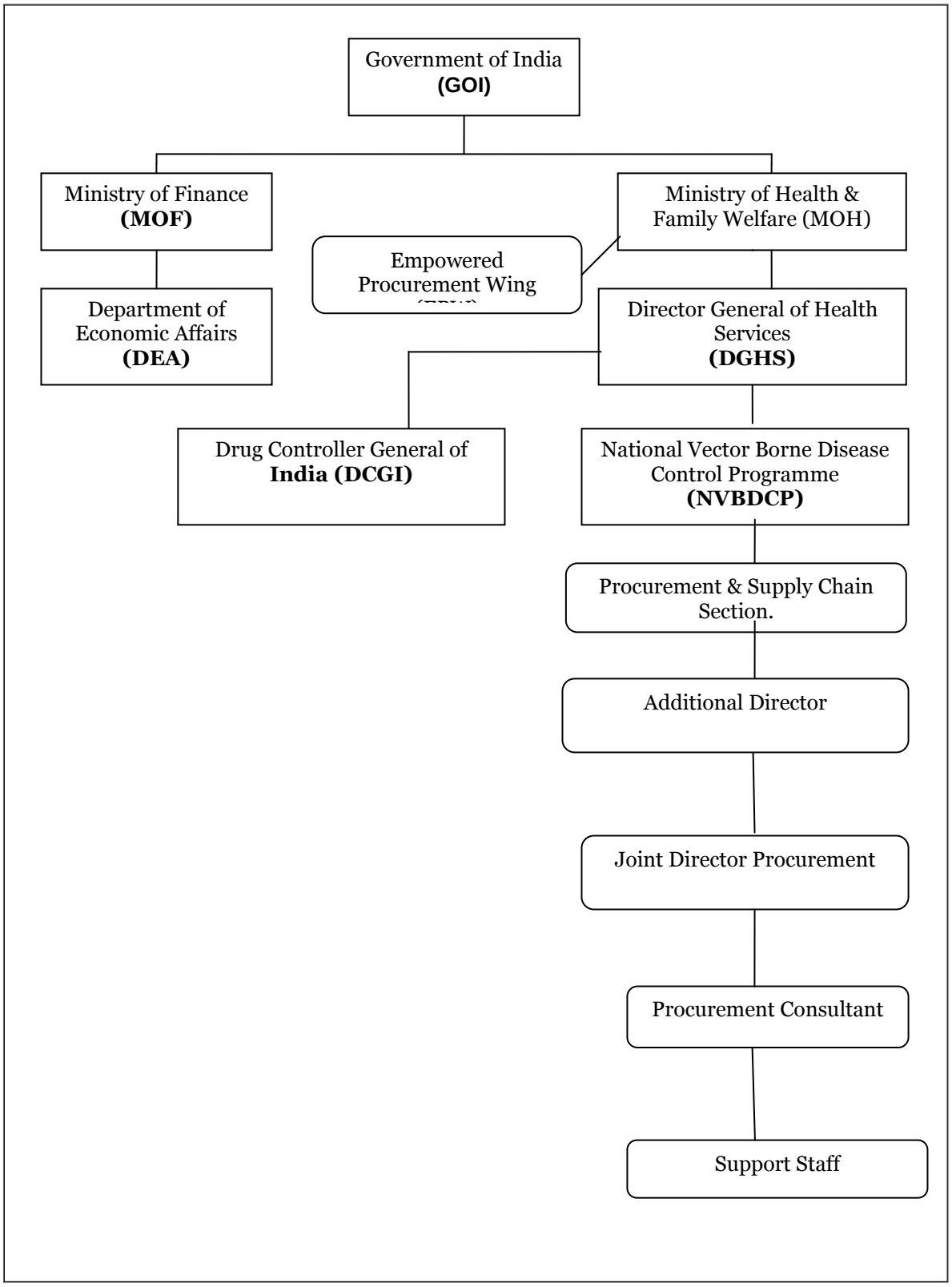
Activity	**Which organization and/or department is responsible for this function? If this function is being outsourced, then indicate this in the table (if more than one, include all organizations).**	**What type of organization is responsible for this function?** **(PR, SR, Procurement Agent or Other)**	**Indicate if there is need for additional staff or technical assistance** **(Yes/No)** **If yes, this should be reflected in the PSM Plan narrative and budget, if appropriate**	**If there is a need indicate whether it was considered in the original proposal** **(Yes/No)** **If no, explain how the need will be addressed and whether sufficient funds are available**
Procurement policies & systems	Empowered procurement Wing (EPW), Ministry of Health and Family Welfare / NVBDCP & M/s RITES Ltd ROH&FW (Guwahati, Imphal, Kolkata, Shillong) State Malaria Control Departments Caritas India(PR II) WHO (Emergency) GFATM-PSS (VPP)	PR 1 (National Program for Vector Borne Disease Control) Procurement Agent GoI Regional Offices for Vector Borne Disease Control Coordination and Monitoring SR- Departments for Vector Borne Disease Control Program under MOH of respective Provincial Governments NGO UN organization Donor agency	**Yes**	**Yes.**
Quality assurance (including quality control of pharmaceuticals)	EPW & Procurement Agency (PA) of MOHFW- M/s RITES Ltd. NVBDCP NIMR	EPW & Procurement agent- M/s RITES Ltd. Pre-dispatch and post dispatch inspection is to be done by the procurement agency through an independent accredited Laboratory. Procurement Agency (RITES) has empanelled independent inspection and Quality assurance agency for *pre*-dispatch quality assurance for all goods PR 1 (National Program for Vector Borne Disease Control) National Institution for Malaria Research (For post	**Yes**	**No (Through Domestic fund of Govt. of India)**

		dispatch QA of RDTs)		
International and national laws (patents)	Ministry of Health and Family Welfare DCG(I)	PR 1 (National Program for Vector Borne Disease Control) Drug Controller General of India	**No**	**No**
Coordination	Ministry of Health and Family Welfare/NVBDCP PSA Caritas India	PR 1 (National Program for Vector Borne Disease Control) Procurement Agency PR 2	**No**	**No**
Management Information Systems (MIS)	NVBDCP Strategic Alliance Management Services India	PR 1 (National Program for Vector Borne Disease Control) / MIS of NVBDCP Outsourced agency for monitoring Logistics and SCM	**Yes**	**No. (Supply Chain & Logistic Agency hired by NVBDCP under WB supported project)**
Product selection	Ministry of Health and Family Welfare (Procurement Committee) / NVBDCP	PR 1 (National Program for Vector Borne Disease Control)	**No**	**No**
Forecasting	NVBDCP Caritas India State Malaria Control Departments	PR 1 (National Program for Vector Borne Disease Control) PR 2 Departments for Vector Borne Disease Control Program under MOH of respective State Governments	**No**	**No**
Procurement and planning	EPW, Ministry of Health and Family Welfare through PA (M/s RITES Ltd.) /NVBDCP /SVBDCP WHO (Emergency) GFATM-PSS (VPP)	PR 1 (National Program for Vector Borne Disease Control) SR States UN organization Donor agency	**No**	**No**
Inventory management	NVBDCP Caritas India State Malaria Control Departments / Govt. Medical store Deptt. (GMSD) GMSDs & ROH&FW District Malaria Control Departments Caritas India	PR 1 (National Program for Vector Borne Disease Control) PR 2 Departments for Vector Borne Disease Control Program under MOH of respective state Governments/GMSDs for maintaining buffer stock SSR- District level Vector Borne Disease Control Program under MOH of respective state Governments PR 2	**Yes** **Additional manpower is required for logistics monitoring & management at National & state level.** **Presently it is being done by a professional agency for Logistic and Supply Chain hired by NVBDCP under the World Bank project.**	**Yes. The logistics manpower at State Head-quarter has been budgeted in the proposal.**

Distribution to other stores and end-users	NVBDCP State Malaria Control Departments GMSD Caritas India	PR 1 (National Program for Malaria Control) Departments for Malaria Control Program under MOH of respective state Governments SSR- District level Malaria Control Program under MOH of respective state Governments Principal Recipient 2	**Yes**	**Yes. Budgeted in the proposal**
Ensuring rational use	NVBDCP Caritas India State Malaria Control Departments	PR 1 (National Program for Vector Borne Disease Control) PR 2 District level Vector Borne Disease Control Program under MOH of respective state Governments	**No**	**No**
Pharmacovigilance	NVBDCP NIMR State Malaria Control Departments DCGI	PR 1 (National Program for Vector Borne Disease Control) National Institution for Malaria Research District level Vector Borne Disease Control Program under MOH of respective state Governments Drug Controller General of India	**No** **NIMR has been identified for this task under the World Bank project**	**No**
Drug Resistance Surveillance	NVBDCP NIMR State Malaria Control Departments	PR 1 (National Program for Vector Borne Disease Control) National Institution for Malaria Research District level Vector Borne Disease Control Program under MOH of respective state Governments	**No** **NIMR has been identified to take up this task Under World Bank project**	**No**

The following organizational chart of the PR's PSM unit indicates how it fits into the overall structure of the PR, NDRA, MOF, MOH.

Representatives of the Principal Recipient



1.2 Procurement policies, systems and capacity

Procurement of goods, which constitutes 66 % of the total approved grant under the Global Fund Project, for the period of IMCP-II Round 9 Phase –II, would be done through a "Procurement Agent" (PA), hired under the World Bank assisted Malaria Control Project through the process of International Competitive Bidding (ICB) by the Empowered Procurement Wing (EPW) of Ministry of Health & family Welfare (MOHFW). Detailed documented procedures and standard bidding documents of the World Bank for procurement of goods and services and the General Financial Rules, 2005 (GFR) wherever applicable, would also be followed under the Global Fund Project. The PR1 has significant years of experience of successful procurement under the World Bank assisted Malaria Control Project as well as Round-4 GFATM supported IMCP and phase I of Rd 9 supported IMCP-II projects. The current period (Oct 2012 to Sept.2015 is extension of the Phase I of the project which started from October 2010 - the PSM plan of which has been approved by the Global Fund.

Further, documented formalities of Government of India clearly define procurement procedures for procurement of goods and services, to ensure efficiency, competitiveness and transparency of the procurement system.

Programme may use the "Voluntary Pooled Procurement" (VPP) method through procurement support service (PSS) provided by GFATM if required. It will also take care of the QA issues and also increase the fund utilization rate. Programme may adopt the method of 'Emergency procurement' through international agencies like WHO or any other international agency as agreeable to GF to meet the requirement for a short period (usually 6 months' requirement) so that there is no interruption in the supplies and there is no stock-out situation at the grass-root level. Accordingly, the cost estimates may change but the overall expenditure shall not be incurred above the total approved grant including all other expenses.

Directorate of NVBDCP is responsible for entering the required procurement data into the Global Fund Price and Quality Reporting Mechanism (PQRM).

The total value of procurement under Externally Aided Component (EAC) is $ 36.60 million during current year (2012-13), out of which GFATM procurement is US $ 12.0 million (Variation may come due to price variation of items due to fluctuation in the dollar rates)

	Indicate which currency (US$ or Euro) is used	GFATM funding
Estimated value of TOTAL procurement for next 12 months (under Externally Aided Component, i.e, World Bank + Global Fund)	US$ 36.60 million	12.00 million USD (21.40%)

**(Conversion 1$=Rs.50)*

1.3 Quality assurance systems and capacity

All statutory requirements of the Government of India, with regard to procurement of goods and pharmaceuticals, would be followed under the Global Fund Project.

The Drug Controller General (India) is the statutory and regulatory authority for approval / registration of drugs and GMP inspections. For procurement of Pharmaceutical products & commodities under World Bank Project, Bidding is conducted through the International Competitive Bidding procedures specified in the World Bank's Guidelines: Procurement under IBRD Loans and IDA Credits agreed by Ministry of Finance are followed. The same procedures shall be applicable for procurement of pharmaceuticals products and commodities under Global

Fund following the World Bank's procurement guidelines and approved technical specification by the Technical Specification Committee (please refer our official web site http://nvbdcp.gov.in/tech-spec-drugs.html). **Pharmaceutical products (Injection Artesunate, ACT Combi-blister Pack containing Tablet Artemether + Lumefantrine) would be procured by funds from project fund /**or domestic budgetary support**.**

Warranty clause for goods and pharmaceuticals for GFATM project would be the same as being followed for the World Bank project. Wherever indicated, action can be initiated by national/ state regulatory authorities for de-registration / blacklisting of the manufacturer/supplier in case of product failure.

LLINs registered with Central Insecticide Board (CIB) having recommendations/approval of WHOPES and Registration Committee of India/Bureau of Indian Standards would be procured following WB procurement guidelines.

Pre-dispatch and post dispatch inspection is to be done by the procurement agency through an independent accredited Laboratory. Procurement Agency (RITES) has empanelled independent inspection and testing agency for *pre*-dispatch quality assurance for all procured goods. The empanelment has been done by following the World Bank recommended process (i.e. initial EOI, short listing and RFP to the shortlisted firms). In case of Quality Control agencies, similar process has been followed based on ISO17025. The agencies finalized by RITES have been accredited by NABL for Chemical, Biological and Mechanical testing. As such RITES have finalized two agencies for this purpose. It is clearly agreed by all stakeholders that, neither pre-dispatch inspection nor Quality Control testing would be carried out by in house Quality assurance division. It will be done by inspection & testing agencies only.

At present, the programme is procuring only *Pf* specific RDT. But now the programme is planning to introduce bivalent RDT. A QA manual also has been prepared and it has been uploaded in the website of NVBDCP http://www.nvbdcp.gov.in/Doc/SOP-Quality-Assurance-RDT.pdf the document indicates on page 51 regarding ISO certification. As regards QA testing of diagnostics (Pre & Post dispatch), the Global Fund QA policy ISO 17025- presently the country does not have labs compatible with GF- ISO 17025**. Presently, QA of diagnostics (RDT) is done by the existing labs of National Institute for Malaria Research(NIMR), under Indian Council Of Medical Research (ICMR), premier medical research agency of the country .Presently the ISO 17025 certified labs in the country are not certified for QA of RDT nor licensed by state Drug Authority for testing of Diagnostics. They are conducting QA for Drugs and Pharmaceuticals only. Therefore the present arrangement may continue till we have ISO 17025 certified labs for QA of RDT in the country.**

For compliance of the QA policy of GF, the conditions have already been initiated to be included in the bid document for procurement cycle 2012-13. With regards to the previous procurement cycles for 2010-11 & 2011-12, as they have already begun therefore it was not possible for NVBDCP to change the clauses of procurement and therefore the past procurement cycle may be considered as the procurement process is long and involves lot of administrative formalities. Such process cannot be stopped mid-way. The cycle for 2010-11 is complete and 2011-12 is under process. Any change of specification at this stage will lead to unnecessary delay in procurement and may hamper the early diagnosis component of the programme which may have adverse impact on the malaria control activities**. However, for the procurement cycle 2012-13, GF guidelines shall be incorporated in the procurement.**

Further, it is reiterated that necessary QA activities (pre and post dispatch inspection quality assurance) under NVBDCP will be carried out by the QA agency. For the Quality assurance, the budget has been included in the handling charges which have been calculated @ 4% of the cost of the pharmaceuticals and health products. Handling charges includes all activities of pre-dispatch inspection, lab. Testing, quality assurance etc.

Currently 25% buffer stock is procured over and above the technical requirement of states to address any unforeseen demand. States and districts are also advised to monitor their stock at their levels and to avoid stock out situations. Moreover, a professional agency for Supply chain and Logistic system monitoring has been engaged at NVBDCP for monitoring logistics and supply chain systems at NVBDCP. Standard Operating Procedure (SOP) Manual for drug stores prepared at NVBDCP clearly defines desired stocking norms for all levels viz the State, district & sub-district level drug stores, maintenance of which shall ensure optimum availability of drug stocks required to ensure uninterrupted supply of drugs. The system envisaged in the SOP shall ensure easy identification of adequacy of drug stocks at all levels, which shall **The proposed system shall ensure availability of drug stocks as per defined stocking norms in addition to buffer stocks at the GMSDs, which could be utilized as per the need of the state. A onetime buffer stock of 25% of total requirement has to be maintained at all times so as to have a regular and un-interrupted supply of logistics for effective programme implementation as many a times, due to administrative formalities the procurement of logistics is delayed. It is envisaged that the buffer stock will take care of stock-outs occurring because of procurement delays.**

The procurement of Drugs and Pharmaceuticals not in compliance with the Global fund QA policy will be financed from the national resources till the time the QA issues are addressed. Till that time, the funds allocated under the head Drugs and Pharmaceuticals shall be utilized for scaling up of LLINs.

Further, NVBDCP has already initiated the process to include WHO pre qualification to meet the Global Fund QA policy. The NVBDCP plans to procure the WHO pre-qualified drugs & diagnostics for malaria from procurement cycle 2012-13.

The bid document for procurement of RDT includes the following para pertaining to the QA of RDTs:
"…… *shown evidence of compliance [for the factory where the specific goods are manufactured and are being offered for supply] with ISO 13485:2003 (or FDA 21CFR 820) by way of accreditation by an independent recognized certification body, and a protocol for testing QUALITY AND SHELF-LIFE of products by the manufacturer.*

Presently there are no WHO prequalified RDTs, only WHO approved manufacturers are there but they are ISO 13485 compliant. As the procurement process for RDTs is already mid-way change of specification will cause delay in procurement. As the procurement is done for the whole country, it will also result in stock- outs in some states which are already having scanty availability of RDTs. This will seriously hamper the early diagnosis component of the malaria control. For the next procurement process, WHO approved manufacturers clause shall be incorporated in the procurement process.

1.4 International and national laws

India has accepted the WTO regime for both process and product patents. When patented drugs are procured, it will be done in accordance with international laws and prevailing national laws. The country has a patent law that allows for the patenting of pharmaceutical and other health products. Need based TRIPS flexibilities may be used, if permitted under the law/policies of the Government of India, subject to its approval. The agreement with the GFATM will be binding on the PR for compliance of the GFATM policies.

1.5 Coordination

NVBDCP is a well organized programme for control of vector borne diseases (including malaria) in the country, funded through Government's domestic budget. Essentially the funding is from 3 sources viz, Domestic Budgetary support for the whole country, the DBS is not exclusively for non –project states as some activities which are not funded by WB or GF are supported by Domestic budget like IRS spray wages for NE states etc. Besides, some amount of funding is done by state resources also. The external funding agencies are-World Bank for 10 project states, Global Fund for 7 NE states excluding Sikkim. The project area identified under the Global Fund Project for malaria would continue to receive domestic budget support as per the existing pattern. The funds from GFATM would be complementary to the domestic budget, for scaling up of malaria control efforts.

The PR II (Caritas India) is involved in the supply management of Logistics. There is a Project Steering Committee which meets regularly to sort out the issues raised for implementation of coordinated malaria control activities. The meetings are conducted as and when necessary and the programme is kept abreast of the progress at each step by the concerned agency. The coordination mechanism is as per the coordination plan prepared for the coordination between PR1 and PR2 and SRs.

As regards coordination for procurement, to ensure the uninterrupted supply, the programme plans in advance and calculate the requirement based on the technical requirements added by the buffer stock. Based on this consignee list is prepared by the NVBDCP, which is shared with the EPW of MOH for starting the procurement through procurement agency (PA). The states are also informed about the quantity and products which they are going to be supplied from the center and accordingly, they plan for storage and distribution. The stock position is monitored with the help of Logistic and Supply chain monitoring agency engaged at the NVBDCP at the macro level and through reporting in M4 at the micro level.

In case of likely stock-out situation, the programme will request international agencies like WHO for emergency procurement (for 6 months' requirement) if it is not possible to procure drugs and diagnostics required for replenishment. If the procurement is delayed due to various reasons in the country, the programme may adopt the VPP procurement mechanism – a procurement support service of GF which takes shorter lead-time for procurement. Thus, based on the need of the time the procurement will be done in coordination with GF and WHO.

1.6 Management Information Systems (MIS) capacity

A well organized paper-based Management Information System exists under NVBDCP for flow of epidemiological and logistic information. A system of monthly submission of logistics reports (in M4 and to the agency hired for Logistic Supply Chain Management) exists at various levels for reporting opening balance, quantity received during the month, stock distributed, balance and requirements. Further, a system of monthly indents exists from peripheral units (Primary Health Centers / Sub-centers) to districts with comprehensive report on stock opening balance/supplies received/consumed during the previous month and requirement for the next month.

An online computerized MIS software i.e., NAMMIS (National Anti Malarial Management Information System) has been developed for NVBDCP and has been implemented. The system envisages capturing sub-centre wise information at district level. NAMMIS has a separate module on logistics management and necessary steps are being taken to make the system operational. However, due to variant capacity for use of NAMMIS the system has not been operationalized fully. The HMIS of NVBDCP is being integrated with NRHM-HMIS. In NRHM-HMIS data will be entered at district level on monthly basis.

NAMMIS is partially implemented by some states. However, the programme MIS(paper based)is well in position and functioning. AS regards HMIS , which shall be an integrated health Information System under NRHM is underway and the software for NVBDCP is under final

stages of incorporation into the HMIS. It is expected that HMIS shall be in place and functioning by early next year. However, the paper based MIS, covering all programme requirements including data for GFATM project indicators shall continue for effective supervision and monitoring at district, state and National level.

SAMS has already taken up Inventory control and SCM monitoring for the whole country and regular data is compiled up to district level, which has further been brought down to sub-district (PHC) level. The data correctness is being ensured by regular contact with the concerned persons at district and sub-district level. SAMS has already submitted a training plan proposal on SCM and logistics for NE states and is under process for approval by MOHFW. In all 7 trainings are proposed at NE states. The training proposal has been incorporated in the Phase II proposal of IMCP II with budgetary details. It may be mentioned here that SAMS has successfully completed training on SCM and Logistics for WB states and the situation has improved.

In addition to professional agency, the stock/ inventory records are maintained at state/ districts / sub-district facilities, which shall also be validated by the Consultant (PSM) at state level, VBD Consultant at district level and Malaria Technical Supervisor (MTS) at sub district level. Every state has different mechanism for indenting and supply of programme commodities inclusive of drugs & diagnostics, depending on endemicity of malaria in respective area. For ensuring the availability of programme commodities and no stock-outs, an agency has been engaged by NVBDCP, who will be responsible for Supply chain Management and monitoring right from National to sub-district level. This agency has developed Standard Operating Procedures (SOPs) Training Manual for State & district levels wherein Stocking Norms (for storage of drugs) have been defined to ensure maintenance of requisite buffer stocks at each storage level. The Stocking Norms shall ensure uninterrupted supply of drugs & supplies at all levels. This has been integrated into the monthly reporting format at state and district levels which clearly define the quantity of stocks required to be issued to the district & sub-district levels there from. Calculations of the requirements are based on the past consumption and the available stocks as on the date of the report. The calculation of various anti-malarials is based on incidence of malaria and the details are placed in the operational manual uploaded at the Dte. website www.nvbdcp.gov.in.

The supplies of drugs shall be issued to down the line field units (District/ PHCs/ Sub-centres) on the basis of pre-defined stocking norms for that level. This shall ensure that only optimum quantities get issued to the lower levels. Similarly, receipt of drugs shall also get monitored and drugs received from the State shall be as per stocking norms. The agency shall undertake extensive field visits to assess inventory management practices at field level followed with two-day trainings to DMOs, VBD Consultants, pharmacists or other staff engaged in management of anti-malarial drugs. In addition, agency will prepare SOP for PHC level also, which shall comprehensively cover all aspects of drug management at PHC and sub-district levels. Apart from the SOPs, agency has prepared extensive training manual (already shared with the GF), which shall comprise part of the material for the trainings to be conducted on Drug Logistics. As part of their monitoring systems, agency shall track & monitor status of all indents placed with the Procurement Agency. This agency will track supplies to the State through the 35 State Drug Store Monthly Reports submitted at NVBDCP.

Efforts to ensure maintenance of proper stock reports through a Stock Register at all stores shall be instituted. The Stock Register format has been provided in the SOP for State & district drug stores which is able to clearly bifurcate total quantity of stocks with regard to their Date of Expiries (DOE). This shall help the drug stores to identify their stocks correctly and also ensure issue of drugs as per principles of FEFO (First-Expiry-First-Out). The practice of a regular system of ensuring physical verification at drug stores has also been emphasized in the SOP. A monthly Physical Verification Sheet (PVS) for the same has also been added in the SOP which shall be required to be filled in compulsorily by each district store & submitted to the State. The PVS shall compare the book balances and the physical balances of the store as on that day & how any discrepancy between the two has been dealt with.

2. Procurement and supply management cycle

2.1 Product selection

Standard Treatment Guidelines are followed in the country under the programme and are documented in the Revised Drug Policy 2010 and the Operation Manual.

Four items, namely LLIN, RDTs, Injection Artesunate and ACT Combi-blister Packs (both adult and pediatric dosages) have been proposed for procurement under the project.

Under NVBDCP drug policy any of the Inj. Artemisinine derivatives can be used for management of severe cases. However, after completion of initial treatment all patients should be given a full dose of ACT.

Injection Artesunate has been approved during recently held meeting of Expert Group of Chemotherapy on 13.02.12 and by the Technical Specification Committee on 15.02.12. The Technical Specification of Artesunate injection is attached at *Annexure A of the final approved PSM plan for Phase I of IMCP-II.* The programme is planning to procure these during the Phase-II.

Initially ACT-SP was introduced in the programme for treatment of all Pf cases as per the Drug Policy 2010 and resistance against it was monitored with the help of NIMR. In 2012, the resistance to ACT-SP has been noted above the critical level of 10% in North East Stats, needing policy change to go for other alternative ACT. The Technical Advisory Committee has now recommended the use of co-formulated Tablet Artemether +Lumefantrine (ACT-AL) in the country as per the prescribed dose schedule given by WHO for the treatment of Pf cases.

Product / Dosage Form (Generic Name) & Strength	WHO		National		Institutional	
	Listed in STG (indicate 1st/2nd line treatment)	Listed in EML (Yes/No)	Listed in STG (indicate 1st/2nd line treatment)	Listed in EML (Yes/No)	Listed in STG (indicate 1st/2nd line treatment)	Listed in EML (Yes/No)
Anti-malarial medicines						
ACT Combi-blister Packs (Tablet Artesunate + Tablet Sulfadoxine-Pyrimethamine)	Yes (1st line treatment)	Yes	Yes (1st line treatment)	Yes	Yes (1st line treatment)	Yes
Coformulated Tablet Artemether 20 mg +Lumefantrine 120 mg - ACT -AL 1 (for >12 years Age; more than 35 kg Body weight)	Yes (1st line treatment)	Yes	Yes (1st line treatment)	Yes	Yes (1st line treatment)	Yes
Arteether injections			Yes (1st line treatment)	Yes	Yes (1st line treatment)	Yes
Injection Artesunate	Yes	Yes	Yes	Yes	Yes	Yes

Rationale for age groups for paediatric cases

ACT for various age groups in paediatric cases is procured under the programme. The age groups for ACT use were finalized in India based on the recommendation of the Technical Advisory committee meetings under the MOHFW. These age groups are in line with the age groups used for treatment of paediatric cases with chloroquine for vivax cases and also falciparum cases earlier. It was conceived that in India where the distribution of vivax and

falciparum cases are almost equal (unlike Africa where there is high predominance of falciparum cases), it will not be appropriate to introduce another age group system for ACT for falciparum cases. The dosages of ACT for the different age group were decided with inputs from the malaria experts in the country. Therefore the preferred age groups as recommended by WHO may not be applicable to India. However, with the introduction of ACT-AL, the paediatric age groups suggested by the WHO has been taken based on the weight groups.

2.2 Forecasting procedures

Forecasting of requirement of anti-malarial drugs is made to avoid stock-outs even in circumstances like unforeseen outbreaks and procurement delays. State-wise requirements are assessed as part of finalization of Annual Action Plans, taking into account stock available, technical requirement, average annual consumption during the previous years, and buffer stock. Seasonal variances in requirement are taken into account while assessing the annual requirement as part of the Annual Action Plan. Forecasting to determine required quantity of products is based on the data of positive malaria cases of the last completed year and 25% additional quantity taken as buffer over the technical requirement, to take care of lead time for supply. Forecasting would be carried out taking into consideration both morbidity and drug consumption patterns.

Estimation of quantities of health products i.e. drugs and diagnostics are based on the programme prescribed formula for estimating the technical requirements for each item including buffer stock, as given in the operational manual of the programme placed at the website www.nvbdcp.gov.in. The targets for diagnosis of fever cases with RDTs and treatment of *Pf* positive cases with ACT are given in ***Annexure A*** (Performance Framework) of the GFATM Round 9 proposal document and revised based on the current epidemiological status in Phase II. Forecasting for annual procurements is largely based upon average technical data of blood slides collected, P*f & Pv* cases and other relevant information for the entire country. For the purpose of quantification, since past 2 years, stocks in hand are being taken into consideration to avoid over-procurement, wherever required. However the assumptions provided for ACT, RDT and LLIN which were shared with Global Fund on December 10 2010 as follows:

The requirements of RDT and ACT given in the PSM plan will not exactly match with cases tested / treated given in PF due to reasons elaborated in the following paragraphs.

ACT

There is a requirement of deploying at least two additional combi-blister packs of ACT of each age group at every village so that a situation does not arise where any malaria case reporting to the village health worker or volunteer does not face stock-out of the life-saving drug. Therefore, ACT is provisioned at a level much higher than the actual number of malaria cases in the project area, especially in the 1st year of the project. The subject matter was deliberated in detail during the Independent Budget Review of TRP clarification process.

The cost of adult combi-blister packs have been estimated on last purchase price. The paediatric combi-blister packs are procured for the first time in the country, as against loose tablets used previously. The rates of combi-blister packs for various age groups are thus yet to be finalized and the figures given are the anticipated costs which may vary from age group to age group. The estimated requirement for various age groups is calculated considering the current ACT used in the programme. **However, if based on the resistance studies, if other ACT is selected for introduction in the project area, then the requirement will vary based on the availability of various age groups.**

Calculation of requirement of ACT-AL

Recently the programme is introducing the ACT-AL in the project areas (from 2013) and so its requirement is calculated as follows:

To avoid stock-outs at the community level, the ASHA/community health volunteer/worker is expected to keep at all times 1 combi-blister packs of ACT-AL as deployment reserve for each of these four age groups. The reserves at the level of MPW at sub-centre have also been worked similarly at a higher amount. The combi-blister packs will also be supplied to health facilities without laboratory technicians. The norms of deployment reserves of ACT are:

- ASHA - 1 courses for each of the 4 age groups (Total – 4 courses)
- Subcentres- 2 courses per pediatric age group + 4 adult courses (Total – 10 courses)
- PHCs - 5 courses per pediatric age group + 10 adult courses (Total – 25 courses)
- CHCs - 10 courses per pediatric age group + 30 adult courses (Total – 60 courses).

As the effective shelf life of ACT-AL is only 18mths, a certain percentage of wastage of the deployment reserves may become unavoidable in spite of best supply chain management methods.

Table:. Estimates of ACT-(AL) requirements in the project area (figures in million)

Year	2012-13	2013-14	2014-15
Total population living in project area (increasing at 1.6% annually)	45.32	46.04	46.78
Number of Pf cases in project area as per epidemiological data - expected to decline from the third year (2012-13) of the project, to decrease by 30% from present levels by 2014-2015.	0.13	0.12	0.11
Number of ACT courses required for cases treated in public sector health facilities	0.13	0.12	0.11
25% extra cases treated by non-govt facilities and ACTs required for those cases	0.03	0.03	0.02
Total cases to be treated in public and private sector facilities	**0.16**	**0.15**	**0.13**
25% Buffer stock for cases treated in public and private health facilities	0.04	0.00	0.03
Deployment reserves stocks to be maintained for 3 different paediatric age groups and one adult age group at all levels to ensure that there is no stock out in public sector and private sector	0.23	0.00	0.23
Total requirements (for public and private sector)	**0.43**	**0.15**	**0.39**

- *The requirements of the Round 9 GFATM grant is based on the estimated Pf case load of 0.13 million in the GFATM project areas. The case load is expected to decrease by 30% by the end of the project period due to the intensive use of the interventions. .*
- *The requirement has been taken based on the number of cases to be treated plus reserves to be maintained at all levels without stock-outs.*
- *Deployment reserves are essential to prevent stock-outs of ACT, which has a short shelf life of only 2 years (at the end point of distribution, the effective shelf life often comes down to only 1.5 years).*
- The deployment reserve shall be replaced at the beginning of 3rd year, as the effective shelf life is only 18 months; hence, even if some reserves are still available at the end of second year, they are going to expire in that year.
- Procurement in the Round 9 project is proposed to be done in such a manner, so as

to minimize the wastage of ACTs.

The replenishment stocks will be kept at the district and state levels on the basis of total *Pf* cases expected to be treated in a year which will include blisters for all age groups. The distribution of cases is as follows:

- Adult case - 70% of total cases
- Paediatric cases - 30% of total malaria cases. Among the paediatric cases, the distribution of cases is as follows:
  - < 4 years - 10%
  - 5 to 8 years - 10%
  - 9 to 12 years - 10%

Even though epidemiological studies indicate that only 3% of falciparum cases become severe malaria cases, the requirements for severe malaria have been calculated at 10% to ensure adequate quantity of drugs at all health facilities with sufficient reserves. The calculation has been done on the basis that adult cases will be treated with artemisinin derivatives and children and pregnant women with quinine. With improved access to quality case management, the incidence of severe malaria and in-patient malaria should decline, as should malaria deaths.

RDT

The year wise requirements of RDT are as under:

Fig in Millions

Year	2012-13	2013-14	2014-15
Total population living in project area (with projected annual increase of 1.6%)	45.32	46.04	46.78
Population estimated to be living in hard-to-reach areas where microscopy results cannot be available within 24 hours (assumed to be about 75%)	33.99	34.53	35.09
RDT requirements to achieve 15% Annual Blood Examination Rate (ABER) of the total population, based on fever rates, i.e. number of fever cases to be tested in Year 1. For Year 2, target is 12% and for year 3 it is 10% considering the reduction in fever cases due to malaria	5.10	4.14	3.51
25% reserve (buffer stock) of RDT	1.27*	Nil*	0.88*
25% deployment requirement	1.27		0.88
Total RDT requirements	**7.64**	**4.14**	**5.27**

** Buffer stocks & deployment requirement will be adjusted with balance of 1st year stocks and in year 3 as Bivalent RDT is being introduced and is having effective life of two years.*

LLIN

The LLIN requirements of 7.7 million will achieve universal coverage by 3rd (5th yr as per original proposal of five years) year of the project of all population living in highest endemic areas of the project, i.e. population with Annual Parasite Incidence (API) of more than 2. The coverage during the first two years is as follows:

Fig in Millions

Row	Year	2012-13	2013-14	2014-15
A	Total population living in project area	45.32	46.04	46.78
B	Total population in high endemic areas (API ≥ 2) targeted for LLIN distribution	13.81	14.03	14.26
C	No. of LLIN required for 100% population coverage	5.52	5.61	5.70
D	**LLIN proposed to be procured from GFATM**	**3.20**	**1.44***	**2.60**

	Round 9			
E	Cumulative LLIN available in households, including 2.21 million LLINs, previously available	5.20	5.60	5.70
F	Population covered by LLIN	13.00	14.00	14.26
G	Percentage of population living in high endemic areas covered by LLIN	**94.14**	**99.78**	**100%**

*The LLIN requirement has been increased from the original estimates considering the requirement for Jhum cultivators and School hostels. The budgetary requirements include these extra LLINs which are not reflected in the above table. The total no. of LLINs to be procured in the year 2 would be 1.44 million.

2.3 Procurement and planning

NVBDCP would identify products to be procured and formulate their technical specifications which are approved by the respective Technical Committee under DGHS. The list of products, technical specifications, consignee lists and estimated costs are provided by NVBDCP to the PA through the Empowered procurement wing (EPW) of Ministry of Health & FW. EPW would design the procurement planning in coordination with NVBDCP and it would be approved by MOHFW and World Bank

The PA would prepare bid documents for Invitation of Bids (IFB), based on details provided by NVBDCP following the standard bidding procedures of the World Bank. The PA would send copies of the Bid Documents to World Bank for approval before the publication of IFB. For procurements made exclusively under GFATM funding, approval of MOHFW will be taken. The IFB would be simultaneously displayed on the website of the MOH&FW & PA. Also for ICB (International Competitive Bidding), the IFB would also be published in UNDB publication and dg market place and hosted on its website as per requirement of the World Bank, also the IFB send to various Embassy for wider publication

Bids would be opened at the date and time specified on the Bid Document, in the presence of representatives of the bidders who choose to be present.

Bids would be evaluated by the Bid Evaluation Committee, having nominated members from the PA, Dte. GHS and NVBDCP. Purchase Advisory Committee under chairmanship of DGHS, having senior officers from MOH&FW and Dte. GHS as members, would review the report of the Bid Evaluation Committee and all other relevant documents, and make recommendation for award of contract. However, as per threshold value, necessary approval of Secretary, MOH, GOI, Hon'ble Minister for Health and Family Welfare, Government of India and the World Bank would be taken before award of contracts by the PA.

Documented World Bank procedures would be followed during the bidding process and award of contracts.

The PA would ensure pre-dispatch inspection of goods through an independent agency, as per terms of the contract, and monitor supply of goods to the specified consignees.

After completion of supplies, the PA would release payments to suppliers on submission of requisite documents (as per terms of the contract), including submission of Acknowledgement of Receipt of Goods and Final Acceptance Certificates (as per pre-designed form) by the respective consignees.

Empowered procurement wing (EPW) would regularly monitor the procurement status from time to time so as to adhere to scheduled procurement plan and ensure delivery of the good quality products in the right time procured from the right source at the competitive price and also undertake routine follow up of procurement process.

Procurement through Voluntary Pooled Procurement:

As the routine procurement through PA engaged by EPW at MoH&FW takes longer lead time and sometimes due to various procedural delays, complaints etc, the procurement is delayed further, the Programme may use the "Voluntary Pooled Procurement" (VPP) method through procurement support service (PSS) provided by GFATM. It will also take care of the QA issues and also increase the fund utilization rate. For this the programme will follow the guidelines set by GF by first registering on the web site of GF and then following the procedures set under VPP. It will be planned in such a way that the supply is not affected. This may increase the cost of products as it will be procured from the international market with assurance of quality. However, it will be ensured that the total expenditure shall not exceed the approved grant amount of the project.

Emergency Procurement:

Routinely, the programme is managing the balance between procurement and availability of supplies at the beneficiary level through annual procurement cycles. However, due to unforeseen circumstances and delays in procurement due to process related matters, the programme may adopt the method of '**Emergency procurement'** through international agencies like WHO or any other international agency as agreeable to GF to meet the requirement for a short period (usually 6 mths' requirement) so that there is no interruption in the supplies and there is no stock-out situation at the grass-root level. If required, the programme will adopt this method of procurement with the approval from the GF as and when it is needed. In that case, the country programme would agree for transfer of fund directly to the procurement agency involved in the emergency procurement. There will be no quality assurance issues in this method, as supplied a product would be meeting with the QA criteria of GF.

Decentralized procurement of drugs and diagnostics:

States have been asked to procure drugs and diagnostics amounting to 25% of the total annual requirement of the state as buffer stock so as to avoid any stock-out at all level of health service deliveries. This procurement shall be done as 'decentralized procurement' by the state and in strict compliance with the GF procurement and QA policies.

2.4 Inventory management (including Storage Arrangements)

A well organized paper based MIS exists under NVBDCP for flow of epidemiological and logistic information. A system of monthly submission of logistics reports exists at various levels for reporting opening balance, quantity received during the quarter, stock distributed, balance and requirements).

Warehousing space for pharmaceuticals and other goods are available at Regional, State, and district levels. Under NRHM the strengthening of storage system is also done throughout the country. In view of the requirement of large volumes of space for storage of LLINs and temperature maintenance requirements for storing RDTs, funds have been proposed for hiring of additional space under the project. The consignees are intimated well in advance to make necessary arrangements for storage of, ACTs, LLINs & RDTs in the project areas, which is a routine practice. Wherever, the storage facility is not adequate the provision of rent for storage also be made.

The necessary guidelines for storage and inventory management have already been prepared and incorporated in Operational Manual. The same has been disseminated to all the concerned states and hosted at NVBDCP web site (www.nvbdcp.gov.in) . Further, a professional agency for Supply Chain Management has been engaged for capacity building of states and monitoring

of inventory. The agency has already conducted a study in three states for accessing storage facility required for various items under NVBDCP. Based on the observation in these states, guidelines for space and requirement at each level has been incorporated in the SOP manual developed at NVBDCP. The states are informed about the quantum of supplies of medicines, distribution of LLINs that will be arriving and the plan for storage requirements before the arrival of these items. The Directorate of NVBDCP/the agency is also undertaking capacity building of state and district level officials for storage and inventory management.

The storage space required for different item worked out by agency is given below: -

Name of Drugs / Insecticides / Larvicides	**Standard Packings (No of Tab / Cap / Inj/ blister pack in each box)**	**Size of Cartons (In inches)**	**Cubic Ft. Space requirement per carton**
(a)	**(c)**	**(e)**	**(f)=(e)/12*12*12**
Chloroquine	1000	21.5*18.5*12.5	2.87
Primaquine 2.5 mg	18000	15*13.5*14.5	1.69
Primaquine 7.5 mg	18000	15*12*12	1.25
ACT Combipacks (Adult Patients) Carton	2500	25*15.6*12	2.708333
ACT Combipacks (Adult Patients) Small Box	25	5.8*4.9*3.8	0.062497685
ACT Combipacks (Children's)			
Arteether Inj	90	5.708*7.08*4.33	0.099
Artesunate Injection	TBD		
Quinine Injection	800	12.5*6.5*12	0.564236111
Quinine Sulphate (Tabs)	24000	22.5*22.5*17	4.98046875
DDT Bags 50 Kg	50 Kg	36*28*9	5.25
SP (WDP) 25 Kg	25 Kg	18*18*36	6.75
Rapid Diagnostic Kits (RDKs)	1250	24*14.5*13.5	2.71875
LLIN's	100	33*33*14	8.822916667

The system of first expiry first out (FEFO) & First in first out (FIFO) will be followed to prevent losses due to expiry, reducing stock holding cost. Stock registers are maintained at all levels and periodic physical checks are done to verify stocks. Standard operating procedures exist for stores as described in Government publications. Stores are sealed at the end of each working day and adequate arrangements are made at storage facilities for security to prevent theft, and to take appropriate action in case of fire/floods.

Supplies are made on an annual basis through Central level procurement to State and District consignees, as per approved Annual Action Plans (finalized at Annual Action Plan Meetings with State level officers at NVBDCP, Delhi). Further, a system of monthly indents exists from sub-centres to PHCs and from PHCs to district headquarters. Districts raise quarterly indent to the State in a similar way. Emergency requirements are met out of buffer stocks kept at Regional (25%) or GMSD level, State (25%) and District (10%) levels.

NVBDCP has hired a professional agency, namely, Strategic Alliance Management Services. During the period of contract the agency will assist to NVBDCP in following grounds:

1. Assisting NVBDCP on forecasting of drugs and commodities on annual basis

2. Strengthen the existing inventory management systems at the State, District and CHC/PHC levels through more stringent monitoring and supervisory practices and establishment of a strong monthly/quarterly reporting mechanism at all levels (viz. State, District, CHCs and PHCs) with a view to strengthening drugs management under the project by establishing a proper monitoring mechanism and/or logistic management information system (LMIS) under NVBDCP and assist NVBDCP to ensure uninterrupted supply of drugs and commodities under NVBDCP
3. Assistance in capacity building in the area of supply chain management of NVBDCP drugs & commodities and Training of NVBDCP staff and officials at the State & District levels engaged in drug management and assist NVBDCP to standardization of existing SOPs and its implementation and monitoring to facilitate Inventory system at all levels.

During the period of contract the agency will go for regular visits to states & districts have been planned to review the supply chain management at all levels and to identify the bottlenecks which need to be addressed. The agency will adjust the requirement for efficient supply chain system after 12 months. Several trainings on capacity building of officials at State, District & PHC levels shall also be done. Officials involved in drug management at state, district & PHC levels shall be trained on the SOPs which should be able to address all key areas concerning drug management. The SOPs shall be revised & updated regularly to ensure that all revisions in policies are addressed immediately.

Further, it is stated that, 2 qualified consultants are hired under National level under World Bank Project and one post under WHO technical assistant for Global Fund is vacant. In addition with, Consultant for Finance and Logistics are hired under State and District level in World Bank States and districts. Whereas, for States and Districts covered under the Global Fund supported project, some states have finance consultant in position and in some the selection of Consultant is under process.

Oversight:

Under the Global fund project qualified Procurement and Supply Chain Consultants (2) will be hired under National (PR level) and states (7 SR level). Further, a Financial & Secretarial Assistant (86) shall also be put into place at district level for regular monitoring of SCM. These are intended to be in place within Ist year of the project. The states have been advised to fill up these posts as these will be state level recruitments. In addition, the professional agency hired by NVBDCP for supply chain Management will also monitor various states including GFATM areas for such purposes. The Professional agency will also help in capacity building by giving training to Consultants (PSM).

2.5 Distribution

Supplies are made on an annual basis through Central level procurement to State and District consignees, as per approved Annual Action Plans (finalized at Annual Action Plan Meetings with State level officers at NVBDCP, Delhi). Further a system of monthly indents exists from peripheral units (Primary Health Centres / Sub-centres) to Districts with comprehensive report on stock opening balance/supplies received/consumed during the previous month and requirement for the next month. For specific items, Districts raise quarterly indent to State in a similar way. Emergency requirements are met out of buffer stocks kept at Regional (25%), State (25%) or District (10%) levels.

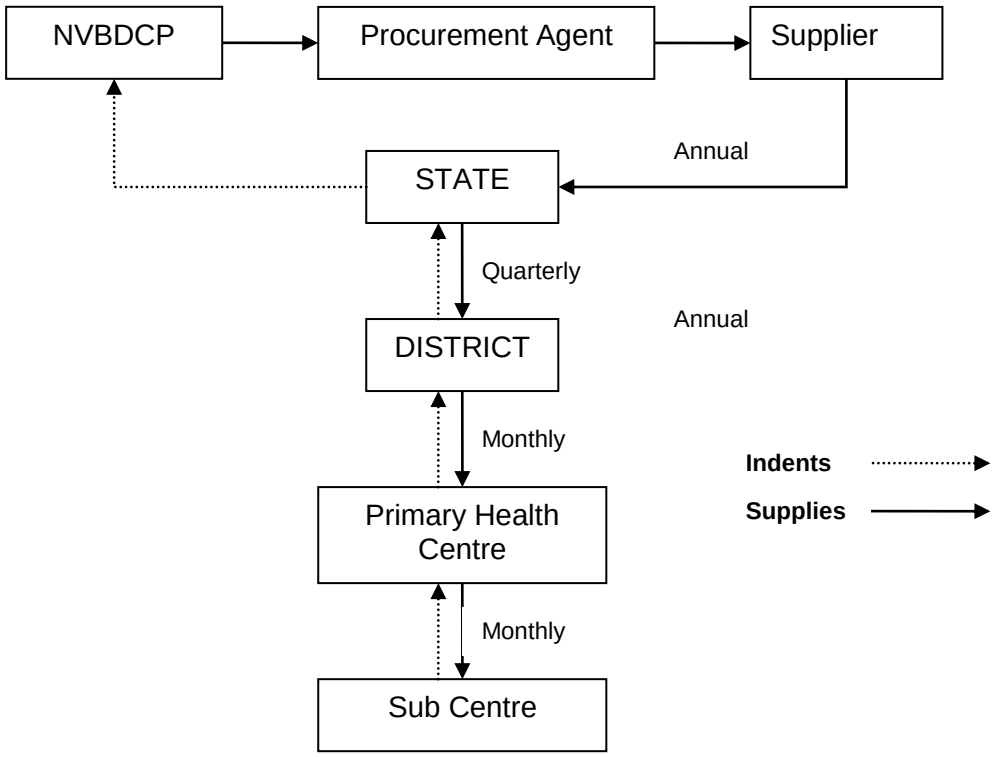
The project areas cover approximately 4% of the country's population. These areas, however, constitute the highest endemic areas for malaria. In the project areas, the stocks of RDTs and anti-malarials will be distributed to 209 CHCs, 1082 PHCs, 7608 Subcentres and 41,798 ASHAs for which the supply chain will be efficiently maintained. The distribution of logistics is also done by Caritas India (PR2) in their areas.

Distribution of stocks to peripheral level is through Government or hired vehicle as per local situation in each district. A monitoring system through regular reports and reviews by supervisory officers during visits to peripheral units is aimed at ensuring adequacy and quality of supplies. Apart from this an agency has been hired by the Programme Division under World Bank funding to manage the supply chain including distribution of stores in coordination with NVBDCP. The transportation cost of the products (LLINs, RDTs and drugs) has been included in the project. This is important as the project areas are forested and hilly with poor road connectivity and widely dispersed populations.

Monitoring and coordination of requirements and utilization of stocks is done through a well-knit paper-based reporting system under NVBDCP. NAMMIS has been developed as the electronic system under NVBDCP as part of the World Bank assisted Malaria Control Project which will be utilized for monitoring of supplies and logistics. Apart from this, supplies and their utilization at peripheral levels is also monitored during supervisory visit of technical officers from Central, Regional and State levels. In case of any seasonal upsurge of cases or other unforeseen circumstances, supplies are mobilized out of buffer stocks kept at Regional GMSDs and state level stores. Supplies are also mobilized from one area to another as per relative requirements or to ensure early utilization of stocks nearing expiry date. Further, hiring of a new agency under competitive bidding process through World Bank funding has been finalized. This agency will monitor the supply chain and inventory management of drugs & commodities in coordination with NVBDCP programme directorate, so as to improve availability and accessibility to antimalarial drugs and commodities. Detail TORs has been placed in website of NVBDCP.

Caritas India is also involved in distribution of Logistics in the areas covered by them. Caritas shall receive the logistics directly from the district/sub-district level as per their requirement.

Distribution Mechanism Flow Chart



2.6 Ensuring rational use of medicines

Standard treatment guidelines exist under NVBDCP for anti-malarial drugs. PHC medical officers would be oriented in standard treatment guidelines during the training programmes.

Appropriate orientation of other health care staff at all levels would be carried out to ensure proper prescribing and dispensing practices at all levels. Appropriate display material would be developed and displayed at all health facilities to ensure rational age-specific use of anti-malarial drugs.

Sentinel sites have been identified for monitoring *Pf* drug resistance for monitoring adverse/toxic reactions to antimalarials. A system for reporting of adverse/toxic reactions (pharmacovigilance) to ACT and Injection Artesunate would also be developed.

Under National Rural Health Mission - a flagship programme of Govt. of India, a large no. of ASHA workers have been providing the healthcare service. To ensure that Health products are stored properly, ASHAs/Health workers are trained on good storage practices as a part of their trainings under the programme. These trainings cover topics on storage conditions like optimal storage temperature, avoidance of humidity and direct sun light, principle of FEFO/FIFO etc. In addition supervisory staff like Health supervisor, MTS, MO PHC is trained to monitor the storage practices in the field and check and redeploy products at risk of expiry. These ASHA workers would also be trained on rational use of medicines (ACTs) at the community level by the SRs in coordination with PRs. Many of them have been trained in last two years in project areas. Further, professional agency is to train the staffs like Logistic manager, DMO, VBD consultant, Store keepers regarding Supply Chain & Logistic component as trainers. Further, trainer will train in the filed officials in the health facility. In addition National Level Consultant has been engaged and will orient to field staff during his field visit.

There is system of recording and reporting of logistics from the level of ASHA up to district in the M formats prescribed in the M&E plan. Records of opening balance, consumption and closing balance are to be maintained by ASHAs which is to be reported at fortnightly/ monthly interval to the sub center. Similar reports are to be compiled and collated at all levels.

The recording and reporting of drugs and commodities are included in the reporting formats initiated at peripheral level i.e. villages. The formats give details of monthly receipt; use and balance of the items and a copy of the M-1 form are attached for ready reference. The personnel at various levels are trained to store and manage health products according to good practices and the details are included in their respective training manual / module.

Monitoring and supervision of health products and their management is ensured by supervisory staff who are provided detailed checklists that are required to be completed during each supervisory visit. This practice of supervision is followed at all levels i.e. central to state, state to district, district to sub-district (block), block to sub-centre and sub-centre to village.

Bivalent RDTs have been approved for use in the programme by the technical committee and are under the process of procurement. It is expected that Bi-valent RDTs shall be available in the project in the Year 1. All ASHAs/CHVs are to be given refresher training for use of Bi-valent RDT as and when they are introduced in the programme. Since it will diagnose both *Pv* and *Pf,* it will be distributed to all malaria endemic areas with special emphasis on difficult, hilly and hard to reach areas.

2.7 Pharmacovigilance

The National Pharmacovigilance programme was launched in India in 2004. It is being revamped under the aegis of Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare in technical collaboration with All India Institute of Medical Sciences (AIIMS) to include all medical colleges, National Health Programmes and health care professionals across the country.

The safety of ACT under large-scale operational use has not been fully assessed. Also the safety of antimalarial treatment in vulnerable populations including pregnant women, children and in patients with coexisting illnesses (such as HIV/ AIDS, Tuberculosis and malnutrition) has

not yet been established. In addition, antimalarials are often purchased from drug shops or pharmacies without consulting health personnel. Such informal use of antimalarials could increase the risk of incorrect dosing, inappropriate treatment and interactions of different medicines, which could have a negative impact on antimalarial treatment safety.

Under the World Bank supported project, NIMR has been entrusted a project on Pharmacovigilance of antimalarials. Procurement of manpower for the project has been completed. Training of staff is in progress in the states. Questionnaires have been prepared, pretested and finalized. The formats of questionnaires have been distributed to 9 states and the analysis of data received is has begun in December 2010. Annual meetings are planned for monitoring the implementation of the Pharmacovigilance programme.

2.8 Drug Resistance Surveillance

Drug resistance in *Plasmodium falciparum* parasite has been monitored since 1978 by NVBDCP through monitoring teams functioning under various ROHFW. The objectives are to obtain information on sensitivity of local strains of the parasite and thus formulate the National Drug Policy.

Since 2002-03, the new WHO protocol on "Therapeutic efficacy of anti-malarial drugs in uncomplicated *P.falciparum* malaria" is being followed to assess the efficacy of antimalarial drugs.

At present, 15 sentinel sites have been operationalized in various parts of the country for conducting therapeutic efficacy studies for ACT with collaboration of NIMR under the World Bank Project.

The National Drug Policy on Malaria (2010) recommends the use of ACT for treatment of all *P.falciparum* cases in the country. The resistance to ACT is also monitored. According to the current studies, the programme has decided to use ACT-AL for all Pf cases in the North-Eastern states.

2.9 Other

Supply chain management is strengthened by hiring an agency at the central level under the World Bank project. Logistic managers are also proposed to be hired at state level under the GFATM Round 9 project.

Beneficiaries under the programme are being provided all services/drugs/commodities totally free of cost and are not charged any money for the same. The same applies to beneficiaries under the proposed GFATM Round 9 Project. In past also no charge is taken for such services under the public healthcare system.

Annex 1a: List of products to be procured (prices and quantities may be estimates) (Ensure quantities are linked to the forecasting and aligned to targets in PF)

List all **pharmaceuticals** to be procured under this grant. Use Year 3 columns only if applicable.

Product Category	Product	Strength	Estimated unit cost (US$/EURO) (indicate per tablet, per inj, per ml, etc)	Year 1 Estimated quantity	Year 1 Total cost (US$/EURO)	Year 2 Estimated quantity	Year 2 Total cost (US$/EURO)	Year 3 Estimated quantity	Year 3 Total cost (US$/EURO)	Procurement conducted by[1]	Procurement method [2]
Antimalarials	ACT for adults (ACT-AL)	Coformulated Tablet Artemether 20 mg + Lumefantrine 120 mg (ACT –AL)	1.73 / per course as quoted by WHO for emergency procurement	300,000 (110000 by emergency proc., 190000 by ICB/VPP)	519,000	105,000	181,650	273,000	472,290	Empowered Procurement Wing (EPW), Ministry of Health & FW through Procurement Agent (PA) /States	International competitive bidding (ICB) /VPP (190000) / emergency procurement Y1(110,000)
	ACT for pediatric use (ACT-AL)	3 Different strengths for different age-groups (<6mths to 4 years, 5-8 years & 9-12 years)	Average of 0.90 per course *(The average price has been calculated based on the price quoted by WHO)*	130,000 (48,000 by emergency proc., 82,000 by ICB/VPP)	117,000	45,000	40,500	117000	105300	Do	International competitive bidding (ICB) /VPP (82,000) / emergency procurement Y1(48,000)
	Injectable Artemisinin Derivatives (Injection Artesunate) vial containing-Artesunate IP 60 mg	60mg	1.95/amp. The price has been taken based on the price quoted by WHO	17,625 (16,000 by emergency proc., 1625 by ICB/VPP)	34370	12000	23400	12000	23400	Do	International competitive bidding (ICB) /VPP (1625) / emergency procurement Y1(16,000)

[1] Indicate name of department or organization conducting procurement
[2] e.g. direct negotiation, national tender, international tender, etc.

	Handling charges which includes pre-dispatch, post dispatch inspection, lab. Testing, quality assurance etc @ 4% of the cost	ACT Adult ACT ped Inj. Artesunate			26815		9822		24040		
All other pharmaceuticals[3]											
					697185	**TOTAL→**	**255,372**	**TOTAL→**	**625030**		

[3] While it is not necessary to list all products in this category, the complete list of specific pharmaceuticals, including quantities and unit costs, must be made available to the LFA for review and assessment

Annex 1b: List of products to be procured (prices and quantities may be estimates)

List the products and services to be procured under this grant. Use Year 3 columns only if applicable.

Prod. Cat.	Product	Estimated unit cost (US$) [1]	Year 1 Estimated quantity	Year 1 Total cost (US$)	Year 2 Estimated quantity	Year 2 Total cost (US$)	Year 3 Estimated quantity	Year 3 Total cost (US$)	Procurement conducted by[2]
Health Products (excluding pharmaceuticals & health equipment)	Rapid diagnostic test (Bivalent RDT)	***0.43***	7,640,000 (5800,00 shall be emergency procuremen t	3,285,200	4140000	1780200	5270000	2266100	***Empowered Procurement Wing (EPW), MOHFW through Procurement Agent (PA)***
	All other diagnostic products, supplies, equipment								
	Bed nets (LLINs, other)	3.68	3,200,000	11787263	1441420	5309499	2600000	9577151	Empowered Procurement Wing (EPW), MOH&FW through Procurement Agent (PA)
	Condoms								
	All other health products[3]								
Health Equipment	Various health equipments[4]								
Services[5] (relate	**MIS systems**								
	QA strengthening								

	Other[6] (related to health product procurement & supply management) e.g. TA, storage, RUD and PV, DRS, etc including handling charges	Processing charges, Storage Transportation Distribution		602899		283588		473730	
Non-Health Products	All non-health products and services[7]	**Human Resource & Training**		342477					
			TOTAL→	**16,017,839**	**TOTAL→**	**7373287**	**TOTAL→**	**12316981**	

1[1] Indicate whether PR/buyer is able to access any special prices (e.g. through Clinton Foundation, other)

1[2] Indicate whether in-house or being outsourced to a procurement agent; indicate name of department or organization conducting procurement

1[3] While it is not necessary to list all products in this category, the complete list of other health products, including quantities and unit costs, must be made available to the LFA for review and assessment

1[4] While it is not necessary to list all products in this category, the complete list of health equipment, including quantities and unit costs, must be made available to the LFA for review and assessment

1[5] The focus of this section is only for services related to procurement and supply management (e.g. consultants to strengthen PSM).

1[6] Indicate type of assistance segmented into categories as listed on table 1.1 (do not provide information that is not related to PSM)

1[7] It is not necessary to itemize this entry; provide a single line entry and include some large value product and service items as examples (e.g. vehicles, computers, construction, financial consultants, etc)

Annex 2:
Compliance with the Global Fund's Quality Assurance Policy[4]

Product / Dosage Form	Strength	Pack size	WHO Prequalification	Registered by a SRA (insert date of registration)	Global Fund ERP list (insert date of expiry of ERP recommendation)
Antiretroviral medicines					
Antimalarial medicines					
Artesunate + [Sulfadoxine + Pyrimethamine(SP)] (infant <1 year))	Artesunate 75mg.+SP (250mg+12.5mg)	Pink Colour (Blister Pack)	NA	NA	GFATM requested to review the same through ERP and consider approval for procurement of the same for use in the programme
Artesunate + [Sulfadoxine + Pyrimethamine(SP)] (age 1-4 Years)	Artesunate 150mg+SP (500mg+25 mg)	Yellow Colour (Blister Pack)	NA	NA	Do
Artesunate + [Sulfadoxine + Pyrimethamine(SP)] (age 5-8 Years)	Artesunate 300mg + SP (750mg + 37.5mg)	Green Colour (Blister Pack)	NA	NA	Do
Artesunate + [Sulfadoxine + Pyrimethamine(SP)] (age 9-14 Years)	Artesunate 450mg + SP (1000mg+ 50mg)	Red Colour (Blister Pack)	NA	NA	Do
Artesunate + [Sulfadoxine + Pyrimethamine(SP)] (Adult)	Artesunate 600mg + SP (1500mg.+ 75mg)	White Colour (Blister Pack)	NA	NA	ERP reviewed product. GFATM would be notified to consider extension of ERP period by NVBDCP
Injectable Artemisinin Derivatives (Arteether)	150mg	Ampoule	NA	NA	Not an ERP reviewed product. Not a WHO prequalified product. GFATM requested to get it reviewed by ERP.
Antituberculosis medicines					

[4] The Global Fund's Quality Assurance Policy: http://www.theglobalfund.org/en/procurement/quality/?lang=en

Product / Dosage Form	Strength	Pack size	WHO Prequalification	Registered by a SRA (insert date of registration)	Global Fund ERP list (insert date of expiry of ERP recommendation)
Antiretroviral medicines					
Antimalarial medicines					
Coformulated Tablet Artemether 20 mg +Lumefantrine 120 mg -ACT -AL 1 (for >12 years Age; more than 35 kg Body weight)	Coformulated Tablet Artemether 20 mg +Lumefantrine 120 mg	Pink Colour (Blister Pack of 24 Tab)	Yes	NA	GFATM requested to review the same through ERP and consider approval for procurement of the same for use in the programme
ACT-AL- (for 9-12 Years Age; 25-35 Kg Body Weight)	Coformulated Tablet Artemether 20 mg +Lumefantrine 120 mg	Yellow Colour (Blister Pack of 18 Tab.)	Yes	NA	Do
ACT-AL (for 5-8- Years Age; 15-25 Kg Body Weight)	Coformulated Tablet Artemether 20 mg +Lumefantrine 120 mg	Green Colour (Blister Pack of 12 Tab.)	Yes	NA	Do
ACT-AL- (for 6 months to 4 Years Age; 5-15 Kg Body Weight)	Coformulated Tablet Artemether 20 mg +Lumefantrine 120 mg	Red Colour (Blister Pack of 6 Tab)	Yes	NA	Do
Injectable Artemisinin Derivatives (Injection Artesunate) vial containing-Artesunate IP 60 mg2	60mg	vial	Yes	NA	WHO prequalified product.
Antituberculosis medicines					

1. ACT-AL = Coformulated Tablet Artemether 20 mg +Lumefantrine 120 mg
2 Inj. Artesunate is new introduction in the programme replacing Inj. Arteether

Abbreviations

ACT	Artemisinin-based Combination Therapy
ARV	Antiretroviral drugs
DRS	Drug Resistance Surveillance
EML	Essential Medicines Lists
ERP	Expert Review Panel
FPP	Finished Pharmaceutical Product
GF	Global Fund
GLC	Green Light Committee
GMP	Good manufacturing practices
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
LFA	Local Fund Agent
MIS	Management Information Systems
MOH	Ministry of Health
MOF	Ministry of Finance
NDRA	National Drug Regulatory Authority
PA	Procurement Agent
PEPFAR	President's Emergency Plan for AIDS Relief
PHPM	Pharmaceutical and Health Product Management
PMI	President's Malaria Initiative
PR	Principal Recipient
PSM	Procurement and Supply Management
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
RDT	Raopid Diagnostic Test
RUD	Rational Use of Drugs
SR	Sub-recipient
STG	Standard Treatment Guidelines
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WHOPES	WHO Pesticide Evaluation Scheme