

भारत सरकार
स्वास्थ्य सेवा महानिदेशालय,
स्वास्थ्य एवं परिवार कल्याण मंत्रालय



केन्द्रीय औषध मानक नियन्त्रण संगठन
पश्चिम खण्ड
उप औषध नियंत्रक (भारत) का कार्यालय
चौथा तल, झोनल एफ.डी.ए.भवन,
जी.एम.एस.डी. कम्पाउंड, विलासी रोड,
मुम्बई सेंट्रल, मुम्बई-400 008.



GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
Directorate General of Health Services

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
WEST ZONE
Office of the Deputy Drugs Controller (India)
4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Rd,
Mumbai Central, Mumbai-400 008.
Tel: 022 – 23002279 / 23002215
Fax : 022-23002271
Email: wzmumbai@cdsco.nic.in

Re. No. 1-33/RTI/WZ-2023/1793

(Email Only)

Date 24 May 2023

To,
Drugs Controller General (India)
CDSCO, (HQ), FDA Bhawan,
New Delhi – 110 002.

Subject: Suo Moto RTI disclosure-updation of Information in the Website of CDSCO-reg

Sir,

This is with reference to the email dated 10.05.2023 from Central Information Commission on the Third Party Transparency Audit for 2022-2023.

Please find attached the information of CDSCO West Zone and its sub-ordinate offices in the format for Suo Moto disclosure for the year 2023 under Section 4 of RTI Act, 2005 for uploading on CDSCO website.

Encl: as stated above.

Yours sincerely

(A. Senkathir)
Dy. Drugs Controller (India)
CDSCO (West Zone) Mumbai

Copy to:

- 1) Director Administration (Drugs), CDSCO (HQ), FDA Bhawan, New Delhi 110 002
- 2) Dy. Director Administration (Drugs), CDSCO (HQ), FDA Bhawan, New Delhi 110 002

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

1. Organisation and Function

1.1 Particulars of its organisation, functions and duties [Section 4(1)(b)(i)]

(i) Name and address of the Organization

CENTRAL DRUG STANDARD CONTROL ORGANIZATION 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)

(ii) 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 quality of drugs, cosmetics and medical devices.

(iii) Function and duties

• **Technical:**

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

1. 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 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), CT-14 (Unapproved Formulations) and CT-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 CT-17 under the provisions of NDCT Rules, 2019 through offline/manual procedures.
 - 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).

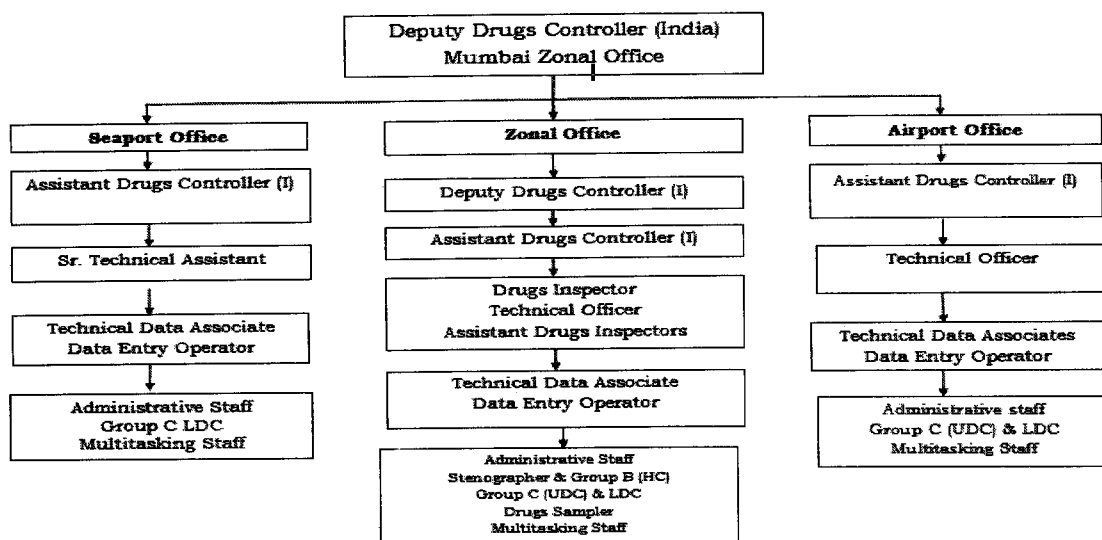
A. Administrative:

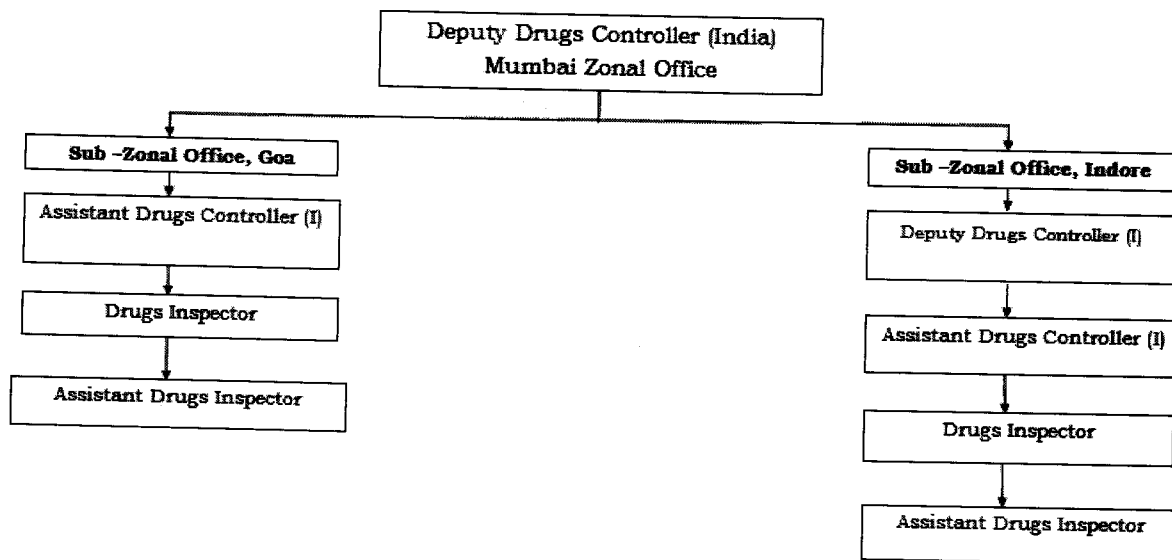
- 1) To Maintain the Service records/leave records of Gazetted and Non-Gazetted Staff and administrative Staff
- 2) To maintain seniority list of Non-Gazetted employees. Under MACP Scheme to Group B (Non-Gazetted) & D Staff.
- 3) To Prepare of annual budgets /preliminary and final estimate of expenditure etc.
- 4) To Prepare reports/replies concerning to the above administrative functions.

- 5) To purchase of stationeries and office items as per the requirements.
- 6) Annual Maintenance Contract (AMC) of office equipment etc.
- 7) Reply of RTI applications under RTI Act, 2005.
- 8) 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 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 CDTL Indore work is under progress in the same building.

CDSCO Sub-zone, Goa headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Goa had started functioning in the Yr. 2011 at 3rd Floor, Customs Building, Customs House, Marmagao, Goa 403803. Since 2017, the O/o. CDSCO, Sub-Zone/Port office, Goa is operating from the Ground Flr., Port Users Complex (Old A O Bldg) Mormugao Harbour, Nr. to Mormugao Sub-Post office, Mormugao, Goa-403803.

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

Table No.2

Designation	Duties
Deputy Drugs Controller	<ol style="list-style-type: none"> 1. Technical head of the office of CDSCO (West Zone) Mumbai, CDSCO Port Offices at Airport Mumbai, JNPT Seaport Panvel and CDSCO Sub-Zone office Goa 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. 3. 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. 4. 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, report submitted, reviewing and forwarding to Drugs Controller General (India) and / or State Licensing Authority for necessary action as applicable.

	<ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> • No Objection Certificates for grant of permissions for import of dual use items which are “Not for Medicinal use” by SUGAM Portal. • No Objection Certificate to manufacture approved /un-approved new drugs in Form 29 for the purpose of examination, test and analysis. • Grant of Test License for the import of Veterinary Drugs or Veterinary Vaccines imported for purpose of examination, test or analysis except for Clinical Trial by SUGAM 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	<ol style="list-style-type: none"> 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 Banks, Blood Products, Vaccines - Sera, rDNA, Large Volume Parenterals) Inspections, Complaints, 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

	<p>sampling etc. as and when directed by the Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai.</p> <ol style="list-style-type: none"> 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. Processing of On-line Test License applications through SUGAM PORTAL 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 since April 2020.
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Technical Officer	<ol style="list-style-type: none"> 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 Drugs & 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 issued for import of drugs intended for non medicinal use prior approval of DDC (I). 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. 11. 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	<ol style="list-style-type: none"> 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 DDC (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) : <ul style="list-style-type: none"> • Blood Bank license, Vaccine/Sera manufacturing units for both human as well as Veterinary, LVP manufacturing units etc. • For notified Medical Devices & Critical Diagnostics manufacturing units. • For Biotech & Bio-similar products manufacturing units. • Inspections of Clinical Trial facilities and BA/BE centers as directed by the Drugs Controller General (India) from time to time. • Inspections for issue of Written Confirmation for export of API to EU. • To carry out joint inspection of Drug Testing Laboratory for the purpose of grant of approval for test/analysis of Drugs & Cosmetics.

	<ol style="list-style-type: none"> 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)
Assistant Drugs Inspector	<ol style="list-style-type: none"> 1. To assist in evaluation of Safety, Efficacy and Quality of Drugs as per requirement of Drugs and Cosmetics Rules, 1945. 2. To carryout field duty in assisting superior/ Drugs Inspectors for taking out samples, enforcement activities like raids/ inspections for launching prosecution etc. 3. To assist CDSCO officers in the matter of monitoring documentation. 4. Details required in respect of RTI and Parliament Questions are submitted to DDC. 5. Prescreening and scrutiny of Form 11 applications in CDSCO Sugam Portal (online) and Dual Use NOC, Form CT-11, Form CT-14, Form CT-15 and Form CT-17 applications received by the O/o CDSCO, WZ, Mumbai. 6. Any other work assigned by the DDC (I)/ ADC(I).
Technical Data Associate	<ol style="list-style-type: none"> 1. To assist CDSCO officers in the matter of monitoring documentation. 2. Prescreening and scrutiny of Form 11 applications in CDSCO Sugam Portal (online) and Dual Use NOC, Form CT-11, Form CT-14, Form CT-15 and Form CT-17 applications. 3. 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 paybills, income tax, e-TDS. Preparation of pension and retirement benefits. Purchase of stationary 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 emails, 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 duty are derived and
(iv) Exercised

Deputy **Drugs** Controller (**India**) is **working** as Zonal Head & **Controlling** Officer under **Drugs** and Cosmetics 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 Device 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.

(v) Work allocation

The **information** is **available in** the Table **no.2**

1.1 Procedure followed in decision making process

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

- a. Process of decision making Identify key decision making points
- b. Final decision making authority
- c. Related provisions, acts, rules etc.
- d. Time limit for taking a decisions, if any
- e. 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)]

- (i) Nature of functions/ services offered
- (ii) Norms/ standards for functions/ service delivery
- (iii) Process by which these services can be accessed
- (iv) Time-limit for achieving the targets
- (i) 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.cdsoonline.gov.in and www.cdscomdonline.gov.in). **Timelimits** are specified in the SOP. The grievances are **redressed through** Public Relation Office. Details of PRO is available on CDSCO website.

1.3 Rules, regulations, instructions manual and records for discharging functions

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

- (i) Title and nature of the record/ manual /instruction.
- (ii) List of Rules, regulations, instructions manuals and records
- (iii) Acts/ Rules manuals etc.
- (iv) Transfer policy and transfer orders

The Drugs and Cosmetics Act, 1940 and Rules made thereunder (Drugs and Cosmetics Rules, 1945, Medical Device Rules, 2017 and New Drugs and Clinical Trials, 2019, 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 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 are available on CDSCO website.

1.4 Categories of documents held by the authority under its control

- (i) Categories of documents
- (ii) Custodian of documents/categories

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

A) Technical:

- a. Manual of Office Procedure
- b. Drugs and Cosmetics Act, 1940
- c. Drugs and Cosmetics Rules, 1945
- d. Medical Device Rules, 2017
- e. New Drugs and Clinical Trials, 2019
- f. Cosmetic Rules, 2020

B) Administrative:

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

1.5 Boards, Councils, Committees and other Bodies constituted as part of the Public Authority [Section 4(1)(b)(viii)]

- (i) Name of Boards, Council, Committee etc.
- (ii) Composition
- (iii) Dates from which constituted
- (iv) Term/ Tenure
- (v) Powers and functions
- (vi) Whether their meetings are open to the public?
- (vii) 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)]

- (i) Name and designation : Shri. A. Senkathir, Deputy Drugs Controller (India)
- (ii) Telephone , fax and email ID :

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

CONTACT DETAILS OF CDSO (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)]

- (i) List of employees with Gross monthly remuneration
- (ii) System of compensation as provided in its regulations

O/o. THE DEPUTY DRUGS CONTROLLER (INDIA) CDSO, WEST ZONE, MUMBAI		
Salary details of various posts with Pay band and Pay level for CDSO, West Zone, Mumbai, Ahmedabad Zone, Sub Zone-Indore, Sub-Zone-Goa		
1	Dy. Drugs Controller (India)	Pay Band 15600-39100 (GP-7600) & Level 12
2	Asstt. Drugs Controller (India)	Pay Band 15600-39100 (GP-6600) & Level 11
3	Technical Officer	Pay Band 9300-34800 (GP-4800) & Level 8
4	Drugs Inspector	Pay Band 9300-34800 (GP-4800) & Level 8
5	Asstt. Drugs Inspector	Pay Band 9300-34800 (GP-4200) & Level 6
6	Head Clerk	Pay Band 9300-34800 (GP-4200) & Level 6
7	Steno Grade-II	Pay Band 5200-20200 (GP-2800) & Level 5
7	UDC	Pay Band 5200-20200 (GP-2400) & Level 4
8	LDC	Pay Band 5200-20200 (GP-2000) & Level 2
9	Drugs Sampler	Pay Band 5200-20200 (GP-1900) & Level 2
10	MTS	Pay Band 5200-20200 (GP-2000) & Level 1

1.10 Name, designation and other particulars of public information officers

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

- (i) Name and designation of the public information officer (PIO), Assistant Public Information (s) & Appellate Authority
- (ii) Address, telephone numbers and email ID of each designated official.

S.no.	Designation	Technical/ Administration Matters
1	Appellate Authority	Deputy Drugs Controller (India) CDSCO West Zone Mumbai Email: wzmumbai@cdsco.rite.in
2	Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: wzmumbai@cdsco.nic.in
3	Assistant Public Information Officer (APIO)	Assistant Drugs Inspector, Email: wzmumbai@cdsco.nic.in

1.11 No. of employees against whom disciplinary action has been taken:

- (i) Pending for Minor penalty or major penalty proceedings - 02
- (ii) Finalised 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 in 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. A. However, transfers of Gr. C employees is done internally within the office of CDSCO West Zone Mumbai/Navi Mumbai by the DDCl, CDSCO West Zone Mumbai.

Transfer policy is available on CDSCO website

2. Budget and Programme

2.1 Budget allocated to each agency including all plans, proposed expenditure and reports on disbursements made etc.

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

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

SPEED POST

F.No.G.26027/04/2022-DC
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(D.C. SECTION)

F.D.A. Bhawan, I.T.O., Kotla Road,
New Delhi.

Dated: 23rd January, 2023

To

Dy. Drugs Controller(I),
CDSCO,(West Zone) Office of the Deputy Drugs Controller(I),
4th Floor, FDA BHAWAN, GMSD Compound, Bellasis Road,
Mumbai Central, Mumbai-400008

Subject:-

Revised Estimates 2022-23 & Budget Estimates 2023-24 in respect of Major Head 2210-06104-Drugs Control (Minor Head) 02-CDSCO-0201- General Component - Reg.

Sir/Madam,

I am directed to inform you that the Revised Estimates 2022-23 and Budget Estimates 2023-24 in respect of your office under each sub. head is as given below:-

(amount in thousands)

SL. NO.	ITEM	R.E. 2022-23	B.E. 2023-2024
1.	Salaries (01)	6,80,00	4,00,00
2.	Wages(02)	--	--
3.	Medical Treatment (06)	5,00	7,00
4.	Allowances (07)	--	3,00,00
5.	Leave Travel Concession (08)	--	5,00
6.	Training Expenses (09)	--	--
7.	Pensionary Charges (04)	--	50,00
8.	Domestic Travel Expenses (11)	75,00	75,00
9.	Office Expenses (13)	1,40,00	1,10,00
10.	RRT for L&B (14)	32,00	34,00
11.	Printing & Publication (16)	--	--
12.	Rent for Others (18)	--	--
13.	Digital Equipment (19)	--	--
14.	Material & Supplies (21)	30,00	40,00
15.	Advertising & Publicity (26)	--	--
16.	Minor Civil Work (27)	78,00	55,00
17.	Professional Services (28)	2,00	4,00
18.	Repair & Maintenance (29)	--	10,00
19.	Other Revenue Expenses (49)	--	--
20.	Other Expenses (020150)	--	--
21.	Swachhta Action Plan(029650)	--	--
	TOTAL	10,42,00	10,90,00

Yours faithfully,

(Amit Kumar)

Dy. Director Administration

Copy to:-

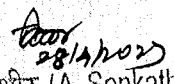
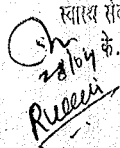
Pay & Accounts Officer,
Ministry of Health & FW, Mumbai

Name of the Office: Dy. Drugs Controller (India),
CDSCO, WZ, Mumbai

(Rs. In Thousand)

Monthly Expenditure Statement for the month of April 2023

Head	Budget Estimate during the Yr. 2023-2024	Expenditure during the Month of April 2023	Progressive Exp. Upto the month of April 2023	Balance Budget for the year 2023-2024
Salaries (01)	40000	7133	7133	32867
Allowances (07)	30000	5856	5856	24144
Leave Travel Concession (08)	500	0	0	500
Pensionary Charges (04)	5000	1157	1157	3843
Medical Treatment (06)	700	0	0	700
Domestic Travel Expenses (11)	7500	202	202	7298
Office Expenses (13)	11000	415	415	10585
Rent Rates & Taxes for Land & Build. (14)	3400	0	0	3400
Prof. Services (28)	400	0	0	400
Repair & Maintenance (29)	1000	0	0	1000
Material & Supplies (21)	4000	0	0	4000
Machinery & Equip.(52)	400	0	0	400
Minor Civil Work (27)	5500	0	0	5500
Total	109400	14763	14763	94637


ए. सेकाथीर / A. Senkathir
 उप औषधि नियंत्रक (भारत) / Deputy Drugs Controller (I)
 भारत सरकार / Government of India
 स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Min. of Health and Family Welfare
 स्वास्थ्य सेवा महानिदेशालय / Dis. General of Health Services
 के.ओ.वा.वि.सं. / CDSCO West Zone Mumbai


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

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

Foreign Tours:

S.no	Name of the Officer	Places Visted	Period of visit	Number of members in the official delegation	Expenditure on the visit
1	2	3	4	5	6
1.	Shri. A. Senkathir Deputy Drugs Controller (I)	Nil			

Domestic Tours:

S. no	Name of the Officer	Places Visted	Period of visit	Number of members in the official delegation	Expenditure on the visit
1	2	3	4	5	6
1.	Shri. A. Senkathir Deputy Drugs Controller (I)	Goa	22.02.2023	Goa Manufacturers Associations for Post AGM Function	11345/-
		Hyderabad	26.02.2023 & 27.02.2023	Chintan Shivir – On drugs quality regulations & enforcement by MOFHW under Chairmanship of Honorable Minister of Health & Family Welfare	26543/-

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 isto be executed.

Nil

2.2 Manner of execution of subsidy programme

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

- (i) Name of the programme of activity
- (ii) Objective of the programme
- (iii) Procedure to avail benefits

- (iv) Duration of the programme/ scheme
- (v) Physical and financial targets of the programme
- (vi) Nature/ scale of subsidy /amount allotted
- (vii) Eligibility criteria for grant of subsidy
- (viii) 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

3.1 Particulars for any arrangement for consultation with or representation by the members of the public in relation to the formulation of policy or implementation thereof

[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

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

Sr. No.	Type of Information
1.	Gazette Notifications
2.	Public Notices
3.	Bioequivalence and Bioavailability
4.	Blood Products
5.	Vaccines
6.	Global Clinical Trial
7.	Ethics Committee
8.	New Drugs
9.	Fixed Dose Combinations (FDCs)
10.	Investigational New Drugs (INDs)
11.	Subsequent New Drugs
12.	Medical Device and In-VitroDiagnostics
13.	Cosmetics

ii. Arrangements for consultation with or representation by

- a) Members of the public in policy formulation/ policy implementation

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:

Office	Designation	Act as	Contact details
Officers of CDSCO, West Zone, Mumbai	Deputy Drugs Controller (India) CDSCO WZ	PRO	wzmumbai@cdsco.nic.in
	Assistant Drugs Controller (India) CDSCO WZ Mumbai	Assisting Officer of the PRO cell	wzmumbai@cdsco.nic.in
Sr. Officer of CDSCO Sub-Zone, Noa	ADCI / Drugs Inspector	Assisting Officer of PRO cell	goasubzone@cdsco.nic.in

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.

Public- Private Partnerships (PPP)

- (i) Details of Special Purpose Vehicle (SPV), if any
- (ii) Detailed project reports (DPRs)
- (iii) Concession agreements.
- (iv) Operation and maintenance manuals
- (v) Other documents generated as part of the implementation of the PPP
- (vi) Information relating to fees, tolls, or the other kinds of revenues that may be collected under authorisation from the government
- (vii) Information relating to outputs and outcomes
- (viii) The process of the selection of the private sector party (concessionaire etc.)
- (ix) All payment made under the PPP project

Nil

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;

- (i) Policy decisions/ legislations taken in the previous one year
- (ii) Outline the Public consultation process
- (iii) Outline the arrangement for consultation before formulation of policy

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

2.2 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://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

3.4 Form of accessibility of information manual/ handbook

[Section 4(1)(b)]

Information manual/handbook available in

(i) **Electronic format**

Sr. No.	Topic	URLs
1.	e-Governance	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/SUGAM_user_manual.pdf

(ii) **Printed format**

Available

3.5 Whether information manual/ handbook available free of cost or not

[Section 4(1)(b)]

List of materials available

(i) **Free of cost**

Electronic format can be accessed through website.

(ii) **At a reasonable cost of the medium**

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

4. **E. Governance**

4.1 Language 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

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 – 400 008

(ii) Details of information made available

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

wzmumbai@cdsc.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://cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?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

S.No	Year	RTI applications received	RTI applications disposed
1.	2019 - 20	37	37
2.	2020 - 21	31	31
3.	2021 - 22	20	20
4.	2022 - 23	14	14

(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.

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

Sr. No.	Details of contract	Name & Address of the Contractor	Amount of contract	Period of Completion of contract
1.	Non-Comprehensive Annual Maintenance Contract for the Split (18 Nos) and Window (01 No.) Air Conditioners Extension Work order No: 1-26/AMCs/WZ-2022/614 dtd. 09/05/2021.	M/s. Shubham Enterprises, Mumbai	@Rs. 28500/- per yr. excluding GST	From 01.06.2022 to 31.05.2023
2	Vehicle (SEDAN) for operational use of office through GeM (01 Vehicle) GeM Contract No: GEMC-511687789063091 dt. 06.04.2023	Shree Datta Travels, A/54, Amar Vikas Mandal, Plot No. 10, B/h. Municipal School, Sewree Cross Rd., Wadala, Mumbai 400 031 09920277072	@ Rs. 39000=00 per month including GST	From 10/04/2023 to 09/04/2024
3.	Alfa Water Purifier (01 No) Work order No: 1-27/WZ-2021/5689 dtd. 28/09/2021	Ace Hygiene Products Pvt. Ltd., 307, A2, Shah & Nahar Indl. Estate, Lower Parel, Mumbai 400 013	@Rs. 2350/- per yr.	01/10/2021 to 30/09/2022 Amc is not finalize further for period 2022-2023

4.	Blue Star 40 ltr. Water cooler Sanitization Service with Non-Comprehensive AMC Work Order No: 1-27/WZ-2021/5688 dtd. 28/09/2021	Ace Hygiene Products Pvt. Ltd., 307, A2, Shah & Nahar Indl. Estate, Lower Parel, Mumbai 400 013	@Rs. 3540/- per yr.	01/10/2021 to 30/09/2022 Amc is not finalize further for period 2022-2023
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(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.

(vii) Frequently Asked Question (FAQs) are available on CDSCO website i.e., <https://cdsco.Nov.in/>

Sr. No.	Topic	URLs
1.	New Drugs	https://cdsco.gov.in/opencms/opencms/system/modules/CDS.CO.WEB/elements/download_file_division.ls?num_id=NDMOMA== Additional FAQs: https://cdsco.Nov.in/opencms/opencms/system/modules/CDS.CO.WEB/elements/download_file_division.jsp?num_id=NDg1Ng== https://cdsco.gov.in/opencms/opencms/system/modules/CDS.CO.WEB/elements/download_file_division.jsp?num_id=NTU4OA==
2	Medical Devices	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Updated-FAQ-MDR_2017.pdf
3	Phytopharmaceuticals	https://cdsco.gov.in/opencms/opencms/system/modules/CDS.CO.WEB/elements/download_file_division.jsp?num_id=MzI0MA==
4	Import of small quantities of drugs for the purposes of examination testing or analysis	https://cdsco.gov.in/opencms/opencms/en/FAO/index.html
5	Blood Bank	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

- (viii) Any other information such as
- Citizen's Charter
 - Result Framework Document (RFD)
 - Six monthly reports on the
 - Performance against the benchmarks set in the Citizen's Charter
- Nil

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

(ii) Details of applications received and disposed

S.No	Year	RTI applications received	RTI applications disposed
1.	2019 - 20	33	33
2.	2020 - 21	30	30
3.	2021 - 22	18	18
4.	2022 - 23	14	14

(iii) Details of appeals received and orders issued

S.No	Year	RTI applications received	RTI applications disposed
1.	2019 - 20	04	04
2.	2020 - 21	01	01
3.	2021 - 22	02	02
4.	2022 - 23	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.

1. 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]

(i) Name & details of

(a) Current CPIOs & FAAs

b) Earlier CPIO & FAAs from 1.1.2015

Sr.No.	Designation	Technical/ Administration Matetrs	Year
1.	Dr. K. Bangarurajan, Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2015-2017 (Till October 2017)
2.	Sh. R. Chandrasekhar, Appellate Authority	Deputy Drugs Controller (India) 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- Till date
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- Till date

(i) Details of third party audit of voluntary disclosure

- (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.

(ii) Appointment of Nodal Officers not below the rank of Joint Secretary/ Additional HoD

- (a) Date of appointment
- (b) Name & Designation of the officers

Not Applicable

(iii) Consultancy committee of key stake holders for advice on suo-motu disclosure

(a) Dates from which constituted

(b) Name & Designation of the officers

No such consultancy committee was constituted so far.

(iv) Committee of PIOs/FAAs with rich experience in RTI to identify frequently sought 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

6.1 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	https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/
2.	Public Notices	https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-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/biologicals/Blood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/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/
9.	Fixed Dose Combinations (FDCs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
10.	Investigational New Drugs (INDs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/
11.	Subsequent New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-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/cosmetics/

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.cdsc.gov.in) is maintained Designed, Developed and Maintained by CDAC as per request provider by CDSCO (HQ), New Delhi