## **1.** Organisation and Function

# **1.1** Particulars of its Organization, 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

Dr. C. Saravanan, M.Pharm. PhD., Drugs Inspector

#### (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

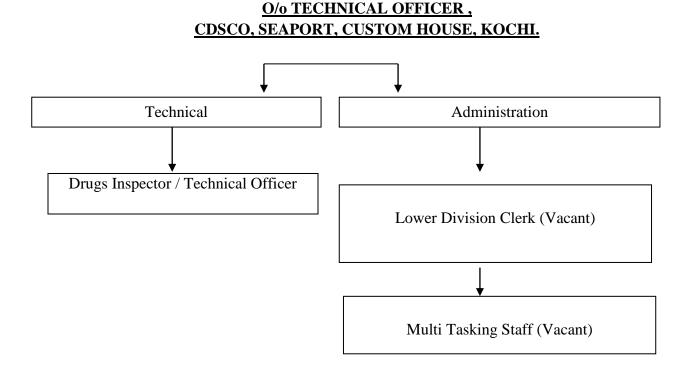
(1) Enforcement of the provisions of Chapter III of the Drugs & Cosmetic Act, 1940

(2) Functioning as a PGA (Participating Govt. Agency) and assisting the Customs by issuing online NOC in the customs single window portal.

(3) As a part of PRO activity, assist the members of the trade with the information required.

(4) To examine unclaimed/seized cargo when referred by customs

#### (v) Organization Chart:



# (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. The main function of CDSCO, Seaport Kochi Office is dealing with bill of entries to ensure that the imported drugs comply with provisions of Chapter III of the D&C 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.

Cochin and Thiruvananthapuram Airport are recently included under Rule 43A of Drugs Rules 1945 through Drugs (Third Amendment) Rules, 2024, Gazette notification of MINISTRY OF HEALTH AND FAMILY WELFARE, Department of Health and Family Welfare, Govt. of India, G.S.R. 293(E) dated 28th May, 2024.

Office of the Technical Officer, Custom House, Kochi – 682009 is functioning as a Participating Government Agency (PGA) to deal with the Goods covered under the Drugs & Cosmetics Act, 1940 and Rules made thereunder and exercising Single window NOC on the

Indian Customs EDI system for the import bills filed at Cochin Sea Port , Cochin Airport & Thiruvananthapuram Airport.

The other public dealing functional are mostly shared by this office and co-coordinate with Customs Authority to ensure that the imported drugs provisions of Chapter III of the D&C Act and Rules there under.

#### 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> <li>Drugs Inspector appointed as per the Sec 21 of D &amp; C Act, 1940</li> <li>Enforcement of the provisions of Chapter III of the Drugs &amp; Cosmetic Act, 1940</li> <li>Executing the power mentioned in Sec 22 by following the procedure as per Sec 23 of the Act</li> <li>as a PGA (Participating Govt. Agency) and assisting the Customs by issuing online NOC in the customs single window portal.</li> </ul>		
Lower Division Clerk	<ul> <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>		
Multi Tasking Staff	<ul> <li>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.</li> <li>In addition to the auxiliary support, have to do basic clerical work also whenever there is a need.</li> </ul>		

# (iii) Rules/ orders under which powers and duty are derived and Exercised Work allocation

Section 11, 21, 22 & 23 of Drugs and Cosmetics Act, 1940 read with Rule 51 & 52 of Drugs Rules 1945

#### 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

Timeline for the online NOC in the Customs EDI systems for the Import of Goods at the

**TOD, Cochin Sea Port,** as per the File No. Import/Misc./39/2018-DC(Pt-12) dated 10<sup>th</sup> September, 2021

Activity	Timeline
only based on documents checks	2-3 hours
Based on document checks and physical	24 – 48 hrs
examination without involving lab testing	
Based on document check, physical	48 – 72 hrs
examination, drawing of sample for testing,	
provided with Letter of Guarantee for testing	
from the Importer	

#### 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

As per 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.

# 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

- a. Guidance document for port office activities
- b. Drugs Rules, 1945
- c. Medical Device Rules, 2017
- **d.** New Drugs and Clinical Trials, 2019
- e. Cosmetics Rules 2020

#### (iii) Acts/ Rules manuals etc.

As per 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.

(iv) Transfer policy and transfer orders

Available with CDSCO, HQ, New Delhi.

#### 1.6 Categories of documents held by the authority under its control

- (i) Categories of documents
- (ii) Custodian of documents/categories

**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?

**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	Dr. C. Saravanan,	Drugs	0484-	todcochin@nic.in
	M.Pharm. PhD.,	Inspector	2666042	
2	Vacant	Lower		
		Division		
		Clerk		
3	Vacant	MTS		

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

S.No.	Name	Designation	Pay Band & Pay Level
1	Dr. C. Saravanan	Drugs	Pay Band: 9300-34800 & Pay level: 8
		Inspector	

(ii) System of compensation as provided in its regulations

1.10 Name, designation and other particulars of public information officers

- (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	Telephone	Email ID
1	Dr. C.	CPIO	0484-	todcochin@nic.in
	Saravanan,		2666042	
	M.Pharm.			
	PhD., Drugs			
	Inspector			
	_			

#### 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
- (ii) Efforts to encourage public authority to participate in these programmes (iii)Training of CPIO/APIO
- (iv)Update & publish guidelines on RTI by the Public Authorities concerned
- **1.13** Transfer policy and transfer orders

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

# 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.26027/04/2020-DC DIRECTORATE GENERAL OF HEALTH SERVICES CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (D.C. SECTION)

F.D.A. Bhawan, I.T.O., Kotla Road, Dated: S February, 2024

To

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

# Subject:- Revised 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 2023-24 in respect of your office under each sub, head is as given below:-

(amount in thousands)

SL.	ITEM	B.E. 2023-24	R.E. 2023-24
NO.	Galacias (01)	10,00	10,00
1.	Salaries (01)		
2.	Wages(02)		
3.	Rewards(05)	1,00	25
4.	Medical Treatment (06)	6.00	
5.	Allowances (07)	0,00	
6.	Leave Travel Concession (08)		
7.	Training Expenses (09)		
8.	Pensionary Charges (04)	2.00	
9,	Domestic Travel Expenses (11)	2,00	
10.		4,00	
11.	RRT for L&B (14)		
12.			
13.	14 (3)		
14.	Digital Equipment (19)		
15.	Material & Supplies (21)		
16.	Advertising & Publicity (26)		
17.			
18.	Professional Services (28)		
19.	Repair & Maintenance (29)		
20			10.1
	TOTAL	23,00	10,2

Yours faithfully,

Shakbi Si-gh

(Shakti Singh) Drawing & Disbursing Officer

Copy to:-

Pay & Accounts Officer. Ministry of Health & FW, Chennai

#### 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.

#### Not applicable

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)

#### Not applicable

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

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 authorisationsd) Date of award of concessions /permits of authorizations

#### Not applicable

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.

#### Not applicable.

## 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]

Arrangement for consultations with or representation by the members of the public

Relevant Acts, Rules, Forms and other documents which are normally accessed by citizens
 <u>https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/</u>

https://edseo.gov.in/openems/openems/en/rotifications/Odzette_rotifications/
https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/
https://cdsco.gov.in/opencms/opencms/en/Notifications/Alerts/
https://cdsco.gov.in/opencms/opencms/en/bioequi bioavail/index.html
https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/
https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/
https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/
https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/
https://cdsco.gov.in/opencms/opencms/en/dcc-dtab-committee
https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/
https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/
https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/

- (ii) Arrangements for consultation with or representation by
  - a) Members of the public in policy formulation/ policy implementation
  - b) Day & time allotted for visitors
  - c) Contact details of Information & Facilitation Counter (IFC) to provide publications frequently sought by RTI applicants

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

#### Not applicable

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

https://cdsco.gov.in/opencms/opencms/en/Notifications/Alerts/

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)

3.4 Form of accessibility of information manual/ handbook

[Section 4(1)(b)]

Information manual/handbook available in

- (i) Electronic format
- (ii) Printed format

3.5 Whether information manual/ handbook available free of cost or not [Section 4(1)(b)]

- List of materials available
- (i) Free of cost
- (ii) At a reasonable cost of the medium

## 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 **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

**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

**4.4** Particulars of facilities available to citizen for obtaining information [Section 4(1)(b)(xv)]

- (i) Name & location of the faculty
- (ii) Details of information made available
- (iii) Working hours of the facility
- (iv) Contact person & contact details (Phone, fax email)

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

S.no	Year	RTI applications received	RTI applications disposed
1.	2023-2024	2	2
2.			
3.			

- (iii) List of completed schemes/ projects/ Programmes-NA
- (iv) List of schemes/ projects/ programme underway-NA
- (v) Details of all contracts entered into including name of the contractor, amount of contract and period of completion of contract-NA
- (vi) Annual Report
- (vii) Frequently Asked Question (FAQs)
- (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

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

(ii) Details of appeals received and orders issued

4.7 Replies to questions asked in the parliament [Section 4(1)(d)(2)]

Details of questions asked and replies given

## 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	First Appellate	Year
			Authority	
1.		Dr. C. Saravanan,	Dr.K.M.Srinivasan,	June 2023 to
		Drugs Inspector	DDC(I), CDSCo,	till date
	O/o The Technical		South Zone.	
2.	Officer, Central Drug	Dr. C. Saravanan,	Dr. B. Kumar,	2022 to June
	Standard Control	Drugs Inspector	DDC(I)	2023
3.	Organization, Seaport,	Mrs.Sudha	Smt.Shanthy	2019 to
	Room No. 15, Custom	Sukumaran	Gunasekaran, DDC(I)	2021
	House, Kochi – 682009.	Nair, Drugs Inspector	Dr. S. Manivannan,	2021-2022
			DDC(I)	
4.		Mrs.Sudha	Dr.P.MANAVALAN,	2018
		Sukumaran Nair,	ADC(I)	
		Drugs Inspector		
5.		Shri. J. Ragupathy,	Smt. V.M. Bharathy,	2017
		Technical officer	ADC(I)	

- (ii) Details of third party audit of voluntary disclosure
  - (a) Dates of audit carried out
  - (b) Report of the audit carried out
- (iii) Appointment of Nodal Officers not below the rank of Joint Secretary/ Additional HoD
  - (a) Date of appointment
  - (b) Name & Designation of the officers
- (iv) Consultancy committee of key stake holders for advice on suo-motu disclosure

- (a) Dates from which constituted
- (b) Name & Designation of the officers
- (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

#### 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
- 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?