SUO MOTU DISCLOSURE UNDER SECTION 4 OF RTI ACT 2005 (CDSCO, West Zone, Mumbai)

- 1. Organization and Function:-
 - 1.1 Particulars of its organization, functions and duties [Section 4(1)(b)(i)]

Name and address of the Organization:-

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO) (WEST ZONE) MUMBAI

Central Drug Standards Control Organization, West Zone, 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai — 400 008

wzmumbai@cdsco.nic.in

https://cdsco.gov.in/ (Website Designed, Developed and Maintained by CDAC as per requirements provided by CDSCO (HQ), New Delhi)

Head of the Organization

Deputy Drugs Controller (India)

(i) Vision, Mission and Key Objectives:

Vision:

To Protect and Promote Public Health in India.

Mission:

To Safeguard and Enhance the Public Health by Assuring the Safety, Efficacy and Qualityof Drugs, Cosmetics and Medical devices.

(ii) Function and duties:-

Technical:

In fulfilling its mission, the CDSCO, Zonal office, Mumbai has following functions:

- To participate in the joint-inspection for grant/ retention of license for manufacturing of Drugs and Cosmetics as per GSR 1337 (E) dated 27th October, 2017.
- 2. To participate in the joint-inspection for grant/retention of Vaccine / Sera manufacturing units for both human as well as veterinary.

- 3. To participate in the joint-inspection for grant/ retention of LVP manufacturing units.
- 4. To participate in the joint-inspection for grant/retention of Bio-tech (r-DNA) & Bio-similar products manufacturing units i.e. recombinant (r-DNA products)
- 5. To participate in the joint-inspection for issuance /revalidation of Certificate of .Pharmaceutical Products (COPPs) as per WHO-GMP Certification Scheme.
- 6. To process application for Written Confirmation (WC) for export of API to European Union as per EU Directives and their inspection, if required.
- 7. To participate in the joint-inspection for grant of approval for Private Testing Laboratory (PTL) for test/ analysis of Drugs & Cosmetics as per the provisions of Drugs & Cosmetics Act and Rules there under.
- 8. To participate in the inspection of Clinical Trial facilities and BA/BE centers as directed by the Drugs Controller General (India) from time to time. To carryout inspection for grant of license of Medical Devices (Class C & Class D) and In-vitro Diagnostic Kit (Class C & Class D) manufacturing units under Medical Devices Rules, 2017.
- 9. To carry out Surprise check/Raids jointly or independently on the basis of complaint received under Whistle Blower scheme and also from other sources.
- 10. Drawing of legal samples of Drugs from the manufacturing & sales / distribution premises including the Govt. establishment.
- 11. Follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices, on the basis of Govt. Analyst test report.
- 12. To pursue the court cases pending in different courts under the zone.
- 13. Technical survey as and when directed by the Drugs Controller General (India) from time to time.
- 14. To discuss the matter with various State Drugs Controllers in the zone in connection with enforcement of the provisions of D & C Act & Rules there under from time to time.
- 15. To co-ordinate for answering the Parliament Questions and for obtaining the data from various State Licensing Authorities under the jurisdiction of the zone.
- 16. Reply of RTI applications under RTI Act, 2005.
- 17. To participate as observer in inspections conducted by various international regulatory agencies as and when informed by HQ.

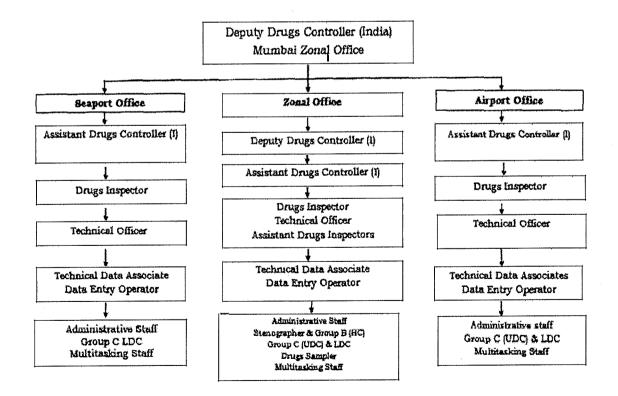
- 18. To organize workshop, seminar etc. as directed by the Controlling Authority.
- 19. To conduct the function of Drugs Controller General (I) as and when delegated by him under rule 22 (b) & 122L and other Rules of the Drugs and Cosmetics Rules, 1945. The following functions delegated to respective zonal officers for carrying out on his behalf: -
- i. Permission for grant of license to manufacture drugs for the purpose of examination, test or analysis under the New Drugs & Clinical Trials Rules, 2019 in Form CT-11 for new drugs/investigational new drugs (Active Pharmaceutical Ingredients & formulations), FormCT-14 (Unapproved Formulations) and FormCT-15 (unapproved APIs) so as to obtain license from State Licensing Authority (SLA) of concerned State under Rules 89 of the Drugs and Cosmetics Rules, 1945 on Form-29 as per requirements.
- ii. Grant of license for import of small quantities of old drugs in Form-11 for the purpose of examination, test or analysis as provided under Rule 33 of the Drugs and Cosmetics Rules, 1945 and for import of small quantities of new drugs in Form CT-17 under the provisions of NDCT Rules, 2019
- iii. Grant of license for import of small quantities of unapproved new drugs in Form CT- 25 by Government Institutions or Autonomous Medical Institutions for treatment of patients under Rule 86 of New Drugs and Clinical Trial Rules, 2019.
- iv. No objection certificates (Dual use NOC) for grant of permissions for import of dual use items, not for medicinal use.
- 20. Any other functions as assigned by JDC (I)/DCG (I).

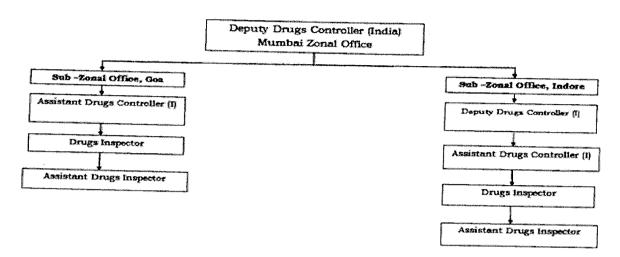
A. Administrative:

- To Maintain the Service records/Leave records of Gazetted and Non-Gazetted
 Technical and Administrative Staff of CDSCO West Zone Mumbai and subordinate
 offices of Ahmedabad, Indore and Goa (under administrative control of CDSCO West
 Zone Mumbai).
- 2) To maintain Seniority list of Non-Gazetted employees.
- 3) Preparation and Grant of MACPs to eligible officials, arrears to officials.
- 4) To prepare Annual Budgets /preliminary and final estimate of expenditure etc.
- 5) To Prepare reports/replies concerning to the above administrative functions.

- To purchase stationeries and office items as per the requirements.
- 7) Annual Maintenance Contract (AMC) of office equipment etc.
- 8) To prepare Pensionary and other benefits of retired officials.
- 9) Processing of TA bills for reimbursement of officials of CDSCO West Zone Mumbai and sub-ordinate offices at Ahmedabad, Indore and Goa.
- 10) Processing of Medical bills for reimbursement of officials of CDSCO West Zone Mumbai and sub-ordinate offices at Ahmedabad, Indore and Goa
- 11) Processing of Professional Service bills for reimbursement of CDSCO West Zone Mumbai and sub-ordinate offices at Ahmedabad, Indore and Goa
- 12) Reply of RTI applications under RTI Act, 2005.
- 13) Any other functions assigned by JDC (I)/DCG (I) from time to time.
- (v) Organization Chart:

Table No.1





VI) Any other details-the genesis, inception, formation of the department and the HoDs from time to time as well as the committees/ Commissions constituted from time to time have been dealt.

The Central Drugs Standard Control Organization (CDSCO), West Zone, Mumbai was started during the year July 1967 at Abubakar Mansion, Colaba, Mumbai 400001, headed by Deputy Drugs Controller (India).

The Zonal office of the CDSCO, WZ Mumbai was initially created to co-ordinate with the various State Drugs Controllers (who are the Licensing Authority) under the Act for uniform implementation and smooth enforcement of the provisions of Chapter IV of the Drugs & Cosmetics Act and Rules. The Said office was shifted to Antop Hill, CGHS Dispensary Building No. 08, Sector-1, Kane Nagar, Nr. Kane Nagar Post office, Antop Hill, Mumbai 400 0037 in the Year 1975. The West Zone office had jurisdiction over the states of Maharashtra, Gujarat, Chattisgarh, Goa, Madhya Pradesh, union Territory of Daman & Diu (Daman) and Dadra & Nagar Haveli (Silvassa). At present the West Zone office is functioning since 11th January 2010 at 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Rd., Mumbai Central, Mumbai 400 008, and has jurisdiction over the States of Maharashtra, Chattisgarh, Union Territory of Daman & Diu (Daman) and Dadra Nagar Haveli (Silvassa).

A new Sub-Zonal office Ahmedabad headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Gujarat had started and is functioning w.e.f. 1st April 2002. Ahmedabad Sub-zonal office was upgraded to Zonal level from 11th July 2011. Deputy Drugs Controller (India) is the head of office at CDSCO Zonal office, Ahmedabad.

The CDSCO, Sub-Zone Indore started its operations from the premises of Container Corporation of India Ltd., Inland Container Depot (ICD), 113-Concor Complex, Sector -3, Pithampur Industrial Area, Pithampur, Dist. Dhar, Madhya Pradesh, w.e.f. 22nd February 2010, to regulate the Export of Drugs & Cosmetics from Indore. In the Yr. 2014, CDSCO Sub-Zone Office shifted to the other premises at Quarter No. 67, 68, 69, 70, 71, 72, Type-1, Griffens Colony and now since

July 2021 CDSCO Sub-Zone office is functioning from CDSCO Bhawan, GPO Square, Residency Area, A B Road, Indore (MP) - 452001 and is headed by the Dy. Drugs Controller (India) with jurisdiction over the State of Madhya Pradesh.

Central Drugs Testing Laboratory (CDTL) - Indore is engaged in the analysis of drugs and pharmaceuticals as per Drugs & Cosmetics Act and rules there under. CDTL is functioning from the same premises of CDSCO Bhawan, GPO Square, Residency Area, A B Road, Indore (MP) — 452001, from where the office of CDSCO Sub-Zone Indore is functioning.

CDSCO Sub-zone, Goa is headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Goa had started functioning in the Yr. 2011 at 3'd Floor, Customs Building, Customs House, Marmagoa, Goa 403803. Since 2017, the O/o. CDSCO, Sub-Zone/Port office, Goa was operating from the Ground Fir., Port Users Complex (Old A O Bldg) Mormugao Harbour, Nr. to Mormugao Sub-Post office, Mormugao, Goa-403803. Since September 2023, the CDSCO, Goa Sub-Zone/Port Office is shifted and functioning at the new premises i.e. Room No. 07 & 08, First Floor, Air Cargo Terminal Building, Manohar International Airport, Dadachiwadi Road, Nagzar, Taluka Pernem, Mopa, North Goa, Goa-403512.

1.2 Power and duties of its officers and employees [Section 4(1) (b)(ii)]

- i) Powers and duties of officers (administrative, financial and judicial) &
- ii) Power and duties of other employees.

Designation	Duties
Deputy Drugs Controller	Technical head of the office of CDSCO (West Zone) Mumbai, CDSCO Port Offices at Airport Mumbai, JNPT Seaport Panvel and
	administrative head for CDSCO Zonal office Mumbai, Ahmedabad and Sub-Zone office Goa and Indore.
	2. Co-ordination and co-operation with the States Drugs Controllers under West Zone (Maharashtra, Goa, Chattisgarh, U.T. of Daman & Diu and Silvassa) in order to ensure uniform enforcement of Drugs & Cosmetics Act and rules and other related legislations for the work relating to inspections for Licensing of Blood Banks, manufacturing of Large Volume Parenterals, Biological Products including Vaccines, Medical Devices as per Medical Device Rules, 2017 and issuance of Certificate of Pharmaceutical Products (CoPP) as per WHO TRS guidelines by Drugs Inspectors of CDSCO and State Licensing Authorities.
	 Coordination with Zonal offices, Sub-Zonal and Port offices of CDSCO of other Zones for uniform administration of Drugs & Cosmetics Act and rules. Co-ordination with other organizations like Customs, DGFT, IPC, NIB, Pharmexcil etc. Deputation of inspectors for inspection on the basis of the applications received for joint inspections, raids, investigations, seizures and drawal of samples etc. as per Drugs & Cosmetics Act and rules.

- 5. Monitoring and evaluation of inspections conducted. submitted, reviewing and forwarding to Drugs Controller General (India) and / or State Licensing Authority for necessary action as applicable.
- 6. Review, monitoring, evaluation of all files, inspection reports submitted by all levels of staff including Drugs Inspectors and Technical officers.
- 7. Deputation, monitoring, evaluation and forwarding of report of joint inspections conducted by CDSCO and State Licensing Authorities under GSR 1337 (E) to concerned State Licensing Authority for necessary action (approval/compliance/rejection).
- 8. Approval and signing authority of:
 - a. No Objection Certificates for grant of permissions for import of dual use items which are "Not for Medicinal use" by SUGAM Portal.
 - b. No Objection Certificate to manufacture approved /unapproved new drugs in Form 29 for the purpose of examination, test and analysis In Form CT-11, Form CT-14 and Form CT-15 by NSWS portal.
 - c. Grant of Test License for the import of Drugs for purpose of examination, test or analysis In Form-11 and Form CT-17 by NSWS portal.
- 9. Monitoring the establishment of Minilabs at Port offices and coordination with Customs Commissioners on matters related to Port offices.
- 10. Taking action on Not of Standard Quality drugs as per Drugs & Cosmetics Act and Rules and as per CDSCO guidance document.
- 11. Deputation of Drugs Samplers at various places of suspicious nature to collect samples as surrogate patient from the sales premises by way of survey to monitor the quality of drugs and also deputation of Drugs Inspectors in case the samples are declared as NSQ by the testing laboratory.
- 12. Monitoring of technical survey of drugs as and when directed by the Drugs Controller General (India).
- 13. Acting as Appellate Authority for CDSCO West Zone for responding to RTI, replying Parliamentary Questions, etc. as and when required.
- 14. Participation in various committees as Technical Expert, Workshops, Seminars as Speakers etc. and other related matters on behalf of DCG (I) including Stakeholders meetings and resolve any issues, matters pertaining to manufacture, testing, import and export of drugs etc.
- 15. Any other functions as assigned by the Drugs Controller General (India) from time to time.

Assistant Drugs Controller (India)

- 1. Responsible for coordination and compliance with the directions of the Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai for carrying out regulatory inspections (Certificate of Pharmaceutical Products, Blood Centres, Blood Products, Vaccines Sera, rDNA, Complaints. Parenterals) Inspections. Raids/Investigations as directed by Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai.
- 2. Monitoring of activities of Drugs Inspectors who are responsible for conduct of joint inspections, complaints investigations and sampling etc. as and when directed by the Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai.
- 3. Coordination with Zonal Offices / State Licensing Authorities /Ports and Other Authorities as and when directed by the DDC (I) CDSCO WZ Mumbai.
- 4. Processing of On-line Medical Device applications through SUGAM PORTAL as a Nodal officer / Medical Device Officer and Reviewing Officer.
- 5. Allotment / processing of On-line Test License applications through NSWS as Nodal Officer.
- 6. Acting as a Central Public Information Officer for RTI applications.
- 7. Responsible for coordinating and compliance with the directions of the Dy. Drugs Controller (India), CDSCO West Zone Mumbai for carrying out regulatory inspections (COPPs, CLAA Inspections and Complaints, Raids/Investigations) as directed by DDC (I) WZ Mumbai.
- 8. Deputation of Drugs Inspector for carrying out joint inspections, complaints investigations, sampling etc. in absence & as and when directed by the DDC (I) CDSCO WZ Mumbai.
- 9. Handling queries from the applicants as a Public Relation Officer and as a Nodal Officer for resolving grievances received from general public.
- 10. Acting as a Drawing and Disbursing Officer (DDO) in administration matters.

Technical Officer

- 1. Entries of applications in the respective registers of applications received for grant / revalidation of WHO GMP Certificate / COPP, Written confirmations, Blood Banks, manufacturing licenses for Dtugs & Cosmetics, vaccines, Public Testing Laboratories, rDNA, BA-BE State Wise (West Zone) etc.
- 2. Providing of applications / files to officers as and when required when the inspections are planned.
- 3. Scrutiny of online Dual Use NOC for import of drugs intended for non medicinal use.
- 4. Scrutiny of Bill of Entries for import of drugs referred by port officers for DDC clarification.
- 5. Assisting the SPC Govt. of India and Dis for preparing Petition and Counters for cases of Drugs imported by the various importers.
- 6. Preparing replies for the technical clarification in respect of import and export of drugs sought by Customs, importers and public.
- 7. Maintaining technical correspondence related to import and export of drugs and attending various queries by public, importer and exporter.
- 8. Timely preparation of pending list of Inspection to be carried out. Monthly & Quarterly.
- 9. Providing of data / details required in respect of framing of replies pertaining to RTI, Parliament Questions etc.
- 10. To co-ordinate for answering the parliament question and for obtaining data from various State Licensing Authorities under the Zone.
- Maintaining of approved license records received from CLAA.
- 12. There are more than 1000 files pertaining to the technical section are maintained.

Drugs Inspector/ Medical Device Officer

- 1. To participate in the joint inspections for issuance/revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO Certification Scheme as and when allotted by the DOC (I).
- 2. To participate in the joint inspections for grant/renewal of licenses with respect to the following as and when allotted by the DDC (I):
 - a. Blood Bank license, Vaccine/Sera manufacturing units for both human as well as Veterinary, LVP manufacturing units etc.
 - b. For notified Medical Devices & Critical Diagnostics manufacturing units.
 - c. For Biotech & Bio-similar products manufacturing units.
 - d. Inspections of Clinical Trial facilities and BA/BE centers as directed by the Drugs Controller General (India) from time to time.
 - e. Inspections for issue of Written Confirmation for export of API to EU.
 - f. To carry out joint inspection of Drug Testing Laboratory for the purpose of grant of approval for test/analysis of Drugs & Cosmetics.
- 3. To carry out surprise check/raid jointly or independently on the basis of complaint received under whistle-Blower Scheme and also from other sources.
- 4. To follow-up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other Zonal offices
- 5. Routine sampling of legal (Form 18) as well as Survey Samples for test/analysis by Central Laboratories.
- 6. When the samples drawn by the central Drugs Inspectors are declared spurious/adulterated/grossly sub-standard etc., the cases are investigated and prosecutions are launched in the appropriate court after obtaining necessary sanction from the Drugs Controller General (India).
- 7. Deputation of Drugs Samplers at various places of suspicious nature and collect samples through them as surrogate patient from the sales premises by way of survey to monitor the quality of drugs. Further surprise check/raid is to be carried out by the Drugs Inspectors in case these samples are declared as NSQ by the testing laboratory.
- 8. To participate in the joint inspections with respect to grant of NOC in Form 29 as per requirements.
- 9. Technical Survey as and when directed by the DDC (I) from time to time.
- 10. To co-ordinate and assist in the training, workshops, seminars etc. as directed.
- 11. Any other work assigned by the DDC (I).

Research Assistant/ Government Analyst (at CDTL Indore)	 To carry out analysis of drugs and pharmaceuticals, preparation of Test Report and signing the final report as a Government Analyst. Handling of various instruments for Analytical work, documentation and other related work. Follow-up of Purchase and Procurement of Laboratory items with CDSCO West Zone Mumbai office.
Assistant Drugs Inspector	 To assist in evaluation of Safety, Efficacy and Quality of Drugs as per requirement of Drugs and Cosmetics Rules, 1945. To carryout field duty in assisting superior/ Drugs Inspectors for taking out samples, enforcement activities like raids/ inspections for launching prosecution etc. To assist CDSCO officers in the matter of monitoring documentation. Details required in respect of RTI and Parliament Questions are submitted to DDC. Prescreening and scrutiny of online Dual Use NOC through SUGAM Portal and Test License applications in Form-12, Form CT-10, Form CT-12, Form CT-13 and Form CT-16 applications on NSWS. Any other work assigned by the DDC (I)/ ADC(I).
Technical Data Associate	 To assist CDSCO officers in the matter of monitoring. Documentation. Prescreening and scrutiny of online Dual Use NOC through SUGAM Portal and Test License applications in Form-12, Form CT-10, Form CT-12, Form CT-13 and Form CT-16 applications on NSWS. Any other work assigned by the DDC (I)/ ADC(I).
Head Clerk	Supervision of administrative and accounts activities like general administration, preparation of salary bills, personal claims of officers & staff, TA claim. Updating and maintenance of service records, leave records.
Stenographer	Preparation of letters/replies, correspondence related to technical and administration matters. Assisting administration staff in day-to-day activities of office. Assisting Officers in their technical work. Carrying out work assigned by HoD and Seniors.
Upper Division Clerk	Preparation of administrative replies, furnishing data for the RTI replies from administrative side, Validation of data in respect of officers and staff in the Personal Information system. Generating expenditure claims such as Office Expenditure, TA Claims, Professional services through PFMS portal. Monthly Expenditure statements, preparation of revised and budget estimate for the current and ensuing year. Reconciliation of accounts with Pay and Accounts Office.

Lower Division Clerk	Typing the official correspondence. Preparation of pay bills, income tax, e-TDS. Preparation of pension and retirement benefit papers. Purchase of stationery and other office equipments through GeM Portal.
Multi Tasking Staff	To open and close the office before and after the arrival and departure of officers and staff. To assist the officers and staff in moving the files from one desk to other. To attend the personal needs of Head of office. In addition to the auxiliary support, have to do basic clerical work, whenever there is a need.
Data Entry Operator	Typing of letters related to technical as directed by Seniors. Digital Signing of online applications of NOCs, Sending e-mails, Scanning reports and hyperlink to respective statements, Maintaining data of inspection reports in the respective registers and computer, Work assigned by Seniors.

(iii) Rules/ orders under which powers and duties are derived and exercised.

Deputy Drugs Controller (India) is working as Zonal Head & Controlling Officer under Drugs and Cosmetics Act 1940 and Rules, 1945. Drugs Inspectors derive their powers from Drugs & Cosmetics Act, 1940 (Section 21, 22 and 23) and Rules made there under (Drugs and Cosmetics Rules, 1945) and Medical Device Officer (Medical Devices Rules, 2017) and subsequent office orders issued by Directorate. Powers and duties of other posts are derived and exercised as per the practice in vogue. Copy of Drugs & Cosmetics Act and Rules under the said Act is available on CDSCO Website.

(iv) Work allocation

The information is available in the Table no.2

Procedure followed in decision making process

[Section 4(1)(b)(iii)]

Process of decision making Identify key decision making points.

Final decision making authority.

Related provisions, acts, rules etc.

Time limit for taking decisions, if any.

Channel of supervision and accountability.

As per Standard operating Procedure (SOP) the process of decision making based on the identified key decision making points is done at every level. SOP, guidance document and directorate order defines the hierarchy/channel of supervision of the office. The time limits for taking decisions are set by internal office orders issued from time to time. Final Decision making authority is vested with the Deputy Drugs Controller (I).

1.2 Norms for discharge of functions

[Section 4(1)(b)(iv)]

Nature of functions/ services offered.

Norms/ standards for functions/ service delivery.

Process by which these services can be accessed.

Time-limit for achieving the targets.

Process of redress of grievances.

The nature of functions /services offered by this office are listed under para no: 1.1.(iv). Various Licenses/Permissions are issued through the SUGAM PORTAL (www.cdscoonline.gov.in and www.cdscomdonline.gov.in).

Time limits are specified in the SOP. The grievances are redressed through Public Relation Office. Details of PRO are available on CDSCO website.

1.3 Rules, regulations, instructions manual and records for discharging functions [Section 4(1)(b)(v)]

Title and nature of the record/ manual/instruction.

List of Rules, regulations, instructions manuals and records.

Acts/ Rules manuals etc.

Transfer policy and transfer orders.

Drugs and Cosmetics Act, 1940 and Rules made there under (Drugs and Cosmetics Rules, 1945, Medical Device Rules, 2017 and New Drugs and Clinical Trials, 2019, Cosmetics Rules 2020, Guidance document for Zonal, Sub-zonal & Port Offices and subsequent office orders issued by Directorate are followed by this office for discharging functions. Further, Manual of Office Procedure and SUGAM online Portal User Manual in electronic format are also followed.

Transfer policy is formulated and transfer orders are issued by the Directorate. Copy of these Act, Rules, circulars, Notice is available on CDSCO website.

Categories of documents held by the authority under its control.

Categories of documents.

Custodian of documents/categories.

Documents are maintained as per the requirements of the following rules and manuals:-

Technical:

Manual of Office Procedure.

Drugs and Cosmetics Act, 1940.

Drugs and Cosmetics Rules, 1945.

CDSCO Guidance Document 2011.

Medical Device Rules, 2017.

New Drugs and Clinical Trials, 2019.

Cosmetic Rules, 2020.

Revised Schedule M, GSR 922 (E) dt. 28/12/2023.

Administrative:

Various documents and records are maintained as per the norms of Government of India https://dopt.gov.in/download/acts

- (i) Boards, Councils, Committees and other Bodies constituted as part of the Public Authority [Section 4(1)(b)(viii)]
- (ii) Name of Boards, Council, Committee etc. Composition
- (ii) Dates from which constituted (iv)Term/ Tenure

Powers and functions

Whether their meetings are open to the public?

Whether the minutes of the meetings are open to the public?

Various Boards and Committees are constituted by the Directorate and information is available. on CDSCO website.

1.6 Directory of officers and employees [Section 4(1) (b) (ix)]

Name and designation: Shri. Jayant Kumar, Deputy Drugs Controller (India)

Telephone, Fax and email ID:

Tel: 022-23002279 / 23002215, Fax: 022-23002271, Email id: wzmumbai@cdsco.nic.in

CONTACT DETAILS OF CDSCO (WEST ZONE), MUMBAI and Sub-Zonal Offices (Indore & Goa)

Refer organization website https://cdsco.gov. in/opencms/opencms/en/Home/

1.9 Monthly Remuneration received by officers & employees including system of compensation

[Section 4(1) (b) (x)]

List of employees with Gross Monthly Remuneration

System of compensation as provided in its regulations

O/o. THE DEPUTY DRUGS CONTROLLER (INDIA) CDSCO (WEST ZONE)

Pay Band and Pay Level of Various Posts --- CDSCO WEST ZONE

CDSCO, West Zone, Mumbai, Ahmedabad Zone, Sub-Zone-Indore, Sub-Zone-Goa and CDTL Indore.

1	Dy. Drugs Controller (India)	Level – 12 (78800-209200) GP 7600
2	Asstt. Drugs Controller (India)	Level 11 (67700-208700) GP 6600
3	Technical Officer	Level – 8 (47600-151100) GP 4800
4	Drugs Inspector	Level - 8 (47600-151100) GP 4800
5	Research Assistant	Level – 7 (44900-142400) GP 4600

6	Asstt. Drugs Inspector	Level - 6 (35400-112400) GP 4200
7	Head Clerk	Level - 6 (35400-112400) GP 4200
8	Steno Grade-II	Level - 5 (29200-92300) GP 2800
9	UDC	Level - 4 (25500-81100) GP 2400
10	LDC	Level - 2 (19900-63200) GP 1900
11	Drugs Sampler	Level - 2 (19900-63200) GP 1900
12	MTS	Level - 2 (19900-63200) GP 1900

1.10 Name, designation and other particulars of public information officers [Section 4(1) (b) (xvi)]

Name and designation of the public information officer (PIO), Assistant Public Information (s) & Appellate Authority

Address, telephone numbers and email ID of each designated official.

Sr No	Designation	Technical/ Administration Matters
1	Appellate Authority	Deputy Drugs Controller (India) CDSCO West Zone Mumbai Email: wzmumbai@cdsco.nic.in
2	Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: wzmumbai@cdsco.nic.in

- **1.11** No. of employees against whom disciplinary action has been taken:
 - (iv) Pending for Minor penalty or major penalty proceedings Nil.
 - (v) Finalized for Minor penalty or major penalty proceedings Nil.
- **1.12** Programmes to advance understanding of RTI (Section 26)

(i) Educational programmes

Training programme or workshop related to RTI is being attended regularly by CPIO of this office.

(ii) Efforts to encourage public authority to participate in these programmes

The department encourages public authority by granting necessary permissions whenever necessary to participate in the training programmes of RTI.

(iii) Training of CPIO/APIO

List of Training Programmes attended by the CPIO are as follows:- Nil, due to Covid-19 pandemic situation and priority for technical work was given

(iv) Update & publish guidelines on RTI by the Public Authorities concerned

- A guidance document related to RTI is published on the website of CDSCO.
- Further, the guidelines issued by Central Information Commission are followed https://cic.gov.in/rti-notifications.

1.13 Transfer policy and transfer orders

[F No. 1/6/2011- IR dt. 15.4.2013]

Transfer policy is formulated and transfer orders are issued by the Directorate for Gr. A and Gr. B (GZ & Non-GZ officials).

However, transfers of Gr. C employees is done internally within the office of CDSCO West Zone Mumbai/Navi Mumbai by the DDCI, CDSCO West Zone Mumbai.

Transfer policy is publically available on CDSCO website.

2. **Budget and Programme**

Budget allocated to each agency including all plans, proposed expenditure and reports on disbursements made etc.[Section 4(1)(b)(xi)]

- Total Budget for the public authority. (i)
- Budget for each agency and plan & programmes. (ii)
- (iv) Revised budget for each agency, if any.
- Report on disbursements made and place where the related reports are available. (v)

The Budget Allocation is provided to CDSCO West Zone Mumbai by the Administration Section, CDSCO (HQ), New Delhi under different Heads of Account to meet the day-to-day expenditure of its own and its Sub-offices viz. CDSCO's Zonal office Ahmedabad, Sub-Zone Indore, Sub-Zone Goa including Central Drugs Testing Laboratory (CDTL) at Indore and Mini Drugs Testing Laboratory (MDTL) at Ahmedabad.

The O/o. CDSCO Zonal office Ahmedabad, CDSCO Sub-Zone Goa, CDSCO Sub-Zone Indore, Central Drugs Testing Laboratory (CDTL), Indore and Mini Drugs Testing Laboratory(MDTL) at Ahmedabad are under the administrative control of CDSCO West Zone Mumbai.

Monthly Expenditure Report

Name of the office: O/o. DDC (I) CDSCO West Zone Mumbai

Month: March Year: 2025

(Rs. in Thousands)

Sr.		R.E	Exp. In	Progressive	Balance
No.	Object Head	2024-25	Month	Exp.	Available
1	Salaries (01)	45725	71	45796	-71
2	Wages(02)	0	0	0	0
3	Rewards (05)	104	0	104	0
4	Medical Treatment (06)	1300	101	1205	95
5	Allowances (07)	42628	0	42557	71
6	Leave Travel Concession (08)	500	20	498	2
7	Training Expenses (09)	0	0	0	0
8	Pensionary Charges (04)	0	0	0	0
9	Domestic Travel Expenses (11)	6300	328	6263	37
10*	Office Expenses (13)	13000	165	12704	296
11	RRT for L&B (14)	3571	201	3571	0
12	Printing & Publication (16)	0	0	0	0
13*	Rent for Others (18)	1200	0	1519	-319
14	Digital Equipment (19)	950	252	821	129
15	Material & Supplies (21)	4000	328	3916	84
16	Advertising & Publicity (26)	0	0	0	0
17	Minor Civil Work (27)	9140	609	9129	11
18	Professional Services (28)	900	204	900	0
19	Repair & Maintenance (29)	0	0	0	0
20	Other Revenue Expenses (49)	0	0	0	0
21	Fuel(24)	0	0	0	0
	Total	129318	2279	128983	335

(Rs. in Thousands)

	Object Head	R.E	Exp. In Month	Progressive Exp.	Balance Available
1	Machinery and equipment(52)	900	358	745	155
2	Moter vehicle(53)	0	0	0	0
3	Furniture & fixture (74)	0	0	0	0
4	Information computer Telecommunication (ICT) (71)	0	О	0	0
5	Building & Structure (72)	0	0	0	0
6	Subscription (57)	0	0	0	0
7	Other Fixed Assets (77)	0	0	0	0
	Total	1100	358	745	155

Foreign and domestic tours (F. No. 1/8/2012- IR dt. 11.9.2012)

- Budget. i)
- Foreign and domestic Tours by ministries and officials of the rank of Joint Secretary to ii) the Government and above, as well as the Heads of the Department.
 - Places visited.
 - The period of visit. b)
 - The number of members in the official delegation. c)
 - Expenditure on the visit.

Foreign Tours:

			icigii icais.		
S.no	Name of the Officer	Places Visited	Period of visit	Number of members in the official delegation	Expenditure on the visit
1	2	3	4	5	6
1.	Shri. Jayant Kumar Dy. Drugs Controller (I)			Nil	

Domestic Tours:

S. no	Name of the Officer		Period of Visit	Number of members in the official delegation	Expenditure on the visit
1	2 Shri. Jayant Kumar Dy. Drugs Controller (I)	3	4	5 Nil	6

Information related to procurements

- a) Notice/tender enquires, and corrigenda if any thereon,
- b) Details of the bids awarded comprising the names of the suppliers of goods/ services being procured,
- c) The works contracts concluded in any such combination of the above-and
- d) The rate /rates and the total amount at which such procurement or works contract is to be executed.

Nil

2.2 Manner of execution of subsidy programme

[Section 4(i)(b)(xii)]

- iii) Name of the programme of activity
- i) Objective of the programme
- ii) Procedure to avail benefits
- iii) Duration of the programme/ scheme
- iv) Physical and financial targets of the programme
- v) Nature/ scale of subsidy /amount allotted
- vi) Eligibility criteria for grant of subsidy
- vii) Details of beneficiaries of subsidy programme (number, profile etc)

Nil

2.4 Discretionary and non-discretionary grants [F. No. 1/6/2011-IR dt. 15.04.2013]

- (i) Discretionary and non-discretionary grants/ allocations to State Govt./ NGOs/other institutions
- (ii) Annual accounts of all legal entities who are provided grants by public authorities

Nil

2.5 Particulars of recipients of concessions, permits of authorizations granted by the public authority

[Section 4(1) (b) (xiii)]

- (i) Concessions, permits or authorizations granted by public authority
- (ii) For each concessions, permit or authorization granted
 - a) Eligibility criteria
 - b) Procedure for getting the concession/ grant and/ or permits of authorizations
 - c) Name and address of the recipients given concessions/ permits or authorisations
 - d) Date of award of concessions /permits of authorizations

Nil

2.6 "CAG & PAC paras [F No. 1/6/2011- IR dt. 15.4.2013]

CAG and PAC paras and the action taken reports (ATRs) after these have been laid on the table of both houses of the parliament.

Nil

3. Publicity Band Public interface

Particulars for any arrangement for consultation with or representation by the members of the public in relation to the formulation of policy or implementation there of [Section 4(1)(b)(vii)]

[F No 1/6/2011-IR dt. 15.04.2013]

Formulation of Policy and Implementation is carried out by Directorate

Arrangement for consultations with or representation by the members of the public

Relevant Acts, Rules, Forms and other documents which are normally accessed by i. citizens at CDSCO website i.e., https://www.cdsco.gov.in/ for following information.

Sr. No.	Type of Information	
1.	Gazette Notifications	
2.	Act & Rules	
3.	Public Notices	
4.	Bioequivalence and Bioavailability	
5.	Blood Products	
6.	Vaccines	
7.	rDNA	
8.	Stem Cells & Cell Based Products	
9.	Global Clinical Trial	
10.	Ethics Committee	
11.	New Drugs	
12.	Fixed Dose Combinations (FDCs)	
13.	Investigational New Drugs (INDs)	
14.	Subsequent New Drugs	
15.	Medical Device and In-Vitro Diagnostics	
16.	Cosmetics	
17.	Public Relation Officer	
18.	Large Volume Parenterals	
19.	Blood Centers	
20.	Circulars	
21.	Vacancies	

- ii) Arrangements for consultation with or representation by-
- a) Formulation of Policy and Implementation is carried out by Directorate.
- b) Day & time allotted for visitors.
- c) Contact details of Information & Facilitation Counter (IFC) to provide publications frequently sought by RTI applicants.

Public Relation office has been established

Centralized PRO is established by Directorate to coordinate with respective division, Zone, Sub-Zone. The contact details are available on CDSCO website, additionally the West Zone office has specified following:

Sr.	Details	Details to be updated on CDSCO Website
No.	Required	
	·	
1.	Name of the	CDSCO Zonal Office (West Zone) Mumbai
1.	Zone	CDSCO Zonai Onice (West Zone) Mumbai
	Zone	
2.	Name of PRO	Dr. Santosh V Indraksha (West Zone -1)
	& Assistant	Deputy Drugs Controller (India)
	Officials of	i) Areas Covered under WZ- Divisions of Amrawati,
	PRO along	Aurangabad, Nagpur, Nashik, Pune in Maharashtra, Daman
	with contact	& Diu, DNH Silvassa, Chattisgarh, Goa
	details.	Execution of all activities of respective divisions and all
	aotanoi	approvals falling in either offline/online mode.
		li) CDSCO Sub-Zone/Port office, Goa
		Names of Assistant Officials of PRO (West Zone 1)
		Sh.Milind P Patil, Asstt. Drugs Controller (India)
		Sh. Vishal T. Kachare, Drugs Inspector
		Smt. Bindu Kumari, Asstt. Drugs Inspector
		Email id:- wz1mumbai@cdsco.nic.in
		Landline Nos. : +91 22 23002279 / 23002215
		CDSCO Sub-Zone/Port office Goa (Under WZ-1)
		Dr. Krishan Kumar Bhardwaj, Asstt. Drugs Controller (India)
		Ph. No. 0832-2201001 Email: goasubzone@cdsco.nic.in
		Dr. Jayant Kumar (West Zone - 2)
		Deputy Drugs Controller (India)
		i) Areas Covered under WZ Divisions of Greater Mumbai
		and Konkan Division
		Execution of all activities of respective divisions and all
		approvals falling in either offline/online mode.
		ii) Port offices of CDSCO Aircargo and JNPT Seaport
		Panvel.
		iii) Additional Charge of Govt. Medical Stores Depot, Mumbai
		Names of Assistant Officials of PRO (West Zone -2) Sh.Akash R Kondalkar, Asstt. Drugs Controller (India)
		Sh. Manvendra S.Teli, Drugs Inspector
		Sh. J. Ravi Kumar, Asstt. Drugs Inspector
		Email id: wzmumbai@cdsco.nic.in
		Landline Nos: +91 22 23002279 / 23002215

Port Offices under WZ-2:
CDSCO JNPT Seaport Panvel
Sh. Rajesh Kumar Verma, ADC (I)
Email: jnpt.mumbai@cdsco.nic.in
Tel: 022-50500161, Fax: 022-50500169
,
CDSCO Airport Aircargo Mumbai
Sh. Pravin A Jagtap, ADC (I)
Email: Aircargo.mumbai@cdsco.nic.in
Tel: 022-26828185, 26828067

Functions of PRO Office:

- 1. To act as single window for disposal of grievance of stakeholders on regulatory issues.
- 2. To provide information to the innovator regarding regulatory norms.
- 3. To guide, assist handhold investors in various phases of business life cycle as per existing focus on "Invest India / Make in India" without compromising quality of regulatory oversiaht.

Public- Private Partnerships (PPP)

- Details of Special Purpose Vehicle (SPV), if any (i)
- Detailed project reports (DPRs) (ii)
- Concession agreements. (iii)
- Operation and maintenance manuals (iv)
- Other documents generated as part of the implementation of the PPP (v)
- Information relating to fees, tolls, or the other kinds of revenues that may be collected (vi) under authorisation from the government
- Information relating to outputs and outcomes (vii)
- The process of the selection of the private sector party (concessionaire etc.) (viii)
- All payment made under the PPP project (ix)
- 2.1 Are the details of policies / decisions, which affect public, informed to them [Section 4(1) (c)] Publish all relevant facts while formulating important policies or announcing decisions which affect public to make the process more interactive;
 - Policy decisions/ legislations taken in the previous one year (i)
 - Outline the Public consultation process (ii)
 - Outline the arrangement for consultation before formulation of policy (iii)

carried Directorate legislations is out bv Policy decisions/ (https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/) Formulation of Policy and Implementation is also carried out by Directorate

Dissemination of information widely and in such form and manner which is easily accessible to the public. [Section 4(3)]

Use of the most effective means of communication Internet (website): https://www.cdsco.gov.in/ for information like below:

Sr. No.	Type of Information
1.	Gazette Notifications
2.	Public Notices
3.	Alerts
4.	Bioequivalence & Bioavailability
5.	Blood Products
6.	Vaccines
7.	Global Clinical Trial
8.	Ethics Committee
9.	New Drugs
10.	Fixed Dose Combinations (FDCs)
11.	Investigational New Drugs (INDs)
12.	Subsequent New Drugs
13.	Medical Device and In-Vitro Diagnostics
14.	Cosmetics
15.	Blood Centers
16.	Large Volume Parenterals
17.	Public Relation office
18.	Circulars
19.	Import & Registration

3.4 Form of accessibility of information manual/ handbook

[Section 4(1)(b)]

Information manual/handbook available in

Electronic format (i)

Sr.	Topic	URLs
No.		
1.	e-Governance	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf-
		documents/SUGAM user manual.pdf

Printed format (ii)

Available

3.5 Whether information manual handbook available free of cost or not [Section 4(1)(b)]

List of materials available

Free of cost. (i)

Electronic format can be accessed through website.

At a reasonable cost of the medium. (ii)

> When information required under RTI Act, fees wi1 be charged as per Rule 4 of The Right to Information (Regulation of Fee and Cost) Rules, 2005.

4 E. Governance

4.1 Languages in which Information Manual/Handbook Available [F No. 1/6/2011-IR dt.

15.4.2013]

English

4.2 When was the information Manual/Handbook last updated?

[F No. 1/6/2011-IR dt 15 4.2013]

Last date of Annual updation. Updation of Manual is carried out by Directorate.

4.3 Information available in electronic form

[Section 4(1)(b)(xiv)]

- (i) Details of information available in electronic form
- (ii) Name/title of the document/record/other information (iii) Location where available Refer Para 3.3
- 4.4 Particulars of facilities available to citizen for obtaining information [Section 4(1)(b)(xv)]
 - (i) Name & location of the facility

Central Drug Standards Control Organization, West Zone, 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai — 400008.

(ii) Details of information made available

All Information available in the public domain of website (www.cdsco.gov.in) Assistance is provided to access required. Information available in the public domain through digitally, using online system.

(iii) Working hours of the facility

9,30 AM to 6.00 PM (except closed holidays)

(iv) Contact person & contact details (Phone, fax email)

All Information is available in the public domain of website (www.cdsco.gov.in) Assistance is provided to access required. Information available in the public domain through digitally using online system.

wzmumbai@cdsco.nic.in / wz1mumbai@cdsco.nic.in

4.5 Such other information as may be prescribed under section 4(i) (b)(xvii)

i) Grievance redressal mechanism

Public Relation office and Grievance redressal mechanism is established at Directorate and West Zone. As and when required the Grievance will be addressed accordingly.

https://cdsco.gov.in/opencms/opencm/system/modu1e,s/CDSCO.WEB/elements/download file division.jso?num id=NTU2Mg==

Functions of PRO Office:

- 1. To act as single window for disposal of grievance of stakeholders on regulatory issues.
- 2. To provide information to the innovator regarding regulatory norms.
- 3. To guide, assist handhold investors in various phases of business life cycle as per existing focus on "Invest India / Make in India" without compromising quality of regulatory oversight.

(ii) Details of applications received under RTI and information provided

Year	RTI applications received	RTI applications disposed
2019 - 20	37	37
2020 - 21	31	31
2021 - 22	20	20
2022 - 23	14	14
2023 - 24	21	21
2024 - 25	12	12

(iii) List of completed schemes/ projects/ Programmes-

This office has not been assigned any Schemes/ Projects/ Programmes.

(iv) List of schemes/ projects/ programme underway-

This office has not been assigned any Schemes/ Projects/ Programmes.

Details of all contracts entered into including name of the contractor, amount of Contract and period of completion of contract. (v)

Sr. No.	Details of contract	Name & Address of the Contractor	Amount of contract	Period of Completion of contract
1.	Comprehensive Annual Maintenance Contract for the Split (18 Nos.) Air Conditioners Gem Contract No. -511687700384750	M/s. Trade Cool Services, B/201, Sapphire, Diamond Park, Khadi Machine Road, Kausa, Mumbra, Thane - 400 612.	@Rs. 167940/- for three years which is Rs. 55980/- per yr. incl. GST.	From 30.10.2024 to 29.10.2027
2.	Vehicle for operational use of office through GeM (01 Vehicle) GeM Contract No: GEMC-511687752605246	Burak Travels, 1001 Sector 34c Plot No 14,Azeem Height,Oval Tower,Navi Mumbai- 410 210.	Rs. 44321/- p.m. incl. GST	From 01/06/2024 to 31/05/2025
3.	AMC for Desktop Computers, Laptops & Peripherals (44 nos) Gem Contract No. 511687748994198	M/s. Ridhima Services, 503/1/B Sai Nivas Society, New Mhada Complax, Jankalyan Nager, Malad West, Mumbai-400095.	@ Rs. 71016/- per year incl. GST	From 07.10.2024 to 06.10.2025
4.	Canon Photocopier Machines (04 nos) Gem Contract No. 511687784257341	B. J. Automation , 2 nd Flr, Off No 37, Bhupat Bhavan, Vaju Kotak Marg, Fort, Mumbai - 400001.	@Rs. 143781/- for Two years which is Rs. 71890.50/- per yr. incl. GST.	From 16.09.2024 to 19.09.2026
5.	Canon/HP/Samsung Laserjet/Multifunction Printers (09 nos) Gem Contract No. 511687796891346	B. J. Automation , 2 nd Flr, Off No 37, Bhupat Bhavan,Vaju Kotak Marg,Fort, Mumbai-400001.	@ Rs. 91950/- per year incl. GST	From 21.04.2025 to 20.04.2026
6.	Alfa Water Purifier (01 No)	Ace Hygiene Products Pvt. Ltd., 307, A2, Shah & Nahar Indl. Estate, Lower Parel, Mumbai 400 013	@Rs. 2350/- per yr. (Exp)	AMC Expired Contract renewal is in process through GeM

7.	Blue Star 40 ltr. Water cooler Sanitation Service with Non- Comprehensive AMC	Ace Hygiene Products Pvt. Ltd., 307, A2, Shah & Nahar Indl. Estate, Lower Parel, Mumbai 400 013	@Rs. 3540/- per yr. (Exp)	AMC Expired Contract renewal is in process through GeM
8.	AO Smith Water Purifier (RO + SCPA)			Warranty Expired AMC is under process

ii) Annual Report

Annual report of CDSCO is prepared by Directorate by compiling the information received under monthly KPIs from all Zonal and Sub-Zonal offices of CDSCO. There is no separate Annual Report for West Zone office.

Frequently Asked Question (FAQs) are available on CDSCO website i.e., iii) https://www.cdsco.gov.in/

Sr. No.	Topic	URLs
1.	New Drugs	https://cdsco.gov.in/opencms/opencms/s stem/modules/CDS CO.WEB/elements/download file division.1s ?num id=ND MOMA== Additional FAQs:
		https://cdsco.gov.in/opencms/opencms/system/modules/CDS CO.WEB/elements/download file division.jsp?numid=ND g1Ng=—
		https://cdsco.gov.in/opencms/opencms/system/modules/CDS CO.WEB/elements/download file division.jsp?numid=NT U4OA—=
2.	Medical Devices	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf -documents/medical-device/Updated-FAQ-MDR 2017.pdf
3.	Phyto pharmaceuticals	https://cdsco.gov.in/opencms/opencms/system/modules/CDS CO.WEB/elements/download file division.jsp?num id=MzlOMA=—

4.	Import of small quantities of drugs for the purposes of examination testing or analysis	https://cdsco.gov.in/opencms/opencms/en/FAO/index.h tml
5.	Blood Centre	https://cdsco.gov.in/opencms/opencms/en/FAO/index.html
6.	Cosmetics	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf -documents/cosmetics/FAQcos.pdf
7.	BA/BE	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf -documents/BA BE/revidsefaqbabe df
8.	Import & Registration	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/P df-documents/import- registration/Import_guidance_doc.pdf

iv) Any other information such as

- a) Citizen's Charter
- b) Result Framework Document (RFD)
- c) Six monthly reports on the Performance against the benchmarks set in the Citizen's Charter
- Citizen Charter :https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/en/Notifications/Citizen-Charter-CDSCO.pdf

4.6 Receipt & Disposal of RTI applications & appeals [F.No 1/6/2011-IR dt.15.04.2013]

(i) Details of applications received and disposed

Year	RTI applications received	RTI applications disposed
2019 - 20	33	33
2020 - 21	30	30
2021 - 22	18	. 18
2022 - 23	14	14
2023 - 24	21	21
2024 - 25	12	12

(ii) Details of appeals received and orders issued

Year	RTI Appeals received	RTI Appeals disposed off.
2019 - 20	04	04
2020 - 21	01	01
2021 - 22	02	02
2022 - 23	01	01
2023 - 24	00	00
2024 - 25	01	01

4.7 Replies to questions asked in the parliament [Section 4(1)(d)(2)1 Replies to questions asked in the Parliament pertaining to this office are forwarded to Directorate for their compilation.

5. Information as may be prescribed

5.1 Such other information as may be prescribed [F.No. 1/2/2016-IR dt. 17.8.2016, F No. 1/6/2011-IR dt. 15.4.2013]

(a) Nama & datails of Provious EAAs

Sr.No.	Designation	Technical/ Administration Matters	Year
1.	Dr. K. Bangarurajan, Appellate Authority	Deputy DrugsController (India) Email: wzmumbai@cdsco.nic.in	2015-2017 (Till October 2017)
2.	Sh. R. Chandrasekhar, Appellate Authority	Deputy Drugs Controller (Índia) Email: wzmumbai@cdsco.nic.in	2017-2018 (Till Feb 2018)
3.	Dr. P.B.N. Prasad, Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2018-2020 (Till June. 2020)
4.	Dr. Rubina Bose, Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2020-2021 (Till June. 2021)
5.	Sh. A. Senkathir Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	June 2021- 2023 (Till June. 2023)
6.	Sh. Jayant Kumar Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	June. 2023Till Date

(b) Name & Details of Previous CPIOs

1.	Sh. Gouri Shankar, Central Public Information Officer (CPIO)	Drugs Inspector Email: wzmumbai@dsco.nic.in	2015-2017
2.	Dr. Kamal K Halder, Central Public Information Officer (CPIO)	Drugs Inspector (2017) Assistant Drugs Controller (India) (2018-2020) Email: wzmumbai@cdsco.nic.in	2017- 2020 (Till Aug 2020)
3.	Sh. Manish Singhal, Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	September 2020- July-2023
4.	Sh. Yogesh Kashinath Shelar Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	July – 2023 to Aug. 2024
5.	Sh. Akash Rama Kondalkar Central Public Information Officer (CPIO)		Aug. 2024 to till date

- Details of third party audit of voluntary disclosure (i)
 - (a) Dates of audit carried out in Year 2022
 - (b) Report of the audit carried out in Year 2022

The checklist for the Transparency Audit was duly filled and submitted to CIC on 12/09/2022.

- Appointment of Nodal Officers not below the rank of Joint Secretary/ Additional HoD (ii)
 - (a) Date of appointment
 - (b) Name & Designation of the officers **Not Applicable**
- Consultancy committee of key stake holders for advice on suo-motu disclosure (iii)
 - (a) Dates from which constituted
 - (b) Name & Designation of the officers

No such consultancy committee was constituted so far.

- Committee of PIOs/FAAs with rich experience in RTI to identify frequently sought (iv) information under RTI
 - (a) Dates from which constituted
 - (b) Name & Designation of the Officers

No such consultancy committee was constituted so far.

6. Information Disclosed on own Initiative - Item / information disclosed, so that public have minimum resort to use of RTI Act to obtain information

Sr No	Type of Information	Related URLs
1.	Gazette Notifications	
2.	Public Notices	https://cdsco.gov.in/opencms/opencms/en/Notifications/Publie-Notices/
3.	Bioequivalence and Bioavailability	https://cdsco.gov.in/opencms/opencms/en/bioequi bioavail/index.html
4.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/bio1ogica1s/Blood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/bio1ogica1s/Vaccines/
6.	Global Clinical Trial	https://cdsco.gov.in/opencms/opencms/en/Clinical- Trial/Global-Clinical-Trial/
7.	Ethics Committee	https://cdsco.gov.in/opencms/opencms/en/Clinical- Trial/Ethics-Committee/
8.	New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/
	Fixed Dose Combinations (FDCs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
	Investigational New Drugs (INDs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/
1	Subsequent New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequen t-New-Drugs/
12.	Medical Device and In-Vitro Diagnostics	https://cdsco.gov.in/opencms/opencms/en/Medical-Device- Diagnostics/InVitro-Diagnostics/
13.	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosme tics/

6.2 Guidelines for Indian Government Websites (GIGW) is followed (released in February, 2009 and included in the Central Secretariat Manual of Office Procedures (CSMOP) by Department of Administrative Reforms and Public Grievances, Ministry of Personnel, Public Grievance and Pensions, Govt. of India)

- (i) Whether STQC certification obtained and its validity.
- (ii) Does the website show the certificate on the Website? Website of CDSCO (www.cdsco.gov.in) is Designed, Developed and Maintained by CDAC as per requirement provided by CDSCO (HQ), New Delhi.

