SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT, 2005
(CDSCO, East 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, EAST ZONE, KOLKATA

Central Drug Standard Control Organization, East Zone, 1st MSO Building, 7th Floor, Nizam Palace, 234/4 AJC Bose Road, Kolkata: 700020

033-22870513,033- 22801391
cdscoez@cdsco.nic.in

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

(ii) Head of the organization

Sh. Arup Kumar Chatterjee,
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/

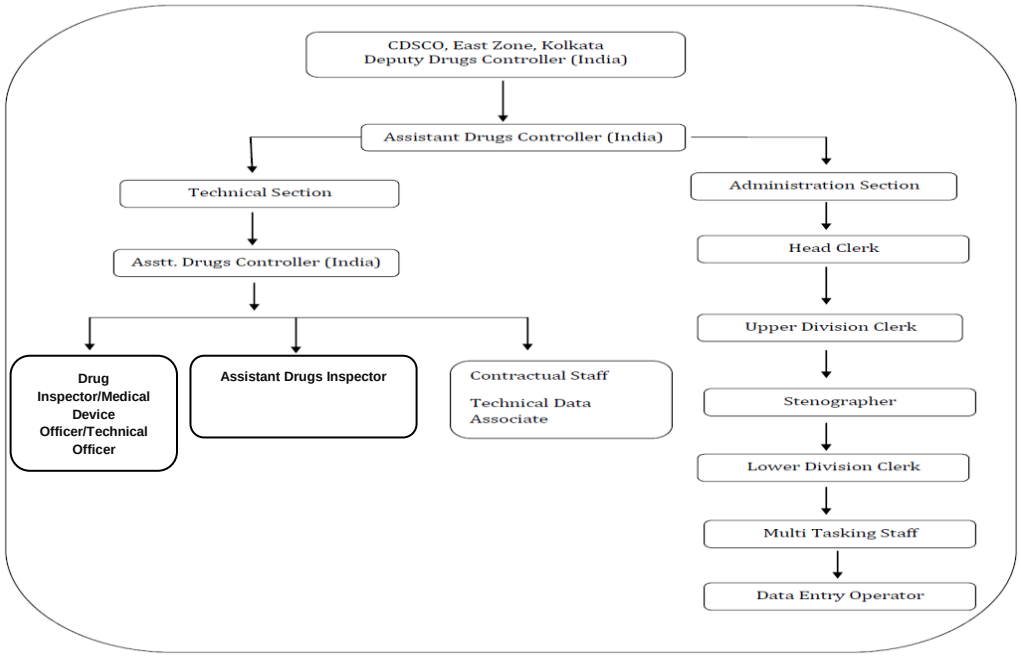
(iv)Function and duties

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 Centre 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 use.**
4. **To participate in the joint inspection for grant/renewal of license for LVP manufacturing units.**
5. **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.**

6. **To carry out Surprise check/Raid jointly/independently on the basis of complaint received under Whistle Blower scheme and also from other sources.**
7. **To carry out joint inspection of Drug Testing Laboratory(s) for the purpose of grant of approval of the site for test / analysis of Drugs & Cosmetics.**
8. **To follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices.**
9. **Drawing of Legal and Survey samples of drugs, cosmetics and medical devices from the manufacturing & sales / distribution premises including the Govt. establishment.**
10. **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).**
11. **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.**
12. **To pursue the court cases pending in different courts under the jurisdiction of this zone.**
13. **Technical survey as and when directed by the Drugs Controller General (India) from time to time.**
14. **To discuss the matter with various State Drugs Controllers in the zone in connection with enforcement of the provisions of D&C Act & Rules there under from time to time.**
15. **To co-ordinate for answering the Parliament Questions and for obtaining the data from various State Licensing Authorities under the zone.**
16. **To act as a Public Authority for responding RTI queries.**
17. **Preparation of Monthly / Quarterly /Annual Reports.**
18. **To participate in the joint inspection with respect to grant of permission in Form CT-11/CT-14/CT-15 as per requirements.**
19. **To participate as observers in international regulatory agencies inspections as and when directed by Directorate.**
20. **To organise workshop, seminar etc. as directed.**
21. **To conduct inspection for grant of license for Class C and Class D notified Medical Devices & Invitro diagonstics.**
22. **To participate in the joint inspection for grant/renewal of license for Bio-Tech & Bio-similar products manufacturing units.**
23. **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.**
24. **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), East Zone, Kolkata was started during the year 1967 headed by Assistant Drugs Controller (India). 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. After the opening of a Sub Zonal office at Guwahati to cater the needs of the North eastern states of India, the current jurisdiction of CDSCO Zonal office at Kolkata includes the states of Bihar, Jharkhand, Odisha, West Bengal, Sikkim and Andaman and Nicobar Islands.

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	1. Responsible for Overall activities of East Zone including technical and non-technical in order to meet good regulatory practices on behalf of CDSCO to achieve patient safety and also to meet quality systems of medicines. 2. Enforcement of various provisions of Drugs and Cosmetics Acts 1940 and Rules 1945 made there under, in accordance with the directive issued by

	Drugs Controller General (India) 3. Coordination with SLAs in case of Inspection of manufacturing premises jointly with State Drug Control Authorities for drugs covered under the CLAA Scheme, i.e., blood, its components and blood products, LVP Notified Medical Devices for the purpose of Grant/renewal of manufacturing licenses. 4. Evaluation of New manufacturing licence application for Central License Approving Authority(CLAA) items i.e. blood, its components and blood products, LVP, Vaccines Notified Medical Devices for grant/renewal of manufacturing licence and application of WHO GMP Certificate (Certificate of Pharmaceutical product) 5. Coordination with SLAs in case Inspection of manufacturing facilities with the State Drug Control Authorities for grant of WHO GMP Certificate (Certificate of Pharmaceutical product). 6. Coordination with SLAs in case of Carrying out Investigation/Surprise check/Raid jointly/independently on the basis of complaint received under Whistle Blower scheme, in the matter of Parliament Question and RTI, matter related to 12th five year plan. 7. Evaluation and Authorization of No objection certificates for grant of permissions for import of dual use items, not for medicinal use, export NOC, Form 11, NOC Form 29 and authorization for Inspection of testing labs, Ethics Committee, ADR Monitoring Centre, Clinical trial sites as observer. 8. Deputation of officers for various inspection/investigation/surprise check/ raids etc. 9. Authorization for Circulation of notifications received from Headquarter, other Zonal/Sub-Zonal offices/ states/UT regarding NSQ drugs. 10. To monitor SUGAM portal, admin activities, training program, QMS, Internal Audit and assistance to DCG(I) office.
Assistant Drugs Controller	1. Assisting the DDC (I) in technical and administrative matter and also to assist DCG(I), New Delhi with respect to Zonal office, East Zone, Kolkata as per the assignment allotted by DDC(I), for approval of Test License, Form 29 NOC, Export NOC and SUGAM portal including Personal License, Dual use NOC pertaining to East Zone, Kolkata. 2. To assist Zonal office in respect of Investigation, Court Cases, Raids and misuse of Oxytocin etc. 3. Assisting and reviewing of documents of Inspection of manufacturing premises jointly with State Drug Control Authorities for drugs covered under the CLAA Scheme, i.e., blood, its components and blood products, LVP Notified Medical Devices for the purpose of Grant/renewal of manufacturing licenses. 4. Assisting in Coordination with the State Drug Control for Inspection of manufacturing facilities for grant of WHO GMP Certificate (Certificate of Pharmaceutical product) 5. Assisting of Investigation/Surprise check/Raid jointly/independently on the basis of complaint received under Whistle Blower scheme. 6. Assisting in Co-ordination with SLAs in the matter of Parliament Question and RTI, matter related to 12th five year plan. **7.** Over viewing the administrative works related to the office viz. expenditure, budget etc. Forwarding the TA/DA bills to the PAO.
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.
Technical Officer	1. To assist Zonal office in respect of Technical Matters pertaining to CDSCO and also to assist ADC(I), DDC(I) of East Zone, Kolkata.

	2. Entries of applications in the respective registers of applications received for grant / revalidation of WHO GMP Certificate / COPP, Written confirmations, Blood Centres, manufacturing licenses for Drugs & Cosmetics, Public Testing Laboratories, BA-BE State Wise (East Zone), Administrative related issues of Zonal office, Kolkata etc. 3. Issuance of approval or query letter based on the evaluation or review of the application done by concerned Drugs Inspector as instructed by Senior Officers of Zonal office (ADC(I)/DDC(I)). 4. Scrutiny of online Dual Use NOC issued for import of drugs intended for non medicinal use prior approval of DDC (I). 5. Scrutiny of Bill of Entries for import of drugs referred by port officers for DDC clarification. 6. Assisting DIs for preparing Petition and Counters for cases of Drugs imported by the various importers. 7. Preparing replies for the technical clarification in respect of import and export of drugs sought by Customs, importers and public. 8. Maintaining technical correspondence related to import and export of drugs and attending various queries by public, importer and exporter. 9. Timely preparation of pending list of Inspection to be carried out, Monthly & Quarterly. 10. Providing of data / details required in respect of framing of replies pertaining to RTI, Parliament Questions etc. 11. To co-ordinate for answering the parliament question and for obtaining data from various State Licensing Authorities under the Zone. 12. Maintaining of approved license records received from CLAA. 13. To prepare correspondence letters, Parliament Letters, Public Grievances (if any), related to Zonal activities and submitting to senior officers.
Assistant Drugs Inspector	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 taking out samples, enforcement activities like raids/ inspections and launching prosecution etc. 3. To assist CDSCO officers in the matter of monitoring documentation. 4. To carry out duties as may be assigned under the Drugs and cosmetics Act and Rules framed there under. 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).
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.

Senior Technical Data Associate	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.
Technical Data Associate	To assist ADI/DI/ADC(I)/ DDC(I) as and when necessary in pre-Screening of various applications related to WHO-GMP (COPPs), Blood Banks, Medical Devices, Large Volume Parenterals, Approved Testing Laboratories, Clinical Trials, ADR Monitoring Centre, Ethics Committee, NOC for Form-29, NOC for Form-11, etc., Follow up sampling correspondences, Preparing monthly pendency report, follow up and compilation of Parliament Questions (all session) and confirmation for reply to head of the Dte.
DataEntry Operator	Inward & Dispatching of all receipts and correspondences including inspection reports of Blood Bank, COPP and Medical devices to DCG(I), applicant and SLAs. Assisting in Admin related works in processing of PFMS and other official bills , records etc.

(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 the Directorate. Powers and duties of other posts are derived and excercised 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 Office orders issued by competent authority 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 Releation 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 : **cdscoez@cdsco.nic.in**

SL.NO.	NAME OF EMPLOYEE	DESIGNATION	LAND LINE NO. 033 2280-1391 WITH EXTENSION NO.
1.	SH. ARUP KUMAR CHATTERJEE,	DDC(I)	233
2.	SH. AKASH RAMA KONDALKAR	ADC(I)	202
3.	SH. DEBASHISH NAYEK	DI	204
4.	SH. PRAKASH KUMAR PARIDA	DI	204
5.	SH. KRISHANU BURMAN	DI	201
6.	SH. ASHUTOSH KUMAR	DI	206
7.	SH. NAGENDRA KUMAR	DI	234
8.	SMT. MONALISA BARMAN	TO	234
9.	SH. BUBUN NATH	TO	234
10.	SHRI NITISH KUMAR	ADI	234
11.	SH. RAMESH CH. BISWAS	STENO GR-II	203
12.	SH. LALIT KUMAR SAH	MTS	234
13.	SH. KAML KUMAR BHATTACHARYYA	Sr. TDA	234
14.	SH. BIJOY KUMAR BANDHOPADHYAY	Sr. TDA	234
15.	SMT. MOUSUMI MONDAL	TDA	208
16.	SH. AKASH LAL BHATTACHARJEE	TDA	208
17.	SMT. MANIKA MONDAL	DEO	210
18.	SH. SOUMIT MUKHERJEE	DEO	203

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

SL.NO.	DESIGNATION	PAY BAND	PAY LEVEL
1.	DDC(I)	15600-39100	12
2.	ADC(I)	15600-39100	11
3.			
4.	DI/TO	9300-34800	8
5.	ADI	9300-34800	6
6.	STENO GR-II	9300-34800	6
7.	STENO GR-III	5200-20200	4
8.	MTS	5200-20200	3

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
1.	Sh. Arup Kumar Chatterjee, First Appellate Authority and Deputy Drugs Controller (I), CDSCO (EZ), Kolkata	033 2280-1391 Ext: 233
2.	Sh. Bubun Nath, CPIO, Technical Officer, CDSCO (EZ), Kolkata	033 2280-1391 Ext. No:234

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 has been attended by concerned persons dealing with RTI 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

One training conducted by NIHFW, New Delhi on 04.02.2020 was attended by this office.

(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

SPEED POST

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

F.D.A. Bhawan, I.T.O., Kotla Road,
New Delhi.
Dated:- 23rd January, 2023

To

Deputy Drugs Controller(I)
CDSCO(East Zone), CGO Building,
Nizam Place, 2nd Floor, 234/4, A.J.C. Bose Road, Kolkata-700020

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

Sir/Madam,

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

(amount in thousands)

SL. NO.	ITEM	R.E. 2022-23	B.E. 2023-2024
1.	Salaries (01)	2,20,00	1,35,00
2.	Wages(02)	7,00	10,00
3.	Medical Treatment (06)	2,00	6,00
4.	Allowances (07)	--	95,00
5.	Leave Travel Concession (08)	--	10,00
6.	Training Expenses (09)	--	--
7.	Pensionary Charges (04)	--	--
8.	Domestic Travel Expenses (11)	35,00	35,00
9.	Office Expenses (13)	37,00	30,00
10.	RRT for L&B (14)	30,00	18,00
11.	Printing & Publication (16)	--	--
12.	Rent for Others (18)	--	--
13.	Digital Equipment (19)	--	--
14.	Material & Supplies (21)	--	--
15.	Advertising & Publicity (26)	--	--
16.	Minor Civil Work (27)	--	--
17.	Professional Services (28)	4,00	6,00
18.	Repair & Maintenance (29)	--	--
19.	Other Revenue Expenses (49)	--	--
20.	Other Expenses (020150)	--	--
21.	Swachhta Action Plan(029650)	--	--
	TOTAL	3,35,00	3,45,00

Yours faithfully,

(Amit Kumar)
Dy. Director Administration

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

iii) Proposed expenditures

GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
(Directorate General of Health Services)
OFFICE OF THE DY. DRUGS CONTROLLER (INDIA)
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(EAST ZONE)

Expenditure Statement upto July, 2023 **(RS. IN THOUSAND)**

Sl No	Minor Head / Sub Head	BE 2023-2024	Expenditure for the Month of July, 2023	Progressive Expenditure upto July, 2023
1	Salaries (01)	13500	1135	5844
2	Wages (02)	1000	57	227
3	Medical Treatment (06)	600	0	22
4	Allowances (07)	9500	818	4461
5	Leave Travel Concession (08)	1000	0	51
6	Domestic Travel Expenses (11)	3500	339	1545
7	Office Expenses (13)	3000	343	1057
8	Professional Services (28)	600	144	284
9	R R T for L & B (14)	1800	0	429
	Total	**34500**	**2836**	**13920**

डॉ. कमल कृष्ण हालदार / Dr. Kamal Krishna Halder
डी. डी. सी. / D.D.O.
के. औ. म. नि. सं., पूर्वी क्षेत्र, कोलकाता
CDSCO, East Zone, Kolkata

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

Nil

(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

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/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 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

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 Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-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 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

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, East Zone, 1st MSO Building, 7th Floor, Nizam Palace, 234/4 AJC Bose Road, Kolkata: 700020.

(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.

(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, East Zone, 1st MSO Building, 7th Floor (Eastern Side), Nizam Palace, 234/4 AJC Bose Road, Kolkata: 700020
033-22870513, 2280-1391 Fax: (033)-22813806
cdscoez@cdsco.nic.in

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

(i) Grievance redressal mechanism

Public Relation office 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.
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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.	2017	25	25
2.	2018	22	22
3.	2019	48	48
4.	2020	15	15
5.	2021	15	15
6.	2022	09	09
7.	2023	15	15
8.	2024 (till 10.05.2024)	02	02

(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 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

4.6 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	24	24
2.	2017 - 18	19	19
3.	2018 - 19	22	22
4.	2019 - 20	19	19
5.	2020 - 21	17	17
6.	2021 - 22	07	07
7.	2022 - 23	09	09
8.	2023 - 24	12	12

(ii) Details of appeals received and orders issued

S.No	Year	RTI applications received	RTI applications disposed
1.	2016 - 17	00	00
2.	2017 - 18	02	02
3.	2018 - 19	01	01
4.	2019 - 20	01	01
5.	2020 - 21	01	01
6.	2022 - 23	02	02
7.	2023 - 24	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
(a) Current CPIOs & FAAs

S.NO	Name of the Officer	Telephone No	Email ID
1.	Sh. Arup Kumar Chatterjee, First Appellate Authority and Deputy Drugs Controller (I), CDSCO (EZ), Kolkata	033-2287-0513 033-22801391 (201)	cdscoez@cdsco.nic.in
2.	Sh. Bubun Nath, CPIO and Technical Officer, CDSCO (EZ), Kolkata .	033-2287-0513 033-22801391	cdscoez@cdsco.nic.in

(b) Earlier CPIO & FAAs from 1.1.2015

FAA: Sh. Satyapal Shani (January, 2015 to November, 2017)
Sh. Soumen Mukhopadhyay (November, 2017 to March, 2018)
Dr. A. Ramkishan (March, 2018 to May, 2022)
Dr. Kamal Krishna Halder (May, 2022 to June, 2023)

CPIO: 1.Dr. Kamal Krishna Halder, 2.Sh. G. Narendra Kumar
3.Sh. Vinod Kumar, 4. Sh . Arup Kr Chatterjee
5. Dr. Kamal Krishna Halder 6. Dr. Sumonta Kumar Ghosh

(ii) Details of third party audit of voluntary disclosure

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

Not Applicable

(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.