

**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)/10/2024-eoffice**  
**E-Comp. No.: 17055**

**Date: 20.01.2025**

To

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

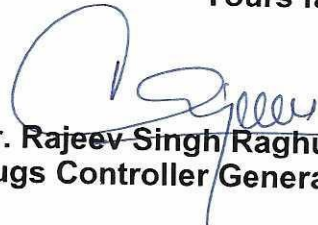
**Sub: Minutes of the 65<sup>th</sup> Meeting of the Drugs Consultative Committee (DCC) held on 20.12.2024 through Hybrid mode - reg.**

Sir/Madam,

65<sup>th</sup> meeting of the Drugs Consultative Committee was held on 20.12.2024 through Hybrid mode.

The minutes of the 65<sup>th</sup> 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

**MINUTES OF 65<sup>th</sup> MEETING (HYBRID MODE) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD ON 20<sup>th</sup> DECEMBER, 2024 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 Shri. Rajiv Wadhawan, Advisor (Cost), Ministry of Health and Family Welfare, Government of India and all the members of the committee.

Advisor (Cost) addressing the DCC welcomed all the members of the DCC and appreciated them for attending the 65<sup>th</sup>DCC meeting and requested all the States/ UTs for the maximum participation in the DCC meetings.

DCG(I) in his opening remarks highlighted the need to carry out inspection of all facilities manufacturing complex/ critical products such as LVP, SVP, Vaccines, r-DNA, etc. at regular basis considering the Risk Based Approach.

He also requested all the States/ UTs to strengthen their State testing laboratories as Central laboratories are already fully occupied/ engaged in testing of samples received from various sources including Central Drugs Inspectorate Staff and may not be able to test the samples forwarded by the Inspectorate Staff of States/ UTs.

DCG(I) further requested all the SLA's for greater participation in the DCC meetings through timely submission of agenda items of important matter tending to secure uniformity throughout India in the administration of Drugs and Cosmetics Act.

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 64<sup>th</sup>DCC MEETING HELD ON 20.12.2024**

The Drugs Consultative Committee deliberated the Action Taken Report (ATR) of the agenda items of 64<sup>th</sup>DCC meeting held on 19.06.2024 and the Action Taken Report was considered as approved.

**Agenda No. 2**

**Proposal to launch State Drug Regulatory Index to support progression of regulatory capacity of all states/UTs**

DCC was apprised that in order to ensure the effective regulation of medical product including drugs, medical devices and cosmetics, it is proposed to create a **State Drug Regulatory Index** to improve the standards of drug regulation across the country and enhance its global standing.

The primary objective of the State Drug Regulatory Index is to enhance the effectiveness and uniformity of drug regulatory mechanisms across the country by strengthening drug safety surveillance, promoting accountability, fostering collaboration, enhancing resource utilization.

DCC deliberated the matter and agreed with the proposal of creating State Drug Regulatory Index. Further, to make the Index more robust, DCC recommended for inclusion of additional metrics/ parameters of enforcement activities carried out by the States/ UTs such as number of raids.

### **Agenda No. 3**

#### **Consideration of the proposal for deterrent action for selling/ storing of spurious drugs**

DCC was apprised that to address this issue more effectively, many measures have been taken including amendment in the Drugs and Cosmetics Act, 1940 in the year 2008 by introducing enhanced penalties for those found guilty of manufacturing or selling spurious drugs.

DCC was also apprised that CDSCO has constituted a committee in this regard for appropriate advice. DCC noted the composition of the committee constituted on the issue pertaining to sale of spurious drugs in the market.

The DCC deliberated the matter in detail and recommended that committee may also seek comments from the SLA's so that the issue is addressed more effectively and recommended that the report of the Committee may be placed before DCC for further deliberation and consideration.

Further, DCC also recommended that the committee shall also be empowered under the terms of reference to co-opt certain experts on need basis.

### **Agenda No. 4**

#### **Consideration of the proposal regarding requirement of loan license application for sterilization purpose by a manufacturer, who has license in Form MD-3/4 or in Form MD-9/10, at the sterilization site having valid license for sterilization in Form MD-3 or Form MD-9**

DCC was apprised that the proposal was earlier deliberated in the 61<sup>st</sup> DCC meeting wherein a sub-committee was constituted for in depth examination of the issue and to propose suitable recommendations in the matter. The sub-committee has submitted its report which was placed for deliberation in the DCC.

DCC after detailed deliberation agreed with the recommendation of the sub-committee subject to inclusion of an appropriate mechanism for submission of documentary evidence to the Licencing Authority in support of proper sterilization of product, at the time of seeking manufacturing licence and further recommended to refer the matter to the DTAB.

### **Agenda No. 5**

**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 the proposal was earlier deliberated in the 62<sup>nd</sup> DCC meeting wherein an expert committee was constituted in the matter. The expert committee has submitted its report which was placed for deliberation in the DCC.

After detailed deliberation, the DCC recommended that the expert committee may relook in the matter w.r.t. framing a process/ guidelines for uniform implementation of the directions of Hon'ble Supreme Court, across the country as the objective of the committee was to suggest stepwise modalities to be followed. In this regard, DCC also recommended that expert committee may also co-opt suitable experts and submit its report within three months.

### **Agenda No. 6**

**Consideration of the proposal for listing of Tapentadol to Schedule X of the Drugs Rules 1945 and inclusion of Pregabalin & its drug formulations in Schedule H1 of the Drugs Rules 1945 in light of misuse & intoxication**

DCC was apprised that the proposal was earlier deliberated in the 62<sup>nd</sup> DCC meeting wherein a sub-committee was constituted in the matter. Accordingly, the sub-committee has submitted its report for deliberation in the DCC.

DCC after detailed deliberation agreed with the recommendation of the sub-committee and further recommended to refer the matter to DTAB.

### **Agenda No. 7**

**Consideration of the proposal regarding inclusion of all antimicrobials in the definition of "New Drug" under New Drugs and Clinical Trial Rules, 2019**

DCC was apprised that the matter was earlier deliberated in the 91<sup>st</sup>DTAB meeting wherein the Board after deliberation, observed that antimicrobial resistance can be caused due to misuse of antibiotic, antiviral, antifungal, etc. and accordingly recommended that the matter may be deliberated in the DCC initially.

After detailed deliberation, the DCC recommended that suitable provisions may be made in the rules for regulatory oversight by CDSCO for approving antimicrobials in the country to ensure uniformity of implementation and compliance with the rules.

### **Agenda No. 8**

#### **Consideration of the proposal to include the name of authorized person responsible for release of batch of product under all the manufacturing licenses under the Drugs Rules, 1945**

DCC was apprised that the manufacturing licenses under Drugs Rules such as (Form 25,25A, 25F, 28, 28A, 28B, 28D, 28DA, 28E & 28F) issued under Drugs Rules have the provision for mentioning the name of competent technical staff for manufacture and testing.

However, the manufacturing license does not bear the name of the authorised person responsible for release of batch product. As batch release is also one of the critical process in manufacturing and testing, it is therefore proposed to include the name of authorized person responsible for release of batch of product under all the manufacturing licenses.

DCC after detailed deliberation agreed with the proposal to include the name of authorized person responsible for release of batch of product, on the licence and the format of batch release certificate and further recommended to refer the matter to DTAB.

### **Agenda No. 9**

#### **Consideration of the proposal for updation of guidelines w.r.t. samples of drugs declared spurious or NSQ in light of the enhanced penalties under the D & C Amendment Act, 2008**

DCC was apprised that the Guidelines for taking action on samples of drugs declared spurious or Not of Standard Quality (NSQ), in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008, were issued as per the recommendation of 40<sup>th</sup>DCC.

DCC was also apprised that the Pharmacopoeias are upgraded from time to time and several testing parameters such as Impurity Profiling etc. are included in various monographs which are not covered under the existing guidelines. Accordingly, it was proposed to update the guidelines w.r.t. samples of drugs declared spurious or NSQ.

DCC after detailed deliberation agreed with the proposal for updation of guidelines and recommended that the existing guidelines may be circulated to all the members of the DCC for their comments/ suggestions for updation.

## **AGENDA FROM JAMMU AND KASHMIR**

### **Agenda No. 10**

#### **Consideration of the proposal for amendment under rule 89 of Drugs Rules 1945, for obtaining licence under Form 29 for different categories falling under Form 25A, 25F, 28A, 28B, 28D, 28DA, 28E & 28F**

DCC was apprised that the rule 89 of Drugs Rules, 1945 states that if the person proposing to manufacture a drug for the purpose of examination, test or analysis **does not hold a licence in Form 25 or Form 28** in respect of such drugs he shall, before commencing such manufacture, obtain a **licence in Form 29**.

The above rule does not have specific provision for obtaining a **licence in Form 29**, in case a person proposing to manufacture a drug for the purpose of examination, test or analysis which is falling under Licenses on Form 25A, 28A, 28D etc.

DCC after detailed deliberation agreed with the proposal to appropriately amend the Drugs Rules, 1945 related to Form 29 for better clarity and also opined that the Licence issued in Form 29 of Drugs Rules is site specific.

## **AGENDA FROM WEST BENGAL**

### **Agenda No. 11**

#### **Consideration of the proposal to correct the strength of Folic Acid w.r.t. Unit of measurement under the Schedule V of Drugs Rules, 1945**

DCC was apprised that the unit of measurement of Folic Acid under the Schedule V of Drugs Rules, 1945 mentioned as milligram (mg) which needs to be corrected to microgram (mcg). Accordingly, it was proposed to correct the unit of Folic Acid to microgram (mcg) from milligram (mg).

DCC deliberated the matter and agreed with the proposal for appropriate amendment in the Drugs Rules.

## **AGENDA FROM KARNATAKA**

### **Additional Agenda 1**

#### **Consideration of the proposal for regulatory oversight of critical sterile products like LVPs, Vaccines, r-DNA products, etc.**

DCC was apprised that to monitor the quality of drugs moving in the market, samples are drawn by Drugs Inspectors regularly under Drugs and Cosmetics Act, 1940 and are sent for test and analysis.

The concerns related to time taken in testing of sterile product was raised by Karnataka State and requested that: -

1. To introduce a mechanism/ provision for partial or Stage Wise Test report in Form 13
2. To implement rapid testing method for critical parameters i.e. Sterility test, BET
3. To provide detailed sterility report providing the type of bacterial and fungal organism detected
4. Prompt investigation and documentation of adverse reactions reported by health care facilities for such preparations

**MINUTES OF 65<sup>th</sup>DCC MEETING HELD ON 20.12.2024**

DCC was also apprised that as per the duties of Government Analyst prescribed under rule 45 (1) of Drugs Rules 1945, “the Government Analyst shall cause to be analysed or tested such samples of drugs as may be sent to him by Inspector or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these rules within a period of sixty days of the receipt of the sample:

Provided that where it is not possible to test or analyse the sample within the specified period, the Government Analyst shall seek extension of time from the Government giving specific reasons for delay in such testing or analysis.”

DCC discussed the matter in length and opined that w.r.t. point no.1 & 4 adequate regulatory provisions to address the issue are already available under the Drugs Rules, 1945. Further, w.r.t. point no. 2 & 3, Indian Pharmacopeia may be referred.

**The meeting ended with vote of thanks to all.**

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**LIST OF THE PARTICIPANTS OF 65<sup>th</sup> DRUGS CONSULTATIVE COMMITTEE MEETING HELD ON 20.12.2024 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            | Shri. Nityanand Kishloya   | Drugs Controller   |
| 4.     | Chhattisgarh     | Mr. Basanth Kumar Kaushic  | Licensing Authority  |
| 5.     | Goa              | Smt. Shweta Dessai         | Director, FDA  |
| 6.     | Gujarat          | Dr. H.G. Koshia            | Commissioner, FDCA   |
| 7.     | Haryana          | Sh. Manmohan Taneja        | Drugs Controller   |
| 8.     | Himachal Pradesh | Dr. Manish Kapoor          | Drugs Controller   |
| 9.     | Jharkhand        | Smt. Ritu Sahay            | Director (Drugs)   |
| 10.    | Karnataka        | B P Arun                   | State Licensing and Approving Authority                        |
| 11.    | Kerala           | Dr. Sujith Kumar           | Drugs Controller   |
| 12.    | Madhya Pradesh   | Shri. Mayank Aggarwal      | Drugs Controller   |
| 13.    | Maharashtra      | Shri. D.R. Gahane          | Drugs Controller   |
| 14.    | Nagaland         | Ms. C. Thungchanbeni Lotha | The Deputy Drugs Controller, Controlling & Licensing Authority |
| 15.    | Odisha           | Mrs. Mamina Patnaik        | Drugs Controller   |
| 16.    | Punjab           | Shri. Sanjiv Kumar         | Joint Commissioner, Licensing Authority                        |
| 17.    | Rajasthan        | Shri Ajay Phatak           | Drug Controller  |
| 18.    | Tamilnadu        | Sh. M. N. Sridhar          | Director of Drugs Control (i/c)                                |
| 19.    | Telangana        | Shri. G. Ramdhan           | Joint Director   |
| 20.    | Tripura          | Shri. Subrata Das          | State Drugs Controller   |
| 21.    | Uttar Pradesh    | Shri. Shashi Mohan         | Drugs Licensing and  |

**MINUTES OF 65<sup>th</sup>DCC MEETING HELD ON 20.12.2024**

| <b>S. No.</b> | <b>State/UT</b>                                 | <b>Name</b>                  | <b>Designation</b>                                   |
|---------------|---|------------------------------|--|
|               |   | Gupta                        | Controlling Authority                                |
| <b>22.</b>    | Uttarakhand                                     | Sh. Tajber Singh             | Drugs Controller                                     |
| <b>23.</b>    | West Bengal                                     | Shri. Arup Boral             | Deputy Director,<br>Licensing Authority              |
| <b>24.</b>    | Dadar and<br>Nagar Haveli<br>and Daman &<br>Diu | Dr. Dharmesh Agarwal         | State Drugs Controller                               |
| <b>25.</b>    | Pondicherry                                     | Dr. E.<br>Anandakirouchenane | Controlling Cum<br>Licensing Authority               |
| <b>26.</b>    | Delhi   | Shri. K R Chawla             | Controlling Authority<br>/Deputy Drugs<br>Controller |
| <b>27.</b>    | Ladakh  | Mrs. NasreenBano             | ADC Cum Licencing<br>Authority                       |
| <b>28.</b>    | Jammu and<br>Kashmir                            | Mrs. LotikaKhajuria          | Drugs Controller                                     |

**B. SPECIAL INVITEE**

| <b>S. No.</b> | <b>NAME</b>          | <b>DESIGNATION</b>                                       |
|---------------|----------------------|--|
| <b>1</b>      | Shri. Rajiv Wadhawan | Advisor (Cost), Ministry of Health and<br>Family Welfare |

**C. CDSCO (HEAD QUARTERS)**

| <b>S. No.</b> | <b>NAME</b>                     | <b>DESIGNATION</b>                |
|---------------|---------------------------------|-----------------------------------|
| 1.            | Dr. Rajeev Singh<br>Raghuvanshi | Drugs Controller General of India |
| 2.            | Dr. S. E. Reddy                 | Joint Drugs Controller (India)    |
| 3.            | Smt. A Visala                   | Joint Drugs Controller (India)    |
| 4.            | Shri. R. Chandrashekar          | Joint Drugs Controller (India)    |
| 5.            | Shri. A. K. Pradhan             | Advisor                           |
| 6.            | Shri. Rishi Kant                | Legal Advisor                     |

**D. Directors of Laboratories of CDSCO**

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

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