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

सत्यमेव जयते

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)

**F. No. DC-DT-14011(11)/1/2026-eoffice**
**Comp. No. 33631**

**Dated: 02.04.2026**

To

All State/ UT Drugs Controllers

**Sub: Minutes of the 68th Meeting of the Drugs Consultative Committee (DCC) held on 20.03.2026 through Hybrid mode - reg.**

Sir/Madam,

68th meeting of the Drugs Consultative Committee was held on 20.03.2026 through Hybrid mode.

The minutes of the 68th 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, Kartavya Bhawan-1, New Delhi
2. PS to JS(R), MoHFW, Kartavya Bhawan-1, New Delhi
3. DDC (I) of Zonal & Sub-Zonal offices
4. Directors of Labs of CDSCO
5. CDSCO website

Tel.: +91-11-23236965 Fax : +91-11-23236973 Email : dci@nic.in Website : www.cdsco.gov.in

# MINUTES OF 68th MEETING (HYBRID MODE) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD ON 20th March 2026 AT CDSCO (HQ), FDA BHAWAN, KOTLA ROAD, NEW DELHI – 110002

## INAUGURAL DELIBERATIONS

Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed all the members of the committee.

In his opening remarks, the DCG(I) emphasized the need to strengthen the nation's Drug Regulatory System and commended the cooperation from all States. He also sensitised upon the resource optimization so as to have effective regulatory control over the drugs moving in the market.

The DCGI urged all States/UTs who have not yet onboarded to join the ONDLS portal at the earliest, to ensure uniformity in the inspection and drug licensing system across the country.

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

## AGENDA NO.1

**Action Taken Report of 67th DCC meeting held on 17.11.2025**

The Drugs Consultative Committee deliberated the Action Taken Report (ATR) of the agenda items of 67th DCC meeting held on 17.11.2025 and the Action Taken Report was considered as approved.

## AGENDA NO. 2

**Consideration of the report of sub-committee constituted by DCC to examine the proposal from National Commission for Protection of Child Rights (NCPCR) regarding Joint Action Plan (Mobile app based Information System (MIS) & Installation of CCTV at medical shops)**

DCC was apprised about the key recommendations of the sub-committee with respect to implementation of Mobile app based Information System (MIS) and installation of CCTV camera at medical stores.

After detailed deliberation, DCC agreed that a separate robust MIS or a centralised drug portal may be developed which should be capable of providing all relevant information including the real time data for such drugs in a comprehensive manner.

Further, DCC also agreed that installation of CCTV camera at medical stores may be made mandatory by amending the Rules. DCC also proposed that camera shall be placed appropriately in the premises so that sale made at such premises may be verifiable.

## AGENDA NO. 3

**Deliberation on Proposal for Development of a Real-Time Digital Portal for Tracking Pharmaceutical Products Regulated under the NDPS Act**

DCC was apprised about the need for a centralized, real-time, end-to-end digital tracking mechanism for manufacture, import/export, sale/distribution, stock etc of pharmaceutical Products regulated under the NDPS Act. DCC also deliberated about the proposed scope of the digital portal, key functional features, regulatory and legal considerations, role of CDSCO and State Drug Regulatory Authorities, Implementation Strategy and its anticipated benefits.

After detailed deliberation, DCC approved the proposal. It was further opined that a meeting of CDSCO may be held with CBN on the matter, as CBN presently maintains a portal for the manufacturing units. DCC also recommended that once this portal is developed, access may be provided to all the concerned agencies for effective surveillance and monitoring.

## AGENDA NO. 4

**Proposal for submission of report of the expert committee constituted to examine the proposal for listing of certain drugs to Schedule H1 and Schedule X of Drugs Rules, 1945 in light of misuse and intoxication**

DCC was apprised about the key recommendations of the sub-committee to examine the matter. DCC deliberated the matter in detail and approved the recommendations of the sub-committee for:

1. Retention of Dicyclomine in Schedule H
2. Inclusion of Flupentixol, Zopiclone, Gabapentin, and Carisoprodol in Schedule H1

## AGENDA NO. 5

**Discussions w.r.t. roadmap proposed for enforcement of all the NDPS drugs listed in NDPS Act, 1985**

DCC was apprised about the action points w.r.t. roadmap proposed to the Ministry of Home Affairs for enforcement of all the NDPS drugs listed in NDPS Act, 1985.

After detailed deliberation, DCC agreed with the proposed action(s). However, as regard to the proposal regarding execution of Risk Based Inspections (RBI) of such drugs, DCC proposed to arrange a stakeholder consultation of States, Narcotics Control Bureau (NCB), Central Bureau of Narcotics (CBN) and CDSCO for taking further necessary action in the matter.

## AGENDA NO. 6

**Consideration of the proposal to examine the recommendations received from High Level Committee (HLC) on Non-Financial Regulatory Reforms**

DCC was apprised about HLC-Sameeksha Portal developed by NITI Aayog for the purpose of Monitoring & Implementation of the recommendations of the HLCs.

DCC discussed on each of recommendations of HLC and opined as under:

1. **Amend the Drugs Rules, 1945 and NDCT Rules, 2019, made under the Drugs and Cosmetics Act, 1940 to enable Notified Bodies to conduct periodic planned audits of drug manufacturing, clinical trial, laboratories and blood bank sites.**

With respect to amending the Drugs Rules, 1945 and NDCT Rules, 2019 to enable Notified Bodies to conduct periodic planned audits of drug manufacturing, clinical trial, laboratories and blood center sites, it was apprised to the DCC that engagement of Notified Bodies is a capacity augmentation exercise to help regulators.

DCC deliberated the matter and recommended that a sub-committee may be constituted to evaluate the issue with respect to enabling of Notified Bodies to conduct periodic planned audits of drug manufacturing, clinical trial, laboratories and blood center sites. Report of the sub-committee may be placed before DCC for further deliberation.

**2. Create public performance dashboard under the DDRS portal with reported average timeline for approvals (separate by category for biologics and other drugs) making it a unified platform for exchange of information related to CDSCO.**

DCC agreed with the recommendations of creation of such public performance dashboard under the DDRS portal as above.

**3. Replace approval under Form 29 from State FDA for examination, test or analysis with a notified-based system.**

**4. Retail Pharmacy deregulation**

(a) Introduce performance-based premises standards aligned with global practice by replacing rigid numeric requirements for pharmacies.
(b) Remove the requirement to include the name of the competent person in-charge on the pharmacy licence.
(c) Allow applicants to notify the Licensing Authority of the appointed qualified person in-charge within 15 days of commencement of operations, and require only a simple notification for any subsequent change
(d) Remove the mandate of registration of lease deed for the purpose of establishment of pharmacy

**For point no. 3 and 4**:

DCC recommended constituting a sub-committee for amending the proposal regarding replacing approval under Form 29 from State FDA for examination, test or analysis with a notification-based system as well as Retail Pharmacy deregulation as proposed above and placing of report before DCC for further deliberation.

## AGENDA NO. 7

**Proposal for debarment of premises and promoter of wholesale licence, Manufacturing Licence, Private Testing Lab, etc. for further licensing under Drugs and Cosmetics Act and Rules if the license has been cancelled**

DCC was apprised that several instances have been reported where license is cancelled by the concerned licensing authority due to various reasons including the non-compliance to GMP norms and in the same premises, other license has been issued immediately or same person applies for other license and thus undermining the regulatory intent.

DCC deliberated the matter and recommended that a sub-committee may be constituted to evaluate the issue with respect to provision for debarment of premises/person/firm from further licensing if its license has been cancelled under the provisions of Drugs and Cosmetics Act and rules thereunder.

## AGENDA NO. 8

**Proposal for displaying the brief details of the firms under RBI, along with recommendations of the inspection team**

DCC was apprised to examine the feasibility of displaying brief details of firms inspected under RBI along with the recommendations of the inspection team, after due consideration of legal implications. DCC noted that at present, there is no system for public disclosure of these recommendations.

DCC deliberated the matter and recommended that a sub-committee may be constituted to deliberate on the feasibility and legal implications of displaying brief details of firms inspected under RBI along with inspection team recommendations on the official CDSCO website.

## AGENDA NO. 9

**Proposal on issue of dispensing exact prescription quantities of strip-packed medicines**

DCC was apprised about a public grievance received highlighting refusal of pharmacies to dispense cut/ loose strips (e.g., 5 tablets when prescribed, but strips contain 10-15), forcing patients to buy excess and incur unnecessary costs (Rs. 5-100 per strip).

DCC deliberated the matter and recommended to refer the matter to sub-committee already constituted in 66$^{th}$ meeting of DCC dated 17.06.2025 to examine the matters of labelling.

## AGENDA NO. 10

**Deliberation on Strengthening Regulatory Oversight and Enforcement against Surrogate Advertising of Prescription-Only Medicines**

DCC was apprised about an advisory issued by CDSCO dated 10 March 2026 regarding the promotion and advertisement of prescription-only medicines, including GLP-1 receptor agonists and similar drugs indicated for obesity and metabolic disorders under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945.

DCC deliberated the matter and agreed with the following recommendations:

1. State and Union Territory Drug Controllers should keep a vigil to ensure that Marketing Authorization Holders strictly comply with approved indications, labelling requirements, ethical marketing practices, and applicable Risk Management Plan (RMP) obligations, and that vulnerable populations are not exploited through misleading promotional practices.

2. Effective enforcement actions for significant violations may be taken by respective state/UT under intimation to CDSCO.

3. IPC to compile a monthly/bi-monthly review of adverse events of such drugs for further necessary action.

## AGENDA NO. 11

**Proposal regarding problem faced by the blind or visually impaired people to read medicines tablets/capsules strips**

DCC was apprised about the key recommendations of the sub-committee constituted to examine the problem faced by the blind or visually impaired people to read a

medicine tablets/capsules strips. DCC also noted that several public comments have been received after placing the sub-committee report on CDSCO website.

After deliberating the matter, DCC opined that the public comments so received may be placed before the existing sub-committee for review. The recommendations by sub-committee further may be placed before DCC.

## AGENDA NO. 12

**Proposal for regulation of Formulation intermediates such as Directly Compressible granules, taste masked granules, Modified release granules/ Pellets and other excipients for direct compression /capsule filling**

DCC was apprised about the opinion of internal technical discussion of CDSCO with respect to uniformity in licensing system for formulation intermediates across the country.

DCC deliberated the matter and recommended to issue a clarification in this regard by CDSCO as under:

1. For New Drugs including SR/ER/PR/DR and other similar intermediate requires CDSCO marketing authorization permission under NDCT Rules 2019

2. For drugs (including intermediates) other than New Drugs including directly compressible granules, the manufacturers may approach SLA.

   Further, in case of use of new/novel excipients, the CDSCO approval will be required.

## AGENDA NO. 13

**Discussion w.r.t. the various recommendations as per the NAP-AMR 2.0**

DCC was apprised regarding the various recommendations as per the NAP-AMR 2.0 which was developed in alignment with the Global action plan on AMR and officially released by Hon'ble Union Minister of Health & Family Welfare on 18th November 2025. DCC deliberated the matter and recommended to constitute a sub-committee to deliberate on the proposal for:

**1.** Development of guidance document for the State Drugs Controllers and especially, the GMP inspectors for management of waste and waste water from the production of Antimicrobials.
**2.** Development of separate guidelines to ensure quality management system for supply chain management of antimicrobials.
**3.** Development of Unified portal for rational use of antimicrobials and implementation of guidance which will ensure better enforcement by the State Drugs Controllers.

4. To prepare guidance for State Licensing Authorities and Pharmacy Associations for implementation of Schedule H & H1 drugs.
5. Appointment of Nodal officer in each state to conduct enforcement activities related to AMR

The report of the sub-committee may be placed before DCC for consideration.

## AGENDA NO. 14

**Consideration of the report of sub-committee constituted by DCC to examine the matter related to labelling of medicinal products**

DCC was apprised about the key recommendations of the report of sub-committee constituted by DCC to examine the matter related to labelling of medicinal products.

DCC deliberated the issue and recommended for inclusion of Retail Pharmacist Association in the sub-committee for reviewing issues faced by consumers/patients.

Report may be placed before DCC after due review as proposed.

## AGENDA NO. 15

**Consideration of the sub-committee Report constituted by DCC to examine the matter for categorization of Thermostable and Thermolabile drugs**

DCC was apprised about the key recommendations of the report of sub-committee constituted by DCC to examine the matter for categorization of Thermostable and Thermolabile drugs.

DCC deliberated the issue and recommended for revision of Schedule P of Drugs Rules 1945 and consequential changes as per sub-committee report.

## AGENDA NO. 16

**Testing of Vaccines/Biological and other products in Private Testing Laboratory (PTL)**

DCC was apprised about the various conditions which are required to be complied by the private testing laboratories before granting approval in Form 37.

As regard to approval for testing of Biological products, DCC deliberated the issue and recommended for amending the rules for granting approval by CLAA for testing of such products.

## AGENDA FROM JHARKHAND

## AGENDA NO. 17

**Deliberation on State/UT level orders/notifications restricting sale and distribution of certain drugs**

DCC was apprised about monitoring and regulation of the sale and distribution of drugs prone to misuse, including Schedule H, H1, and NDPS-linked formulations by several State Drug Controllers through issuance of notifications/orders from time to time. These actions were taken in view of increasing incidents of abuse, diversion, and illegal circulation of such drugs, as highlighted in NCORD meetings and various State-level review meetings.

DCC deliberated the present issue raised by the State Drugs Controller, Jharkhand.

DCC noted that the matter is sub-judice and DCC may wait for court's decision.

Meeting ended with the vote of thanks to the Chair.

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# LIST OF PARTICIPANTS

**List of the participants of 68th Drugs Consultative Committee meeting held on 20.03.2026 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.** | Andhra Pradesh | Shri. MPR Prasad | Director |
| **2.** | Assam | Shri Biswajit Talukdar | Drugs Controller |
| **3.** | Bihar | Sh. Dev Kumar, DCO | Representative of DC |
| **4.** | Chhattisgarh | Shri. B. R . Sahu | SLA |
| **5.** | Goa | Smt. Shweta Dessai | Director, FDA |
| **6.** | Gujarat | Sh. H.L. Rawat | Joint Commissioner |
| **7.** | Haryana | Sh. Ripan Mehta | Deputy State Drugs Controller, FDA |
| **8.** | Himachal Pradesh | Dr. Manish Kapoor | Drugs Controller |
| **9.** | Jharkhand | Smt. Ritu Sahay | Director (Drugs) |
| **10.** | Karnataka | Dr. Umesh | Additional Drugs Controller |
| **11.** | Kerala | Dr. Sujith Kumar | Drugs Controller |
| **12.** | Madhya Pradesh | Sh Dinesh Shrivastava | SLA |
| **13.** | Maharashtra | Sh Vijay Jadhav | Joint commissioner Drugs Greater Mumbai |
| **14.** | Manipur | Sh. Seram Baleshwar Singh | Drugs Licensing Authority |
| **15.** | Meghalaya | Mrs Aurelia Rela Kharwanlang | Drugs Controller |
| **16.** | Mizoram | Shri. F Lalliantluanga | Drugs Controller |
| **17.** | Nagaland | Ethungbemo ezung | Assistant Drugs Controller |
| **18.** | Odisha | Mrs. Mamina Patnaik | Drugs Controller |
| **19.** | Punjab | Sh. Sanjeev Kumar | Joint Commissioner (Drugs) |
| **20.** | Rajasthan | Shri Ajay Phatak | Drug Controller |
| **21.** | Sikkim | Shri. Lyangain Martin Targain | Director & Licensing Authority |
| **22.** | Tamil Nadu | Thiru. S. Gurubharathi | Deputy Director of Drugs |

| S. No. | State/UT | Name | Designation |
|---|---|---|---|
| | | | Control |
| **23.** | Telangana | Sh. Shahnawaz Qasim | Deputy Director<br>DCA Telangana |
| **24.** | Tripura | Shri. Subrata Das | State Drugs Controller |
| **25.** | Uttar Pradesh | Shri. Shashi Mohan Gupta | Drugs Licensing and Controlling Authority |
| **26.** | Uttarakhand | Sh. Tajber Singh | Drugs Controller |
| **27.** | West Bengal | Sh. Rathindra Nath Roy<br>Sh. Arup Boral, ADC | Directorate Of Drugs Control |
| **28.** | Chandigarh | Sh. Dinesh | ADC |
| **29.** | Dadar and Nagar Haveli | Dr. Dharmesh Agrawal | Drugs Controller |
| **30.** | Pondicherry | Dr. E. Anandakirouchenane | Drugs Controller |
| **31.** | Delhi | Sh. Rajeev Bhargava | Deputy Drugs Controller/Controlling Authority |
| **32.** | Ladakh | Mrs. Nasreen Bano | ADC Cum Licencing Authority |
| **33.** | Jammu and Kashmir | Sh. Rajesh Kumar | SDC |
| **34.** | Lakshadweep | Aneesa Hassan PV, DI | Representative of DC |

**B. CDSCO (Head Quarters)**

| S. No. | Name | Designation |
|---|---|---|
| 1. | Dr. Rajeev Singh Raghuvanshi | Drugs Controller General of India |
| 2. | Dr. A Visala | Joint Drugs Controller (India) |

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

**D. Deputy Drugs Controllers of CDSCO HQ**

**E. Special Invitees: -**

1. Sh. Dinesh Bouddh, Narcotics Commissioner
2. Sh. Brijendra Chowdhary, Deputy Narcotics Commissioner CBN
3. Sh. D.S.Singh, Assistant Commissioner, CBN
4. Sh. Sunil Kumar Verma, CBN, Gwalior
5. Dr. Vivekanandan Kalaiselvan, Secretary-cum-Scientific Director, IPC