

## SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT, 2005

(CDSCO, Seaport, Kochi)

### 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, SEA PORT, KOCHI**

Central Drug Standard Control Organization, Office of The Technical Officer,  
Room No.-15, Custom House, Willingdon Island, Kochi-682009.

Phone Number: 0484-2666042 Email Id: todcochin@nic.in

<https://cdsco.gov.in/opencms/opencms/en/Port/>

##### (ii) Head of the organization

Mrs.Sudha Sukumaran Nair, Drugs Inspector

<https://cdsco.gov.in/opencms/opencms/en/Port/>

##### (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) Scrutiny of the Bills of entry with a view to ensure that the imported drugs comply with the provisions of Chapter III of the Drugs & Cosmetic Act and Rules there under and Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules & Narcotic Drugs and Psychotropic Substances Act(NDPS) & Rules there under and any other law for the time being in force.

(2) To check the shipping bills for export for compliance of Drugs & Cosmetics Act and keep control under Narcotic Drugs and Psychotropic Substances Act & Rules.

(3) In the case of Narcotic Drugs and Psychotropic Substances Act & Rules, a certificate issued by Narcotics commissioner must be checked for import/export and details

furnished to Drugs Controller General (India) through the Deputy Drugs controller (India) of the respective Zones.

(4) To ensure that no New Drug is imported into the country unless its import permitted by the Drugs Licensing Authority under Rules (Rules 122 A & 30-AA).

(5) To ensure that small quantities of drugs imported for Test, Examination and Analysis or clinical trials or for personal use are duly covered by Test License (11 or 11-A) or Permit License as (12 B) as the case may be.

(6) Maintenance of Statistics data regarding imports/export of all Drugs/cosmetics/medical devices and submit the same on monthly basis to the Deputy Drugs Controller (India) of the respective zones and to other authorities as and when required.

(7) Co-ordination with the Commissioner of Customs – The Port Officers should have enough knowledge of the relevant portions for Customs Act and DGFT policies.

(8) Import of raw materials under Advance Licenses/100% EOU cases must be intimated to the concerned State Drugs Controller to examine proper post-import check with a copy marked to the DDC(I) of the concerned Zone.

(9) Assist members of the trade with the information required.

(10) Preparation and forwarding of Quarterly and Annual Reports.

(11) Examination of post parcels couriers for import and export of drugs, cosmetics and medical devices.

(12) Coordination with the customs and other investigating agencies for the matters of violation of import/export under intimation to the DDC (I) of the concerned zone.

(13) To examine the re-import/re-export consignment as per the procedures.

(14) To draw samples from import/export and re-import consignment as per laid down procedures.

(15) To examine unclaimed/seized cargo when referred by customs and offer opinion as per procedure laid down.

(16) In case of drugs and cosmetics of not of standard quality/spurious, to be informed to all the port offices directly with a copy marked to the Deputy Drugs controller of the concerned zone.

(17) Grant of permission for small quantities of drugs imported for personal use as per DCG(I) order No. DCG(I)/Misc/2013(34) dated 12/02/2014

(18) Handling of Parliamentary Questions and RTI matters

(19) Handling of Administration work as DDO and other administrative activities by O/o. ADC(I), Seaport, Chennai.

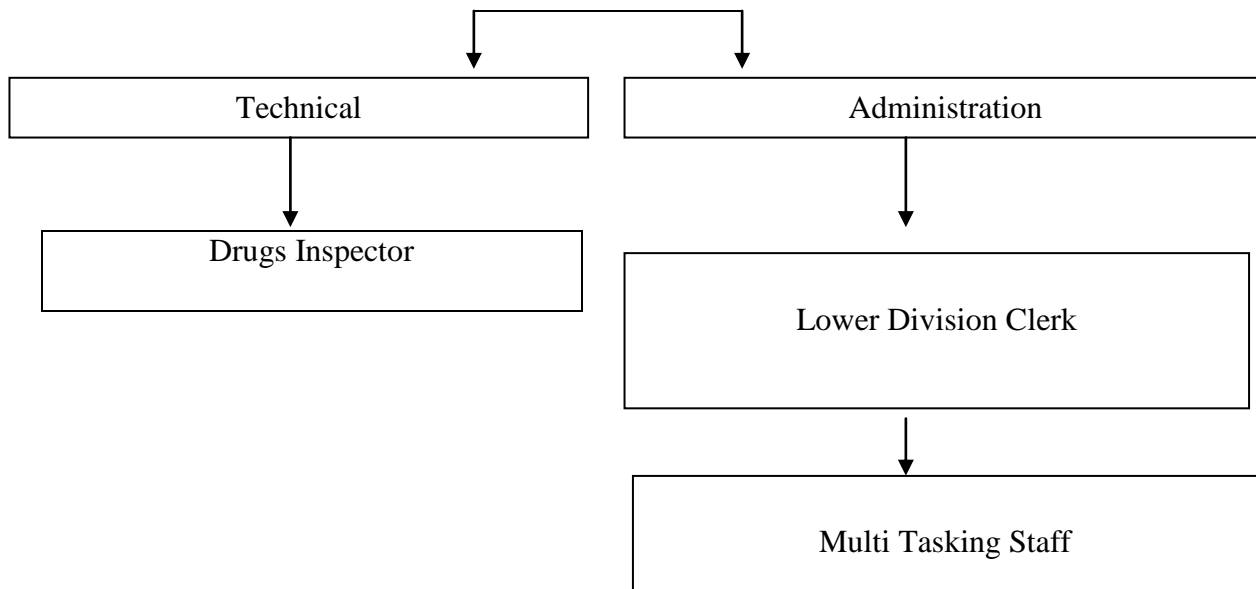
(20) Periodically conducting stakeholders meetings.

(21) Forwarding the monthly activity report to DDC(I), South Zone, DCG(I) and NPPA.

(22) Any other work assigned by DDC(I), South Zone and DCG(I) as an required.

**(v) Organization Chart:**

**O/o TECHNICAL OFFICER ,**  
**CDSCO, SEAPORT, CUSTOM HOUSE, KOCHI.**



**(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, Seaport, Kochi was started during the year 1954 under the Administrative control of the Drugs Controller General of India, Ministry of Health and Family Welfare, New Delhi.

## 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
Drugs Inspector	<ul style="list-style-type: none"><li>➤ Scrutiny of the Bills of entry with a view to ensure that the imported drugs comply with the provisions of Chapter III of the Drugs &amp; Cosmetic Act and Rules there under, Medical Device Rules 2017, Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules and Narcotic Drugs and Psychotropic Substances Act (NDPS) and Rules there under and any other law for the time being in force.</li><li>➤ To check the shipping bills for export for compliance of Drugs &amp; Cosmetics Act and keep control under Narcotic Drugs and Psychotropic Substances Act &amp; Rules.</li><li>➤ In the case of Narcotic Drugs and Psychotropic Substances Act &amp; Rules, a certificate issued by Narcotics commissioner must be checked for import/export and details furnished to Drugs Controller General (India) through the Deputy Drugs controller (India) of the respective Zones.</li><li>➤ Preparation and Maintenance of Statistics data regarding imports/export of all Drugs/cosmetics/medical devices and submit the same on monthly basis to the DCG(I) with copy to Deputy Drugs Controller (India)-South Zone and to other authorities as and when required.</li><li>➤ Co-ordination with the Commissioner of Customs.</li><li>➤ Assist members of the trade with the information required.</li><li>➤ Preparation and forwarding of Quarterly and Annual Reports.</li><li>➤ Coordination with the customs and other investigating agencies for the matters of violation of import/export under intimation to the DDC (I) of the concerned zone.</li><li>➤ To examine the re-import/re-export consignment as per the procedures.</li><li>➤ To draw samples from import/export and re-import consignment as per laid down procedures.</li><li>➤ To examine unclaimed/seized cargo when referred by customs and offer opinion as per procedure laid down.</li><li>➤ In case of drugs and cosmetics of not of standard quality/spurious, to be informed to all the port offices directly with a copy marked to the Deputy Drugs controller of the concerned zone.</li><li>➤ Handling of Parliamentary Questions and RTI matters</li><li>➤ Handling of Administration work as DDO Checker and other administrative activities.</li><li>➤ Forwarding the monthly activity report to DCG(I).</li></ul>

	<ul style="list-style-type: none"> <li>➤ Any other work assigned by DDC (I), South Zone and DCG (I) as an required.</li> <li>➤ Forwarding of drugs including Schedule C &amp; C(1) and Cosmetics to various government laboratories (CDL,CDTL,NIB)/and or local labs for test and maintaining their relevant records. Verifying the test reports of Drugs and Cosmetics with respective pharmacopeias monograph and BIS Specification.</li> <li>➤ Preparation of letters in reply to other department correspondence.</li> </ul>
<b>Lower Division Clerk</b>	<ul style="list-style-type: none"> <li>➤ Preparation of all Pay bills under the respective Heads such as Office Expenses Head, Salary Head, Medical Treatment Head, Travelling Expenses Head etc.</li> <li>➤ Other than Bill preparation works like Preparation of Monthly Expenditure etc.</li> <li>➤ Maintenance of various Registers like Maintaining of Bill Register, Service books, Stamp Register, Letter of Guarantee register etc.</li> <li>➤ Preparation of Income tax statement and filing of TDS etc.</li> <li>➤ Preparation of reply to all administrative emails.</li> <li>➤ Any other administrative related works.</li> <li>➤ Giving inward and out ward number to different letter/OM etc.</li> <li>➤ Other works assigned by DI.</li> </ul>
<b>Multi Tasking Staff</b>	<p>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.</p>

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

**(iv) Exercised**

**(v) Work allocation**

Powers and duties of all posts are derived and exercised as per the practice in vogue. The work allocation information is available in the **Point 1.2**

### **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 Assistant Drugs Controller (I) / Drugs Inspector.

#### **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**
- (v) **Process of redress of grievances**

The nature of functions/services are listed in point no: 1.2 (i),(ii). NOC issued through the ICEGATE portal maintained by Customs Department. Time limits is specified in the guidance document and instructions issued from Customs Authority / Directorate on time to time basis. The grievances are redressed through Deputy Drugs Controller (I)/ Assistant Drugs Controller (I)/ Drugs Inspector.

#### **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. 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. Guidance Document issued by Directorate

**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

S.No.	Name	Designation	Telephone	Email ID
1	Mrs.Sudha Sukumaran Nair	Drugs Inspector	0484-2666042	todcochin@nic.in
2	Mr.K.V. Baba Maqbool	Lower Division Clerk	0484-2666042	
3	Mr.K.Surendran	MTS	0484-2666042	

**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

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	Designation	Pay Band & Pay Level
1	Mrs.Sudha Sukumaran Nair	Drugs Inspector	Pay Band: 9300-34800 & Pay level: 8
5	Mr. K.V. Baba Maqbool	Lower Division Clerk	Pay Band: 5200-20200 & Pay level: 2
6	Mr.K.Surendran	MTS	Pay Band: 5200-20200 & Pay level: 1

1.11 Number 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 proceedings
- (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

Nil

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

A guidance document related to RTI is published in website of CDSCO

<https://cdsco.gov.in/opencms/opencms/en/RTI/>

[https://cdsco.gov.in/opencms/export/system/modules/CDSCO.WEB/resources/pdf/RTI/guidance\\_documents1.pdf](https://cdsco.gov.in/opencms/export/system/modules/CDSCO.WEB/resources/pdf/RTI/guidance_documents1.pdf)



Further, followed the guidelines issued by Central Information Commission  
<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

## **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
- (iii) Proposed expenditures
- (iv) Revised budget for each agency, if any
- (v) Report on disbursements made and place where the related reports are available



F.No.G.26027/14/2019-DC  
DIRECTORATE GENERAL OF HEALTH SERVICES  
( D.C. SECTION )

SPEED POST

F.D.A. Bhawan, I.T.O., Kotla Road,  
New Delhi.  
Dated: 30<sup>th</sup> January, 2020

Technical Officer/In charge,  
Central Drugs Standard Control Organization,  
Custom House, Cochin -682009

**Subject:-** Revised Estimates 2019-20 & Budget Estimates 2020-21 in respect of Major Head 2210-06104-Drugs Control (Minor Head ) 02-CDSCO-0201- General Component - Reg.


Sir/Madam,

I am directed to forward Revised Estimates 2019-20 and Budget Estimates 2020-21 in respect of your office under each sub-head is as given below:-

( RS. IN THOUSAND )

SL. NO	ITEM	B.E. 2019-20	R.E. 2019-20	B.E. 2020-21
1.	SALARIES	25,00	15,00	20,00
2.	WAGES	--	--	--
3.	M.T.	1,00	50	2,00
4.	T.E.	3,00	50	3,00
5.	O.E.	6,00	1,00	2,00
6.	R.R.T.	--	--	--
7.	PUB.	--	--	--
8.	S&M	--	--	--
9.	M/W	--	--	--
10.	P/S	--	--	--
11.	O.C.	--	--	--
	<b>TOTAL</b>	<b>35,00</b>	<b>17,00</b>	<b>27,00</b>

Yours faithfully,

  
(Pratima kerketta)  
Dy. Director Administration(D)

Copy to:- Pay & Accounts Officer,  
Ministry of Health & FW, Chennai

*Account  
Auditor  
or  
relation*

## 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
- (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 subsidyprogramme (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 there of

[Section 4(1)(b)(vii)] [F No 1/6/2011-IR dt. 15.04.2013]

#### **Formulation of policy and its implementation is carried out by Directorate**

- (i) Relevant Acts, Rules, Forms and other documents which are normally accessed by citizens

<b>Sr. No.</b>	<b>Type of Information</b>	<b>Related URLs</b>
1.	Gazette Notifications	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/</a>
2.	Public Notices	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/</a>
3.	Bioequivalence and Bioavailability	<a href="https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html">https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html</a>
4.	Blood Products	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/</a>
5.	Vaccines	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/</a>
6.	Global Clinical Trial	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/</a>
7.	Ethics Committee	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/</a>
8.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/</a>
9.	Fixed Dose Combinations (FDCs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/">https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/</a>
10.	Investigational New Drugs (INDs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/</a>
11.	Subsequent New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/</a>
12.	Medical Device and In-Vitro Diagnostics	<a href="https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/">https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/</a>
13.	Cosmetics	<a href="https://cdsco.gov.in/opencms/opencms/en/Cosmetics/co">https://cdsco.gov.in/opencms/opencms/en/Cosmetics/co</a>

- (ii) Arrangements for consultation with or representation by
  - a) Members of the public in policy formulation/ policy implementation  
**Policy formulation and its implementation is done by Directorate**
  - b) Day & time allotted for visitors  
**Office timing (10:00 AM to 05:30 PM)**
  - c) Contact details of Information & Facilitation Counter (IFC) to provide publications frequently sought by RTI applicants

Mrs.Sudha Sukumaran Nair, Drugs Inspector, Phone Number: 0484-2666042  
Email Id: todcochin@nic.in

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

**Policy decisions/ legislations is carried out by Directorate**  
[\(https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/\)](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 Notifications	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/</a>
2.	Public Notices	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/</a>
3.	Bioequivalence and Bioavailability	<a href="https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html">https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html</a>
4.	Blood Products	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/</a>
5.	Vaccines	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/</a>
6.	Global Clinical Trial	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/</a>
7.	Ethics Committee	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/</a>
8.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/</a>
9.	Fixed Dose Combinations (FDCs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/">https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/</a>
10.	Investigational New Drugs (INDs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/</a>
11.	Subsequent New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/</a>
12.	Medical Device and In-Vitro Diagnostics	<a href="https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/">https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/</a>
13.	Cosmetics	<a href="https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/">https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/</a>

### 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.	Sugam Portal	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/SUGAM_user_manual.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/SUGAM_user_manual.pdf</a>
2.	eSanchit	<a href="https://www.icegate.gov.in/Download/eSANCHIT_Process_Guide_updated.pdf">https://www.icegate.gov.in/Download/eSANCHIT_Process_Guide_updated.pdf</a>

- (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]

- (i) English
- (ii) Vernacular/ Local Language
- (iii)  
**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 and Customs Department**

##### **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 to para 3.3**

##### **4.4 Particulars of facilities available to citizen for obtaining information**

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

- (i) Name & location of the faculty  
Central Drug Standard Control Organization, Office of The Technical Officer,  
Room No.-15, Custom House, Willingdon Island, Kochi-682009.
- (ii) Details of information made available  
**Information available in the public domains**  
(<https://www.icegate.gov.in/index.html>) ([www.cdsc.gov.in](http://www.cdsc.gov.in))

(iii) Working hours of the facility  
**Office timing (10:00AM to 05:30PM) on working days**

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

Central Drug Standard Control Organization, Office of The Technical Officer,  
Room No.-15,Custom House, Willingdon Island,Kochi-682009.  
Phone Number: 0484-2666042 Email Id: todcochin@nic.in

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

(i) Grievance redressal mechanism  
**Mechanism is either by email, Telephone, direct meeting with DDC(I)/ADC(I)/DI**

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

S.no	Year	RTI applications received	RTI applications disposed
1.	2017	06	06
2.	2018	07	07
3.	2019 till date	03	03

(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.	Topic	URLs
1.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0MA==">https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0MA==</a>  Additional FAQs: <a href="https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDg1Ng==">https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDg1Ng==</a> <a href="https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU4OA==">https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU4OA==</a>



2	Medical Devices	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Updated-FAQ-MDR_2017.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Updated-FAQ-MDR_2017.pdf</a>
3	Phytopharmaceuticals	<a href="https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzI0MA==">https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzI0MA==</a>
4	Import of small quantities of drugs for the purposes of examination testing or analysis	<a href="https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html">https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html</a>
5	Blood Bank	<a href="https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html">https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html</a>
6	Cosmetics	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/cosmetics/FAQcos.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/cosmetics/FAQcos.pdf</a>
7	BA/BE	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/BA_BE/revidsefaqbabe.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/BA_BE/revidsefaqbabe.pdf</a>
8	e-SANCHIT	<a href="https://www.icegate.gov.in/Download/eSANCHIT_FAQs.pdf">https://www.icegate.gov.in/Download/eSANCHIT_FAQs.pdf</a>

- (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

- (i) Details of applications received and disposed

S.no	Year	RTI applications received	RTI applications disposed
1.	2017	06	06
2.	2018	07	07
3.	2019 till date	03	03

- (ii) Details of appeals received and orders issued

S.no	Year	RTI applications received	RTI applications disposed
1.	2017-18	Nil	Nil
2.	2018-19	Nil	Nil
3.	2019 till date	Nil	Nil

#### 4.7 Replies to questions asked in the parliament

[Section 4(1)(d)(2)]

Details of questions asked and replies given

**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  
(b) Earlier CPIO & FAAs from 1.1.2015

S.No	Name of the Office	CPIO	Appellate Authority	Year
1	O/o The Technical Officer, Central Drug Standard Control Organization, Seaport, Room No. 15, Custom House, Kochi – 682009.	Mrs.Sudha Sukumaran Nair, Drugs Inspector	Smt.Shanthy Gunasekaran, DDC(I)	2019 to till date
2		Mrs.Sudha Sukumaran Nair, Drugs Inspector	Dr.P.Manavalan, ADC(I)	2018
3		Shri. J. Ragupathy, Technical officer	Mr. B. Kumar, ADC(I) Mrs. V.M. Bharathy ADC(I)	2015 - 2017

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

**Nil**

- (iii) Appointment of Nodal Officers not below the rank of Joint Secretary/ Additional HoD  
(a) Date of appointment  
(b) Name & Designation of the officers

**Nil**

- (iv) Consultancy committee of key stake holders for advice on suo-motu disclosure  
(a) Dates from which constituted  
(b) Name & Designation of the officers

**Nil**

- (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

Nil

## 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	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/</a>
2.	Public Notices	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/</a>
3.	Bioequivalence and Bioavailability	<a href="https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html">https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html</a>
4.	Blood Products	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/</a>
5.	Vaccines	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/</a>
6.	Global Clinical Trial	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/</a>
7.	Ethics Committee	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/</a>
8.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/</a>
9.	Fixed Dose Combinations (FDCs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/">https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/</a>
10.	Investigational New Drugs (INDs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/</a>
11.	Subsequent New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/</a>
12.	Medical Device and In-Vitro Diagnostics	<a href="https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/">https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/</a>
13.	Cosmetics	<a href="https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/">https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/</a>

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.**