

**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)

**F. No. DC-DT-13011(11)/4/2025-eoffice**  
**Comp. No. 31059**

**Dated: 10.03.2026**

**To**

All Members of DTAB

**Subject: Minutes of the 93<sup>rd</sup> meeting of the Drugs Technical Advisory Board (DTAB) held on 16.02.2026 through Hybrid mode.**

Sir/Madam,

93<sup>rd</sup> meeting of Drugs Technical Advisory Board was held on 16.02.2026 through Hybrid mode.

The minutes of the 93<sup>rd</sup> meeting of Drugs Technical Advisory Board duly approved by the Chairperson, is annexed for your information please.

**Yours faithfully,**

  
**Dr. Rajeev Singh Raghuvanshi**  
**Drugs Controller General (India)**  
**Member Secretary (DTAB)**

**Encl:** Minutes of meeting

**Copy to:**

1. PPS to DGHS, MoH&FW, Kartavya Bhawan, New Delhi
2. PS to JS(R), MoH&FW, Kartavya Bhawan, New Delhi

**MINUTES OF THE 93<sup>rd</sup> MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 16.02.2026 AT FDA BHAWAN, KOTLA ROAD, NEW DELHI (THROUGH HYBRID MODE)**

**INAUGURAL DELIBERATIONS**

Dr. Rajeev Singh Raghuvanshi, DCG(I) and Member-Secretary DTAB, welcomed the Chairperson of the Board, Dr. Sunita Sharma, DGHS as well as all the esteemed members participating through physical and online mode for sparing their valuable time. The Chairperson of the Board had a brief introduction of all the participants.

Thereafter, with the permission of the Chair, DCG(I) Dr. Rajeev Singh Raghuvanshi initiated the agenda-wise proceedings of the meeting for its deliberations.

**AGENDA NO.1**

**Action Taken Report (ATR) for 92<sup>nd</sup> DTAB meeting held on 24.04.2025**

The Action Taken Report (ATR) on the recommendations of DTAB in 92<sup>nd</sup> meeting was approved by the Board. As regard to point no. 8 of the ATR i.e. proposal to include all antimicrobials in the definition of “New Drugs” under NDCT Rules, 2019, the Board was apprised that it has been desired to revisit the proposal.

After detailed deliberation, Board reiterated its earlier stand and in principle agreed for inclusion of all antimicrobials in the definition of “New Drugs” under NDCT Rules, 2019. In addition, Board also suggested sending a detailed proposal to all the Members highlighting the pathway of licensing system in this regard.

Further, the Board also recommended that proposal should be made effective prospectively and the existing license holders may continue to manufacture for sale or distribution without the need of any additional requirement.

**AGENDA NO. 2**

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

The Board was apprised about the agenda as well as about the recommendations of 66<sup>th</sup> DCC meeting held on 17.06.2025.

DTAB after deliberation suggested certain minor corrections in the guidance document and agreed to appropriately amend the Drugs Rules, 1945 for imparting legal sanctity to the suggested guidelines for all the firms holding license to manufacture for sale, sell, stock, exhibit or offer for sale or for distribution of drugs.

## **AGENDA NO. 3**

### **ISSUES PERTAINING TO REVISED SCHEDULE M**

#### **PART (A)**

#### **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**

The Board was apprised about the proposal as well as about the DCC recommendations.

DTAB after deliberation agreed for the proposed amendment to revise the limit for microbial contamination mentioned in Table II of Para B under the Part XIID of Schedule M in line with the WHO TRS 1044 Annexure II.

#### **PART (B)**

#### **Relaxation in requirement of Schedule M for specific categories like disinfectants**

The Board was apprised that under pre-revised Schedule M certain exemptions to regulatory requirements were provided in the Note under the Part related to “Requirement of Plants and Equipment” for certain product categories for which Stakeholders have requested to further consider this exemption under the revised Schedule M.

DTAB deliberated the matter in detail and opined that certain requirements of Revised Schedule M (G.S.R. 922(E) dated 28.12.2023) may not be relevant to certain categories of drugs namely Medical gases, empty gelatin capsules and disinfectant fluid. Accordingly, the Board recommended to continue the exemptions provided under Schedule M prior to the amendment for the categories of drugs.

## **AGENDA NO. 4**

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

The Board was apprised about the proposal as well as about the 67<sup>th</sup> DCC dated 17.11.2025 recommendations. DTAB after deliberation recommended that Drugs Rules, 1945 may be amended by incorporating suitable provisions for issuance of license for marketers for monitoring and better regulatory control.

## **AGENDA NO. 5**

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

The Board was apprised about the proposal as well as about the 67<sup>th</sup> DCC dated 17.11.2025 recommendations. DTAB after deliberation recommended that suitable provisions may be made in the Drugs Rules, 1945 that no advertisement of drugs specified in Schedule H, H1 and X shall be made except with the previous sanction of Central Government for firms holding licence to sell, stock or exhibit or offer for sale or distribute.

## **AGENDA NO. 6**

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

The Board was apprised about the proposal for a separate Form for wholesale of bulk drug licence and was also apprised about the DCC recommendations.

DTAB after deliberation agreed with DCC recommendations to:

1. Create a separate 'FORM' for bulk drug license for wholesale in such a way that the information regarding wholesalers dealing with NDPS category is captured in the license
2. Qualification of competent person may be degree in Science with two years experience in dealing of such raw materials or a registered pharmacist.

The Board also recommended providing adequate time to the existing wholesaler licenses to obtain the proposed bulk drug license. Accordingly, rules may be amended suitably for the consequential changes.

## **AGENDA NO. 7**

### **Consideration of the proposal to amend rule 64 of the Drugs Rules, 1945 in respect of qualification of the competent person**

The Board was apprised about the agenda to amend rule 64 of the Drugs Rules, 1945 in respect of qualification of the competent person. DTAB re-deliberated the proposal in detail and recommended that qualification of competent person may be a registered pharmacist or a degree in Science with two years experience in dealing of drugs including six months online certificate course recognized by PCI, NIPER, Skill Development Council etc for the purpose.

The Board noted that the matter was also discussed earlier in 70<sup>th</sup> DTAB meeting dated 18.08.2015 and 91<sup>st</sup> DTAB meeting dated 14.08.2024.

Accordingly, the rules may be amended suitably for qualification of competent person under rule 64 of Drugs Rules, 1945.

## **AGENDA NO. 8**

**Consideration of proposal for prohibition of manufacturing, import, sale and distribution of Carboxypenicillins, Combinations of Cephalosporin's with beta-lactamase inhibitors and Phosphonic acid derivatives for Growth purpose or yield increase in the food producing animals**

The Board was apprised about the proposal.

DTAB deliberated the matter and agreed with the recommendations of DAHD and accordingly, recommended for **prohibition** of manufacturing, import, sale and distribution of Carboxypenicillins and Phosphonic acid derivatives for animal use.

## **AGENDA NO. 9**

**Deliberation of the proposal to amend entry no.33 of Schedule K exemption from the provision of sale license**

The Board was apprised about the proposal. Board was also apprised about the ICMR as well as Tobacco Control Division (TCD) recommendations in the matter.

DTAB after deliberation recommended that entry no. 33 of Schedule K shall be amended to include only unflavored Nicotine gums 2 mg with the following conditions:

- (a) permission should be limited to unflavored gums (2 mg) and not extended to any other form of NRT.
- (b) sale to minors must be strictly prohibited and online accessibility to be closely monitored.
- (c) post-marketing surveillance should be conducted to monitor and report any adverse effect.
- (d) Marketing of NRT by the tobacco industry may be restricted due to the significant conflict of interest.

Further, DTAB recommended that Nicotine lozenges 2 mg shall be excluded from Schedule K exemptions.

## **AGENDA NO. 10**

**Proposal to amend Drugs Rules, 1945 for streamlining the process to import drugs for the purpose of examination, test or analysis in Form 11**

The Board was apprised about the proposal. Board was also apprised that Central Government vide G.S.R. 46(E) dated 20.01.2026 amended New Drugs and Clinical Trials Rules providing system of prior intimation instead of obtaining permission from Central Drugs Standard Control Organization (CDSCO) for manufacture of certain categories of drugs for analytical and preclinical testing.

DTAB after deliberation recommended that prior intimation system may be introduced in the rules for licensed manufacturers to import a drug for analytical and non-clinical testing (excluding drugs of category of sex hormones, cytotoxic, beta lactam, and narcotics and psychotropic drugs)

## **AGENDA NO. 11**

### **Proposal regarding amendment in Schedule C & C1 to update Biological origin product and related labelling requirement**

The Board was apprised about the proposal. DTAB after deliberation agreed with the proposal to amend the Drugs Rules suitably for including definition of 'Biological Product' and their related labeling requirements for clearly indicating the origin of the drug for such products. Further, Board also considered that consequential changes may also be undertaken in the rules.

## **AGENDA NO. 12**

### **Consideration of the proposal to amend entry number 31 of Schedule K relating to homoeopathic medicines so as to allow allopathy drugs wholesale dealers to keep homoeopathic medicines for maintaining the supply chain of homoeopathic medicines in allopathic retail stores**

The Board was apprised about the proposal. As recommended by DTAB in its 90<sup>th</sup> meeting dated 25.01.2024, the Board was also apprised about the recommendations of the Ayurvedic, Siddha, Unani Drug Technical Advisory Board (ASUDTAB) meeting held on 25.5.2023. DTAB deliberated the matter in detail and agreed with the proposal to extend the exemption provided under Schedule K to wholesale drugs licence under Rule 61.

## **AGENDA NO. 13**

### **Consideration of the proposal to amend Drugs Rules, 1945 for including mandatory provision of pharmaceutical companies to spend at least one per cent of their net profit for providing free medicines in medicine bank to be used by the Central Government during health emergencies, disaster or any other circumstances considered necessary by the Central Government as part of Corporate Social Responsibility (CSR)**

The Board was apprised about the proposal. Board was also apprised about the reply received from the Ministry of Corporate Affairs in the matter. DTAB after deliberation agreed with the proposal to defer the proposal since any amendment in the CSR framework does not fall under the ambit of Drugs and Cosmetics Act and rules made thereunder. The matter may not be pursued further.

## **AGENDA NO. 14**

### **Consideration of the proposal to amend Drugs Rules, 1945 to prohibit advertisements of drugs specified in schedule G**

The Board was apprised about the proposal. Board noted that DTAB in its 92<sup>nd</sup> meeting dated 24.04.2025 has already recommended that all drugs mentioned under Schedule G shall be shifted to Schedule H Drugs for better regulatory control.

DTAB after deliberation agreed with the proposal to withdraw the draft notification published vide G.S.R. 375(E) dated 10.07.2024 to prohibit the advertisements of drugs specified in Schedule G as once these drugs are shifted to Schedule H, the issue will get addressed automatically.

## **AGENDA NO. 15**

### **Consideration of the proposal to make appropriate provisions under Part VII of Drugs Rules, 1945 for requirement of an authorised person responsible for batch release of product**

The Board was apprised about the proposal as well as about the recommendations of 92<sup>nd</sup> DTAB in the matter. As desired, the matter was re-deliberated by DTAB and after detailed deliberation, Board recommended that provisions related to appointment of authorized person responsible for release of batch product shall be made under the rules related to manufacturing instead of mentioning the name of authorized person responsible for batch release on the licence.

## **AGENDA NO. 16**

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

The Board was apprised about the proposal as well as the recommendations of 67<sup>th</sup> DCC meeting held on 17.11.2025. DTAB after deliberation agreed with the recommendations of 67<sup>th</sup> DCC which is as follows:

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 DCC sub-committee report.

Board recommended that rules may be amended accordingly.

## **AGENDA NO. 17**

### **Report of DTAB sub-committee to examine the matter regarding submission of periodic safety update reports annually for subsequent years till the drug product is marketed**

The Board was apprised about the proposal. Board also noted the recommendations of the DTAB sub-committee report.

DTAB after deliberation agreed with the following recommendations of the sub-committee:

- the PSUR submission frequency for categories of new drugs as detailed under (i), (ii), and (iii) of Rule 2(w) of the New Drugs and Clinical Trial Rules, 2019, shall remain unchanged, "the periodic safety update reports shall be submitted every six months for the first two years after approval of the drug is granted to the applicant. For subsequent two years - the periodic safety update reports need to be submitted annually.
- the PSUR submission frequency for categories of new drugs as detailed under (iv) of Rule 2(w) of the New Drugs and Clinical Trial Rules, 2019, shall be "the periodic safety update reports shall be submitted every six months for the first two years after approval of the drug is granted to the applicant. For subsequent two years - the periodic safety update reports need to be submitted annually and then once every three years till the drug product is marketed.
- the PSUR submission frequency for categories of new drugs as detailed under (v) of Rule 2(w) of the New Drugs and Clinical Trial Rules, 2019, shall be "the periodic safety update reports shall be submitted every six months for the first two years after approval of the drug is granted to the applicant. For subsequent years - the periodic safety update reports need to be submitted annually till the drug product is marketed.

Board recommended that NDCT Rules, 2019 may be amended accordingly.

## **AGENDA NO. 18**

### **Proposal to restricts the manufacture, sale or distribution of all formulations of fixed dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride in continuation to the Gazette notification vide S.O. No. 1717 (E) dated 15.04.2025**

The Board was apprised about the agenda and after detailed deliberation agreed with the proposal that such formulations shall not be used in children below four years of age and a gazette notification may be issued accordingly.

**AGENDA NO. 19**

**Consideration of proposal to amend rule 26 and rule 38 of Medical Device Rules, 2017 to include the intimation of any reportable events of medical devices including In-Vitro Diagnostic Medical Devices to the Licensing Authority**

The Board was apprised about the agenda and after deliberation agreed with the proposal to suitably amend the Medical Devices Rules for incorporating the definition of 'Reportable Events' along with consequential changes for reporting of such events.

*As regard to other agendas pertaining to Medical Devices, Board opined that these may be deliberated initially at the CDSCO level for further consideration.*

**Meeting ended with vote of thanks to the Chair.**

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**LIST OF ATTENDEES**

1. **Dr.Sunita Sharma,** Chairman  
Director General of Health Services,  
Kartavya Bhawan, New Delhi
2. **Dr. Rajeev Singh Raghuvanshi,** Member-Secretary  
Drugs Controller General (India),  
FDA Bhawan, New Delhi
3. **Dr. Rakesh Kumar Rishi,** Member  
Director (I/C),  
Central Drugs Laboratory,  
Kolkata
4. **Dr Dimple Kasana,** Member  
Member Director,  
Central Research Institute, Kasauli  
(Attended Online)
5. **Dr. P Dhar,** Member  
Member  
Principal Scientist,  
IVRI, Bareilly, U.P.  
(Attended Online)
6. **Dr. Abhijit Sheth,** Member  
Chairman,  
National Medical Commission  
(Attended Online)
7. **Dr. Montu M. Patel,** Member  
President,  
Pharmacy Council of India  
(Attended Online)
8. **Smt. Shweta Dessai,** Member  
Director,  
Directorate of Food and Drugs  
Administration, Goa  
(Attended Online)

**Minutes of 93<sup>rd</sup> DTAB meeting held on 16.02.2026**

9. **Dr. Manish Kapoor,** Member  
State Drugs Controller,  
Drugs Control Administration,  
Himachal Pradesh  
(Attended Online)
10. **Dr. Atul Kumar Nasa,** Member  
Member, Executive Committee,  
Pharmacy Council of India  
(Attended Online)
11. **Shri. Sudarshan Jain,** Member  
Secretary General,  
Indian Pharmaceutical Alliance  
(Attended Online)
12. **Dr. Jerin Jose Cherian,** Member  
Scientist E,  
Division of Basic Medical Sciences,  
ICMR  
(Attended Online)
13. **Dr. Bhavesh Vyas,** Member  
Assistant Professor,  
Department of Pharmacology,  
Narendra Modi Medical College,  
Ahmedabad, Gujarat  
(Attended Online)
14. **Dr. R. N. Gupta,** Member  
National President,  
Indian Pharmaceutical Association  
(Attended Online)
15. **Shri. A L Srivastava,** Member  
Govt. Analyst, Govt. Public Analyst  
Laboratory,  
Lucknow, U.P.  
(Attended Online)

**Dr Radha Rangarajan**, Director of Central Drug Research Institute, Lucknow, **Dr. Vijay Oza**, President, Post Graduate Medical Education Board (PGMEB), National Medical Commission, India and **Shri P. Venkateswarlu**, Govt. Analyst, Drugs Control Laboratory, Vijayawada, Andhra Pradesh were not able to attend the meeting.

**SPECIAL INVITEES**

1. **Dr. V. Kalaiselvan,**  
Secretary-cum-Scientific Director,  
Indian Pharmacopoeia Commission

**CDSCO REPRESENTATIVES**

- 1 **Shri. R. Chandrashekar,**  
Joint Drugs Controller (I), CDSCO (HQ), New Delhi
- 2 **Dr. Annam Visala,**  
Joint Drugs Controller (I), CDSCO (HQ), New Delhi
- 3 **Dr. Rubina Bose,**  
Deputy Drugs Controller (I), CDSCO (HQ), New Delhi
- 4 **Shri. Aseem Sahu,**  
Deputy Drugs Controller (I), CDSCO (HQ), New Delhi
- 5 **Shri. Sanjeev Kumar,**  
Deputy Drugs Controller (I), CDSCO (HQ), New Delhi
- 6 **Shri. Arvind Kukrety,**  
Deputy Drugs Controller (I), CDSCO (HQ), New Delhi
- 7 **Shri. Ashish Kumar Rai,**  
Assistant Drugs Controller (I), CDSCO (HQ), New Delhi
- 8 **Shri Roshan Lal Meena,**  
Drugs Inspector, CDSCO (HQ), New Delhi
- 9 **Shri. Ranjeet Singh Patel,**  
Drugs Inspector, CDSCO (HQ), New Delhi
- 10 **Ms Shweta Ahuja,**  
Drugs Inspector, CDSCO (HQ), New Delhi

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