डॉ. राजीव सिंह रघुवंशी
औषधि महानियंत्रक (भारत)
केंद्रीय औषधि मानक नियत्रंण संगठन
स्वास्थ्य एवम परिवार कल्याण मंत्रालय
भारत सरकार
एफ.डी.ए. भवन, कोटला रोड
नई दिल्ली–110002

सत्यमेव जयते

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Cental Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road
New Delhi - 110002 (India)

F. No. X-19013/03/2023-DC **Dated:** 17/10/2023

To

All State/ UT Drug Controllers/ DDC (I) of Zonal & Sub-zonal offices/ Directors of Labs of CDSCO

Sub: Minutes of the 62nd Meeting of the Drugs Consultative Committee (DCC) held on 26.09.2023 through Hybrid mode - reg.

Sir/Madam,

62nd meeting of the Drugs Consultative Committee was held on 26.09.2023 through Hybrid mode.

The minutes of the 62nd meeting of the Drugs Consultative Committee is annexed herewith for your kind information and taking further necessary action, wherever required as per recommendations decided therein.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Encl. Copy of the minutes

Copy for information to:-

1. PPS to Secretary, MoHFW, Nirman Bhawan, New Delhi
2. PPS to JS(R), MoHFW, Nirman Bhawan, New Delhi

MINUTES OF 62nd MEETING (HYBRID MODE) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD THROUGH WEB CONFERENCE ON 26th SEPTEMBER, 2023 AT CDSCO (HQ)

Inaugural Deliberations

Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed all State Drugs Controllers and thanked them for attending the meeting through web conference on such a short notice.

DCG(I) mentioned that there are certain important agendas which include the safe pharmaceutical inactive bulk imported /manufactured are used in drug formulations, Uniformity in sampling procedure, robust uniform system in the country for quick actions on NSQ/spurious results including uploading on website etc., which need to be addressed to ensure uniform implementation of the provisions of the Act and Rules. Therefore, this 62nd DCC meeting has been convened to deliberate on these important issues. Further the DCG(I) requested all the SLA's to strengthen/upgrade their State Drug Testing Laboratories with the funds released by the Central Government as the Central Drugs Laboratories are overburden with the samples sent by the CDSCO Drugs Inspectors

Accordingly, DCC deliberated the agenda items one by one. The details of the deliberation and recommendations are as under:

AGENDA NO.1

CONSIDERATION FOR APPROVAL OF REPORT OF 61st MEETING OF DCC HELD ON 01.06.2023 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

Committee was apprised regarding the action taken report (ATR) on the agenda items of 61st DCC meeting held on 01.06.2023.

The DCG(I) emphasized on the Agenda No. 3 of the ATR regarding the proposal to bring uniformity in enforcement through Risk Based Inspection of drug manufacturing sites as per the guidance document shared by CDSCO and all the States/UTs LAs were requested to share comments within two weeks on the guidance document so that same may be finalized.

With respect to Agenda No. 4 of the ATR, the DCC was apprised that SOP for sampling has been circulated to SLAs & CDSCO offices through e-mail dated 01.09.2023 and all the States have been requested to provide inputs on the uniform procedure for sampling throughout the country. It was also considered that Drugs Inspector should collect the purchase invoices of the drug samples during sampling.

As regards to Agenda No. 8 of ATR, it was deliberated that mentioning of all the excipients on the product label is a practical challenge and there is no mandatory requirement. DCC deliberated and suggested for capturing this information through the QR code or by capturing these information in the package insert. DCC recommended that GSR No. 823 (E) dated 17.11.2022 may be amended for capturing the requisite information in the QR code at least for Top 300 brands initially.

In respect of Agenda No. 10 of ATR, regarding Eye drops in opaque vials, it was opined that the matter requires stake holder's consultation. In respect of Agenda No. 18 of ATR point 3, for overcharging of blood, it was opined that blood is not for sale, it is only for supply and only processing cost may be charged by the blood centre. Further, it was opined to issue and advisory to all blood centres regarding NBTC revised guideline for recovery of processing charges for blood and blood components. Further, the matter may also be deliberated in the forthcoming DTAB. It was also discussed that the renewal of license of many blood centres have been pending since last many years, although the blood centres might have paid the requisite fees but renewal of license is still pending. Therefore SLAs were requested to identify such blood centres in their jurisdiction and do the needful as per the Drugs Rules.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL FOR APPROPRIATE REGULATORY INTERVENTION TO ENSURE THAT THE SAFE AND PHARMACEUTICAL INACTIVE BULKS IMPORTED /MANUFACTURED ARE USED IN DRUG FORMULATIONS

DCC was apprised that adulteration of pharmaceutical excipients has been reported several times. Control of pharmaceutical excipients is important w.r.t to their quality specification as they are directly used in manufacturing of formulation. The various excipients are already listed in the pharmacopoeia for their quality specification;

1. Representation has been received that technical/industrial grade Gelatin imported from China is being used for manufacturer of capsules (soft/Hard). Further NAGRTK UPBHOKTA MARGDARSHAK MANCH has also reported that some of the capsule manufacturers are knowingly or unknowingly using industrial grade gelatine imported from China in the manufacturing of capsules intended for human consumption. There is increasing evidence that low cost industrial/technical grade gelatine unfit for human consumption is being imported mainly from China, by unscrupulous traders and sold to soft capsule manufacturers who blend it with high quality gelatin made in India, in the manufacturing of capsules. Technical gelatin is prohibited for human consumption due to the presence of certain toxic (carcinogenic) compounds of chromium etc as there is no regulation specifying maximum limit of chromium / other heavy metals/salmonella and requirement for drawl of samples for testing of industrial grade gelatin to ensure safety.

2. Representation has also been received that India imports around 120,000 MT of industrial grade IPA. While 170,000 MT of IPA consumed by the pharmaceutical industry and only about 15-17% is pharmacopoeia grade. Thus Industrial grade IPA lands in the pharma industry, apart from serving the other industries like coatings, cleaning etc. Imports mainly come from China, South Korea, Taiwan, Europe, and USA.

   IPA is an important solvent for pharmaceutical applications. However, usage of industrial grade IPA that does not fulfill pharmacopeia criteria is dangerous and hazardous to health. Industrial grade IPA, which does not meet various critical parameters covered in Pharmacopeia Standards such as UV absorbance test, identification of unsaturated hydrocarbons and rapidly carbonizable material can adversely affect the quality of the drug.

3. Recently, during RBI inspections and international complaint investigation it was observed that excipients like Glycerin, Propylene Glycol etc. were imported from different countries as Industrial grade and supplied by traders/ not licensed under Drugs and Cosmetics Act and Rules thereunder to the Pharmaceutical Manufacturing units.

Drugs & Cosmetics Act & Rules thereunder have following relevant provisions for Excipient/ inactive bulk:

As per Rule 24A (8), no import registration certificate is required in respect of an inactive bulk substance.

Further Rule 43 & Schedule D provide exemption for Substances not intended for medicinal use excluding those intended to be used as drugs after further purification or rendering them sterile. Dual Use NOCs issued by CDSCO include excipient category. The excipient like Hard Gelatin capsules, Glycerin IP etc. Imported under Dual Use NOCs should be used for non-medicinal purpose only.

The Drug definition under the Drugs and Cosmetics Act, 1940 include all substances intended for use as component of a drug including empty gelatin capsules are required manufacturing licence and compliance of GMP is mandatory.

The matter was deliberated in the DCC, and it was opined that as per the Drugs and Cosmetics Act only pharma grade excipients shall be used and therefore proper enforcement need to be done to tackle the issue. The DCC deliberated the matter and following recommendations were made:-

(i) To issue an advisory to all SLAs to direct all the manufacture's under their jurisdiction to use only pharma grade excipients for manufacturing of drug formulations.

(ii) The sub-committee may be constituted for examining the matter and give a comprehensive report within three months time.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL ON DRUGS: QUALITY, REGULATIONS & ENFORCEMENT REGARDING SAMPLING AND TESTING

DCC was apprised that consideration of use of digital platform for improving transparency in the inspection & drawing and testing of samples have been discussed at the higher level of the government. The exact point is reproduced below:

"Digital platforms can also be leveraged to prevent corruption and reduce the scope for discretion. For instance, D/o H&FW is working on online entry of recommendations during inspection by drug inspectors. Other technologies such as videography may be leveraged to prevent tampering of samples, integrity of drug-testing processes etc".

The matter was deliberated in the DCC, and it was stressed for preparing an SOP for videography of the procedures of sample receipt, seal opening and sample distribution to the analyst. Further it was discussed that the laboratory head may visit any of the Central Forensic Laboratory (CFL) to get idea regarding their procedures before preparing the SOP in this regard. It was decided to form a sub-committee comprising of two persons from Central lab, two persons from State lab, one from CDSCO and one technologist having expertise in the field to deliberate and give recommendations in the matter.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL FOR UNIFORM IMPLEMENTATION AND ACTION TAKEN BY SLAs FOR VIOLATIONS OF THE PROVISIONS OF SALE AND DISTRIBUTION OF THE DRUGS AS PER THE DRUGS & COSMETICS ACT AND RULES.

CDSCO has received a representation regarding enforcement activities with respect to sale and distribution of drugs in one of the State. It stated that the concerned State is not having Standard Operating Procedure for deciding violations of Act (Critical, major and minor) and decisions are affected by the pressure from Media, Politics or administration and proposed timelines for suspension for 1st up to fifth time offender are specified.

It was also stated that there was no uniform SOP for administrative action taken by various State Licensing Authority for (Critical, Major and Minor) violations under Drugs and Cosmetics Act and Rules thereunder.

The matter was deliberated in the DCC and it was decided to form a sub-committee having members from Madhya Pradesh, Maharashtra, one from CDSCO and two from consuming States to examine the matter and give its recommendations for preparation of an SOP. The sub-committee may also see the best practices followed by other States while preparing the SOP.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL TO HAVE ROBUST UNIFORM SYSTEM IN THE COUNTRY FOR QUICK ACTIONS LIKE CIRCULATION OF THE NSQ/SPURIOUS RESULTS INCLUDING UPLOADING ON WEBSITE, SUSPENSION/CANCELLATION OF WHOLESALE/RETAIL LICENSE FOR SALE OF SPURIOUS PRODUCTS.

Isolated cases of spurious products of various companies are reported from the various part of Country. It is observed that Wholesale/ Retail outlets are allowing circulation of these products for some extra profit and bypassing the authorized channel of distribution.

In general, sampling is carried by Drugs Inspectors of Central and State drugs control as per Section 22 & 23 of the Drugs & Cosmetics Act 1940 and Rules thereunder for routine drugs quality surveillance. The test reports are issued by State and Central Government Analysts.

Every state has their own system/SOP for circulation/handling of NSQ results by various methods.

Test reports (Form-13) of NSQ/Spurious/Adulterated drugs received by CDSCO, HQ from Central Laboratories are uploaded as Drug Alert on the CDSCO Website on monthly basis as per Drugs Alert SOP. As per the SOP, as and when the reports are received, the manufacturers as per the label of the product (as per Test Report) are requested to initiate Product Recall irrespective of proceeding by Drugs Inspector. In some cases, the manufacturer reports to CDSCO that the products are not manufactured by them and product declared as NSQ is purported to be Spurious. Subsequently, such cases are examined at CDSCO, HQ and accordingly depending on the details available Drug Alert is revised with Remark: "The actual manufacturer (as per label claim) has informed that the impugned batch of the product has not been manufactured by them and that it is a spurious drug. The Product is purported to be spurious, however, the same is subject to outcome of the investigation."

It is noticed that in case of Spurious product the website alert having manufacturer name alone is not serving the purpose for awareness of stakeholder/ healthcare professional/ patients to discontinue the identified Spurious product.

There should be robust uniform system in the country for quick actions like circulation of information on NSQ/Spurious results including uploading on website, suspension/cancellation of wholesale/retail license for sale of Spurious Product.

It was deliberated that all SLA's should share such data to CDSCO and it was already opined to share a format with SLAs for submission of NSQ details to CDSCO. All States agreed to share the data on monthly basis preferably before 10th of every month.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF STATE REGULATORY AUTHORITIES IN MATERIOVIGILANCE PROGRAMME OF INDIA

DCC was apprised that a Proposal was received from Indian Pharmacopoeia Commission, Ghaziabad, to bring attention about the vital role of the State Regulatory Authorities in the Materiovigilance Programme of India (MvPI). According to MDR Rule 2017, Post Marketing Surveillance data (Vigilance reporting) the dossier should contain the Post Marketing Surveillance or Vigilance Reporting procedures and data collected by the manufacturer encompassing the details of the complaints received and corrective and preventive actions taken for the same.

NCC-MvPI through the presentation proposed to address following points in the meeting-

1. MvPI focus on ensuring patient safety and enhancing the quality of medical devices.
2. The active involvement of the State Regulatory Authorities is crucial in achieving the program's objectives effectively.

3. State Regulatory Authorities inclusion in the MvPI would enhance the accuracy and comprehensiveness of adverse event reporting, as well as facilitate timely intervention and corrective actions.

The State Regulatory Authority can play a pivotal role in promoting awareness about the MvPI among healthcare professionals, manufactures and consumers across the states.

The matter was presented by Dr. Kalaiselvan from IPC and all the States/UTs SLAs were requested to submit the ADR reports of materiovigilance to IPC on Class A & B medical devices. All the manufacturers need to be directed by SLAs to submit ADR reports to IPC on Class A & B Medical Devices.

AGENDA NO. 7 & 12

CONSIDERATION OF PROPOSAL FOR LISTING OF TAPENTADOL TO SCHEDULE X OF THE DRUGS RULES 1945

DCC was apprised that Tapentadol has been categorized in USA under Schedule II of the Control Substances Act. It is also a controlled drug in some other countries. The drug Tapentadol is not Scheduled under the NDPS Act in India or any International Conventions. However, the WHO expert committee on Drug Dependence (ECDD) in the 36th report (2014) reviewed the substance Tapentadol, and recommended that owing to the insufficiency of the data regarding dependence, abuse and risk to the public health, Tapentadol may not be placed under international control but may be kept under surveillance. In this regard Department of Revenue, Ministry of Finance, Govt. of India has requested for analysing Tapentadol for its scheduling under the NDPS Act, 1985.

& AGENDA NO. 12
AGENDA FROM THE STATE OF PUNJAB
CONSIDERATION OF THE PROPOSAL FOR INCLUDING PREGABALIN & ITS DRUG FORMULATIONS in Schedule H1 of the Drugs Rules 1945 IN LIGHT OF MISUSE & INTOXICATION

DCC was apprised that the drug formulations (Tablets & Capsules) containing Pregabalin are available in different strengths in the market containing Pregabalin from75mg to 300mg per unit dosage form. The drug formulations containing Pregabalin are generally prescribed by the Doctors for the management of Neuropathic pain, to treat fibromyalgia. Pregabalin capsules/ tablets are used along with other medications to treat certain types of seizures in adults and children of 1month of age and older. It has been observed by the FDA Punjab that the drugs formulations containing Pregabalin 150mg / 300mg are being misused for intoxication and these formulations are being seized from the licensed Chemists & unlicensed premises by the Drugs Control Officers of FDA Punjab due to violations of the provisions of Drugs &Cosmetics Act/Rules. At present the drug formulations containing Pregabalin are neither Schedule H nor in Schedule H1 of the Drugs Rules1945.

Therefore, the Pregabalin & its preparations may be included in Schedule H1 of the Drugs Rules 1945, as the drugs formulations containing Pregabalin 150mg & 300mg are being misused for intoxication. Further, as the said drugs do not have much therapeutic usage and are being misused for intoxication, continuation of DCGI approvals of the dosage forms containing Pregabalin 150 mg and 300 mg may be re-evaluated.

The matter was deliberated regarding drug formulations (Tablets & Capsules) containing Pregabalin & Tapentadol. It was also deliberated if Tapentadol can be included in Schedule X considering its misuse potential.

DCC deliberated and opined that putting Tapentadol in Schedule X may restrict its availability as it is widely used medicine and therefore it needs further in depth deliberation. It was recommended to form a sub-committee comprising of one regulator from CDSCO, one from State, one or two clinicians (psychiatrist) and one pharmacologist for examining the matter in respect of both Pregabalin and Tapentadol and give its recommendation.

AGENDA NO. 8

CONSIDERATION OF PROPOSAL FOR REQUIREMENT TO CREATE A REPOSITORY OF IN-HOUSE/ NON-PHARMACOPOEIAL SPECIFICATIONS FOR TESTING OF DRUGS, COSMETICS AND MEDICAL DEVICES BY THE STATE AND CENTRAL LABORATORIES TO RELEASE THE TEST REPORT WITHIN THE 60 DAYS TIME AS PER THE RULES.

DCC was apprised that the laboratories of CDSCO do not receive in-house specifications with the drug samples sent by the Drugs Inspectors. There is a requirement to create a repository of In-house/ Non-Pharmacopoeial Specifications for testing of Drugs, Cosmetics and Medical Devices by the State and Central laboratories to release the test report within the 60 days time as per the rules. It may be explored if manufacturers may be requested to upload the IH test methods and specifications on the SUGAM Labs Portal.

The matter was deliberated in DCC, and it was opined that now the time has come to have a data base for specifications and method of analysis (MOA) approved by LA. The matter was deliberated at length and it was decided to discuss the issue with CDAC for creation of such platform for uploading the data by the SLA's. Further advisory may be issued from CDSCO to States for preparation and uploading of data by SLAs.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL TO MAKE PROVISIONS FOR DEFINING RESPONSIBLE PERSON (RP) OF A LICENSEE WHO SHALL BE RESPONSIBLE FOR DAY TO DAY AFFAIRS OF THE COMPANY & SHALL BE THE SINGLE POINT OF CONTACT OF THE LICENSEE FOR SERVING ALL THE NOTICES, LETTERS ETC. FOR VARIOUS PURPOSES ISSUED BY THE SLA OR CLA.

DCC was apprised that Drug Licenses are issued to firms, the constitution of which may be proprietary, partnership, Private Ltd, Limited etc.

Many a time's the SLA or the CLA need to issue letters, circulars, notices etc. to the firm and the person who is responsible for the day to day affairs of the firm is not known.

Lack of information of the responsible person, sometimes delay in obtaining the requisite reply or information from the firm. In cases of NSQ drugs it is becoming extremely difficult to obtain the requisite information with respect to the recall of the drug, acknowledge the receipt of a notice issued by a drugs inspector or a LA, information on the constitution of the firm, investigation etc.

There is a need to have a single point of contact to a licensee so that all the notices, letters, data for various purposes etc. can be served to this responsible person (RP). Such RP will reduce the delays in obtaining simple information such as the products licensed to them, manufactured by the firm, submission of various data sought by the authorities from time to time.

The matter was deliberated in the DCC, and it was opined that a sub-committee may be constituted comprising the regulator from Delhi, Karnataka, Andhra Pradesh and DDC Shri Ranga Chandrashekhar, CDSCO Baddi Zone as convenor for deliberation of the matter and submit the comprehensive report with recommendation.

AGENDA NO. 10

Proposal regarding information about forthcoming Global Bench Marking of vaccines (NRA assessment)

Global Bench Marking (GBT) tool is followed by WHO for assessment or benchmarking of a country with respect to various regulatory functions and this being a prerequisite for procurement of Vaccines by UN agencies from Indian Vaccines manufacturers, CDSCO along with other associated institutions like Central Drugs Laboratory, AEFI etc. are assessed by WHO.

WHO may plan the re-benchmarking of CDSCO very soon with respect to vaccines, once formally agreed by the Ministry.

All the State/ UT Drugs Controllers are required to furnish various information on the Human resources, GDP inspection reports of vaccine distributors and retail premises using uniform checklist and procedures including action taken & closure of inspection, uniform checklist and procedures for licensing of premises (sales and manufacturing) of vaccine, data base of all sales

premises, Risk Based Sampling plan of vaccines including details of samples drawn and outcome etc.

Further, data base of all technical staff at all levels are required to be provided for implementation of Good Regulatory Practices, Good Review Practices and Quality Management System.

The matter was briefed by Dr. Rubina Bose, DDCI, CDSCO HQ and raised the issue that many states has not provided the data to CDSCO in response to the letter issued by CDSCO in the matter. Further, it was informed that some of the states got confused that they are not vaccine manufacturing states, hence not provided the data. But the data from all states is required for the manufacturing as well as sales premises. It was stressed that the data is required in view of upcoming NRA assessment. It was also stated that CDSCO will share the checklist and SOP for manufacturing as well as sales premises to the States for common practice on inspection process and uniform inspection reports among the States. Risk based sampling of the vaccines by all States and CDSCO zonal office and the information need to be provided to CDSCO-HQ. Accordingly all the state / UT Drugs Controllers were requested to provide the information at the earliest.

AGENDA NO. 11

AGENDA FROM THE STATE OF PUNJAB

CONSIDERATION OF THE PROPOSAL FOR ISSUING GUIDELINES UNDER SECTION 33P OF THE DRUGS AND COSMETICS ACT 1940 FOR ITS UNIFORM IMPLEMENTATION BY ALL THE STATES / UTS IN LIGHT OF ORDER DATED 28-8-2020 OF HON'BLE SUPREME COURT IN CR. APPEAL NO. 200/2020 (SLP CRIMINAL NUMBER 4178/2019) IN THE CASE UNION OF INDIA VERSUS ASHOK KUMAR SHARMA AND OTHERS.

DCC was apprised that in the case Union of India Versus Ashok Kumar Sharma and Others, 2020(3) R.C.R.(Criminal) 726, the constitutional bench of Hon'ble Supreme Court has issued directions in Cr. Appeal No. 200/2020 (SLP Criminal Number 4178/2019) w.r.t. cognizable offences regarding power of Drugs Inspectors under the Drugs and Cosmetics Act, 1940: -

The matter was briefed by the DC, Punjab and requested for issuance of uniform guideline in this regard. DCC after detailed deliberation recommended to constitute a sub-committee comprising of members from those States where arrests have been done by Drugs Inspectors i.e. Himachal Pradesh, Rajasthan and CDSCO, East Zone for deliberation and recommendation.

AGENDA NO. 13

AGENDA FROM THE STATE OF TAMIL NADU

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 TO PROVIDE EXEMPTION FROM LABELLING REQUIREMENTS AS PER SCHEDULE H UNDER RULE 96(1)(xi) OF THE SAID RULES AND FOR ITS INCLUSION UNDER THE ENTRY NO. 40 OF SCHEDULE K OF THE DRUGS RULES 1945 TO PROVIDE EXEMPTION FOR IT'S OVER-THE-COUNTER (OTC) SALE BY RETAIL WITHOUTPRESCRIPTION OF A REGISTERED MEDICALPRACTITIONER (RMP).

The DCC was apprised the details as per the agenda regarding the sale of hormonal contraceptives including emergency contraceptives.

The matter was briefed by DC, Tamil Nadu. DCC after detailed deliberation recommended to constitute a sub-committee to examine the matter comprising of DC, Tamil Nadu, one from CDSCO, two to three ggynaecologist and one pharmacologist. One expert from ICMR may also be included.

AGENDA NO. 14

AGENDA FROM THE STATE OF TAMIL NADU

CONSIDERATION OF THE PROPOSAL FOR FRAMING OF RULES UNDER SECTION 32B OF THE DRUGS AND COSMETICS ACT 1940.

DCC was apprised that the Section 32B of the Drugs and Cosmetics act 1940 was inserted vide Drugs and Cosmetics (Amendment) Act, 2008 & its Date of enforcement is from 10.08.2009.

However, Rules were not framed for the sum to be paid for compounding of offences punishable under section 13 (1) (b), Section 28 & Section 28A of the said Act.

At this juncture, the Government of India vide the Jan vishwas (Amendment of provisions) Act, 2023 (enforcement date yet to be notified) has inserted Section 27(d) and Section 27A (ii) in Section 32B of the Said Act for compounding of offences.

Hence it is proposed to frame Rules for Compounding of offences for section 32B of Drugs and Cosmetics Act 1940.

DCC was apprised that a draft in this regard has been prepared and the matter is under further examination and consideration.

AGENDA NO. 15

AGENDA FROM THE STATE OF GOA

CONSIDERATION OF THE PROPOSAL FOR PERMISSION TO TRANSIT THE UNDER TEST/QUARANTINE BATCHES TO DEPOT FOR STORAGE TILL FINAL RELEASE OF BATCHES.

The DCC was apprised that Goa FDA has been in receipt of request from manufacturing firm to allow them to transfer the under test batches to their Mumbai depot before final release of batches.

The matter was discussed in detail. However, it was informed by DC, Goa that they will provide further details in the matter for more clarity so that the issue can be addressed.

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ANNEXURE-A

List of the participants of 62nd Drugs Consultative Committee meeting held on 26.09.2023 under the Chairmanship of Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) via Video Conference

A. STATE/UTs DRUGS CONTROL ORGANIZATIONS

S. No.	STATE/UT	NAME	DESIGNATION
1.	Andhra Pradesh	Shri. K.V.S.N Gupta	Joint Director, DCA, A.P.
2.	Assam	Shri. Hridayanand Mahanta	State Drugs Controller
3.	Chhattisgarh	Shri Basant Kaushik	Deputy Drugs Controller
4.	Goa	Smt. Jyothi Sardesai	Director, FDA
5.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
6.	Haryana	Lalit Kumar Goel	Deputy Drugs Controller
7.	Himachal Pradesh	Shri. Navneet Marwaha	Drugs Controller
8.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
9.	Karnataka	Shri. Amaresh Tumbagi	State Drugs Controller (A/C)
10.	Kerala	Shri Sujeet	State Drugs Controller(I/C)
11.	Maharashtra	Shri. D.R. Gahane	Joint Commissioner
12.	Mizoram	Shri Lal Sawma	Drugs Controller
13.	Odisha	Shri. Ashok Kumar Patra	Drugs Controller
14.	Punjab	Shri. Sanjiv Kumar	Joint Commissioner(Drugs)
15.	Rajasthan	Shri Ajay Phatak	Drugs Controller
16.	Tamil Nadu	Shri M.N. Sridhar	JD cum Controlling Authority
17.	Telangana	Shri. Ramdhan	Joint Director (I/C) Drugs Control, Telangana
18.	Tripura	Smt. Kachan Sinha	Drug Licensing Authority
19.	Uttarakhand	Shri Tajbeer Singh	Dy. Drugs Controller
20.	West Bengal	Smt. Sumana Pyne	Drug Licensing Authority
		Shri. Sukumar Chandra Das	Assistant Director of Drugs Control
		Shri Ananda Sankar Basak	Assistant Director of Drugs Control
21.	Chandigarh	Shri. Amit Duggal	Sr. Drug Control Officer
22.	J&K	Mrs. Lotika Khajuria	Drug Licensing Authority
23.	Ladakh	NAWANG PC	Drug Licensing Authority
24.	Delhi	Shri. K R Chawla	Controlling & Licensing Authority and Deputy Drugs Controller
25.	Pondicherry	Dr. E. Anandakirouchenane	Controlling Authority Cum Licensing Authority

B. INVITEE

S. No.	OFFICES	NAME	DESIGNATION
1	Indian Pharmacopoeia Commission	Dr. Vivekanandan Kalaiselvan	Senior Principal Scientific Officer

C. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
ZONES			
1.	North Zone, Ghaziabad	Shri K. Narendran	Deputy Drugs Controller (India)
2.	East Zone, Kolkata	Shri Arup Kumar Chatterjee	Deputy Drugs Controller (India)
3.	West Zone, Mumbai 1	Shri Shiv Kumar	Deputy Drugs Controller (India)
4.	West Zone, Mumbai 2	Shri Jayant Kumar	Deputy Drugs Controller (India)
5.	South Zone, Chennai	Shri K N Shrinivasan	Deputy Drugs Controller (India)
6.	Hyderabad Zone	Dr. A. Ramkishan	Deputy Drugs Controller (India)
7.	Ahmedabad Zone	Dr. Ravikant Sharma	Deputy Drugs Controller (India)
8.	Baddi Zone	Shri Ranga Chandrasekhar	Deputy Drugs Controller (India)
9.	Bangalore Zone	Shri Rajshekar	Deputy Drugs Controller (India)
SUB-ZONES			
1.	Guwahati Sub-zone	Shri. Gulshan Taneja	Deputy Drugs Controller (India)
2.	Indore Sub-zone	Shri. Gaurav Kumar	Deputy Drugs Controller (India)
3.	Varanasi Sub-zone	Shri. Mukesh Kumar	Asst. Drugs Controller (India)
4.	Jammu Sub-zone	Smt. Minakshi Vashistha	Asst. Drugs Controller (India)
5.	Goa Sub-zone	Shri Krishan Bhardawaj	Asst. Drugs Controller (India)
6.	Visakhapatnam Sub-zone	Smt. K. Bhvaneshwari	Asst. Drugs Controller (India)
7.	Rishikesh Sub-zone	Shri Jay Jyoti Roy	Asst. Drugs Controller (India)

D. CDSCO (HEAD QUARTERS)

S. No.	NAME	DESIGNATION
1.	Dr. Rajeev Singh Raghuvanshi	Drugs Controller General of India
2.	Shri. A. K. Pradhan	Joint Drugs Controller (India)

S. No.	NAME	DESIGNATION
3.	Dr. S. Manivannan	Joint Drugs Controller (India)
4.	Smt. A. Visala	Deputy Drugs Controller (India)
5.	Dr. Rubina Bose	Deputy Drugs Controller (India)
6.	Shri. Sanjeev Kumar	Deputy Drugs Controller (India)
7.	Smt. Swati Srivastava	Deputy Drugs Controller (India)
8.	Dr. Ajay Sachan	Deputy Drugs Controller (India)
9.	Dr. I.S. Hura	Deputy Drugs Controller (India)
10.	Shri. Rahul Panwar	Assistant Drugs Controller (India)
11.	Shri. Bibekanada Behera	Drugs Inspector
12.	Shri. Ranjeet Singh Patel	Drugs Inspector
13.	Smt. Maradani Meena Devi	Asst. Drugs Inspector

E. DRUGS TESTING LABORATORIES

S. No.	OFFICES	NAME	DESIGNATION
1.	CDL, Kolkata	Dr. Saroj Kumar Ghosh	Director-In-Charge
2.	CDL, Kasauli	Dr. Sushil Sahu	Director-In-Charge
3.	CDTL, Mumbai	Mrs. Sayali U. Warde	Director-In-Charge
4.	RDTL, Chandigarh	Dr. Debasis Maiti	Director-In-Charge
5.	RDTL, Guwahati	Shri. Gulshan Taneja	In-charge & Deputy Drugs Controller (India)
6.	CDTL, Chennai	Smt. C Vijayalakshmi	Director-In-charge
7.	CDTL, Hyderabad	Smt. A. Visala	Director (In-charge) & Deputy Drugs Controller (India)