

डॉ. राजीव सिंह रघुवंशी

औषधि महानियंत्रक (भारत)
केंद्रीय औषधि मानक नियंत्रण संगठन
स्वास्थ्य एवम परिवार कल्याण मंत्रालय
भारत सरकार
एफ.डी.ए. भवन, कोटला रोड,
नई दिल्ली-110002



Dr. Rajeev Singh Raghuvanshi

Drugs Controller General (India)
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road
New Delhi-110002 (India)

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Dated: 29.09.2026

To

All State/ UT Drugs Controllers

Sub: Minutes of the 70th Meeting of the Drugs Consultative Committee (DCC) held on 18.09.2026 through Hybrid mode - reg.

Sir/Madam,

The 70th meeting of the Drugs Consultative Committee was held on 18.09.2026 through Hybrid mode.

The minutes of the 70th meeting of the Drugs Consultative Committee are annexed herewith for your kind information and for taking further necessary action, wherever required, as per the 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, MoH&FW, Kartavya Bhawan-1, New Delhi
2. PS to JS(R), MoH&FW, Kartavya Bhawan-1, New Delhi
3. DDC (I) of Zonal & Sub-Zonal offices
4. Directors of Labs of CDSCO
5. CDSCO website

**MINUTES OF 70th MEETING (HYBRID MODE)
OF
DRUGS CONSULTATIVE COMMITTEE (DCC)
HELD ON 18th Sept 2026 AT CDSCO (HQ), FDA BHAWAN, KOTLA ROAD, NEW
DELHI – 110002**

INAUGURAL DELIBERATIONS

Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) and Chairman of the Drugs Consultative Committee (DCC), welcomed the members and appreciated the continued cooperation extended by the States/UTs.

In his opening remarks, he emphasised the need to further strengthen the country's drug regulatory system through coordinated efforts.

He also urged the States/UTs that have not yet onboarded the Online National Drugs Licensing System (ONDLS) portal to do so at the earliest to promote uniformity in licensing and inspection processes across the country.

Further, DCC deliberated the agenda items one by one. The list of participants is annexed.

The details of the deliberation and recommendations are as follows:

AGENDA NO. 1

Action Taken Report of the 69th DCC meeting held on 24.06.2026

The Drugs Consultative Committee (DCC) deliberated on the Action Taken Report of the 69th DCC meeting held on 24.06.2026. The Action Taken Report was considered and approved.

While reviewing the action taken on earlier recommendations, the Committee noted the progress of the sub-committees constituted pursuant to the 69th DCC meeting and advised the sub-committees to expedite the deliberations and submission of the reports for consideration by the DCC.

AGENDA NO. 2

Deliberation on the proposal regarding the continued manufacture, import and export of mercury-added products/topical antiseptics (Mercurochrome/Merbromin) and approval for extension of the exemption under the Minamata Convention on Mercury

DCC was apprised about the status of mercury-added topical antiseptics under the Minamata Convention on Mercury to protect human health and the environment from mercury emissions. Committee was also apprised about the inclusion of Mercurochrome in containers not exceeding 100 mL under Schedule K of the Drugs Rules, 1945. It was also informed that only a limited number of manufacturers appeared to be manufacturing the product and that alternative topical antiseptics are already available.

The Committee observed that the matter should be examined primarily from the standpoint of patient safety and clinical need. DCC recommended that the opinion of the Directorate General of Health Services be obtained, along with the available data on manufacture and use of the product in the country. A final view on discontinuation of manufacture, import and export and the consequential position under Schedule K may be taken after consideration of the said opinion.

AGENDA NO. 3

Consideration of the proposal regarding concerns over the rampant prescribing of cough syrups to infants

DCC was apprised of the concern regarding the use of cough syrups in young children despite the advisory issued by the Directorate General of Health Services. The proposal to prescribe a statutory warning under Rule 96 of the Drugs Rules, 1945 was deliberated.

DCC agreed in principle that cough syrup labels should prominently bear the following warning in red color on the label:

"WARNING: Cough syrup shall not be used in children below 4 years of age."

The Committee further opined that pictures of infants, toddlers, toys or similar depictions which may suggest use in small children should not appear on such labels to avoid any confusion. Further, the warning should be displayed prominently in an appropriately increased font size. Necessary action for amendment of the Drugs Rules, 1945 may be initiated accordingly.

AGENDA NO. 4

Consideration of the proposal to examine the existing regulatory framework governing pharmaceutical preparations containing narcotic drugs and psychotropic substances, identify the regulatory and implementation gaps contributing to their possible diversion, and provide appropriate recommendations/measures to strengthen the regulatory mechanism for prevention and detection of illegal pharmaceutical diversion

DCC was apprised of the target assigned to CDSCO under the Vision Document on Drug Control 2026 to 2029 as launched during the 10th Apex level NCORD meeting. The purpose of the assigned task is to address regulatory gaps relating to illegal diversion of pharmaceutical preparations containing narcotic drugs and psychotropic substances by March 2027.

The Committee discussed the issue in detail and the need for a reliable national database on manufacture, sale, stocking, inspections and enforcement action of such products.

DCC recommended preparation of a comprehensive action plan after collating the existing directions, State-level controls and standard operating procedures. CDSCO shall circulate a uniform format for monthly submission of data by States and Union Territories, including the number and categories of licences, quantities handled, inspections and audits conducted, and enforcement action taken. The format may be finalized in consultation with the State regulators.

The Committee further recommended development of a common digital platform for regular submission and analysis of such data. The information so collected shall be used to identify regulatory and implementation gaps and to formulate the roadmap for meeting the target stipulated in the Vision Document. The Committee also suggested exploring the feasibility of using the online portal made by CBN by customizing the same as per the required fields for end-to-end track and trace of such drugs.

AGENDA NO. 5

Consideration of the proposal on Measures to Curb Spurious Medicines in India

DCC was apprised of the recommendations forwarded by the National Human Rights Commission following the Open House Discussion on Measures to Curb Spurious Medicines in India held on 25.02.2026. The Committee noted that some recommendations were already being acted upon, whereas others require inputs from the

States as well as coordinated action involving drug regulators, police, laboratories, prosecutors and forensic institutions.

DCC recommended that the NHRC recommendations be circulated to all States and Union Territories for their specific comments, details of the measures already being implemented and suggestions on the proposed national mechanism. On receipt of the inputs, CDSCO may prepare a consolidated proposal and constitute a small group by including a few States to prepare a consolidated reply to the NHRC and also prepare a way forward for the tasks which need to be addressed in future.

AGENDA NO. 6

Consideration of the proposal to review the framework for the issuance of retail and wholesale drug licences

DCC deliberated the representation received from the Pharmacists Association seeking review of the framework for grant of retail and wholesale drug licences, including the suggestion to regulate the ratio between such licences.

Members observed that the requirements differ considerably between urban, rural, industrial and geographically remote areas and that a uniform numerical ratio would not be practicable throughout the country.

DCC did not recommend a uniform cap or ratio for retail and wholesale licences. The Committee opined that State Licensing Authorities may assess the requirement and risk of misuse in their respective jurisdictions and adopt suitable measures within the existing statutory framework.

AGENDA NO. 7

Deliberation on issues relating to retention of drug licences under Rule 63 of the Drugs Rules, 1945 including processing through the Online National Drugs Licensing System

DCC deliberated the practice of requiring licensees to obtain a separate retention certificate and to submit documents resembling a fresh grant or renewal application, although Rule 63 provides for retention of the licence on payment of the prescribed fee.

DCC recommended that payment of the retention fee be integrated with the Online National Drugs Licensing System and that the system should automatically generate an electronic acknowledgement and maintain a searchable database of such retained licences. No separate retention certificate or repetition of documents as required at the stage of grant should ordinarily be insisted upon unless specifically required under the Rules.

Further, it was also opined that the States not yet integrated with ONDLS may align their payment and retention process accordingly.

AGENDA NO. 8

Requirement of furnishing details of a competent person/qualified person for grant of licence in Form 20D (wholesale sale of Homoeopathic medicines) through the ONDLS portal

DCC noted the anomaly that the application process seeks details of a competent person for a licence in Form 20D, while the relevant qualification and experience are not expressly prescribed under the Drugs Rules, 1945. DCC also noted the recommendations of the ASUDCC in the matter.

DCC agreed that the anomaly should be addressed by the necessary amendment of the Rules.

AGENDA NO. 9

Consideration of the proposal to amend Rule 49 of the Drugs Rules, 1945 to include recognised qualifications in Homoeopathy for appointment of Inspectors for Homoeopathic drugs under Section 21 of the Drugs and Cosmetics Act, 1940

DCC deliberated on the absence of a specific qualification in Rule 49 for inspection of Homoeopathic drugs. It was observed that inspection of a manufacturing facility involves assessment of the system of medicine as well as common manufacturing, quality-control and good manufacturing practice requirements.

DCC agreed in principle that suitable provisions should be included in the rules for recognized qualifications and experience in Homoeopathy only for manufacturing at present, as inspection of the manufacturing units requires subject expertise.

AGENDA NO. 10

Consideration of the proposal for inclusion of all sterile drug products under the CLAA scheme

DCC deliberated at length on the proposal to bring all sterile drug products under the Central Licence Approving Authority scheme so that it becomes the shared responsibility of the Centre and State. The Committee acknowledged that sterile products are high-risk products and require specialized scrutiny. Members also discussed the existing provision

for joint inspections and the practical and legal implications of altering the present division of licensing responsibility.

DCC deliberated and opined that a sub-committee may be constituted to review the proposal and its feasibility and to also take considered legal opinion.

AGENDA FROM RAJASTHAN

AGENDA NO. 11

Consideration of the proposal for examination of issues relating to disposal of machinery from non-compliant pharmaceutical units

DCC deliberated on the risk that machinery removed from closed or non-compliant pharmaceutical units may be diverted for manufacture of spurious or contraband drugs. The Committee observed that an effective mechanism would have to cover the wider supply chain of pharmaceutical machinery and not merely disposal of machinery by a closed unit.

DCC deliberated the proposal and opined that even if some regulatory framework is created, its implementation seems to be very poor.

DCC recommended that the State Drugs Controller, Rajasthan may submit a detailed and comprehensive proposal covering identification, manufacture or supply, ownership, transfer, decommissioning and disposal of pharmaceutical machinery, together with the monitoring mechanism, resource implications and other aspects like scrap monitoring after disposal, etc. The proposal may thereafter be placed before DCC for further deliberation.

AGENDA NO. 12

Consideration of the proposal for creation of a digital platform for public disclosure of quality control and test reports of batches of drugs manufactured by pharmaceutical manufacturers

DCC deliberated the proposal for mandatory uploading of manufacturers' batch test reports or certificates of analysis on a public digital platform. Members observed that mere uploading of a document supplied by the manufacturer would not establish its authenticity or ensure the quality of the batch unless supported by effective verification and regulatory oversight.

DCC did not agree to the proposal in its present form. The Committee emphasized that risk-based inspections, effective audits, independent sampling and firm enforcement

action would contribute more directly to improvement of drug quality. Any future digital disclosure mechanism should therefore be examined only as part of a broader verifiable regulatory system and not as a substitute for regulatory inspection and testing.

AGENDA FROM NAGALAND

AGENDA NO. 13

CONSIDERATION OF THE PROPOSAL FOR MANDATING SEPARATE PREMISES FOR WHOLESALE AND RETAIL DRUG LICENCES

DCC deliberated the proposal received from Nagaland. Members expressed different views on whether separation of premises would address the stated concern, particularly because transfer of stock between wholesale and retail operations of the same entity may remain permissible through appropriate accounting and stock-transfer records.

As no consensus emerged, DCC decided that the matter should be discussed initially further among the State regulators, taking into account the actual regulatory issue, infrastructure requirements and existing business and taxation practices.

AGENDA NO. 14

Consideration of the proposal for revisiting the scope of Schedule K concerning dispensing of medicines by Registered Medical Practitioners to their patients

DCC considered the concern that Schedule K does not prescribe a maximum quantity of medicines that a Registered Medical Practitioner may stock for dispensing to his or her own patients. The Committee also noted the conditions already attached to the exemption and the practical need for practitioners to keep medicines for treatment and emergency use.

DCC was of the view that action can be taken under the existing provisions where the exemption is misused for unauthorised retail sale. In the absence of sufficient evidence of a nationwide regulatory problem and in view of the earlier decision of DTAB, the Committee did not recommend amendment of Schedule K at this stage.

AGENDA FROM HIMACHAL PRADESH

AGENDA NO. 15

Consideration of the proposal for the provision of a common testing facility for two adjacent Drugs, Cosmetics, or Medical Devices manufacturing facilities having licences in the same name or under the same management

DCC deliberated the request for permitting a common quality-control laboratory for independently licensed adjacent manufacturing facilities. The Committee distinguished between multiple manufacturing blocks within one licensed premises and separate licensed premises divided by a public road or otherwise requiring movement of samples outside the licensed premises.

DCC did not agree to a common testing facility for separately licensed premises merely on the ground that the facilities are adjacent or under the same management. A common laboratory may continue to be considered for multiple blocks forming part of the same premises/ complex, subject to the applicable licensing and good manufacturing practice requirements.

AGENDA FROM GOA AND TELANGANA

AGENDA NO. 16

Consideration of the proposal for inclusion of the definition of "Change in Constitution" under Rule 2 of the Drugs Rules, 1945

DCC noted that the expression change in constitution is defined under the Medical Devices Rules, 2017 and the Cosmetics Rules, 2020 but is not specifically defined under the Drugs Rules, 1945.

DCC agreed to the insertion of a suitable definition in the Drugs Rules, 1945, aligned as far as practicable with the corresponding definitions under the Medical Devices Rules, 2017 and the Cosmetics Rules, 2020. The Committee also opined that any addition or deletion of partners and other changes in the constitution of a partnership firm is also considered as a change in constitution for the purpose.

AGENDA FROM TELANGANA

AGENDA NO. 17

Consideration of the proposal for amendment of Rule 30(1) of the Medical Devices Rules, 2017 to provide for cessation of manufacture, sale or distribution and destruction of medical devices and stocks thereof in appropriate cases of contravention of the Act and Rules

DCC deliberated the proposal to expressly empower the Licensing Authority to direct stoppage of manufacture, sale or distribution and, where necessary, destruction of medical devices and stocks in cases of contravention of the Act and Rules.

DCC noted that similar provisions have already been provided under the Drugs Rules, 1945.

DCC agreed with the proposal and recommended suitable amendment in the Medical Devices Rules, 2017.

ADDITIONAL AGENDA FROM HIMACHAL PRADESH

Consideration of the proposal for prescribing a reduced timeline for testing and reporting of drug samples

DCC deliberated the proposal to reduce the timeline for testing of drug samples from sixty days to fifteen days or one month. Members pointed out the shortage of laboratory personnel, high sample load, complexity of certain tests and delays in obtaining methods of analysis, reference standards and other materials.

DCC did not agree to reduce the statutory timeline of sixty days. The Committee observed that a State may prescribe an internal standard operating procedure for priority testing of critical, life-saving or urgent public-health samples according to its capacity. To avoid delay in obtaining methods of analysis, Government laboratories should use the method submitted with the product approval and obtain the same from CDSCO headquarters or the authorised database instead of seeking it from the manufacturer.

DCGI also suggested that all States/ UT Drugs Controllers initiate onboarding on SUGAM labs, an integrated digital portal of CDSCO which has been made live for end-to-end digital management of regulatory enforcement, sampling, laboratory testing and post-marketing surveillance. This will automatically address the issue by and large.

In the closing remarks, DCGI also requested all the members to forward the monthly NSQ data along with the test reports in a timely manner so that the CDSCO website may be updated accordingly.

The meeting ended with a vote of thanks to the Chair.

LIST OF PARTICIPANTS

List of the participants of 70th Drugs Consultative Committee meeting held on 18.09.2026 through hybrid mode under the Chairmanship of Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)

A. State/UTs Drugs Control Organizations

S. No.	State/UT	Name	Designation
1.	Assam	Shri Biswajit Talukdar	Drugs Controller
2.	Bihar	Sh. Nityanad Kishloya	Drugs Controller
3.	Chhattisgarh	Sh. B.R. Sahu	Drugs Controller
4.	Goa	Sh. Venkatesh M Sinari	Deputy Director
5.	Gujarat	Sh. R. M. Patel	Joint Commissioner
6.	Haryana	Sh. Ripan Mehta	State Drugs Controller
7.	Himachal Pradesh	Dr. Manish Kapoor	Drugs Controller
8.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
9.	Karnataka	Dr. Umesh S	Additional Drugs Controller
10.	Kerala	Dr. Sujith Kumar	Drugs Controller
11.	Madhya Pradesh	Sh. Dharmesh Bigoniya	Drugs Inspector
12.	Manipur	Sh. Seram Baleshwar Singh	Drugs Licensing Authority
13.	Meghalaya	Mrs Aurelia Rela Kharwanlang	Drugs Controller
14.	Mizoram	Shri. F Lalliantluanga	Drugs Controller
15.	Nagaland	Ethungbemo Ezung	Asst. Drugs Controller
16.	Odisha	Mrs. Mamina Patnaik	Drugs Controller
17.	Punjab	Sh. Sanjeev Kumar	Joint Commissioner (Drugs)
18.	Rajasthan	Shri Ajay Phatak	Drugs Controller
19.	Tamil Nadu	Shri S. Gurubharathi	Deputy Director of Drugs Control
20.	Telangana	Sh. K. Dass	Deputy Director

S. No.	State/UT	Name	Designation
21.	Tripura	Shri. Subrata Das	State Drugs Controller
22.	Uttarakhand	Sh. Tajber Singh	Additional Commissioner
23.	Delhi	Sh. Rajeev Bhargava	Deputy Drugs Controller/Controlling Authority
24.	Ladakh	Mrs. Nasreen Bano	ADC Cum Licensing Authority
25.	Jammu and Kashmir	Sh. Rajesh Kumar Angurana	Drugs Controller
26.	Andaman and Nicobar Islands	Dr Ganesh Samadder	Deputy Director (Medical)
27.	Maharashtra	Sh Ganesh Rokade	State Drugs Controller, FDA
28.	Andhra Pradesh	Sh M Pandu Ranga Prasad	Director, DCA
29.	Uttar Pradesh	Sh Shashi Mohan Gupta	Drugs Controller

B. CDSCO (Headquarters)

S. No.	Name	Designation
1.	Dr. Rajeev Singh Raghuvarshi	Drugs Controller General of India
2.	Dr. A Visala	Joint Drugs Controller (India)
3.	Dr. Ranga Chandrashekar	Joint Drugs Controller (India)

C. Directors of Laboratories of CDSCO

D. Deputy Drugs Controllers / Assistant Drugs Controllers from Zonal and Sub-zonal offices of CDSCO

E. Deputy Drugs Controllers of CDSCO HQ

F. Special Invitee: - Dr. Jai Prakash, Sr. Principal Scientific Officer, IPC on behalf of Chairman, IPC (*joined virtually*)
