SUO MOTU DISCLOSURE UNDER SECTION 4 OF RTI ACT 2005
(CDSCO, SUB ZONE INDORE)

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 (CDSCO) SUB ZONE INDORE

Central Drug Standard Control Organization, CDSCO Bhawan, GPO square, Residency Area A.B. Road, Indore -452001

indoresubzone@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 qualityof drugs, cosmetics and medical devices.

(iii) Function and duties

- **Technical:**

In fulfilling its mission, the CDSCO, Sub Zone office has following functions:

1. To participate in the joint-inspection for grant/ retention of license for manufacturing ofDrugs and Cosmetics.
2. To participate in the joint-inspection for grant/retention of Vaccine / Sera manufacturingunits 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.
9. 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.
10. To carry out Surprise check/Raids jointly or independently on the basis of complaint received under Whistle Blower scheme and also from other sources.
11. Drawing of legal samples of Drugs from the manufacturing & sales / distribution premises including the Govt. establishment.
12. 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.
13. To pursue the court cases pending in different courts under the Sub zone jurisdiction.
14. Technical survey as and when directed by the Drugs Controller General (India) from time to time.
15. To discuss the matter with various State Drugs Controllers in connection with enforcement of the provisions of D & C Act & Rules there under from time to time.
16. To co-ordinate for answering the Parliament Questions and for obtaining the data from various State Licensing Authorities under the zone.
17. Reply to RTI applications under RTI Act, 2005.
18. To participate as observer in inspections conducted by various international regulatory agencies as and when informed by HQ.
19. To organize workshop, seminar etc. as directed by the Controlling Authority.

20. 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 sub 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), Form CT-14 (Unapproved Formulations) and Form 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 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.

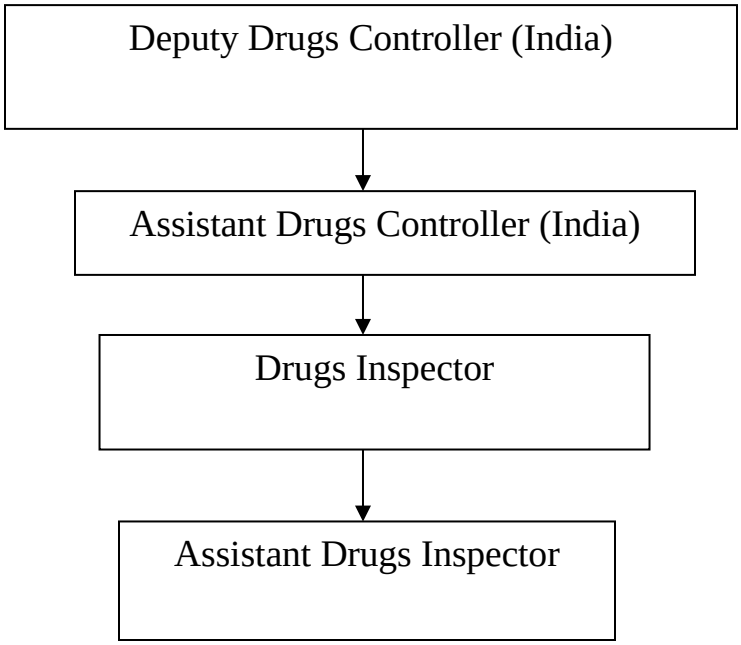
21. Any other functions as assigned by JDC (I)/ DCG (I).

(IV). Administrative:

1) All the administrative activities of this office comes under the purview of CDSCO West Zone office Mumbai

(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 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 Central Drugs Testing Laboratory (Indore) is now functional in the same building.

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	1. Technical head of the office of CDSCO (Sub Zone) Indore. 2. Co-ordination and co-operation with the States Drugs Controller under Sub Zone (Madhya Pradesh) 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. 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 /un-approved new drugs in Form 29 for the purpose of examination, test and analysis In Form CT-11, Form CT-14 and Form CT-15 c. Grant of Test License for the import of Drugs for purpose of examination, test or analysis In Form-11 and Form CT-17 9. Taking action on Not of Standard Quality drugs as per Drugs & Cosmetics Act and rules and as per CDSCO guidance document. 10. 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. 11. Monitoring of technical survey of drugs as and when directed by the Drugs Controller General (India). 12. Acting as Appellate Authority for CDSCO Sub Zone for responding to RTI, replying Parliamentary Questions, etc. as and when required. 13. 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. 14. 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, Sub Zone, Indore 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, Sub Zone, Indore. 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, Sub Zone, Indore. 3. Coordination with Zonal Offices / State Licensing Authorities /Ports and

	Other Authorities as and when directed by the DDC (I) CDSCO Sub Zone, Indore. 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 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 Sub Zone, Indore for carrying out regulatory inspections (COPPs, CLAA Inspections and Complaints, Raids/Investigations) as directed by DDC (I) Sub Zone, Indore. 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 Sub Zone, Indore. 9. Handling queries from the applicants as a Public Relation Officer and as a Nodal Officer for resolving grievances received from general public.
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)
Assistant Drugs Inspector	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 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 . 6. Any other work assigned by the DDC (I)/ ADC(I).

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

Deputy Drugs Controller (India) is working as Sub 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.

(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 a 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).

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,NSWS & ONDLS.

(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
The 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 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.

1.4 Categories of documents held by the authority under its control

Categories of documents
Custodian of documents/categories

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

Technical:
Manual of Office Procedure
Drugs and Cosmetics Act, 1940
Drugs 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

1.6 Boards, Councils, Committees and other Bodies constituted as part of the Public Authority [Section 4(1)(b)(viii)]
Name of Boards, Council, Committee etc.
Composition
(iii) 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.

1.7 Directory of officers and employees [Section 4(1) (b) (ix)]
Name and designation: Shri. Gaurav Kumar, Deputy Drugs Controller (India)

Telephone , fax and email ID :

Tel: 0731-2707966
Email id : indoresubzone@cdsco.nic.in

1.8 CONTACT DETAILS OF CDSCO Sub-Zonal Office Indore

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 (SUB ZONE)		
Salary details of various posts with Pay Band and Pay Level for CDSCO, Sub Zone-Indore,		
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	Drugs Inspector	Pay Band 9300-34800 (GP-4800) & Level 8
4	Asstt. Drugs Inspector	Pay Band 9300-34800 (GP-4200) & Level 6

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 Sub Zone Indore Email: indoresubzone@cdsco.nic.in
2	Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) CDSCO Sub Zone Indore Email: indoresubzone@cdsco.nic.in

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

(i) Pending for Minor penalty or major penalty proceedings – Nil

(ii) 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

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. B (GZ & Non-GZ officials).

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.

The budget and programme of this office are governed by CDSCO West Zone office, Mumbai

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. Gaurav Kumar Dy. Drugs Controller (I)				Nil

Domestic Tours:

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
	Shri. Gaurav Kumar Dy. Drugs Controller (I)	Nil			

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

2.3 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

2.4 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

2.5 "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

i. Relevant Acts, Rules, Forms and other documents which are normally accessed by 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) 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

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 Sub Zone office has specified following:

Office	Designation	Act as	Contact details
Officers of CDSCO, Sub Zone, Indore	Dy. Drugs Controller (India) CDSCO SZ Indore	PRO	indoresubzone@cdsco.nic
	Assistant Drugs Controller (India) CDSCO SZ Indore	Assisting Officer of the PRO Cell	indoresubzone@cdsco.nic

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

3.1 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

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

3.2 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

3.3 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 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 Standard Control Organization, CDSCO Bhawan, GPO square, Residency Area A.B. Road, Indore -452001

(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 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.

indoresubzone@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.1so?num_id=NTU2Mg==

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

Sr.No.	Year	RTI applications received	RTI applications disposed
1.	2022	9	9
2.	2023	13	13
3.	2024 till date	2	2

(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.

This office has not entered into any contract

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 Sub Zone office.

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

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

3.	Phyto pharmaceuticals	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download file division.jsp?numid=MzI 0MA=—
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/CDSCOWEB/Pdf-documents/cosmetics/FAQcos.pdf
7.	BA/BE	https://cdsco.gov.in/opencms/export/sites/CDSCOWEB/Pdf-documents/BA BE/revidsefaqbabe df
8.	Import & Registration	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-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

a) 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**

S. No	Year	RTI applications received	RTI applications disposed
1.	2022	9	9
2.	2023	13	13
3.	2024 till date	2	2

(ii) Details of appeals received and orders issued

S. No	Year	RTI applications received	RTI applications disposed
1.	2022	0	0
2.	2023	0	0
3.	2024 till date	0	0

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) Name & details of Current CPIOs & FAAs

Sr.No.	**Designation**	**Technical/ Administration** Matters	**Year**
1.	Sh. Gaurav Kumar, Appellate Authority	Deputy Drugs Controller (India) Email: indoresubzone@cdsco.nic.in	**2023-Till now**
2.	Sh. Mahesh N A Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: indoresubzone@cdsco.nic.in	**2023-Till now**

(b) Earlier CPIO & FAAs **from 1.1.2015**

S. No.	**Name of the office**	**CPIO**	**Appellate authority**	**Year**
1.	Central Drugs Standard Control, Organization, CDSCO Bhawan, GPO square, Residency Area A.B. Road, Indore -452001	Sh. Sanjeev Kumar	Sh. Sanjeev Kumar	2016
2.		Sh. Sunil M. Josh	Sh. Sunil M. Joshi	2017
3.		Dr. S.P Sani	Dr. S.P Sani	2022
4.		Sh. A.Senkathir	Sh. A.Senkathir	2022

(i) Details of third party audit of voluntary disclosure

Third party audit will be carried by RTI Cell CDSCO HQ New Delhi as per RTI Act

(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-moto 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

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