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)/2/2025-eoffice
Comp. No. 28492

Dated: 25.11.2025

To

All State/ UT Drugs Controllers

Sub: Minutes of the 67th Meeting of the Drugs Consultative Committee (DCC) held on 17.11.2025 through Hybrid mode - reg.

Sir/Madam,

67th meeting of the Drugs Consultative Committee was held on 17.11.2025 through Hybrid mode.

The minutes of the 67th 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 67th MEETING (HYBRID MODE) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD ON 17th NOV, 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 importance of enhancing the Drug Regulatory System throughout the country and expressed appreciation for the cooperation extended by all States. During his remarks, the DCGI requested all the SLAs to start preparing for conducting the inspections of the manufacturing units for verifying the compliance to the requirements as prescribed under revised Schedule M which has been communicated vide CDSCO letter dated 07.11.2025.

DCGI also requested all the States/UTs (who haven't yet on boarded) to onboard on ONDLS portal at the earliest so as to achieve uniformity in the inspection and licensing system across the country.

DCGI further requested all the States/UTs for their urgent action to ensure compliance with respect to requirements of BA/BE studies for BCS Class II and IV drugs for which a communication dated 11.09.2025 has already been forwarded to all the States/UTs.

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 66th DCC meeting held on 17.06.2025

The Drugs Consultative Committee deliberated the Action Taken Report (ATR) of the agenda items of 66th DCC meeting held on 17.06.2025 and the Action Taken Report was considered as approved.

AGENDA NO. 2

Consideration of the proposal to review the exemptions provided under entry no. 13 of Schedule K of Drugs Rules, 1945

DCC was apprised about the recent incidences due to contaminated cough syrup and it was proposed that the exemption provided under **Entry no.13** of Schedule K of Drugs Rules, 1945 in respect of syrups for cough may be deleted.

DCC deliberated the matter and approved the proposal.

AGENDA NO. 3

Consideration of the proposal for regulation of formulation intermediates

DCC was apprised on regulation of formulation intermediates such as DC granules / Pellets containing API and other excipients for direct compression /capsule filling which have to be considered as formulated bulk to meet the applicable quality standards such as dissolution profile, etc.

DCC deliberated the issue in detail and opined that the matter may be examined internally at **CDSCO** and shall be placed before the DCC for appropriate action.

AGENDA NO. 4

Consideration of the proposal for separate 'FORM' for bulk drug license for wholesale

DCC was apprised that sale and distribution of bulk drugs including APIs are covered under a whole sale license which is common for formulation as well as bulk meaning there are no separate forms for licensing of API/Excipient and formulation for wholesale. These two activities are not common as bulk drug sellers deals with the manufactures while formulations sellers deal with retail sellers. Further, there is no data in the country that how many wholesalers are dealing with the bulk drugs.

DCC deliberated the matter in detail and agreed with the proposal for separate requirements and form(s) for bulk drugs and excipients. DCC also suggested incorporating provision in such a way that the information regarding wholesalers dealing with NDPS category is captured in the license and also recommended that qualification of competent person may be degree in Science with one year experience in dealing of such raw materials or a registered pharmacist.

AGENDA NO. 5

Consideration of the proposal for issuance of license to marketer falling under the definition of Rule 2(ea) of Drugs Rules, 1945

DCC was apprised that at present there is no provision for monitoring the functions of marketers to ensure quality, safety and efficacy of products marketed. In many cases, the Marketer details (address & Constitution details) are also not readily available for communication for various regulatory purposes. Provisions need to be included in the rules requiring that no marketer shall market any drug without license obtained from the licensing authority.

DCC deliberated and recommended that Rules may be amended by incorporating provisions for issuance of **license** for marketers by including various conditions.

AGENDA NO. 6

Proposal for Implementation of Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high risk solvents

DCC was apprised and sensitised regarding letter issued by CDSCO dated 7.10.2025 with respect to implementation of Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high risk solvents wherein all States/UTs Drug Controllers were requested to ensure that pharma grade solvent manufacturers upload details on the ONDLS portal regarding each batch manufactured with quantity, CoA, etc. and details of the vendors to whom the high risk solvents are sold from time to time. State Drug Controllers of all States/UTs were accordingly informed to ensure that no batch is available in the market without complying with the above direction.

DCC noted and gave its concurrence in the matter.

AGENDA NO. 7

Concerns on usage of high risk solvents including Propylene Glycol and its related impurities in the oral liquid formulations

DCC was apprised that various cases regarding concerns on the use of Propylene Glycol and its related impurities i.e. DEG and EG in the Syrups for usage in Pediatric Population for therapeutic use have been reported.

It has been observed that many oral liquid formulations are manufactured using high risk solvents including Propylene Glycol. Therefore, there is risk of contamination of these formulations with DEG/EG.

The matter of using alternative excipients/formulations was also deliberated by the DCC.

In view of above, DCC opined that CDSCO may initially have consultation with the stakeholders to take stock of situation and to collate the details of the formulations that are manufactured using high risk solvents for taking further appropriate action.

AGENDA NO. 8

Consideration of issue of cancellation and suspension of Licenses granted under CLAA

DCC was apprised about importance of cancellation and suspension of Licences under CLAA scheme. DCC deliberated and recommended for developing a SOP in this regard for uniform implementation across the country. DCC also suggested to have legal opinion/vetting while preparing this SOP.

DCC recommended that draft SOP once prepared can be circulated to all stakeholders before its finalisation and adaption.

AGENDA NO. 9

Issue of use of brand name extensions by the pharmaceutical firms

DCC was apprised about a representation received alleging that a pharmaceutical company is marketing multiple drug formulations under the same established brand name with different extensions.

Concerns have been raised that the use of the same brand name for drugs with different active ingredients may mislead consumers and create confusion regarding their therapeutic use.

DCC deliberated the matter in detail and opined to carry out a stakeholder consultation in the matter considering various aspects.

AGENDA NO. 10

Consideration of the proposal for effective enforcement of medicine standards nationwide uniformly

DCC was apprised that concerns have been raised regarding “effective enforcement of medicine standard nationwide uniformly” wherein following issues have been raised:

1. Some states are lagging behind in the uniform implementation of prescribed drugs standards, testing facility of laboratories, skilled development of staff and creation of centralized agency for effective enforcement of drugs standard on national level.
2. Low conviction rate due to reasons like insufficient investigations, delay in testing results and ineffective prosecution services.
3. To implement rigorous scrutiny of adulteration in imported pharmaceuticals products.

DCC deliberated the matter in detail and stressed on the need for uniform implementation of standards nationwide. DCC also recommended that a letter may be written to all States to take proactive steps to address these issues. It was further suggested that Government may write a letter to the State Governments for providing the necessary infrastructure including the adequate manpower as highlighted under State Health Regulatory Excellence Index (SHRESTH).

AGENDA NO. 11

Consideration of the proposal for amendment in rules under Chapter VI Sales of Drugs other than Homeopathic medicines w.r.t. advertisement

DCC was apprised about the concern over the widespread and unchecked advertisement of prescription-only and potent drugs including life-saving injectables, antibiotics, hormonal preparations, psychotropic substances, anti-cancer drugs and narcotic drugs.

DCC noted that there is already provision in the Drugs Rules for the manufacturers under the conditions of licence that no advertisement of drugs specified in Schedule H, H1 and X shall be made except with the previous sanction of Central Government.

DCC deliberated the matter and recommended that similar provisions may be made in the Rules for licensees holding licence for sale or distribution.

AGENDA NO. 12

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 importance of assessment of NRA by CDSCO as per the Global Benchmarking Tool. DCC was also apprised that only the few States are sharing NSQs data with the CDSCO.

DCC recommended constituting a sub-committee in the matter to provide the modalities for preparing a comprehensive policy and a National Action Plan (NAP) in this regard.

Further, all the members of DCC also confirmed that NSQ data will be shared with CDSCO every month as per the provided format.

AGENDA NO. 13

Consideration of proposal to expand the WHO NRA benchmarking for medicines

DCC was apprised regarding the consideration of proposal to expand the WHO global benchmarking for medicines also. Therefore, it has been proposed that the states wherein well established regulatory system for medicines is already present, may voluntarily come forward for self-assessment and preparation for further benchmarking (assessment) of their regulatory system by WHO.

DCC deliberated the matter and recommended for conducting a consultation meeting for manufacturing States/UTs along with the WHO officials in this regard for better understanding and meaningful outcome.

AGENDA NO. 14

Consideration of the proposal for ensuring timely renewal of Licences of Blood Centres and mandatory conduct of Transfusion-Transmissible Infections (TTI) Testing by ELISA

DCC was apprised about the concerns of non-compliances of the provisions Drugs rules as observed in the recent incidents in the Hospital based blood centres and was requested as under:

1. Ensure periodic inspections of the all blood centres including the government hospital-based blood centres to verify compliance with the applicable rules. Special focus may be accorded to the testing of viral markers to ensure supply of safe blood.
2. The procedure laid down by the NBTC has to be followed while recommending the grant of blood centre licenses to charitable and voluntary organisations.
3. Disposal of applications for renewal in a time-bound manner to ensure compliance with the provisions.

States were sensitized in the matter and the DCC agreed to take all necessary measures to ensure compliances by the Blood Centres.

AGENDA NO. 15

Consideration of the report of the sub-committee to examine the proposal on drug regarding sampling and testing

As per the 62nd DCC recommendation, the report of the sub-committee was presented in the matter.

DCC noted the recommendation of the sub-committee and recommended that the States/UTs may adopt the procedure as may be feasible for improving the transparency in the sampling and testing procedure.

AGENDA NO. 16

Consideration of the report of sub-committee constituted by DCC to examine the action to be taken for implementation of the interventions/activities as per the National Action Plan (NAP-AMR) relating to regulatory agencies

As per the 61stDCC recommendation, the report of the sub-committee was presented in the matter.

DCC noted the recommendation of the sub-committee and recommended that CDSCO may share the report with all the States for appropriate action.

AGENDA NO. 17

Consideration of the report of the expert-committee constituted to examine the issues related to contraceptives

As per the 62nd DCC recommendation, the reports of the sub-committee were presented in the matter. DCC was apprised about the various recommendations of the DCC sub-committee.

DCC noted that based on the 91st DTAB meeting dated 14.08.2024, a draft notification has already been issued to avoid contradiction between provisions under Schedule K & Schedule H by providing a foot note under Schedule H that "Class of drugs mentioned at serial no. 15 of Schedule K shall not be covered under this Schedule". Hence the recommendation of DCC sub-committee for amendment in Schedule H w.r.t. chemical contraceptives mentioned under entry no. 15 of Schedule K of Drugs Rules, 1945 is already addressed.

Further, as regard to sub-committee recommendation for inclusion of Ulipristal in Schedule H, DCC noted that DTAB in its 92nd meeting held on 24.04.2025 has already recommended for updating the Schedule H list which also includes Ulipristal.

DCC didn't agree with sub-committee recommendation w.r.t. amendment under entry no. 31, 142, 186 and 304 of Schedule H as the proposed amendment may not serve the purpose as it will exclude certain categories of drugs from Schedule H i.e. androgenic anabolic.

However, based on other recommendations of the sub-committee, DCC agreed that:

1. Levonorgestrel Tablets 0.75mg/1.5mg that are emergency contraceptives shall be included/added as S.No.06 of entry No. 15 of Schedule K of Drugs Rules 1945
2. These should include the following boxed warnings on the primary & carton label and in package insert:
    a. Does not offer any protection against HIV or any sexually transmitted infections.
    b. Do not take this medicine for more than twice in a month.
    c. Use of alternative methods of contraception is encouraged in consultation with Registered Medical Practitioner.
3. The package insert shall include the details as recommended in the sub-committee report.

AGENDA NO. 18

Consideration of the report of the Expert- committee to examine the proposal for issuing guidelines 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

As per the 62nd DCC recommendation, the reports of the sub-committee were presented in the matter. DCC was apprised about the various recommendations of the DCC sub-committee.

DCC noted the recommendations of the sub-committee and recommended for circulation of the report to all the States/UTs for appropriate action.

AGENDA FROM HIMACHAL PRADESH

AGENDA NO. 19

Consideration of the proposal to insert Provision of registration of licensing for radio pharmaceuticals

DCC was apprised that under Schedule K of Drugs Rules, 1945, class of drugs listed at serial no. 20 exempts Radio Pharmaceuticals from all the provisions of Chapter IV of the Act and Rules made thereunder.

DCC deliberated the matter and recommended that a sub-committee may be constituted to evaluate the issue. Report of the sub-committee may be placed before DCC for further deliberation.

AGENDA NO. 20

Consideration of the proposal to include necessary provisions under Drugs Rules, 1945 to monitor the sale of certain drugs that are mentioned under Drugs Rules as well as NDPS Act

DCC was apprised about the agenda. DCC noted that there could be many issues related to enforcement of NDPS Drugs as various States are facing different types of problems in this regard.

DCC deliberated and recommended that a sub-committee may be constituted to evaluate all the issues at once. Report of the sub-committee may be placed before DCC for further deliberation.

AGENDA FROM GOA

AGENDA NO. 21

Consideration of the proposal to review Para 14.15 of revised Schedule M

DCC was apprised about the agenda.

DCC after deliberation opined that robust vendor validation is very important before approving any vendor for purchase of raw materials. Therefore, the Para 14.15 of revised Schedule M under Part 1 has be read with the other Rules as well as relevant provisions under the Schedule M.

Meeting ended with the vote of thanks to the Chair.

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LIST OF PARTICIPANTS

List of the participants of 67th Drugs Consultative Committee meeting held on 17.11.2025 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 Biswajit Talukdar	Drugs Controller I/c
3.	Bihar	Shri. Nityanand Kishloya	Drugs Controller
4.	Chhattisgarh	Shri. Deepak kumar Aggrawal	Drugs Controller
5.	Goa	Smt. Shweta Dessai	Director, FDA
6.	Gujarat	Sh. H.L. Rawat	Joint Commissioner
7.	Haryana	Sh. Lalit Goel	Drugs Controller
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	Shri. Dinesh Shrivastava	Controller, Food and Drugs Administration
13.	Maharashtra	Shri. D.R. Gahane	Drugs Controller
14.	Meghalaya	Ms. Aurelia Rela Kharwanlang	Assistant Drugs Controller (I/c)
15.	Mizoram	Shri. F Lalliantluanga	Drugs Controller
16.	Nagaland	Mr. Ethungbemo	Assistant Drugs Controller
17.	Odisha	Mrs. Mamina Patnaik	Drugs Controller
18.	Punjab	Shri. Sanjiv Garg	Joint Director (Drugs)
19.	Rajasthan	Shri Ajay Phatak	Drug Controller
20.	Sikkim	Shri. Lyangain Martin Targain	Chief Drugs Inspector/ Licensing Authority
21.	Tamil Nadu	Mr Nanda Kumar Ms Esther	Deputy Director Drugs Drugs Inspector
22.	Telangana	Shri. G. Sreeniwas	Deputy Director DCA Telangana

S. No.	State/UT	Name	Designation
23.	Tripura	Shri. Subrata Das	State Drugs Controller
24.	Uttar Pradesh	Shri. Shashi Mohan Gupta	Drugs Licensing and Controlling Authority
25.	Uttarakhand	Sh. Tajber Singh	Drugs Controller
26.	West Bengal	Shri. Arup Boral	Senior Inspector
27.	Chandigarh	Shri. Tajender Singh	Drugs Inspector
28.	Dadar and Nagar Haveli	Dr. Dharmesh Agrawal	Drugs Controller
29.	Pondicherry	Dr. E. Anandakirouchenane	Controlling Cum Licensing Authority
30.	Delhi	Shri. K R Chawla	Head of Department and State Licensing Authority
31.	Ladakh	Mrs. Nasreen Bano	ADC Cum Licencing Authority
32.	Jammu and Kashmir	Mrs. Lotika Khajuria	Drugs Controller
33.	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.	Dr. A Visala	Joint Drugs Controller (India)
3.	Shri. Chandrashekar Ranga	Joint Drugs Controller (India)
4.	Shri. A. K. Pradhan	Advisor
5.	Shri. Rishi Kant Singh	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,
Secretary-cum-Scientific Director,
IPC

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