# SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT, 2005 (CDSCO, Baddi Zone)

# **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, BADDI ZONE, BADDI

Central Drugs Standard Control Organisation Baddi, (Container Corporation of India Ltd. Complex) Village- Sheetalpur, Tehsil-Baddi, District- Solan, Himachal Pradesh-173205.

01795-246112, 247112 chandigarh@cdsco.nic.in

https://cdsco.gov.in/opencms/opencms/en/Zonal-office/

#### (ii) Head of the organization

Dr.Ajay. Sachan, Deputy Drugs Controller (India), https://cdsco.gov.in/opencms/opencms/en/Zonal-office/

#### (iii) 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.

https://cdsco.gov.in/opencms/opencms/en/About-us/Vision/

#### (iv) Function and duties

- 1. To participate in the joint inspection for issuance / revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO certification scheme after receiving the application from the manufacturing firm.
- 2. To participate in the joint inspection for grant/renewal of Blood Bank license.
- 3. To participate in the joint inspection for grant/renewal of license for Vaccine / Sera manufacturing units for both human as well as veterinary.
- 4. To participate in the joint inspection for grant/renewal of license for LVP manufacturing units.

- 5. To conduct inspection for grant of license for Class C and Class D notified Medical Devices & Invitro diagonstics.
- 6. To participate in the joint inspection for grant/renewal of license for Bio-Tech & Biosimilar products manufacturing units.
- 7. 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.
- 8. To carry out Surprise check/Raid jointly/independently on the basis of complaint received under Whistle Blower scheme and also from other sources.
- 9. To carry out joint inspection of Drug Testing Laboratory for the purpose of grant of approval for test / analysis of Drugs & Cosmetics.
- 10. To follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices.
- 11. Drawing of Legal and Survey samples of drugs, cosmetics and medical devices from the manufacturing & sales / distribution premises including the Govt. establishment.
- 12. When the samples drawn by the Central Drugs Inspector are declared spurious / adulterated / grossly sub-standard etc., the cases are investigated and prosecution are launched in the appropriate court after obtaining necessary sanction from the Drugs Controller General (India).
- 13. Information regarding cancellation/suspension of manufacture licenses or withdrawal of product permission by the State Licensing Authority is circulated to other State Licensing Authorities in the zone and other zonal offices.
- 14. To pursue the court cases pending in different courts under the zone.
- 15. Technical survey as and when directed by the Drugs Controller General (India) from time to time.
- 16. 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.
- 17. To co-ordinate for answering the Parliament Questions and for obtaining the data from various State Licensing Authorities under the zone.
- 18. Preparation of Monthly / Quarterly / Annual Reports.
- 19. To participate in the joint inspection with respect to grant of permission in Form CT-11/CT-14/CT-15 as per requirements.
- 20. To participate as observers in international regulatory agencies inspections as and when directed by Directorate.
- 21. To organise workshop, seminar etc. as directed.
- 22. To conduct the function of Drugs Controller General (I) as delegated by him under rule 22 (b) & 122L and other rules of the Drugs & Cosmetics Act. Presently (w.e.f. 20.06.2011), the following functions are delegated to respective zonal officers for carrying out on his behalf:
  - a. Grant of Permission in Form CT-11/ CT-14 & CT15 to manufacture drugs for the purpose of examination, test or analysis.
  - b. Permit for import of small quantities of drugs for personal use under Form 12B of the Drugs and Cosmetics Rules.
  - c. No objection certificates for grant of permissions for import of dual use items, not for medicinal use.
- 23. Any other functions as assigned by DCG(I) / DDC(I).

#### (v) Organization Chart:

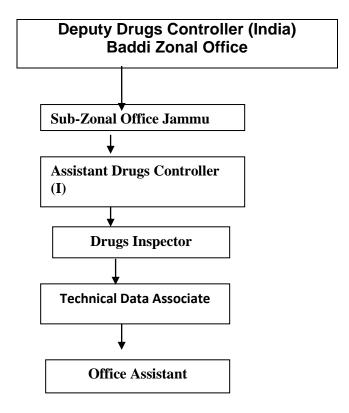


Table No.1

# (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), Sub Zone, Chandigarh, was started during the year 2013 in the Regional Drugs Testing Laboratories, Sector-39, Chandigarh and shifted to Baddi in August 2016 at Container Corporation of India Ltd. Complex Village- Sheetalpur, Tehsil-Baddi, District- Solan, Himachal Pradesh-173205 headed by Deputy Drugs Controller (India). Further, in 2022 Baddi sub zone was converted to Baddi Zone. The Zonal office of the CDSCO was initially created to co-coordinate 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 D&C Act and Rules. The Baddi Zone office had jurisdiction over the states of Himachal Pradesh, Punjab, Haryana and Union Territory of Chandigarh. A sub Zonal office headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Jammu & Kashmir. At present the Baddi Zone office is functioning in Container Corporation of India Ltd. Complex Village- Sheetalpur, Tehsil-Baddi, District- Solan, Himachal Pradesh-173205 has the jurisdiction over the States of Himachal Prades of Himachal Pradesh, Punjab, Baddi, District- Solan, Himachal Pradesh-173205 has the jurisdiction over the States of Himachal Pradesh Pradesh, Punjab, Haryana and Union Territory of Chandigarh.

- 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	1. As a zonal Department head, ensure uniform implementation
Controller	of Drugs and Cosmetics Act and Rules in coordination with
	State Drugs Licensing Authorities of Himachal Pradesh,
	Punjab, Haryana and Union Territory of Chandigarh.
	2. Oversee the activities of Drugs Inspectors under the zone and
	forward the recommendation letter to the concerned SLAs.
	3. Issuing of NOCs for Dual use items/ Permissions for CT
	Applications/License for import under Form 11 & CT-17 for
	test, analysis and examination.
	4. Handling of General Court cases.
	5. Preparation of monthly/ quarterly/ annual report.
	6. Apart from the above mentioned technical duties, performing
	as a Head of Office as well as drawing and disbursing officer
	from the administrative and account side. Attending the
	Drugs Consultative meeting at CDSCO, HQ, New Delhi.
	7. First Appellate authority for RTI Questions for the (1) O/o
	Deputy Drugs Controller (India), CDSCO, Baddi Zone.
Assistant Drugs	1. Issuing of NOCs for dual use items.
Controller	2. Handling of general court cases.
	3. Whenever the deputy Drugs controller (India) is on official tour
	or on leave, Assistant Drugs controller (India) will be the in-
	charge of O/o. Deputy Drugs Controller(India), CDSCO, Baddi Zone, Baddi.
	Zone, Dauui.

# Table No.2

Technical Data	1. Scrutiny of CoPP files.		
Assistant	2. Scrutiny of Blood Center files, LVP files.		
	3. Timely preparation of pending list of Inspection to be carried		
	out, Monthly, Quarterly and Annual reports.		
	4. Details required in respect of RTI Parliament Questions are		
	submitted to DDC.		
	5. There are more than 1000 files pertaining to the technical		
	section are maintained.		
Drugs Inspector	1. Work in accordance with the provisions of Section 21, 22 & 23		
	of Drugs and Cosmetic Act, 1940 and rules made there under.		
	2. Sampling of Drugs, Cosmetics and Medical Devices by		
	Section and Survey.		
	3. Following up of NSQ reports and launching of prosecution.		
	4. Any other work assigned by DDC (I) from time to time.		
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 end to other. To attend the personal needs of Head of		
	office. In addition to the auxiliary support, have to do basic clerical		
	work also whenever there is a need.		
Data Entry	Dispatching of inspection reports of Blood Bank, COPP and Medical		
Operator	devices to DCG(I), applicant and SLAs. Assisting to preparation of		
	Quarterly and annual Technical reports.		

(iii) Rules/ orders under which powers and duty are derived and (iv)Exercised

Drug Inspectors derive their powers from Drugs and Cosmetics Act, 1940 and Rules made thereunder (Drugs and Cosmetics Rules, 1945, 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. 1.3 Procedure followed in decision making process

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

- (i) Process of decision making Identify key decision making points
- (ii) Final decision making authority
- (iii) Related provisions, acts, rules etc.
- (iv) Time limit for taking a decisions, if any
- (v) 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 and guidance document 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).

- 1.4 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 (<u>www.cdsconline.gov.in</u> and <u>www.cdscomdonline.gov.in</u>) & NSWS Portal. Time limits are specified in the SOP. The grievances are redressed through Public Relation Office.

- 1.5 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.

- 1.6 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. Guidance document for zonal activity
- b. Drugs and Cosmetics Act, 1940
- c. Drugs and Cosmetics Rules, 1945
- d. Medical Device Rules, 2017
- e. New Drugs and Clinical Trials, 2019
- B) Administrative:

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

1.7 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?

#### Boards and Committees are constituted by the Directorate.

**1.8** Directory of officers and employees

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

- (i) Name and designation
- (ii) Telephone , fax and email ID Email id:chandigarh@cdsco.nic.in

Sl.No	NAME OF THE	<b>DESIGNATION OF THE</b>	
•	EMPLOYEE	EMPLOYEE	LANDLINE
1	Dr.Ajay Sachan	Deputy Drugs Controller(I)	01795-246112
2	Dinesh Kumar	Assistant Drugs Conntroller (I)	01795-246112
3	Dr.Kailash Chand Malik	Assistant Drugs Conntroller (I)	01795-246112
4	Munish Kakkar	Drugs Inspector	01795-246112
5	Rakesh Negi	Drugs Inspector	01795-246112
6	Deepanshu Manchanda	Drugs Inspector	01795-246112
7	Ashish Chauhan	Drugs Inspector	01795-246112
8	Vivek Gill	Drugs Inspector	01795-246112
9	Sushil Soni	Drugs Inspector	01795-246112
10	Kamla	Drugs Inspector	01795-246112
11	Mohd Ahmed	Drugs Inspector	01795-246112
12	Rana	Drugs Inspector	044-28278186
13	Manoj Kumar	Drugs Inspector	044-28278186

# LIST OF EMPLOYEES OF CDCSO SOUTH ZONE

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 DE	O/O DEPUTY DRUGS CONTROLLER (I), CDSCO ZONAL OFFICE, BADDI (HP)			
	DETAILS OF POSTS WITH PAY BAND & PAY LEVEL			
Sr. No.	Sr. No. Name of Post Pay Band and Pay Le			
1.	Deputy Drugs Controller (India)	15600-39100 Level 12		
2.Assistant Drugs Controller (India)15600-39100 Level		15600-39100 Level 11		
3.	Drugs Inspector	9300-34800 Level 08		

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	Name of the Officer	Telephone No	Email ID
1.	Dr. Ajay Sachan	01795-247112	chandigarh@cdsco.nic.in
	Deputy Drugs Controller		
	(India), First Appellate		
	Authority and Deputy Drugs		
	Controller (I), Baddi		

2.	Sh. Dinesh Kumar, CPIO	01795-247112	dinesh@cdsco.nic.in

1.11 No. Of employees against whom Disciplinary action has been proposed/ taken (Section 4(2))

No. of employees against whom disciplinary action has been

- (i) Pending for Minor penalty or major penalty proceed
- (ii) Finalizedised 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:-

1. One day workshop-cum-training programme on Transparency Audit on Suo moto Disclosure under Section 4 of RTI Act held at National Institute of Health and Family Welfare, New Delhi on 04.02.2020.

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

- A guidance document related to RTI is published in website of CDSCO <u>https://cdsco.gov.in/opencms/opencms/en/RTI/</u> <u>https://cdsco.gov.in/opencms/export/system/modules/CDSCO.WEB/resou</u> <u>rces/pdf/RTI/guidance\_documents1.pdf</u>
- Further, the guidelines issued by Central Information Commission are followed <a href="https://cic.gov.in/rti-notifications">https://cic.gov.in/rti-notifications</a>

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

#### 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

# ii) Proposed expenditures

# Budget and proposed espenditures allocation has been carried out by CDSCO, North Zone as CDSCO, Baddi has no DDO power.

**2.2** 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.

S.no	Name of the Officer	Places Visted	The period of visit	Number of members in the official delegation	Expenditure on the visit
1	2	3	4	5	6
1.	Dr.Ajay Sachan, Deputy Drugs Controller(I)		None	for last 5 years.	

(iii) 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

2.3 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**

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

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

- (iii) Concessions, permits or authorizations granted by public authority
- (iv) 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 authorizations
  - 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

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 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

Sr. No.	Type of Information	Related URLs
1.	Gazette	https://cdsco.gov.in/opencms/opencms/en/Notifications/
	Notifications	Gazette-Notifications/
2.	Public Notices	https://cdsco.gov.in/opencms/opencms/en/Notifications/
		Public-Notices/
3.	Bioequivalence and	https://cdsco.gov.in/opencms/opencms/en/bioequi_bioav
	Bioavailability	ail/index.html
4.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/biologicals/Bl
		ood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/V
		accines/
6.	Global Clinical	https://cdsco.gov.in/opencms/opencms/en/Clinical-
	Trial	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	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
	Combinations	
	(FDCs)	
10.	Investigational	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investi
	New Drugs (INDs)	gational-New-Drugs-/
11.	Subsequent New	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subseq
	Drugs	uent-New-Drugs/
12.	Medical Device and	https://cdsco.gov.in/opencms/opencms/en/Medical-
	In-Vitro	Device-Diagnostics/InVitro-Diagnostics/
	Diagnostics	
13.	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/co
		smetics/

- 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

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/d ownload\_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 t o 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

3.2 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

# Policydecisions/legislationsiscarriedoutbyDirectorate(https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/Formulation of Policy and Implementation is also carried out by Directorate

3.3 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)

Sr. No.	Type of Information	Related URLs
1.	Gazette	https://cdsco.gov.in/opencms/opencms/en/Notifications/
	Notifications	Gazette-Notifications/
2.	Public Notices	https://cdsco.gov.in/opencms/opencms/en/Notifications/
		Public-Notices/
3.	Alerts	https://cdsco.gov.in/opencms/opencms/en/Notifications/
		<u>Alerts/</u>
4.	Bioequivalence and	https://cdsco.gov.in/opencms/opencms/en/bioequi_bioav
	Bioavailability	<u>ail/index.html</u>
5.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/biologicals/Bl
		ood-Products/
6.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/V
		accines/
7.	Global Clinical	https://cdsco.gov.in/opencms/opencms/en/Clinical-
	Trial	<u>Trial/Global-Clinical-Trial/</u>
8.	Ethics Committee	https://cdsco.gov.in/opencms/opencms/en/Clinical-
		Trial/Ethics-Committee/
9.	New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/New-
		<u>Drugs/</u>
10.	Fixed Dose	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
	Combinations	
	(FDCs)	
11.	Investigational	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investi
	New Drugs (INDs)	gational-New-Drugs-/

12.	Subsequent New	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subseq
	Drugs	uent-New-Drugs/
13.	Medical Device and	https://cdsco.gov.in/opencms/opencms/en/Medical-
	In-Vitro	Device-Diagnostics/InVitro-Diagnostics/
	Diagnostics	
14.	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/co
		smetics/

3.4 Form of accessibility of information manual/ handbook

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

### Information manual/handbook available in

(i) Electronic format

Sr. No.	Торіс	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 wil 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

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

**4.2** 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

**4.3** 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, Baddi Zone, Container Corporation of India Building, Village Sheetalpur, Tehsil Baddi, District Solan (HP) -173205.

(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 laptops.

(iii) Working hours of the facility

#### 9.30 AM to 6.00 PM (except holidays)

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

Central Drug Standard Control Organization, Baddi Zone, Container Corporation of
India Building, Village Sheetalpur, Tehsil Baddi, District Solan (HP) -173205.
01795-247112,
<u>chandigarh@cdsco.nic.in</u>

- 4.4 Such other information as may be prescribed under section 4(i) (b)(xvii)
  - (i) Grievance redressal mechanism

Public Relation office was established https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download fil e\_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 t o 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.	2016 - 17	06	06
2.	2017 - 18	08	08
3.	2018 - 19	14	14
4.	2019-20	20	20
5.	2020-21	16	16
6.	2021-22	20	20
7.	2022-23	21	21
8.	2023-2024	19	19

- (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.
- (vi) Annual Report

# Annual report of CDSCO is prepared by Directorate by compiling the information from the Field formations.

(vii) Frequently Asked Question (FAQs)

Sr. No.	Торіс	URLs
1.	New Drugs	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.W EB/elements/download file_division.jsp?num_id=NDM0MA==
		Additional FAQs:
		https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.W EB/elements/download file division.jsp?num id=NDg1Ng==

		https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.W EB/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/CDSCO.W EB/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/FAQ/index.html
5	Blood Bank	https://cdsco.gov.in/opencms/opencms/en/FAQ/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.pdf

- (viii) Any other information such as
  - a) Citizen's Charter
  - b) Result Framework Document (RFD)
  - c) Six monthly reports on the
  - d) Performance against the benchmarks set in the Citizen's Charter Nil
- 4.5 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	<b>RTI</b> applications received	<b>RTI applications disposed</b>
1.	2016 - 17	06	06
2.	2017 - 18	08	08
3.	2018 - 19	14	14
4.	2019-20	20	20
5.	2020-21	16	16
6.	2021-22	20	20
7.	2022-23	21	21
8.	2023-2024	19	19

(ii) Details of appeals received and orders issue	(ii)	i)	Details (	of appeal	ls received	and	orders issue	d
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S.No	Year	RTI applications received	RTI applications disposed
1.	2016 - 17	Nil	Nil
2.	2017 - 18	Nil	Nil
3.	2018 - 19	Nil	Nil
4.	2019-20	Nil	Nil
5.	2020-21	Nil	Nil
6.	2021-22	Nil	Nil
7.	2022-23	01	01
8.	2023-2024	Nil	Nil

4.6 Replies to questions asked in the parliament [Section 4(1)(**d**)(2)

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]

(i) Name & details of (a) Current CPIOs & FAAs

S.No	Name of the Officer	Telephone No	Email ID
1.	Dr.Ajay Sacchan,	01795-247112	chandigarh@cdsco.nic.in
	First Appellate Authority		
	and Deputy Drugs		
	Controller (I), CDSCO,		
	Baddi.		
2.	Sh. Dinesh Kumar, CPIO	01795-247112	chandigarh@cdsco.nic.in
	and Assistant Drugs		
	Controller (India), CDSCO		
	(SZ), Chennai.		

# (b) Earlier CPIO & FAAs from 2016

			Appellate authority
S.No.	Name of the office	CPIO	
1	O/o Deputy Drugs Controller(I), Central Drugs Standard Control	Sh Munish Kakkar, Drugs Inspector wef 22.08.2016 to 01.11.2018	B.K Samanthra. DDC(I), 22.08.2016- 26.05.2020
	Organization, Baddi Zone, Container Corporation of India Building, Village Sheetalpur, Tehsil Baddi, District Solan (HP)- 173205	Sh. Sushant Sharma, Assistant Drugs Controller (India) w.e.f from 02.11. 2018 to 2023 Ms.Minakshi Vashistha, Drugs Inspector w.e.f. 16.06.2023	Arvind Kukrety. DDC(I) 27.05.2020 to 28.01.2022 Chandrashekar Ranga, DDC(I) 01.06.2022- 08.04.2024
		Dinesh Kumar, Assistant Drugs Controller (India) w.e.f 25.06.2023 to till dated	Dr.Ajay Sacchan, DDC(I) Apr,2024 to till dated

- (ii) Details of third party audit of voluntary disclosure
  - (a) Dates of audit carried out
  - (b) Report of the audit carried out
- (iii) 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**

- (iv) 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.

- (v) 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	https://cdsco.gov.in/opencms/opencms/en/Notifications/
	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_bioav ail/index.html
4.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/biologicals/Bl ood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/V accines/
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/Investi gational-New-Drugs-/

11.	Subsequent New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subseq uent-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/co smetics/

- 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 maintained by Directorate (FDA Bhawan, Kotla Road, New Delhi.