

SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT, 2005
(CDSCO, South 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, SOUTHZONE, CHENNAI

Central Drug Standard Control Organization, South Zone, 2nd Floor, Shastri Bhawan,
Annexe, 26, Haddows Road, Chennai – 600 006.

044-28278186, 28268186

ddcsz@nic.in

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

(ii) Head of the organization

Ms. Shanthi Gunasekaran,
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/>

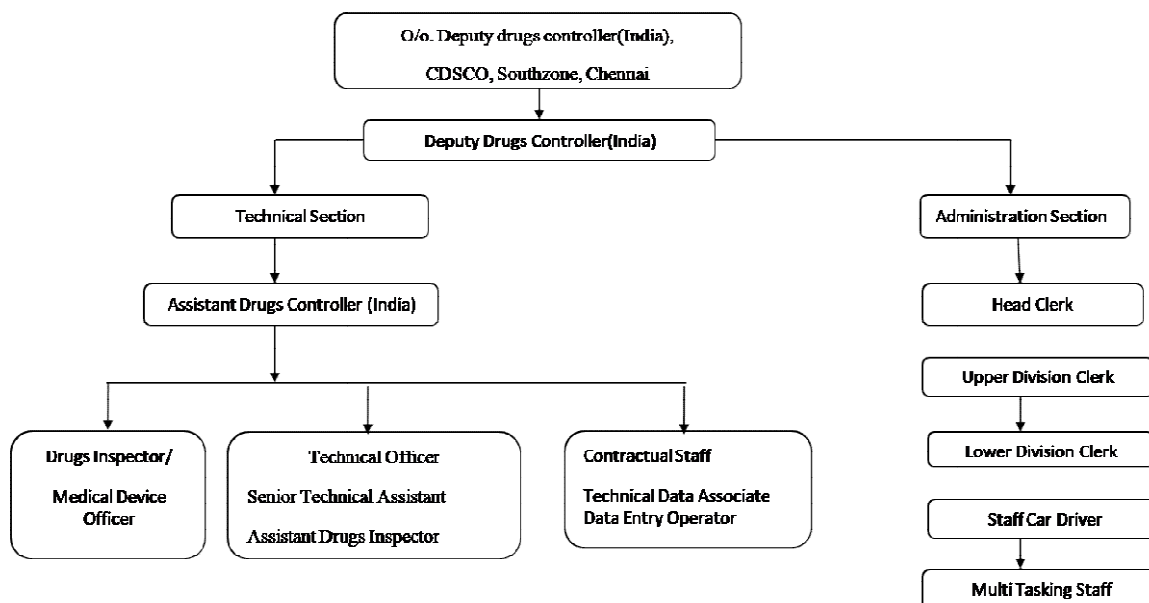
(iv) Function and duties

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 diagnostics.

6. To participate in the joint inspection for grant/renewal of license for Bio-Tech & Bio-similar 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



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), South Zone, Chennai was started during the year 1968 in the Custom House, Chennai-1 headed by Assistant Drugs Controller (India). The Zonal office of the CDSCO was initially created to co-ordinate with the various State Drugs Controllers (who are the Licensing Authority under the Act) for uniform implementation and smooth enforcement of the provisions of Chapter IV of the D&C Act and Rules. The South Zone office had jurisdiction over the states of Tamil Nadu, Andhra Pradesh, Karnataka, Kerala and Union Territory of Pondicherry. During the year 1979 this office was upgraded with Deputy Drugs Controller(India). A sub Zonal office headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Andhra Pradesh had started and functioning during the year 1995. A new Sub Zonal office of Bangalore was set up with Assistant Drugs Controller (India) on 01.09.2009 for the State of Karnataka. At present the South Zone office is functioning in 2nd Floor, Shastri Bhavan Annexe, No. 26, Haddows Road, Chennai 600 006 has the jurisdiction over the States of Tamil Nadu, Kerala, Union Territories of Puducherry and Lakshwadeep.

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

(i) Powers and duties of officers (administrative, financial and judicial) &

(ii) Power and duties of other employees

Table No.2

Designation	Duties
Deputy Drugs Controller	<ol style="list-style-type: none">1. As a zonal Department head, ensure uniform implementation of Drugs and Cosmetics Act and Rules in coordination with State Drugs Licensing Authorities of Tamil Nadu, Pondicherry, Kerala and Lakshadweep.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/Form 29/ Export of banned and unapproved drugs.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 meeting at custom house at Chennai with stake holders and 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, South Zone, Chennai, (2) O/o. Assistant Drugs controller (India), Seaport, Chennai, (3) O/o. Assistant Drugs Controller(India), Airport, Chennai and (4) O/o Technical Officer, Custom House, Cochin
Assistant Drugs Controller	<ol style="list-style-type: none">1. Issuing of NOCs for dual use items/Form 29/Export of banned and unapproved drugs.2. Handling of general court cases in the Honorable High court of Madras.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, South Zone, Chennai.

Technical Officer	<ol style="list-style-type: none"> 1. Scrutiny of Dual Use NOC issued for import of drugs intended for non medicinal use prior approval of DDC (I). 2. Scrutiny of Bill of entries for import of drugs referred by port officers for DDC clarification. 3. Assisting the SPC Govt. of India and DIs for preparing petition and Counters for cases of Drugs imported by the various importers. 4. Preparing replies for the technical clarification in respect of import and export of drugs sought by Customs, importers and public. 5. Maintaining Biometric Attendance data and sent monthly report to the Directorate. 6. Maintaining all technical correspondence related to import and export of drugs and attending various queries by public, importer and exporter. 7. Attending offices of Chennai and Cochin port in the absence of respective port officers.
Senior technical Assistant	<ol style="list-style-type: none"> 1) Timely preparation of pending list of Inspection to be carried out, Monthly, Quarterly and Annual reports. 2) Details required in respect of RTI Parliament Questions are submitted to DDC. 3) There are more than 1000 files pertaining to the technical section are maintained.
Drugs Inspector	<ol style="list-style-type: none"> 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.
Assistant Drugs Inspector & Technical Data Associate	<ol style="list-style-type: none"> 1. To assist in evaluation of Safety, Efficacy and Quality of Drugs as per requirement of Drugs and Cosmetics Act 1940. 2. To carryout field duty in assisting superior/ Drugs Inspectors in

	<p>taking out samples, enforcement activities like raids/ inspections and launching prosecution etc.</p> <p>3. To assist CDSCO officers in the matter of monitoring documentation.</p> <p>4. To carry out duties as may be assigned under the Drugs and cosmetics Act and Rules framed there under.</p> <p>5. Prescreening and scrutiny of Form 11 applications in Sugam portal (online) and Dual Use NOC, Form CT-11, Form CT-14, Form CT-15 and Form CT-17 applications received by the O/o CDSCO, SZ (offline).</p>
Head Clerk	Supervision of administrative and accounts activities like general administration, preparation of salary bills, personal claims of officers & staff, TA claim. Updating and maintenance of service records, leave records.
Upper Division Clerk	Preparation of administrative replies, furnishing data for the RTI replies from administrative side. Validation of data in respect of officers and staff in the Personal Information system. Generating expenditure claims such as Office Expenditure, TA Claims, Professional services through PFMS portal. Monthly Expenditure statements, preparation of revised and budget estimate for the current and ensuing year. Reconciliation of accounts with Pay and Accounts Office.
Lower Division Clerk	Typing the official correspondence. Preparation of paybills, income tax, e-TDS. Preparation of pension and retirement benefits. Purchase of stationary and other office equipments through GeM Portal.
Multi Tasking Staff	To open and close the office before and after the arrival and departure of officers and staff. To assist the officers and staff in moving the files from one 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 Operator	Dispatching of inspection reports of Blood Bank, COPP and Medical 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.

- (v) Work allocation

The information is available in the Table no.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 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 (www.cdsconline.gov.in and www.cdscomdonline.gov.in). Timelimits 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. 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

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 :

ddcsz@nic.in

LIST OF EMPLOYEES OF CDSCO SOUTH ZONE CHENNAI				
Sl.No	Name of the Employee	Designation of the Employee	Land Line With Extn. No.	
1	SHANTHY GUNASEKARAN	Deputy Drugs Controller (India)	044-2821 3079	
			044-2827 8186	200
2	V. M. BHARATHY	Asst. Drugs Controller (India)	044-2827 8186	210
3	J. RAGUPATHY	Technical Officer	044-2827 8186	209
4	M. SHAKUNTALA	Drugs Inspector	044-2827 8186	220
5	Dr. KASI SANKAR VENUGOPAL	Drugs Inspector	044-2827 8186	216
6	D. HEMALATHA	Drugs Inspector	044-2827 8186	221
7	HARIBABU J	Drugs Inspector	044-2827 8186	225
8	BALAKUMAR MAHALINGAM	Drugs Inspector	044-2827 8186	223
9	V. SOORAJ	Drugs Inspector	044-2827 8186	217
10	Dr. S. GOPINATH	Drugs Inspector	044-2827 8186	222
11	J. SURESH KUMAR	Drugs Inspector	044-2827 8186	218
12	P. SELVARAJ	Drugs Inspector	044-2827 8186	219
13	C. SARAVANAN	Drugs Inspector	044-2827 8186	224
14	R. AARTHY	Asst. Drugs Inspector	044-2827 8186	232
15	K. PRASHANTH KUMAR	Asst. Drugs Inspector	044-2827 8186	231
16	BULUSU SAI GAYATRI	Asst. Drugs Inspector	044-2827 8186	--
17	M. ASWINI	Asst. Drugs Inspector	044-2827 8186	--
18	M. MEENA DEVI	Asst. Drugs Inspector	044-2827 8186	229
19	R. VENKATESHWARLU	Asst. Drugs Inspector	044-2827 8186	--
20	M. SUNDARA KARTHIKEYAN	Asst. Drugs Inspector	044-2827 8186	--
21	GANNAMANI SWATHI	Asst. Drugs Inspector	044-2827 8186	--
22	PAVANI KILLAMSETTY	Asst. Drugs Inspector	044-2827 8186	228
23	MIDHUN KUMAR DUDDU	Asst. Drugs Inspector	044-2827 8186	--
24	D. SENTHIL KUMAR	Senior Technical Assistant	044-2827 8186	227
25	R. SUNDARAVADANAM	Head Clerk	044-2827 8186	244
26	N. BALAMURUGAN	Upper Division Clerk	044-2827 8186	241
27	G.T. PUGALENDHI	Lower Division Clerk	044-2827 8186	242
28	N. MANOGARAN	Staff Car Driver (Spl Gr)	044-2827 8186	--
29	K. SRINIVASAN	Multi Tasking Service	044-2827 8186	--

1.9 Monthly Remuneration received by officers & employees including system of compensation
[Section 4(1) (b) (x)]

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

O/o. THE DEPUTY DRUGS CONTROLLER (INDIA), CDSCO, SOUTH ZONE, CHENNAI		
DETAILS OF POST WITH PAY BAND & PAY LEVEL		
Sl.No	Name of the Post	Pay Band & Pay Level
1	Deputy Drugs Controller (India)	Pay Band : 15600 - 39100 & Pay Level: 12
2	Asst. Drugs Controller (India)	Pay Band : 15600 - 39100 & Pay Level: 11
3	Technical Officer	Pay Band : 9300 - 34800 & Pay Level: 8
4	Drugs Inspector	Pay Band : 9300 - 34800 & Pay Level: 8
5	Senior Technical Assistant	Pay Band : 9300 - 34800 & Pay Level: 7
6	Asst. Drugs Inspector	Pay Band : 9300 - 34800 & Pay Level: 6
7	Head Clerk	Pay Band : 9300 - 34800 & Pay Level: 6
8	Upper Division Clerk	Pay Band : 5200 - 20200 & Pay Level: 4
9	Lower Division Clerk	Pay Band : 5200 - 20200 & Pay Level: 2
10	Staff Car Driver	Pay Band : 5200 - 20200 & Pay Level: 2
11	Multi Tasking Service	Pay Band : 5200 - 20200 & Pay Level: 1

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

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

S.NO	Name of the Officer	Telephone No	Email ID
1.	Smt. Shanthi Gunasekaran, First Appellate Authority and Deputy Drugs Controller (I), CDSCO (SZ), Chennai	044-28268186 & 044-28278186	ddcsz@nic.in
2.	Dr. Kasi Sankar Venugopal, CPIO and Drugs Inspector, CDSCO (SZ), Chennai.	044-28268186 & 044-28278186 Ext. No:216	ddcsz@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 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

List of Training Programmes attended by the CPIO are as follows:-

- 1. Training programme on RTI Act held at RTC, Chennai on 20.05.2019**
- 2. 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**

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

https://cdsco.gov.in/opencms/export/system/modules/CDSCO.WEB/resources/pdf/RTI/guidance_documents1.pdf

- **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

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

F.No.G.26027/07/2017-DC
DIRECTORATE GENERAL OF HEALTH SERVICES
(D.C. SECTION)

F.D.A. Bhawan, I.T.O., Kotla Road,
New Delhi.
Dated:- 11 January, 2019

To

Dy. Drugs Controller(I),
CDSCO(South Zone)2nd Floor,
Shastri Bhawan Annexe, 26, Haddows Road,
Chennai-600006.

Subject:- Revised Estimates 2018-19 & Budget Estimates 2019-20 in respect of Major Head 2210-06104-Drugs Control (Minor Head) 02-CDSCO-0201- General Component - Reg.

Sir/Madam,

I am directed to inform you that the Revised Estimates 2018-19 and Budget Estimates 2019-20 in respect of your office under each sub. head is as given below:-


(RS. IN THOUSAND)

SL. NO.	ITEM	B.E. 2018-19	R.E. 2018-19	B.E. 2019-20
1.	SALARIES	3,50,00	3,80,00	4,00,00
2.	WAGES	--	--	--
3.	M.T.	5,50	5,50	5,50
4.	T.E.	23,00	30,00	25,00
5.	O.E.	88,00	88,00	60,00
6.	R.R.T.	--	--	--
7.	PUB.	--	--	--
8.	S&M	--	--	--
9.	M/W	--	--	--
10.	P/S	30,00	20,00	24,00
11.	O.C.	--	--	--
	TOTAL	4,96,50	5,23,50	5,14,50

Yours faithfully,

Tripat Kaur

(Tripat Kaur Gujral)
Section Officer

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

iii) Proposed expenditures

O/o. DEPUTY DRUGS CONTROLLER (INDIA), CDSCO, SOUTH ZONE, CHENNAI

APPENDIX - IV

Revised Estimates 2019-20
Budget Estimates 2020-21
Demand No. 042

(Rs. in thousands)

Revenue/ Capital	6 level Accounting Classification as in the Demands For Grants	Budget Estimates 2019-20	Exp. up to 26 th December 2019	Revised Estimates 2019-20	Budget Estimates 2020-21	Remarks (explanations for major variations and other information)
1	2	3	4	5	6	7
	221006104020101 Salaries	4,00,00	3,31,41	-4,05,00	-4,50,00	Anticipated expenditure from 01/20 to 03/20 = 68,59 (*)
Total (Gross)	221006104020106 Medical Treatment	5,50	4,07	5,50	6,00	Anticipated expenditure from 01/20 to 03/20 = 1,43
Recoveries (if any)	221006104020111 Domestic Travel Expenses	25,00	14,71	20,00	25,00	Anticipated expenditure from 01/20 to 03/20 = 5,79 (**)
Net	221006104020113 Office Expenses	60,00	27,61	60,00	60,00	Anticipated expenditure from 01/20 to 03/20 = 32,39 (***)
	221006104020128 Professional Services	6,00	5,01	6,00	5,00	Anticipated expenditure from 01/20 to 03/20 = 99

(*) Salary - Expected salary per month (Rs. 34, 00,000 x 2months) Increment on 1st January 2019 for some officials, CEA & LTC / HT, TC

(**) Domestic Travel Expenses - Anticipated expenditure includes Pending bills for clearance, Average bill per month Rs.2, 00,000 x 3months = Rs. 6, 00,000 and expected Transfer TA bills.

(***) Office Expenses - Since Estimate of Mini Lab, Chennai forwarded to HQ for approval, Chennai Airport, fund retained for payment of rent, if any, for the next 3 Months and additional expenditure for the new building if any.

Shanthy Gunasekaran
SHANTHY GUNASEKARAN
DEPUTY DRUGS CONTROLLER (I)
C.D.S.C.O., SOUTH ZONE
SHASTRI BUILDING, CHENNAI - 600 007

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.	Smt.Shanthy Gunasekaran, Deputy Drugs Controller(I)	World Health Organization (WHO), Geneva	24.10.2018 to 26.10.2018	N.A (Invitation from WHO to nominate one officer from organization)	Met by World Health Organization.(WHO)

(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

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 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 Notifications	https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/
2.	Public Notices	https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/
3.	Bioequivalence and Bioavailability	https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html
4.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/
6.	Global Clinical Trial	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/
7.	Ethics Committee	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/
8.	New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/New-

		Drugs/
9.	Fixed Dose Combinations (FDCs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
10.	Investigational New Drugs (INDs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/
11.	Subsequent New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/
12.	Medical Device and In-Vitro Diagnostics	https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/
13.	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/

- ii. Arrangements for consultation with or representation by
- Members of the public in policy formulation/ policy implementation

Formulation of Policy and Implementation is carried out by Directorate

- Day & time allotted for visitors
- 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/download_file_division.jsp?num_id=NTU2Mg==

Functions of PRO Office:

- To act as single window for disposal of grievance of stakeholders on regulatory issues.
- To provide information to the innovator regarding regulatory norms
- 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)

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

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	https://cdsco.gov.in/opencms/opencms/en/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/Alerts/
4.	Bioequivalence and Bioavailability	https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html
5.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/
6.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/
7.	Global Clinical Trial	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/
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-Drugs/
10.	Fixed Dose Combinations (FDCs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
11.	Investigational New Drugs (INDs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/
12.	Subsequent New	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subseq

	Drugs	uent-New-Drugs/
13.	Medical Device and In-Vitro Diagnostics	https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/
14.	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/

3.4 Form of accessibility of information manual/ handbook

[Section 4(1)(b)]

Information manual/handbook available in

(i) **Electronic format**

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

(ii) **Printed format**

Available

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

[Section 4(1)(b)]

List of materials available

(i) **Free of cost**

Electronic format can be accessed through website.

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

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

4. **E. Governance**

4.1 Language in which Information Manual/Handbook Available

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

English

4.2 When was the information Manual/Handbook last updated?

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

Last date of Annual updation

Updation of Manual is carried out by Directorate

4.3 Information available in electronic form

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

- (i) Details of information available in electronic form
- (ii) Name/ title of the document/record/ other information
- (iii) Location where available

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, South Zone, 2nd Floor, Shastri Bhawan, Annexe, 26, Haddows Road, Chennai – 600 006.

- (ii) Details of information made available

**All Information available in the public domain of website (www.cdscsco.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 Closed holidays)

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

**Central Drug Standard Control Organization, South Zone, 2nd Floor, Shastri Bhawan, Annexe, 26, Haddows Road, Chennai – 600 006.
044-28278186, 28268186
ddcsz@nic.in**

4.5 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_file_division.jsp?num_id=NTU2Mg==

Functions of PRO Office:

1. To act as single window for disposal of grievance of stakeholders on regulatory issues.
2. To provide information to the innovator regarding regulatory norms

3. To guide, assist handhold investors in various phases of business life cycle as per existing focus on “Invest India / Make in India” without compromising quality of regulatory oversight.

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

S.No	Year	RTI applications received	RTI applications disposed
1.	2016 - 17	08	08
2.	2017 - 18	22	22
3.	2018 - 19	30	30

(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	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0MA== Additional FAQs: 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=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.WEB/elements/download_file_division.jsp?num_id=MzI0MA==
4	Import of small quantities of drugs for the purposes of	https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html

	examination testing or analysis	
5	Blood Bank	https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html
6	Cosmetics	https://cdsco.gov.in/opencms/export/sites/CDSKO_WEB/Pdf-documents/cosmetics/FAQcos.pdf
7	BA/BE	https://cdsco.gov.in/opencms/export/sites/CDSKO_WEB/Pdf-documents/BA_BE/revidsefaqbabe.pdf

- (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.	2016 - 17	08	08
2.	2017 - 18	22	22
3.	2018 - 19	30	30

- (ii) Details of appeals received and orders issued

S.No	Year	RTI applications received	RTI applications disposed
1.	2016 - 17	01	01
2.	2017 - 18	02	02
3.	2018 - 19	01	01

4.7 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
- Current CPIOs & FAAs

S.NO	Name of the Officer	Telephone No	Email ID
1.	Smt. Shanthi Gunasekaran, First Appellate Authority and Deputy Drugs Controller (I), CDSCO (SZ), Chennai	044-28268186 & 044-28278186	ddcsz@nic.in
2.	Dr. Kasi Sankar Venugopal, CPIO and Drugs Inspector, CDSCO (SZ), Chennai.	044-28268186 & 044-28278186 Ext. No:216	ddcsz@nic.in

(b) Earlier CPIO & FAAs from 1.1.2015

S.no	Name of the Office	CPIO	Appellate Authority	Year
1.	O/o Deputy Drugs controller(I), Central Drug Standard Control Organization, South Zone, 2nd Floor, Shastri Bhawan, Chennai-600006	Smt.K.Bhuvaneshwari, Drugs Inspector with effect from 3 rd March 2015	Dr.Manivannan, DDC(I),	2015
		Mr. Ankit Sharma ADC(I) with effect from 25 th May 2015		
		Mr. Ravindra Ramchandra Shripad, Drugs Inspector with effect from 14th July 2016	Dr.Manivannan, DDC(I),	2016
		Dr.Kasi Sankar Venugopal, Drugs Inspector with effect from 19 th September 2016		
		Dr.Kasi Sankar Venugopal, Drugs Inspector	Dr.Manivannan, DDC(I),	2017
			Smt. Shanthi Gunasekaran, DDC(I), from October 2017	
		Dr.Kasi Sankar Venugopal, Drugs Inspector	Smt. Shanthi Gunasekaran, DDC(I),	2018
		Dr.Kasi Sankar Venugopal, Drugs Inspector	Smt. Shanthi Gunasekaran, DDC(I),	2019
		Dr.Kasi Sankar Venugopal, Drugs Inspector	Smt. Shanthi Gunasekaran, DDC(I),	2020

(ii) Details of third party audit of voluntary disclosure

- (a) Dates of audit carried out
- (b) Report of the audit carried out

The checklist for the Transparency Audit was duly filled and submitted to CIC on 03/08/2018 and further reply from CIC is awaited.

- (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 Notifications	https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/
2.	Public Notices	https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/
3.	Bioequivalence and Bioavailability	https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html
4.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/
6.	Global Clinical Trial	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/

7.	Ethics Committee	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/
8.	New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/
9.	Fixed Dose Combinations (FDCs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
10.	Investigational New Drugs (INDs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/
11.	Subsequent New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/
12.	Medical Device and In-Vitro Diagnostics	https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/
13.	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/

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

- (i) Whether STQC certification obtained and its validity.
- (ii) Does the website show the certificate on the Website?

Website of CDSCO (www.cdsco.gov.in) is maintained by Directorate.