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)/1/2025-eoffice
Comp. No. 23335

Dated: 24 JUN 2025

To

All State/ UT Drugs Controllers

Sub: Minutes of the 66th Meeting of the Drugs Consultative Committee (DCC) held on 17.06.2025 through Hybrid mode - reg.

Sir/Madam,

66th meeting of the Drugs Consultative Committee was held on 17.06.2025 through Hybrid mode.

The minutes of the 66th 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. PS to Advisor (Cost), MoHFW, Nirman Bhawan, New Delhi
3. DDC (I) of Zonal & Sub-zonal offices
4. Directors of Labs of CDSCO
5. CDSCO website

MINUTES OF 66TH MEETING (HYBRID MODE) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD ON 17TH JUNE, 2025 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.

DCG(I) in his opening remarks highlighted the need for strengthening of Drug Regulatory System throughout the country and appreciated the support extended by all the States.

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 (ATR) of 65thDCC meeting held on 20.12.2024.

The Drugs Consultative Committee deliberated the Action Taken Report (ATR) of the agenda items of 65th DCC meeting held on 20.12.2024 and the Action Taken Report was considered as approved.

Agenda No. 2

Consideration of the proposal for sensitizing the State Regulatory Authorities w.r.t. various initiatives taken by the Ministry of Health and Family Welfare and CDSCO

DCC was apprised that in recent past, CDSCO has taken a number of steps where cooperation of State Licensing Authorities is required. Some of the concern areas are as under:

- Implementation of revised Schedule M.
- To refrain from issuance of licence without new drug permission from DCGI.
- Issuance of product licence without having BA/ BE study data for BCS Class II & IV drugs.
- To take action as recommended during Risk Based Inspection.
- Uploading and verification of details of manufacturers and their products on online portal as per the requirement of rule 84AB.
- Implementation of State Drug Regulatory Index.
- Capacity building of the Government drug testing laboratories.
- Onboarding on ONDLS
- Action against spurious and NSQ drugs

It was discussed that States should accord priority for the above issues to ensure uniformity and compliance.

The DCC Chairman also placed on record its appreciation to all States/ UTs for their cooperation in carrying out more than 1000 RBI across the country.

DCC was apprised that only 16 States/ UTs have on-boarded on ONDLS portal for manufacturing and sale related licenses and other states are yet to on-board. The Chairman apprised about the importance of on boarding on ONDLS for achieving uniformity in the processing of application across the country. Further, all the members were also requested to obtain application of LVP and Blood Centre through ONLDS portal only.

All the States were requested to provide their continued support on the various activities as stated above and also to make proactive approach in taking suitable/ appropriate regulatory action against manufacture(s) not complying with the requirements and repeatedly manufacturing the NSQ product.

It was also recommended that the States while taking such regulatory action shall also keep CDSCO informed for taking better regulatory decisions in order to further strengthen the drug regulatory system in the country.

Agenda No. 3

Consideration of the proposal to incorporate suitable provisions under Drugs Rules, 1945 for better availability of pharmacist in the rural areas

DCC was apprised that an O.M. was received from CTP Division, Ministry of Cooperation on the subject cited above wherein one of the discussion point is as under:

“vii. Drug Controller General of India to devise a suitable policy through necessary modifications/ amendments in existing rules to resolve the problem of availability of pharmacist in the rural areas.”

DCC was also apprised that a letter dated 11.06.2025 has also been written to the State/ UTS Drugs Controller requesting them to provide comments/opinion on devising a suitable policy and necessary amendments in this regard at the earliest.

DCC deliberated the issue in length related to better availability of pharmacist in rural areas. During the discussion, the various SLAs informed that they have not faced any such problem in their state regarding the non-availability of pharmacist.

However, it was proposed that in case such professionals face any problem in registering them as pharmacist, SLAs can assist for the purpose.

DCC also opined that currently there are plenty of pharmacy colleges and adequate number of pharmacist in the country. Further, there are already provisions of granting restricted licensees under Drugs and Cosmetics Act and rules made

thereunder which can be invoked by the SLAs as these licensees do not require presence of registered pharmacist.

DCC recommended that Ministry of Corporation may be informed accordingly.

Agenda No. 4

Consideration of the proposal for amendment in Form 27D, 27DA, 28D and 28DA to include the word "Cell or Stem Cell derived products, Gene Therapeutic products or Xenografts, etc."

DCC was apprised that the matter was deliberated in the 63rd meeting of DCC wherein the committee agreed with the proposal and thereafter the matter was deliberated in the 91st DTAB meeting wherein the Board agreed for proposed amendment under Form 27D, 27DA and Form 28D and Form 28DA of Drugs Rules, 1945 for inclusion of the words "Cell or Stem Cell derived products, Gene Therapeutic products or Xenografts, etc."

DCC was also apprised that a draft notification was prepared in the matter. However, it was decided for a stakeholder consultation in the matter along with deliberation in the DCC.

Thereafter, a stakeholder consultation was conducted in the matter wherein all stakeholders agreed with the proposed agenda.

DCC after detailed deliberation agreed with the proposal to appropriately amend the Drugs Rules, 1945.

Agenda No. 5

Consideration of the proposal to amend Drugs Rules, 1945 to regulate alcohol content in tinctures/ other alcoholic preparations to curb their illegal sale across pharmacies

DCC was apprised that the proposal was deliberated in 92nd DTAB meeting wherein the DTAB agreed that the rules may be amended and exemption provided for alcoholic preparations containing the alcohol content 30ml or above in Schedule K may be removed and such preparations may be included in Schedule H1.

DCC was also apprised that a draft notification was prepared in the matter. However, it was decided to discuss the matter in the DCC afresh.

DCC discussed the draft notification prepared for the purpose and after detailed deliberation agreed with the proposal to appropriately amend the Drugs Rules, 1945.

Agenda No. 6

Consideration of the proposal for exemption from the requirement of wholesale licence for liquid antiseptic for house hold use and exemption for the requirement of retail sale licence for hospital grade antiseptic under Schedule K of Drugs Rules, 1945

DCC was apprised that the proposal was deliberated in 91st DTAB meeting and after deliberation the Board agreed for amendment at entry no. 39 of Schedule K of Drugs Rules, 1945 w.r.t. liquid antiseptic.

DCC was also apprised that a draft notification was prepared in the matter. However, it was decided for a stakeholder consultation in the matter along with deliberation in the DCC.

Thereafter, a stakeholder consultation was conducted in the matter wherein all stakeholders were of the view to consider the proposed agenda.

DCC after detailed deliberation agreed with the proposal to appropriately amend the Drugs Rules, 1945.

Agenda No. 7

Consideration of the proposal for affixing Bar code/ QR code on the label of all Vaccines, Antimicrobials, Anticancer and Narcotics Drugs & Psychotropic Substance mention under NDPS Act

DCC was apprised that the proposals regarding affixing of Bar code/ QR code on the label of all Vaccines, Antimicrobials, Anticancer and Narcotics Drugs & Psychotropic Substance mention under NDPS Act were deliberated and agreed by 90th and 91st DTAB meetings.

DCC was also apprised that as per the recommendation of 90th and 91st DTAB meetings w.r.t. subject cited proposals, a draft notification was prepared in the matter. However, it was decided for a stakeholder consultation in the matter along with deliberation in the DCC.

Thereafter, a stakeholder consultation was conducted in the matter on 16.05.2025, during the meeting two of the stakeholders have raised concerns that the usages in terms of scanning is dismal (0.3%) and capital investment is appreciable. Further industry also does not benefit in brand equity after spending additional in crores.

DCC after detailed deliberation opined that the manufacturers should raise public awareness regarding the use of QR code and the concerns raised by the stakeholders do not appear to be substantial in public interest and accordingly agreed with the proposal to appropriately amend the Drugs Rules, 1945.

Agenda No. 8

Consideration of the proposal for regulation of newer Anti-TB drugs (Bedaquiline, Delamanid, Pretomanid and Rifapentine in the private market

DCC was apprised that CDSCO has received letter from the Central TB division, Ministry of Health and Family Welfare wherein it is stated that the patent for bedaquiline drug and Delamanid expired last year leading to its production by multiple Pharma Companies have started manufacturing the molecule and the drug has been made freely available in the private market. This open market access risks indiscriminate use, potentially increasing cases of treatment failure and resistance to these drugs.

To mitigate thisrisk, it has been requested to issue the licenses with condition **for use of Bedaquiline, Delamanid, Pretomanid and Rifapentine as per Standards of TB Care in India (STCI) & Conditional access through National TB Elimination programme (NTEP)** and also stated that if such condition is not mentioned in the existing licenses issued to all the current license holders of the drug, it then be modified accordingly.

DCC was also apprised that as these drugs have already crossed more than 4 years and now do not bear the status of a new drug, the SLAs are requested to issue the licenses with condition **for use as per Standards of TB Care in India (STCI) & Conditional access through National TB Elimination programme (NTEP).**

Further, the label on the immediate container of the drug as well as the packing in which the container is enclosed should bear the following "**WARNING: For the use in National TB Elimination Programme (NTEP)"** which shall be in box with red background.

DCC after detailed deliberation agreed with the proposal to issue suitable guidance to all the SLAs to uniformly address the issue. DCC also recommended that in case some of the SLAs had already issued the manufacturing licence for such product. They can issue separate letter for communicating the above conditions to such manufacturers.

Agenda No. 9

Consideration of the proposal regarding guidelines on Good Distribution Practices for pharmaceutical products

DCC was apprised that the proposal was deliberated in the 64th DCC meeting wherein it was observed that and draft guideline for inclusion as schedule under the Drug Rules has been prepared in line with revised WHO TRS guidelines and applicable rules. After detailed deliberation, the committee opined that the proposed guidance document may be deliberated in consultation with stakeholders before taking further action.

Thereafter a stakeholder's consultation was conducted on the GDP guidelines and the comments received were deliberated by the DCC.

DCC was also apprised about the concerns raised by the stakeholders and DCC after detailed deliberation agreed with the proposal to appropriately amend the Drugs Rules, 1945.

Agenda No. 10

Consideration of the proposal for revision of limits for microbial contamination in "Grade A'' area in Schedule M as per WHO Technical Report Series (TRS) 1044 annexure II

DCC was apprised about the mismatch between the requirement of recommended limit of antimicrobial contamination mentioned in Table II of Para B under the Part XIID of Schedule M as well as the requirement mentioned in WHO TRS 1044 Annexure II.

DCC after detailed deliberation opined that said limit for antimicrobial contamination mentioned in Table II of Para B under the Part XIID of Schedule M may be appropriately amended in line with the WHO TRS 1044 Annexure II.

Agenda No. 11

Consideration of the proposal for implementation of recommendations/Institutional Development Plan (IDP) w.r.t. Market Surveillance and Control function subsequent to WHO NRA assessment

DCC was apprised about the various recommendations of Institutional Development Plan (IDP) w.r.t. Market Surveillance and Control function subsequent to WHO NRA assessment.

The matter was deliberated with the DCC members along with the CDSCO proposal for compliance. The members agreed to take suitable action as proposed by CDSCO for the Institutional Development Plan (IDP) on Market Surveillance and Control function. DCC also recommended that a detailed letter from DCGI may be written to all the States/ UTs Drugs Controllers in the matter along with the appropriate SOPs/ Formats, etc. to enable the States to implement the action point in a uniform manner.

Agenda No. 12

Discussion on issuance of product permission/ license to the manufacturers for New Drug by SLAs without approval from the CLA

DCC was apprised that as per the rules, the State Licensing Authorities must check the approval, in writing, in favour of the applicant to manufacture drug formulations

falling under the purview of new drug as defined in rule 2(w)(iv) of NDCT Rules, 2019, from theCentral Licensing Authority (CLA).

Time and again it has been brought to the knowledge of CDSCO that manufacturing permission for such new drugs are issued by State Licensing Authorities without necessary permission from theCLA.

DCC was also apprised that various directions as well as letters have also been issued in this regard.

After detailed deliberation, all the members unanimously agreed for compliance of necessary permission from CLA before granting any licence to the manufacturers.

Agenda No. 13

Consideration of the proposal regarding various concerns of consumers w.r.t. labelling of medicinal products

DCC was apprised that the Various concerns have been received from the consumers in their Public Grievances from time to time w.r.t. the labelling of medicinal products. Some of the concerns raised are as follows:

1. The paper where expiry date is mentioned is torn while taking out the medicine.
2. The surface of the medicine strip is too shiny to read the details.
3. The letters of expiry date are too small.
4. The name of the medicine should be printed on continuous basis instead of at one place only.
5. There should be universally recognised symbol on the generic medicines that will distinguish it from the branded medicines.

DCC after deliberation recommended that the DCGI may constitute a sub-committee to look in to the matter of packaging issue in detail and submit its report. DCC also recommended to include one packaging expert in the sub-committee. Further, the sub-committee shall also evaluate the feasibility of incorporating suitable regulation for suppliers of packaging materials/ printed foils, etc. under Drugs Rules, 1945.

Agenda No. 14

Consideration of the proposal regarding problem faced by the blind or visually impaired people to read medicines tablets/capsules strips

DCC was apprised that the proposal was deliberated in the 58th DCC meeting and after thorough deliberation, the DCCrecommended for constituting a sub-committee to examine the issue in detail for its further consideration.

Accordingly, the sub-committee has submitted its report for further deliberation in the meeting.

DCC after deliberation opined that the recommendations of the sub-committee may be placed on the CDSCO website for public comments along with the below mentioned additional points:

I. Secondary packaging containing more than 10 units of medicines may have some braille cards for giving to such population as and when required.

II. Medicines can have QR code linked with voice assistance.

Agenda No. 15

Consideration of the proposal from Botswana and Burkina Faso, on behalf of the Africa region, to amend Part I and Part II of annex A of the Minamata convention on mercury on cosmetics to be considered by the conference of the parties at its fifth meeting

DCC was apprised that the proposal was deliberated in the 63rd DCC meeting wherein DCC opined that a sub-committee may be constituted which may also include medical health hazard experts dealing with elemental impurity, an expert from the Ministry of Environment & Forest. Further, it was also opined that the sub-committee may also look into India's obligations in respect of the Minamata Convention on Mercury, if any.

Accordingly, the sub-committee has submitted its report for further deliberation in the meeting.

DCC after detailed deliberation opined that at present the Cosmetics Rules, 2020, under Drugs and Cosmetics Act, 1940, are in line with the Minamata convention on mercury on cosmetics and at present no further amendment is required in the rules. Ministry of Environment and Forest may be informed accordingly.

AGENDA FROM TAMILNADU

Agenda no. 16

Consideration of the proposal to revise the guidelines for taking action on samples of drugs declared as Not of Standard Quality in light of new rules- Drugs and Cosmetics (Compounding of Offences) Rules, 2025

DCC was apprised about the agenda. DCC noted that the similar proposal for updation of guidelines w.r.t. samples of drugs declared as spurious or NSQs was already discussed in 65th DCC.

During the closing remarks, the DCGI also requested all the SLAs to monitor the small marketing companies involved in supplying of medicines in rural areas so that they can be made accountable and action shall be taken against such marketer under the Drugs Rules, 1945, for any non-compliance to the quality standards.

Meeting ended with the vote of thanks to the Chair.

****

List of participants enclosed.

List of the participants of 66th Drugs Consultative Committee meeting held on 17.06.2025 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. BiswajitTalukdar	Drugs Controller
3.	Bihar	Shri. NityanandKishloya	Drugs Controller
4.	Goa	Smt. Shweta Dessai	Director, FDA
5.	Gujarat	Shri. R M Patel	Deputy Commissioner, FDCA
6.	Haryana	Sh. Manmohan Taneja	Drugs Controller
7.	Himachal Pradesh	Dr. Manish Kapoor	Drugs Controller
8.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
9.	Karnataka	Shri. B P Arun	State Licensing and Approving Authority
10.	Kerala	Dr.Sujith Kumar	Drugs Controller
11.	Madhya Pradesh	Shri. Mayank Aggarwal	Drugs Controller
12.	Maharashtra	Shri. D.R. Gahane	Drugs Controller
13.	Manipur	Shri. Seram Baleshwar Singh	Drugs Controller
14.	Mizoram	Shri. F Lallian	Drugs Controller
15.	Odisha	Mrs. Mamina Patnaik	Drugs Controller
16.	Punjab	Shri. Amit Duggal	Assistant Commissioner
17.	Rajasthan	Shri Ajay Phatak and Shri. Raja Ram Sharma	Drug Controller
18.	Sikkim	Shri. Lyangain Martin Targain	Director and State Licensing Authority
19.	Tamilnadu	Sh. M. N. Sridhar	Director of Drugs Control (i/c)
20.	Telangana	Shri. G. Ramdhan	Joint Director
21.	Tripura	Shri. Subrata Das	State Drugs Controller

S. No.	State/UT	Name	Designation
22.	Uttar Pradesh	Shri. Shashi Mohan Gupta	Drugs Licensing and Controlling Authority
23.	Uttarakhand	Sh. Tajber Singh	Drugs Controller
24.	West Bengal	Shri. Rathindranath Ray	State Licensing Authority
25.	Andaman and Nicobar	Dr.MunniSingania	Drugs Controller and State Licensing Authority
26.	Chandigarh	Dr.Suman Singh	Director Health Services and Drugs Controller
27.	Pondicherry	Dr. E. Anandakirouchenane	Controlling Cum Licensing Authority
28.	Delhi	Shri. K R Chawla	Head of Department and State Licensing Authority
29.	Ladakh	Mrs. NasreenBano	ADC Cum Licencing Authority
30.	Jammu and Kashmir	Mrs. LotikaKhajuria	Drugs Controller
31.	Lakshadweep	Shri. Barani DHS	Drugs Controller

B. CDSCO (Head Quarters)

S. No.	Name	Designation
1.	Dr. Rajeev Singh Raghuvanshi	Drugs Controller General of India
2.	Smt. A Visala	Joint Drugs Controller (India)
3.	Shri. R. Chandrashekar	Joint Drugs Controller (India)
4.	Shri. A. K. Pradhan	Advisor
5.	Shri. Rishi Kant	Legal Advisor

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. Vivekanandan Kalaiselvan, IPC