GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE

OPERATIONAL PLAN
For

STRENGTHENING OF DRUG ADMINISTRATION AND MANAGEMENT (SDAM)
July 2011-June 2016

HEALTH, POPULATION AND NUTRITION SECTOR DEVELOPMENT PROGRAM
(HPNSDP)

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
105-106 Motijheel C/A, Dhaka

September, 2011

INDEX

Operational Plan

1. Name of the Operation Plan (OP):
STRENGTHENING OF DRUG ADMINISTRATION AND MANGEMENT

2. Name of the Sector Programme:
HEALTH POPULATION AND NUTRATION SECTOR DEVELOPMENT PROGRAM (HPNSDP)

3. Sponsoring Ministry:
MINISTRY OF HEALTH & FAMILY WELFARE

4. Implementing Agency:
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

5. Implementation Period:
Commencement: 01-07-2011
Completion: 30-06-2016

6. Objectives of the OP:

6.1 ***General Objective*****:** To ensure the quality, efficacy and safety of pharmaceutical products by a competent workforce working together in strategic advancement towards improving the health of the people.

6.2 ***Specific Objectives*****:**

- To support the pharmaceutical industries to produce quality drugs;
- To strengthen and build capacity of the National Regulatory Authority for Drugs.
- To enhance Post Marketing Surveillance Activities.
- To improve the capacity and standard of Govt. Drug Testing Laboratory for Quality Control of Drugs.
- To facilitate the Rational Use of Drugs
- To update and implement the drug regulatory functions.

7.1 ***Estimated Cost*****:**

(Taka in lakh)

PIP / OP Cost	Total	GOB	PA (RPA)	Source of PA
Approved cost of the PIP (Development Budget)	2217666.00	860350.00	1357316.00 (869791.00)	WB, JICA, USAID, EC, WHO, others
Estimated Cost of the OP	3,155.00	1,005.00	2,150.00 (1,527.00)	Pooled Fund, USAID, WHO
Cost of OP as % of PIP	0.14%	0.11%	0.15% (0.17%)	

7.2 ***Estimated Cost (According to Financing Pattern)***

(Taka in lakh)

Source	Financing Pattern	2011-12	2012-13	2013-14	2014-16	Total	Source of fund
GOB	GOB Taka (Foreign Exchange)	815.00	19.00	16.00	155.00	1005.00	
	CD-VAT						
	GOB Others (e.g. JDCF)						
	Total GOB=	**815.00**	**19.00**	**16.00**	**155.00**	**1005.00**	
PA	RPA (Through GOB)	490.00	327.00	644.00	66.00	1527.00	Pooled Fund
	RPA (Others)	--	--	--	--	--	
	Subtotal RPA=	490.00	327.00	644.00	66.00	1527.00	
	DPA	107.00	356.00	40.00	120.00	623.00	WHO, USAID
	Total PA=	**597.00**	**683.00**	**684.00**	**186.00**	**2150.00**	
Grand Total=		**1412.00**	**702.00**	**700.00**	**341.00**	**3155.00**	

8. OP Management Structure and Operational Plan Components (Attached Management set up at Annexure-I, Page No. 18)

8.1 ***Line Director***: Director General of the DGDA will be the line director of this OP. The PM, DPM and the staff list for this OP are shown in the organogram at annexure-I.

8.2 ***Major Components of OP and their Program Managers / DPM*:**

Major Components	Program Manager	Deputy Program Manager
Strengthening and management of DGDA	Deputy Director Directorate General of Drug Administration	Assistant Director Directorate General of Drug Administration

8.3 Manpower in the development budget:

(Taka in Lakh)

Sl. No.	Name of the Post	Number of post	Pay Scale	Grade	Consolidated Pay per Person/month	Total Month	Total Pay (Taka in Lakh)
	Officer	-	-	-	-	-	-
	NONE						
	Staff						
	NONE						
	Total(A+B)=	**NONE**					

9. Description

a) Background information, current situation and its relevance to National Policies, Sectoral policy, MDG, Vision 2021, Sixth five year plan, MTBF etc.

A. ***Background Information***:

i) The Government of Bangladesh has given highest priority for the production and export of Pharmaceutical products as such included in the Export policy as well as in the Industrial policy. Bangladesh has achieved significant development with respect to manufacturing of quality medicine. A number of Pharmaceutical Industries have established their manufacturing units of international standard which have been inspected, assessed and certified by the international certificate awarding body like Medicine and Health care Regulatory Authority of UK-MHRA, EU, GCC, TGA (Australia), ANVISA (Brazil), etc. As a result the drug manufacturing companies of Bangladesh are capable to enter into the export market of the world including highly regulated USA, Canada and European market. This development trend of pharmaceutical industry is going up and Bangladesh is expecting to have significant share of medicine export market of the world. Presently Bangladesh is exporting medicines to 85 countries of the world.

ii) Sufficient number of competent qualified personnel such as pharmacist, chemist and microbiologists are working in the pharmaceutical industry in the country and also engaged in the respective field of other country like USA, UK, Middle East etc. They are contributing a lot in manufacturing of quality medicine. Different types of high-tech pharmaceutical products like vaccines, hormones, anti-cancer, bio-similar products are producing in the country.

iii) The drug sector of Bangladesh is expanding very fast. A competent and effective National Drug Regulatory Authority is urgently needed to regulate entire sector properly and efficiently. The present status of Directorate General of Drug Administration has to be strengthened further for better control of the drug sector.

iv) The Directorate of Drug Administration was established in the year 1976 as a Drug Regulatory Authority (DRA) under the Ministry of Health and Family Welfare. The organization has been upgraded to Directorate General of Drug Administration in the year 2010. This organization is entrusted with the responsibilities of overall control and management of the pharmaceutical sector of the country. It regulate and perform various activities related to manufacture, quality control, storage, distribution, sale, post-marketing surveillance, import and export of drugs in the country. In addition, the DGDA acts as the Licensing Authority and issues Licenses for the manufacture, distribution, export, import and sale of drugs and medicines. The Directorate is also responsible for implementation of the National Drug Policy in order to establish discipline in production, distribution and use of drugs at all levels of health care delivery. It also ensures Good Manufacturing Practices (GMP) in production and quality control of drugs.

v) The Directorate of Drug Administration, which has now been raised to that of a Directorate General level, has about 65% of its posts vacant (previous and created). These posts need to be filled up on a priority basis and also recruitment to be done against the posts. However, it is in progress.

vi) The Drug Act 1940, The Drug Rules 1945 and 1946 and the Drug (Control) Ordinance 1982 have been printed in booklet form. The Essential Drug List was updated following model list of WHO. Inspection check list has been updated following WHO GMP guidelines, printed and distributed to the concern companies and officials. Awareness building interventions (posters, workshops, advertisement in mass media) were taken up on rational use of drugs, ADR form and code of pharmaceutical marketing practices were printed, re-printed and distributed. Training provided on QA and GMP to the pharmacists, chemists and other qualified personnel working in the pharmaceutical industries..

vii) The NRA is the sole authority responsible for controlling and monitoring production and distribution of vaccines in the country. The Directorate General of Drug Administration is needed to be strengthened by increasing skilled manpower and the issues need to be addressed seriously. As such various activities such as consultation, logistic and financial support for this purpose is necessarys.

viii) The National Drug Policy of 1982 was updated in the form of the National Drug Policy 2005, to make the country a producer and exporter of good quality medicines and to strengthen the Directorate of Drug Administration into an effective regulatory authority. The main functions of DGDA are: to upgrade the criteria of registration for import of all systems of medicines; assist in the attainment of self sufficiency in manufacturing of both drugs and pharmaceutical raw materials; exercise government control over advertisement; ban manufacture, sale and distribution of counterfeit, adulterated and sub-standard medicines, make medicines accessible to people in all areas of the country; controlling of prices of the commonly used essential medicines; encouraging both local and multinational manufacturers to establish full-fledges research facilities in the country; encouraging investors to set up facilities for manufacturing pharmaceutical raw materials in the country, e.g., by setting up industrial park; to ensure rational use of medicines; ensure monitoring of adverse reactions of drugs, training of the officer of Drug Administration on QMS, GMP, QA, etc; preparation of a list of non-prescription (OTC) drugs and upgrade it from time to time; registration of medicine based on bioavailability and bioequivalence data of the medicine applied for registration.

ix) Since 1982 the growth of local drug production has been accelerated. There are 20,000 brand named drugs on the market, which involve 1200 generic and locally produced drugs that meet 95% of the local drug demand. Being a drug exporting least developed country, Bangladesh has a unique position in the region, for not having to adhere to the TRIPS Agreement until 2016.

x) The country has about 90,000 drug licensed drug outlets. The licensing process is going on.

xi) ***Drug Testing Laboratory:***

Presently there are two government Drug Testing Laboratories in Bangladesh. Drug Testing Laboratory, Dhaka was established in 1953 and Drug Testing Laboratory, Chittagong was established in 1969. Currently both are working under the control of Directorate General of Drug Administration (DGDA). DGDA tests most of the medicine samples in these two laboratories. The testing capacity of vaccines in these laboratories is extremely limited and there is no separate facility or infrastructure for this activity.

A modern laboratory to test and analysis of vaccines and biological products, setting up of a National Control Laboratory with necessary equipment and construction is under progress.

xii) ***Adverse Drug Reaction (ADR)***

Monitoring and reporting of any undesired or unintended effect of medicine/ drug yet to be established. This will encourage ADRs-surveillance and Spromote reporting of ADRs by health professionals such as pharmacists, physicians, nurses or even patients. ADR will include mechanism for monitoring, detecting, evaluating, documenting, and provide feedback to prescribing physicians. A monitoring cell will be necessary to address ADRs for the country.

xiii) ***Rational Use of Drugs***

The reasons of irrational use of drugs include lack of knowledge, skills or independent information, unrestricted availability of medicines, overwork of health personnel, inappropriate promotion of medicines and profit motives from selling medicines. Among the WHO recommended core interventions Essential Drugs List has been prepared. Evidence based standard guideline/ prescribing policies with appropriate training, reinforced by prescription audit and feedback yet to be done. A mandated multidisciplinary national body to coordinate medicine use policies, Drugs and therapeutic

committees in districts and hospitals, in-service training, mass awareness, supervision, audit and feedback and other activities to be considered in the next sector program.

b) ***Drug Policy***

Since the introduction of the Drug Policy, in the last three decades, there have been spectacular changes in the socio-economic sectors nationally and internationally. Besides, the world has witnessed remarkable achievements in the areas of pharmaceutical industry, medical science and also in the usage of medicines. To keep pace with the changed circumstances, it has become imperative to modernize and expand our pharmaceutical sector aiming beyond national horizon to the international export markets and also to attract the foreign investment in this sector.

Implementation of "National Drug Policy (NDP) 1982" resulted tremendous positive effect leading to rapid development of the pharmaceutical industries in Bangladesh. Production of allopathic and other traditional medicines increased substantially. Bangladesh has recently turned in to quality medicine exporting country. The potential is very high as many countries are making desperate efforts to source their medicines from a country which is able to supply high quality products at competitive price.

c) ***Sixth Five Years Plan***

Initiatives have been taken to revise existing drug policies to ensure easy access to essential drugs at fair prices and to provide quality drugs, and also to bring self-sufficiency in the production of medicines of international standard along with promotion of their export. Directorate of Drug Administration is planned to strengthen, expand and modernize its regulatory capacities. Increased attention will be given to popularize rational use of drugs by educating both the physicians and users on appropriate prescription practices and use of appropriate drugs with dosages. Plan has been taken for modernization and up-gradation of both the existing drug testing laboratories at Dhaka and Chittagong.

d) ***Present situation***

Presently there are 830 licensed drug manufacturing companies comprising 262 Allopathic, 268 Unani, 202 Ayurvedic, 79 Homoeopathic, and 19 Herbal drug manufacturing units. Two manufacturers are in advanced stage of setting up vaccine manufacturing units. Manufacturing companies produce around 25000 brands of drugs. UN organizations purchase billions of dollars worth of vaccines and drugs each year to fight many diseases and are constantly looking for inexpensive source of suppliers. Bangladesh may be qualified as potential supplier for UN agencies during their procurement process. It may be mentioned that the approval process requires certification from WHO qualified National Control Laboratory (NCL) and Drug Testing Laboratory (DTL). Unfortunately the two Government Drug testing laboratories are not compliance with WHO requirements.

A number of local pharmaceutical companies have developed facilities which have received certification from developed countries. Many of them are producing high tech medicines like amino acids, proteins, hormones, vaccines, complex organic compounds etc. To keep pace with the development of pharmaceutical sciences, NCL and DTL need to be upgraded for test and analysis of vaccine and other high-tech products.

There is immense opportunity for Bangladesh to export medicines. Bangladeshi drug manufacturers will require certificate from drug testing laboratory under National Regularity Authority to comply with the requirement of importing countries. This laboratory must have the facilities to test and provide certificates of quality for the locally produced medicines.

The proposed NCL and DTL must be given highest priority and will be implemented immediately. These laboratories ensure the high quality of vaccines and drugs considering the health safety of the peoples. Unfortunately the current NCL is not capable to test many vaccines, biological and other high tech drugs.

e) ***Issues to be addressed***

- In order to safeguard the health of the people of Bangladesh each and every drug and vaccine must be tested before release in to the market. At present the two existing laboratories are not capable of testing vaccines, biological and many high tech drugs. As a result the government is facing difficulties to assess the quality standard of a large number of products currently available in the market.
- The combined testing capacity of the two laboratories is inadequate to test the huge number of medicines and vaccines available in the market. In order to ensure the quality standard of the drugs and medicines, the government needs to evaluate the quality standard of each drug available in the market on a routine basis. In addition, the government needs to test the quality of all new drugs, vaccines and other samples of drugs from various institutions.

  UN organizations and other Donor agencies are buying huge quantity of medicines each year and they rely on WHO pre-qualification scheme for approval of quality standard. Country must have functional NCL to be qualified for sale of drugs to UN agencies.

  Considering the above mentioned rationale the Government recently handed over Drug Testing Laboratory (DTL), Dhaka from IPH to Directorate General of Drug Administration (DGDA) and decision taken to renovate the and procure new equipment of the existing building of DTL The present Anti-sera building will be renovated and expanded to accommodate animal house, training cum office arrangement with the consultation and technical support from WHO in order to function this laboratory as NCL. The works have been started with the allocated fund of HNPSP (2003-2011). To complete the remaining works required fund is proposed under this OP. Proposed laboratory will be of internationally recognized standard. The project will be in Dhaka. Thus the service will be nation wide. It will be provided technical assistance regionally and globally. To establish the laboratory of international standard all the activities related to renovation, construction and procurement of equipment need to be done directly by either WHO or by appropriate technically expert agencies to complete the task successfully.

  The DGDA as a result of these activities, will be substantially strengthened and its capacity will be built to carry on its responsibilities efficiently and effectively. A strong Drug Regulatory Authority is also required to deal with the production, quality control, distribution and use of safe, efficacious and good quality drugs and medicines in the country. This will result in improved drug manufacturing, better quality, safety management and more rational use of drugs. It will help to curb spurious drug manufacturing and marketing.

  In order to protect the general people from ignorance, misuse of drugs and exploitation of the unscrupulous drug manufacturers and traders, strengthening and up-gradation of the Drugs Administration Directorate is absolutely essential. A strong NRA is also needed to compete efficiently with other drug producing and exporting countries of the world. Capacity building of the DGDA, automation of the licensing and registration system as well office management and necessary logistics support will be addressed.

  Through the implementation of this OP the peoples of Bangladesh will have better health care through quality medicine. Moreover, Bangladesh will be an export oriented medicines producing country in addition to its self sufficiency and the sector will create lot of employment opportunity for the concerned personnel.

f) ***Related Strategy in the PIP:***

The strategy is the strengthening drug management and improves quality drug provision through the following initiatives:

- To ensure drug safety and pricing in the country through enhancing collaboration between the DGDA and other regulatory agencies/stakeholders in the Health Sector. DGDA will ensure substantial funds to train the officers and staff of the DGDA including drug testing laboratories in monitoring drug quality. In addition, DGDA will establish an effective drug testing laboratory of International standard. The existing laboratories will be modernized. The irregular retail trade of drugs and medicines, the functioning of spurious drugs or below standard drug and the dispensing of drugs by unregistered physicians or unauthorized sellers to be controlled by deploying more staff at district levels and at possible 'DGDA outlet stations'.

- Quality control and quality assurance systems of Pharmaceutical companies will be monitored. GMP guidelines will be implemented for manufacturing of pharmaceutical products. Continuation of testing the randomly collected samples in the Government Drug Testing Laboratories will be maintained through effective post-marketing surveillance.

- Data on production, import, export, procurement, storage, distribution and sale will be compiled, monitored and evaluated to ensure availability of medicines in all health care facilities in both public and private sectors.

- Automation of the drug administration and management system will be ensured. Drugs production information and quality control records, drug registration information system, industry production status and management of drugs, drugs exports, ADR records etc will be part of automation. On line licensing and registration procedure will be incorporated in this system.

- Rational Use of Drug (RUD) will be ensured by conducting surveys on the systems of prescribing, dispensing and patient compliance. The DGDA in consultation with the expert committee shall update from time to time the list of essential medicines in line with the current EDL of WHO.

10. Priority activities of the OP:

1. *Up gradation and modernization of NCL and DTL*

In order to ensure the quality standard of drugs and vaccines, the government needs to evaluate the quality standard of each drug / vaccine available in the market on a routine basis. Expansion and modernization of these testing laboratories at the divisional level would be considered on the basis of priority.

Activities:

1. Procurement of Laboratory Equipment
2. Repair & Renovation of NCL and DTL
3. Repair and Maintenance of Laboratory Equipment

2. *Updating the National Drug Policy for ensuring quality drugs and Rational Use of Drugs*
Up gradation of national drug policy 2005 is needed

1. To ensure the essential drugs for all at affordable price.
2. To support the national Drug Manufacturing Industry to keep pace with the changed global scenario.
3. To modernize and expand our pharmaceutical sector aiming beyond national horizon to the international export markets.
4. To attract the foreign investment in this sector.

Activities:

1. Consultancy for National Drug Policy and Rational Use of Drugs
1. Committee meetings
2. Workshops / Seminars

3. ***Establishing Drug Information and Adverse Drug Reactions Monitoring Cell***

- To make available all the information related to drugs such as marketing authorization procedure, Registered Drugs, Licensed Manufacturing Unit, Licensed drug Outlets, related drugs law and policies etc.
- To collect the information about Adverse Drug Reaction, evaluation of ADR and awareness dissemination
- To ensure Rational Use of Drug to minimize side effects and avoid misuse of drugs

Activities:

1. Printing and Publications ADR Bulletin, Awareness Poster, etc.
2. Procurement of Office Equipment
3. Procurement of Machinery and Other Equipment
4. Awareness and Sensitization for RUD
5. Procurement of Computer and Accessories
6. Training on Computer and ICT

4. ***Strengthening field monitoring and quality assurance of drugs***

A strong Drug Regulatory Authority is essential for evaluation of manufacturing facilities of drugs and for ensuring use of safe, efficacious and good quality medicine in the country through post marketing surveillance. The Directorate General of Drug Administration needs strengthening and building capacity to carry on its responsibilities effectively.

Activities:

1. Construction of Office Building*
2. Procurement of Vehicles
3. Procurement of Furniture and Fixture
4. Procurement of Telecommunication equipment
5. Automation of DGDA
6. Training for DGDA Officers on GMP, **QMS, IMS, Accreditation System,** Quality Control and Quality Assurance of Drugs and Vaccines

** Construction of office building will be done by HED.*

11. Relevant Result Frame Work Indicators (s): Base line, Projected Target for the planned year

11.1 ***Relevant RFW Indicators: None***

11.2 *OP indicators (Output/Process)*

Indicators	Unit of Measurement	Base line (Year and Source)	Projected Target	
			Mid-2014	Mid-2016
Drug/vaccine testing laboratory modernized and functional	Functional Laboratory	NA	1	2
National Drug Policy revised and approved	Approved policy	NA	Done	Done
Adverse drug reaction (ADR) cell established	Functional cell	NA	Done	Done
Number of Drug samples tested	Number of test	3500/year (2010)	10000	20000
Number of Drug Manufacturing units inspected.	Number of Inspection	700/year (2010)	2200	4000
Number of drug shops inspected	Number of Inspection	26000/Year 2010	70000	100000
Number of Batches of staff received training on GMP, QMS, Accreditation, quality control and vaccines	Number of batches	NA	6	10

11.3 ***Source and methodology of data collection:*** Primary data will be available under the DGDA head quarter. The line director office will also be the source of data / information regarding the program related activities. The other data sources are planning wing, MOHFW and IMED. Due to proposed automation, data generated at all level particularly at the industry (secondary source), DGDA, QC, dispensing, ADR records and exports (secondary source) through defined formats and software use data will be collected.

Implementation records particularly laboratory/ field reports, monthly financial and physical progress reports prepared by LD, reports for the Planning Commission, IMED, Prime Minister's Office will be the means of verification.

12. **Estimated Budget:**

12.1 *Estimated summary of development budget:*

(Taka in Lakh)

Name of the Components	Economic Code	GOB	Project Aid			Total	% of the total cost
			RPA		DPA		
			Through GOB	Others			
1	2	3	4	5	6	7	8
a) Revenue Component							
	4800 Supplies and Services	80.00	58.00		248.00	386.00	12.23
	4900 Repair and Maintenance	845.00				845.00	26.78
Sub total (Revenue Component)		**925.00**	**58.00**		**248.00**	**1,231.00**	39.02
b) Capital Component							
	6800 Acquisition of Assets/ Purchase	80.00	779.00		375.00	1,234.00	39.11
	7000 Construction Works		690.00			690.00	21.87
Sub total (Capital Component)		**80.00**	**1,469.00**		**375.00**	**1,924.00**	60.98
Grand Total (a+b)		**1,005.00**	**1,527.00**		**623.00**	**3,155.00**	

14. Location-wise break-up of the components (Attached Annexure)

(Taka in lakh)

Name of the components	National	Name of Division	Name of District	Name of Upazilla	Estimated cost
Strengthening, Regulatory and monitoring functions of DGDA, and RUD	**1**	**Dhaka**	**All Districts**	**-**	**3155.00**

15. **Log Frame (As per Annexure- II)**

16. **Annual Procurement Plan for Goods, Works, Services (Separate table for a. Goods, b. Works, c. Services): (As per Annexure- III a, b, c)**

17. **List of Machinery & Equipments (Annexure-IV):**

18. **List of Furniture-Fixture (Annexure-V):**

19. **List of Vehicle (Annexure-VI):**

20. **List of training and estimated cost (Annexure-VII):**

21. **Related Supporting Documents (if any): NA**

22. **Name & Designation of officers responsible for the preparation of this OP:**

(1) A. A. Salim Barami, Deputy Director, Directorate General of Drug Administration

(2) Md. Ruhul Amin, Assistant Director, Directorate General of Drug Administration

(3) Md. Altaf Hossain, Assistant Director, Directorate General of Drug Administration

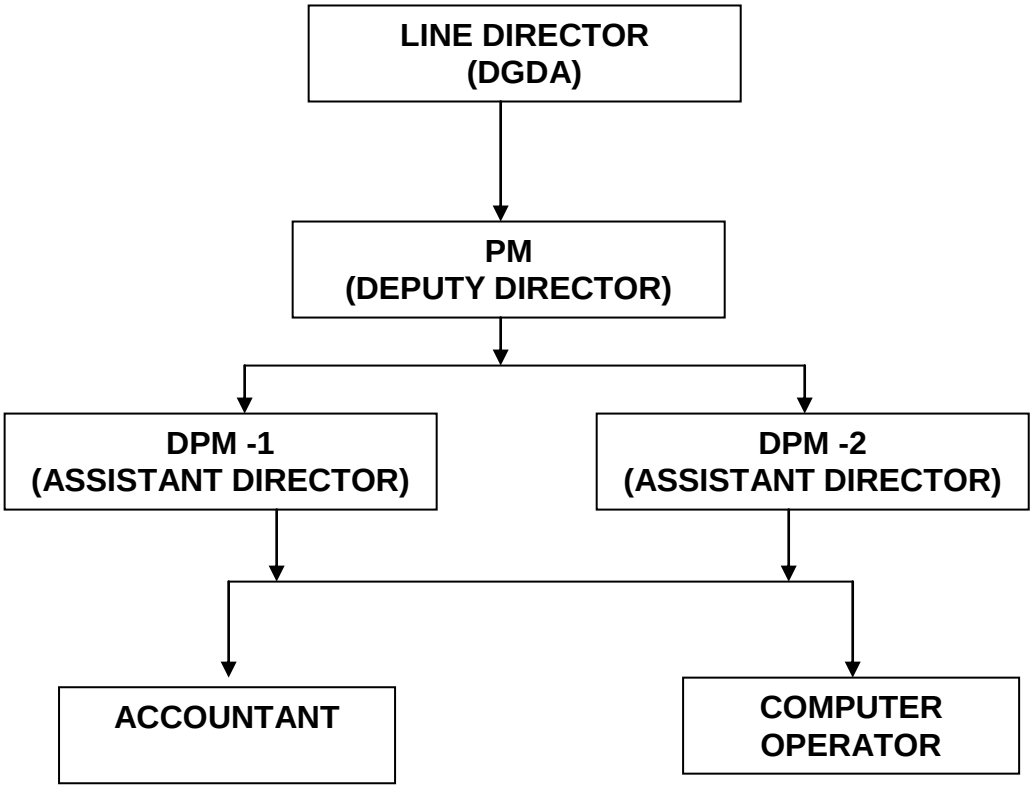
23. **Recommendation and Signature of the Head of the Implementing Agency with seal & date:**

Major General Md. Abul Kalam Azad
Director General
Directorate General of Drug Administration
&
Line Director, Strengthening of Drug Administration and Management

24. **Recommendation of the Signature of the Secretary of the sponsoring Ministry with seal & date:**

Annexure-I

Organogram



Annexure-II

Log-frame

(i) Planned date of completion: 30 June, 2016

(ii) Date of summary preparation: 17 August, 2011

	NARRATIVE SUMMARY	OBJECTIVELY VERIFIABLE INDICATORS	MEANS OF VERIFICATION	IMPORTANT ASSUMPTIONS
Programme/OP Goal	Ensured quality, efficacy, and safety of pharmaceutical products towards improving the health of the people	➢ Improved drug manufacturing with better quality and safety management and curbing spurious drug manufacturing and marketing, lessening drug-abuse, and use of drugs rationally.	National Drug Policy Foreign money earned by exporting drugs PCR - IMED	
OP Purpose	Established and utilized efficient drug testing system with laboratory facilities to ensure quality of drugs	➢ Drug testing, quality products, accreditation and licensing is automated stored and used for evidence-based decision making	Quarterly OP report	Ensured quality of product
OUTPUTS	1) Ensure essential drugs for all 2) Support drug-manufacturing industries keeping pace with changed global scenario 3) Modernize pharmaceutical sector aiming beyond national horizon to the international export markets	1) Made available all the information related to drugs such as marketing authorization procedure, registered drugs, licensed manufacturing unit, licensed drug outlets, related drug law and policies 2) Evaluated Adverse Drug Reaction (ADR) and findings made available to public for awareness 3) Ensured Rational Use of Drugs to minimize side effects and avoid misuse of drugs 4) Build capacity of Drug Regulatory Authority for conducting evaluation of manufacturing facilities of drugs and for ensuring use of safe, efficacious and good quality medicine in the country through post marketing surveillance	Quality OP report IMED Report	Adequate technical support is in place Availability of forecasting and procurement plan

	NARRATIVE SUMMARY	OBJECTIVELY VERIFIABLE INDICATORS	MEANS OF VERIFICATION	IMPORTANT ASSUMPTIONS
INPUTS/Activities	1) Establish modern drug/vaccine testing laboratory 2) Update National Drug Policy for ensuring quality drugs in the market 3) Establish Drug Information and Adverse Drug Reactions Monitoring Cell 4) Strengthening field monitoring and quality assurance of drugs	***Component 1:*** ➢ Procurement of Laboratory Equipment (16 Nos.) ➢ Repair & Renovation of Drug Testing Laboratory (2 Labs) ➢ Repair and Maintenance of Laboratory Equipment Component 2: ➢ Committee meetings held (15 meetings) ➢ Workshops/Seminars organized (3 Workshops) ***Component 3:*** ➢ Printing and Publications ADR Bulleting, Awareness Poster, etc. ➢ Procurement of Office Equipment (45 Nos.) ➢ Procurement of Machinery and other equipment (34 Nos.) ➢ Awareness and sensitization for RUD ➢ Procurement of Computer and Accessories (202 Nos.) ➢ Training on Computer and ICT ***Component 4:*** ➢ Construction of Office Building (3 Divisional Office) ➢ Procurement of Vehicles : (28 Nos.) ➢ Procurement of Furniture and Fixture ➢ Procurement of Telecommunication Equipment ➢ Automation of DGDA ➢ Training for DGDA Officers on GMP, QMS, IMS, Accreditation System, quality Control and Quality Assurance of Drugs and Vaccines (217 persons)	Quarterly OP report Software and database inventory IMED Report	Prepared proper software Prepared appropriate logistics procurement Plan and implement Support received from HPNSDP availability of fund.