F.No. D.21013/39/2017-DC
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
(Central Drugs Standard Control Organization)

FDA Bhawan, Kotla Road,
New Delhi-110002,
dated the 13th April, 2017

Office Order

Revised channel of submission and level of disposal of cases in respect of various Divisions of CDSCO (HQ) is enclosed for compliance by all concerned with immediate effect.

2. Further, as per Rule 24 of Drugs & Cosmetics Rules, 1940, the Licencing Authority may delegate the powers to sign Licence & Registration Certificate to any other person with the approval of the Central Government.

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To

1) All officers /Divisions in CDSCO (HQ)
2) DDCs of all Zones/Sub-Zones
3) Directors, CDSCO Labs
4) PPS to AS (F&D)/ PPS to JS (R)/ O/o DCGI
5) Director (Admin), CDSCO (HQ)
6) Guard file.

REVISED CHANNEL OF SUBMISSION AND LEVEL OF DISPOSAL OF CASES

Common subject matter

Sr. No.	Name of Work /Item	Level through which is crosses	Final Decision making authority***
1	**Clinical Trial Permission**		
	A) Vaccine/Stem cells and cell based products/-r-DNA products	ADI-DI-ADC-DDC-JDC-Advisory Committee (SEC/IND-CBBTDEC/TC-Apex)-ADI-DI-ADC-DDC-JDC	DCG (I)
	B) Veterinary Vaccine	ADI-DI-ADC-DDC-Advisory Committee-Ministry of Agriculture-ADI-DI-ADC-DDC-JDC	DCG (I)
2	**Market Authorization Permission (Indigenous in 46,46A and imported products in Form 45,45A,)**		
	A. Vaccine and r-DNA Products	ADI-DI-ADC-DDC** -JDC-Advisory Committee (SEC)-ADI-DI-ADC-DDC-JDC **In case of vaccines parallel review at CDL & in case of r-DNA products parallel review by RCGM	DCG (I)
	B. Stem cell and cell based products	ADI-DI-ADC-DDC-JDC-Advisory Committee (CBBTDEC-Apex)-ADI-DI-ADC-DDC-JDC	DCG (I)
	C. Veterinary Vaccines	ADI-DI-ADC-DDC-Advisory Committee-Ministry of Agriculture-ADI-DI-ADC-DDC-JDC	DCG (I)
3	**Post approval changes**		
	D. Vaccine and r-DNA Products	ADI-DI-ADC-DDC-CDL, Kasauli/NIB, Noida ADI-DI-ADC-DDC	JDC (I)
	A. Other biological products	ADI-DI-ADC-DDC	JDC (I)
4	**Registration Certificate for imported biological products (Form 41)**	ADI-DI-ADC-DDC-JDC	DCG (I)
5	**Import License for imported biological products (in form 10)**	ADI-DI-ADC-DDC	JDC (I)
6	**License for manufacture biological products under CLAA scheme (Form 28D)**	ADI-DI-ADC-DDC-JDC	DCG (I)
7	**Test license in form 11**	ADI-DI-ADC-DDC	JDC (I)
8	**NOC for form 29**	ADI-DI-ADC-DDC	JDC (I)

9	**Export NOC for unapproved and banned biological products**	ADI-DI-ADC-DDC	JDC (I)
10	**Query/clarification raised on review for all type of applications**	ADI-DI-ADC On receipt of response same channel mentioned in sr.1 to 9 being followed	DDC(I)/JDC(I)/DCG(I)
11	**Parliament Questions**	ADI/DI/DDC/JDCI-DCG(I) secretariat	DCG (I)
12	**Court cases**	ADI/DI/DDC/JDCI-Legal Consultant	DCG(I) Secretariat
13	**Other Miscellaneous Ministry queries/status notes, other ministerial letters**	ADI-DI-ADC-DDC-JDC	DCG (I)
14	**RTI matters**	ADI-DI-ADC-DDC-JDC	CPIO
15	**Public Grievances**	ADI-DI-ADC-DDC	JDC (I)
16	**Policy Matters on administration and regulation**	ADI-DI-ADC-DDC-JDC	DCG (I)

Revised Level of disposal

***Query letter may be issued by concern Drug Inspector

Post approval changes, protocol amendments, forwarding for expert opinion letter may be issued by ADC(I).

Approval of CT/MA/RC/Import license may be issued by DDC (I)

Abbreviations:

ADI:- Asst. Drugs Inspector

DI:- Drugs Inspector

ADC(I):- Assistant Drugs Controller (India)

DDC(I):- Deputy Drugs Controller (India)

JDC(I):- Joint Drugs Controller (India)

DCGI:- Drugs Controller General of India

CDL:- Central Drugs Laboratory, Kasauli

NIB:- National Institute of Biologicals, Noida

SEC:- Subject Expert Committee

IND:- Investigational New Drug Committee

CBBTDEC:- Cell Biology Based Therapeutic Drug Evaluation Committee

TC:- Technical Committee

RCGM:- Review committee on genetic manipulation.

Revised Channel of Submission and Level of Disposal of Cases / common subject matters

S. No.	Name of work /item	Level through which it crosses	Final decision making authority
1.	**Matters / Issues related to DCC/DTAB :** Convening meetings of DCC and DTAB, preparation of agendas for the respective meetings, correspondence with the members, follow up of the recommendations of the committees, processing of proposals relating to amendments of D&C Rules, processing of amendments, compilation of comments received and finalisation of draft rules published by Mo H & FW, providing necessary technical inputs for the annual reports, etc.	TDA /ADI-DI-STC (LK) - DDC – JDC	DCG(I)
2.	**Matters /Issues related to Risk Based Inspections**: Planning meetings related to Risk Based Inspections (RBI), correspondence to all State /UT Licensing authorities for confirmation of manufacturing sites ready for RBI teams planned for inspections, updating information based on reports received for review based on requirements of Sch. M and Sch. L1 of D&C Rules, evolving the strategy and forwarding directions to the concerned SLAs for effective implementation of the provision of Act and Rules in the country, Follow up of action taken by SLAs on Risk Based Inspections, Review of Inspection data and monitoring inspections phase wise.	TDA / ADI – DI – DDC - JDC	DCG(I)

ENFORCEMENT DIVISION

Revised Channel of Submission and Level of Disposal of Cases

S. No	Name of the work/item	Level through which it crosses	Final decision making authority
1	**Issues/Complaints regarding sub-standard/ Spurious drugs:** Complaints received by Post/e-mail regarding manufacturing/sale licenses, throughout India, Sub-Standards/Spurious drugs and other miscellaneous correspondence with State Regulatory Authorities, Zonal/Sub Zonal Offices of CDSCO and other Ministry Govt. references.	TDA/ADI-DI-DDC	DCG(I)
2	**Matters related to NSQ drugs and prosecutions**: - 1. Recommendations for NSQ Drug Screening by CDSCO Zonal/Sub Zonal offices. 2. Meetings of the NSQ Drug Screening Committee. 3. Communication of decision/approval of the Competent Authority to CDSCO Zonal/Sub Zonal offices. 4. Various representations w.r.t. screening committed decisions.	ADI-DI-DDC-JDC(VGS)	DCG(I)
3	**Compilation of Countrywide data:** Compilation of different data w.r.t. Spurious/NSQ/Expired drugs, functioning of regulatory authorities from States/UTs, Laboratories, Port Offices for answering Parliament Questions, Delivery Monitoring Unit and for information to Ministry etc.	TDA/ADI-DI-DDC	DCG(I)
4	**Joint Surprise Check:** Monthly joint surprise check are regularly carried out in different states by drawing samples of different therapeutic categories of drugs by CDSCO Drugs Inspectors to check the quality of drug samples from Government Hospitals, Retail & wholesale Dealers	TDA/ADI-DI-DDC	DCG(I)
5	**Drug Alert:** List of Drugs, Medical Devices and Cosmetics declared as not of standard quality/spurious/adulterated/misbranded by CDSCO Drugs Testing Laboratories are being regularly uploaded month-wise in the web site of CDSCO and letters are communicated to the concerned Licensing Authorities of States/U.Ts along with the test reports of NSQs for necessary action in the matter.	TDA/ADI-DI-DDC	DCG(I)
6	**Processing of Parliament Questions** related to spurious/NSQ/adulterated/Misbranded drugs and AYUSH Ministry related issues.	TDA-DI-DDC(SD)-DDC(AKP)-JDC(VGS)	DCG(I)

7	**Processing of RTI applications:** Prompt processing of RTI applications related to this Division is carried out.	TDA/ADI-DI-DDC	CPIO
8	**PMO references**: - Various complaints and received at PMO and forwarded through Ministry of Family Health and Welfare are examined and suitable reply sent.	TDA/ADI-DI-DDC	DCG(I)
9	Processing of Public Grievances	TDA/ADI-DI-DDC	DCG(I)
10	Correspondences/Follow up related to the Survey of Extent of Problems of Spurious and Not of Standard Quality (NSQ) drugs in the Country being conducted under the guidance of supervision of Director I/c NIB, Noida.	TDA/ADI-DI-DDC	DCG(I)
11	Preparation of DMU Reports monthly/quarterly.	TDA/ADI-DI-DDC	Director (Admin)
12	**Notification of Central Labs/Govt. Analyst** 1. Correspondence with Central Labs for Government Analyst notification. 2. Correspondence with SLAs regarding notification of Central Laboratory Analysts as Govt. Analysts of respective states.	TDA/ADI-DI-DDC	DCG(I)
13	**AYUSH Matters**: - 1. Supervision of communication / correspondences of AYUSH related matters with AYUSH Ministry and other applicants. 2. Inspections of Ayurvedic medicine manufacturers for grant of Certificate of Pharmaceutical Products (COPP) along with personnel of AYUSH Ministry and State AYUSH Authority and work related to issuance of COPPs. 3. The list of COPP holders is regularly uploaded in the CDSCO website. 4. Attended various meeting at the Ministry of AYUSH.	ADI-DI-DDC	DCG(I)

Cosmetics Division

Revised Channel of Submission And Level of Disposal of Cases

Sr. No.	Name of the Work/item	Level through which is crosses	Final Decision making authority
1.	Cosmetics Import Registration Applications	TDA/ADI-DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
2.	Applications for NOC /Clarification relating to cosmetic import	TDA/ADI-DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
3.	RTI queries	ADI-DI-ADC(I)-DDC(I)-CPIO	CPIO
4.	BIS letters / other Government correspondences	ADI-DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
5.	Parliament Questions	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
6.	VIP reference letters/ Ministry letters	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
7.	Representations/Grievances of stakeholders /public/NGOs/Consumer forums etc.	ADI-DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)

~~ANNEXURE-A~~

REVISED CHANNEL OF SUBMISSION AND LEVEL OF DISPOSAL OF CASES

S. No.	Name of work/item	Level through which crosses	Final decision making authority
1.	**Medical Device Division**		
	(i) CLA Approval	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
	(ii) Grant of CT approval	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
	(iii) Grant of New Drug Approval	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
	(iv) Grant of Registration Certificate	ADI/DI-ADC(I)-DDC(I)-JDC(I)	JDC(I)
	(v) Renewal of RC	ADI/DI-ADC(I)-DDC(I)	DDC(I)
	(vi) Grant of Import license/TL	ADI/DI-ADC(I)-DDC(I)-JDC(I)	DDC(I)
	(vii) Query Raised	ADI/DI-ADC(I)-DDC(I)	ADC(I)
	(viii) Parliament matters, VIP References, Ministry References	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
2.	**FDC Division**		
	(i) Grant of CT NOC	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
	(ii) Grant of New Drug Permission	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)
	(iii) Grant of BA/BE NOC	ADI/DI-ADC(I)-DDC(I)-JDC(I)	JDC(I)
	(iv) Grant of TL/CDTL NOC	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DDC(I)
	(v) Query Raised	ADI/DI-ADC(I)-DDC(I)	ADC(I)
	(vi) Parliament matters, VIP References, Ministry References	ADI/DI-ADC(I)-DDC(I)-JDC(I)-DCG(I)	DCG(I)

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