

Annexure – I CDSCO, MUMBAI

POINTS ON WHICH ACTION NEEDS TO BE TAKEN

a.	The particulars of its Organization, functions and duties	Office of the Deputy Drugs Controller (India) CDSCO, Directorate General of Health Services, MHFW, GOI with its Headquarters in New Delhi and has jurisdiction over the States of Maharashtra, Goa, Gujarat, Madhya Pradesh, Chattisgarh, UTs of Dadra & Nagar Haveli and Silvassa. Functions and Duties are annexed.
b.	The powers and duties of its officers and employees	Attached
c.	The procedure followed in the decision making process, including channles of supervision and accountability	Attached
d.	The norms set by it for its functions	As per the provisions of Drugs & Cosmetics Act, the manufacturing units covered under the CLAA Scheme are required to be inspected once in a year. As regarding GMP Certification which is a voluntary exercise, this office will never have an information as how many firms are getting ready or proposing to apply for the WHO GMP Certification till they make an application.
e.	The rules, regulations, instructions manuals and records held by it or under its control or used by its employees for discharging its functions	The entire functioning of the office is as per the provisions of Drugs & Cosmetics Act and directions periodically received from the Headquarters i.e. Drugs Controller General (I) heading the Central Drugs Standard Control Organisation. Company wise files are maintained for firms under CLAA Scheme and WHO GMP applications.
f.	A statement of the categories of documents that are held by it or under its control	As above

g.	Particulars of any arrangement exist for consultation with or representation by the members of public in relation to the formulation of its policy or implementation thereof.	This is a peripheral office and all policy matters are decided by the Headquarters i.e. CDSCO New Delhi.
h.	A statement of the boards, councils, committees and other bodies consisting of two or more persons constituted as its apart or for the purpose of its advice and as whether meetings of those boards councils committees and otehr bodies are open to public or the minutes of such meetings are accessible for public.	This is a small office and no Board or Council has been formed.
i.	A directory of its officers and employees	Attached
j.	The monthly remuneration by each of its officers and employees including the system of compensation as provided in its regulations.	Attached
k.	The budget allocated to each of its agency indicating the particulars of all plans proposed expenditure and reports on disbursement made.	Attached
l.	The manner of execution of subsidy program including the amounts allocated and the details of beneficiaries of such program	This office is a regulatory deptt. And has no provision or powers to grant subsidies to any organisations.
m.	Particulars of recipient of concessions permits or authorisations granted by it.	Do not arise
n.	The particulars of facilities available to citizen for obtaining information including the working hours of library or reading room if maintained for public use.	This office follows Central Govt. timings for office hours and is known to general public.
o.	The names designations and other particulars of the Public Information Officer	There is no separate PIO. The Head of the Office and Officers respond to any queries from any public.
p.	Such other information as may be prescribed and thereafter update these publications every year.	This office do not carry out any publications.

Attachment: Pt. (a)

The Zonal Office of the CDSCO have to perform the following functions:

1. Inspection of manufacturing firms jointly with State Government covered under the CLAA Scheme i.e. I V Fluids, Large Volume Parenterals, Vaccine & Sera, Blood & Blood Products, rDNA products (Biotech Products) etc. for the purpose of grant / renewal of licenses.
2. Inspection of testing laboratories approved in Form 37
3. Inspection of manufacturing facilities of the firms for grant of WHO GMP Certification Scheme.
4. Inspection of firms for capacity assessment and other provisions at the request of the Ministry of Health & Family welfare Department.
5. Inspection of firms for registration with Government Medical Store Depots
6. Special inspections by the directions of the Drugs Controller General (India) for product such as reagents and kits etc.
7. Inspections to investigate complaints received from various forums.
8. Post Market Surveillance of the quality of drugs marketed in the country.
9. Periodical surveys of the market
10. Scrutiny of protocols of blood products imported into the country through the port of entry.
11. Approval of plans of the manufacturing units engaged in the manufacture of items covered under the CLAA Scheme.
12. Evaluation of quality of drugs moving in the market through Drugs Inspectors and Drug Samplers.
13. Interaction with various Industry Associations like IDMA, OPPI etc.
14. Co-ordinating with the State Drug Controllers in the Western Region for problems involved in the interstate commerce.
15. Representing Government of India on various Court cases filed in the High Courts of the Western region.
16. To launch prosecutions in cases detected by this office pertaining to Drugs & Cosmetics.

Attachment – Pt. b
Duties of Drugs Inspectors

Drugs Inspectors are engaged in the Inspection of:

- Manufacturing premises requesting grant of WHO GMP Certificate
- Inspection of Blood Banks for grant or renewal of licenses.
- Inspection of LVP Manufacturing Units for grant or renewal of licenses and
- Inspection of the units engaged in the manufacture of Sera & Vaccines
- Inspection of Private Testing Laboratories
- Sales Establishments and places like Government Medical Stores Depots for drawal of samples for test.
- Conduct investigations, raids in case samples are found to be spurious, counterfeit or sub-standard.
- Inspector also launch prosecution in respective courts.

There are instances that the manufacturing establishments are being inspected by WHO officials for UNICEF supplies and Inspectors have to accompany WHO officials or participate in inspection by them.

At times, assistance is also given to officials of Ministry of health for capacity assessment and in case the inspection is being carried out for supplies of items such as Copper T, Tubal Rings or Condomn etc.

There are writ Petitions filed in Mumbai High Court on various matters and Drugs Inspectors attend the court on behalf of Drugs Controller General (India).

Job functions of Sr. Technical Assistant (STA)

All the applications received for grant / renewal of licenses of LVP / Sera-Vaccines and also for grant / re-issue of WHO GMP Certificates, State-Wise are entered in respective registers before any further action is decided. This is a chronology of applications received.

There are number of applications for grant of WHO GMP Certificates regarding additional products. This information is maintained.

In order to prepare monthly, quarterly, annual reports, daily information of sequence of events of this office is maintained and based on the information compiled, the above reports are prepared and sent to the DCG (I), new Delhi.

List of pending inspections is also regularly updated and put up at the time of distribution of work.

Information regarding samples drawn by Drugs Inspectors as well as Drugs Samplers is also maintained and the same is included in monthly, quarterly and annual reports.

Also test reports received from government laboratories on these samples are also noted in different registers.

Action on sub-standard test reports drawn by Drugs Samplers is also taken.

All important files, such as Directorate Ruling, Draft Amendments, Final Admndments, DCC, Spurious Drugs, Toxic Drugs etc are also maintained.

Information regarding complaints received and action taken are also maintained.

Inspection Related Activities:

Checking of Inspection reports, remarks and recommendations submitted by the Drugs Inspectors of the Blood banks situated in maharashtra, gujarat, MP, Goa, chattisgarh, Damana nd Silvassa in order to grant or renewal of license.

Maintenance of license files of blood banks

Processing of licenses for renewal and sent to respective State Drug Controllers.

All the inspecytion registers are being maintained

All the applications are scrutinised for approval and if any deficiencies are observed then the concerned Blood Banks are informed accordingly.

We maintained the approved licenses records received from CLAA.

Protocols of Blood products received from different pharmaceutical companies are checked and scrutinised for approval.

DRUGS SAMPLERS:

Drawal of Samples of items of medicines from far flung areas in the Zone.

Noting proper identity of the test purchase and place of drawal of samples in the registers.

Preparation of forwarding memos for despatch of samples for test to respective laboratory.

Despatch of samples for test.

Accompanying Drugs Inspectors for Investigations in case the samples drawn are found counterfeit or grossly substandard.

Attachment (pt. c)

The office receives applications for grant/renewal of licenses from the manufacturers located in the states under the jurisdiction of Western Region for drugs covered under CLAA Scheme. On receipt of applications it gets scrutinised for compliance to requirements. Joint Inspections with concerned State Drug Controllers are planned and carried out with or without expert based on the recommendations of the inspection team. Licenses are recommended for grant / renewal and the concerned State Drugs Controller is advised to prepare the licenses and forward to Delhi. In case of grant/renewal of LVPs Vaccine and Seras, rDNA products and in case of renewal of blood bank, licenses are to be forwarded to this office. Drawal of samples is carried out by the Inspectors as per the statutory provisions laid down under the Drugs and Cosmetics Act. Under WHO GMP Certification on receipt of applications, the Site Master File gets scrutinised for compliance to WHO GMP requirements. Joint Inspections are planned with State FDA Officials. Based on the observations a grant of certificate or rejection of certificate is recommended to concerned State Drugs Controllers.

Attachment – i Directory of Officers & Employees

**OFFICE OF THE DY. DRUGS CONTROLLER (INDIA), CDSCO
WEST ZONE, MUMBAI**

<u>GROUP</u>	<u>GAZETTED/NON- GAZETTED</u>	<u>POSTS</u>	<u>DESIGNATION</u>
GROUP A (INDIA)	GAZETTED OFFICE	ONE	DY. DRUGS CONTROLLER
GROUP B	GAZETTED OFFICER	SIX	DRUGS INSPECTOR
GROUP B	NON-GAZETTED OFFICER	THREE	SR. TECHNICAL ASSISTANT
GROUP C	NON GAZETTED	EIGHT	HEAD CLERK/ STENOGRAPHERS/ UDC/LDCs/DRUGS SAMPLERS
GROUP D		TWO	PEON/DAFTRY

Attachment: Pt. J**Monthly Remuneration by each of its officers & Employees including the system of compensation as provided in its regulations**

Sr. No.	Name of the Officer/Employee	Pay Scale	Gross Salary Monthly Remuneration
1	Dr. M Venkateswarlu Dy. Drugs Controller (India) Gr. A Gazetted	12000-375-16500	Rs. 31167/-
2	Shri S E Reddy	7500-250-12000	Rs. 17089/-
3	Dr. V G Somani		Rs. 21652/-
4	Shri A Ramkishan Drugs Inspectors Gr. B Gazetted		Rs. 21652/-
5	Shri A V Samel	6500-200-10500	Rs. 23577/-
6	Smt. A A Wagh		Rs. 17035/-
7	Smt. K A Majid Sr. Technical Assistants Gr. B Non-Gazetted		Rs. 17035/-
8	Head Clerk, Gr. C	5000-150-8000	Rs. 16482/-
9	Shri M M Mohanan Sr. Stenographer, Gr. C	5000-150-8000	Rs. 15147/-
10	Smt. S Damodaran Jr. Stenographer, Gr. C	4000-100-6000	Rs. 13764/-
11	Shri P B Bhable U.D.C, Gr. C	4000-100-6000	Rs. 13008/-
12	Shri B V Gurav	3050-75-3950- 80-4590	Rs. 10894/-
13	Smt. P P Salunkhe L D C, Gr. C		Rs. 8568/-
14	Shri S G Hiroji	3050-75-3950- 80-4590	Rs. 8737
15	Shri J K Singh Drugs Sampler, Gr. C		Rs. 6245/-
16	Shri C B Bhurkunde Daftry, Gr. D	2610-60-3150-65	Rs. 9592/-
17	P D Kashale Peon, Gr. D	2550-55-2660- 60-3200	Rs. 6029/-

Attachment - K

The Budget Allocated to each of its agency indicating the particulars of all plans proposed expenditure and reports on disbursement made

BUDGET ESTIMATE 2004-05

	NON PLAN	PLAN
Salaries	26.20	-
T.E.	01.20	01.20
O.E.	01.00	02.50
	28.40	03.70

BUDGET ESTIMATE 2005-06

	NON PLAN	PLAN
Salaries	27.90	-
T.E.	01.20	01.20
O.E.	01.50	02.50
	30.60	03.70