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-13011(11)/1/2025-eoffice
Comp. No. 21508

Dated: 28 APR 2025

To

All Members of DTAB

Subject: Minutes of the 92nd meeting of the Drugs Technical Advisory Board (DTAB) held on 24.04.2025 through Hybrid mode.

Sir/Madam,

92nd meeting of Drugs Technical Advisory Board was held on 24.04.2025 through Hybrid mode.

The minutes of the 92nd meeting of Drugs Technical Advisory Board duly approved by the Chairman, 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, MoHFW, Nirman Bhawan, New Delhi
2. PS to JS(R), MoHFW, Nirman Bhawan, New Delhi

MINUTES OF THE 92nd MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 24.04.2025 AT (445-A), DGHS, NIRMAN BHAWAN, NEW DELHI (THROUGH HYBRID MODE)

ATTENDEES

1. **Prof. (Dr.) Atul Goel**, Chairman
   Director General of Health Services,
   Nirman 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. Montu M. Patel**, Member
   President, Pharmacy Council of India

5. **Dr. Manish Kapoor**, Member
   State Drugs Controller, Drugs Control Administration,
   Himachal Pradesh

6. **Dr. Atul Kumar Nasa**, Member,
   Member, Executive Committee,
   Pharmacy Council of India

7. **Shri. Sudarshan Jain**, Member
   Secretary General,
   Indian Pharmaceutical Alliance

8. **Dr. Jerin Jose Cherian**, Member
   Scientist E,
   Division of Basic Medical Sciences, ICMR

9. **Dr. P Dhar**, Member
   Principal Scientist,
   IVRI, Bareilly, U.P. (Attended Online)

10. **Smt. Shweta Dessai**, Member
    Director, Directorate of Food and Drugs Administration,
    Goa (Attended Online)

11. **Dr. Vijay Oza**, Member
    Post Graduate, Medical Education Board,
    National Medical Commission, India (Attended Online)

12. **Dr. R. N. Gupta,** Member
    National President,
    Indian Pharmaceutical Association (Attended Online)

13. **Shri. Govinda Krishna**, Member
    Govt. Analyst, Drugs Control Laboratory,
    Vijayawada, Andhra Pradesh (Attended Online)

14. **Shri. A L Srivastava**, Member
    Govt. Analyst, Govt. Public Analyst Laboratory,
    Lucknow, U.P. (Attended Online)

The Director of Central Research Institute, Kasauli, Chairman of National Medical Commission, India, Director of Central Drugs Research Institute, Lucknow and Dr. Bhavesh Vyas, elected member of Indian Medical Association could not attend the meeting because of their other commitments.

SPECIAL INVITEES

1. **Dr. Sunita Sharma,**
   Additional Director General of Health Services (Addl. DGHS),
   Nirman Bhawan, New Delhi

2. **Shri. Rajiv Wadhawan,**
   Adviser (Cost), MoHFW

3. **Dr. Adhiraj Mishra**,
   Assistant Commissioner (AH), DAHD

4. **Shri. Gaurav Pratap Singh**,
   Senior Scientific Officer, IPC

CDSCO REPRESENTATIVES

1. **Shri. R. Chandrashekar**,
   Joint Drugs Controller (I), CDSCO (HQ), New Delhi

2. **Shri. A. K. Pradhan**,
   Advisor, CDSCO (HQ), New Delhi

3. **Shri. Aseem Sahu**,
   Deputy Drugs Controller (I), CDSCO (HQ), New Delhi

4. **Shri. Sanjeev Kumar**,
   Deputy Drugs Controller (I), CDSCO (HQ), New Delhi

5. **Shri. Vijay Vitthalrao Chandankar,**
   Deputy Drugs Controller (I), CDSCO (HQ), New Delhi

6. **Shri. Ashish Kumar Rai**,
   Assistant Drugs Controller (I), CDSCO (HQ), New Delhi

7. **Shri. Ranjeet Singh Patel**,
   Drugs Inspector, CDSCO (HQ), New Delhi

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

The Chairman requested all the members to actively participate in the discussions so that a meaningful decision may be taken in public interest. Further the Chairman also requested all the members to follow the principle of confidentiality.

Thereafter, with the permission of the Chairman, 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 91st DTAB meeting held on 14.08.2025

The Action Taken Report (ATR) on the recommendations of DTAB in 91st meeting was approved by the Board.

PART-A (Related to Drugs)

Agenda No. 2

Proposal to amend NDCT Rules, 2019 for streamlining the process for permission to manufacture for new drug and investigational new drugs for clinical trial, BA/BE study or for examination test and analysis:

The Board was apprised with respect to streamlining the process for issuance of permission to manufacture for new drug or investigational new drugs for clinical trial, BA/BE study or for examination test and analysis.

DTAB deliberated the matter and agreed for the following proposed amendment under the NDCT Rules, 2019;

1. Notification system may be introduced for application to manufacture for Analytical and Preclinical Testing of drugs excluding sex hormones, cytotoxic, beta lactam, Biologics with live microorganism and narcotics & psychotropic drugs.
2. To reduce timelines for processing of applications for permission for other categories of new drug and IND under Chapter VIII of NDCT Rules from 90 working days to 45 working days.

Agenda No. 3

Consideration of the proposal for withdrawal of Notification published vide G.S.R. 220 (E) dated 26.03.2020 for door step delivery of certain medicines

The Board was apprised about the matter. The DTAB deliberated the issue and recommended to constitute a sub-committee to examine the matter in detail before considering withdrawal of the notification.

Agenda No. 4

Consideration of Proposal to amend Schedule F, Part XII-C under Sub-heading "G" i.e. Testing of Blood products

The Board was apprised about the agenda as well as status in various pharmacopoeias in the matter. The board noted that the monograph in the IP or other pharmacopeia specify the screening tests to be conducted for blood products.

After detail deliberation, DTAB agreed for omitting condition mentioned in the Drug Rules requiring that final product shall be tested for freedom from HIV I and HIV II antibodies. Hepatitis B surface antigen and Hepatitis C Virus antibody, in line with the International practices.

Agenda No. 5

Consideration of the proposal for extension of timelines for implementation of revised Schedule M for manufacturers having turnover less than 250 crores

The Board was apprised about the notification G.S.R. 27(E) dated 11.02.2025 published by the Central Government regarding extension of timelines for implementation of revised Schedule M for manufacturers having turnover less than 250 crores. DTAB deliberated the matter and ratified the said notification.

Agenda No. 6

Consideration of the proposal for retaining of Tapentadol in Schedule H1of the Drugs Rules 1945 and inclusion of Pregabalin & its drug formulations in Schedule H1 of the Drugs Rules 1945 in light of misuse & intoxication

The Board was apprised about the DCC sub-committee report. After detailed deliberation, DTAB agreed with recommendation of sub-committee for appropriate amendment in the rules.

DTAB also agreed that the Department of Revenue may be requested to schedule Tapentadol as a Psychotropic substance under NDPS Act similar to Tramadol.

Agenda No. 7

Consideration of Proposal to examine the effect of Nimesulide on adult human being

The Board was apprised about the agenda as well as the report submitted by the ICMR to study the effect of Nimesulide on adult Human beings for further course of action in light of the fact that Nimesulide drug has been prohibited in children below 12 years of age. DTAB opined that Nimesulide is one of the effective drug to reduce fever and used for short term treatment.

After detailed deliberation, DTAB recommended that ICMR may be requested to conduct the systemic review for use of Nimesulide drug below 12 years of age, 12 to 18 years of age as well as 60 years of age and above for further deliberation. However committee agreed with the following recommendations as per the ICMR report:

- Nimesulide should be used only as a second line drug, only after exhausting first line options
- Nimesulide should not be used in pregnant, lactating and women planning for pregnancy.
- Nimesulide should not be used in patients with renal and hepatic impairment and also should not be co-administered with other hepatotoxic and renal toxic drugs.
- All oral formulations of Nimesulide above 100 mg in immediate release dosage form should be prohibited.

Agenda No. 8

Consideration of the proposal to examine the safety related to Ranitidine drug due to presence of NDMA impurity

The Board was apprised about the agenda alongwith report of expert committee constituted for this purpose. Board observed that the matter is related to the presence of NDMA impurity in the ranitidine drug.

After detailed deliberation, Board recommended that a larger committee is required to be constituted which will look into all the aspects including the storage conditions of the ranitidine drug. DTAB further also recommended that ICMR may conduct a study for assessing the safety of ranitidine drug considering the presence of NDMA impurity. Further the board opined that manufacturers should monitor the NDMA levels in the API/formulation and also take risk based measurers such as reducing the shelf life etc.

Agenda No. 9

Consideration of the proposal for inclusion of all antibiotics in the definition of "New Drug'' in New Drugs and Clinical Trials Rules, 2019

The Board was apprised about the DCC recommendations.

After detail deliberation, DTAB recommended that all the antimicrobials shall always be deemed to be considered as New Drug under the definition of "New Drug'' under New Drugs and Clinical Trials Rules, 2019 in public interest. Accordingly consequential changes may be made in the Rules.

Agenda No. 10

Consideration of the proposal for creation of guidelines on disposal of expired/ unused drugs

The Board was apprised about the DCC sub-committee guidance document for safe disposal of expired/ unused drugs.

After detail deliberation, DTAB recommended that CDSCO may put the guidance document on its website and also circulate to all State/UT Drugs Controllers.

Further Board also recommended that the guidance document may also be shared with DGHS office for its circulation to all the Medical Colleges.

Agenda No. 11

Consideration of the proposal for submission of report of the Expert Committee constituted for review and revise the Schedule H of Drugs Rules, 1945

The Board was apprised about the DCC sub-committee report. DTAB agreed with sub-committee report and recommended that appropriate amendments may be made in the Rules.

Agenda No. 12

Consideration of the proposal for submission of report of the Sub-Committee constituted to examine the matter of Over-The-Counter (OTC) Drugs

The Board was apprised about the draft G.S.R. 393(E) dated 25.05.2022 and subsequently DTAB sub-committee constituted for the purpose.

After detail deliberation DTAB agreed with recommendation of sub-committee and recommended that -

i. Legal provisions to be enabled under Drugs Rules, 1945 along with manner of submitting application, prescribe the licensing requirements for the sale of OTC drugs which does not require the supervision of registered pharmacist, requirements for considering a drug as an OTC, Labelling requirements, etc. and incorporation of separate Schedule.

ii. The list as submitted by the sub-committee may be considered initially which will be dynamic and updated from time to time.

Agenda No. 13

Evaluation of 16 FDCs by DTAB sub-committee which were earlier considered as irrational in the Expert Committee report of the Prof. Kokate Committee

The Board was apprised about the subcommittee report under Chairpersonship of Dr. Nilima Kshirsagar which declared all the 16 FDCs as irrational and recommended for prohibition as these may pose risk to the human beings.

After detail deliberation, DTAB agreed with the recommendation of the subcommittee report.

Agenda No. 14

Consideration of the report of evaluation of Fixed Dose Combinations (FDCs) related to Vitamins, Minerals Formulations, etc., considered as Irrational by the Prof. Kokate Committee

The Board was apprised about the agenda and recommended that the 29 irrational FDCs as declared by the Kokate committee may be referred to Dr. Nilima Kshirsagar sub-committee of DTAB for further examination and other FDCs as recommended by Kokate Committee may be disposed as per the earlier procedure.

Agenda No. 15

Status report w.r.t.examination of proposal to regulate FDC Antibiotic and its irrational use

The Board was apprised about the progress in the issue. DTAB noted that DCG(I) has given several reminders to SLAs for obtaining the requisite information. The non-submission of the desired information by the SLAs is not justified. DTAB opined that the DCG(I) may take up the matter with SLAs for withdrawal of the product license of such FDCs for appropriate action as per the provisions.

Agenda No. 16

Consideration of the proposal to prohibit the manufacture, sale and import of Lindane

The Board was apprised about the agenda. DTAB also noted that the Ministry of Agriculture and Farmer Welfare (MoAFW), vide Gazette Notification No S.O. 637(E) Dated 25/03/2011) has already banned the Manufacture, Import or Formulate the Lindane, as per the power conferred under insecticide Act' 1968. Board also observed that topical preparation of Lindane is used as a second line treatment for scabies and lice infestations and Stockholm convention also permits such use.

After detailed deliberation, DTAB opined that Lindane is an affordable and effective drug available treatment for scabies and lice infestations and recommended for continued marketing of drug. However, a guidance may be issued for safe disposal of the drug at all levels including instruction on the label.

Agenda No. 17

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

The Board was apprised about the recommendations of DCC. The Drugs Controller, Himachal Pradesh also apprised the board stating that there is an order from Hon'ble High Court, Himachal Pradesh wherein the Hon'ble High Court has directed that all the drug manufactures in the State of Himachal Pradesh to incorporate name of the approved competent technical person for testing/analysis, etc. with signature on the certificate of analysis.

After detailed deliberation Board agreed with recommendation of DCC, as under:-

- To include the name of authorized person responsible for release of batch of product on the licence and
- To prescribe the format of batch release certificate

Agenda No. 18

Consideration of the proposal for amendment under rule 89 of Drugs Rules1945, for obtaining licence under Form 29 for different categories falling under Form 25A, 25F, 28A, 28B, 28D, 28DA, 28E & 28F

The Board was apprised about the DCC recommendations. DTAB recommended that Rule 89 should be amended to the extent by incorporating "Form 25A, 25F, 28A, 28B, 28D, 28DA, 28E & 28F".

Agenda No.19

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-regarding

The Board was apprised about the DCC recommendations.

DTAB recommended to correct the unit of Folic Acid from milligram to microgram.

PART-B (Related to Medical Devices)

Agenda No. 20

Consideration of the proposal for no 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

The Board was apprised about the DCC sub-committee report and DTAB 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 subject to the condition that the license number of the sterilization site should be mentioned on label of the device.

Agenda No. 21

Consideration of the proposal to include suitable provisions to address the issue of change in constitution in case of Notified Body registered under Sub-rule (6) of Rule 13 as well asin case of Registration Certificate issued under sub-rule (4) of Rule 87 (A) for sale, respectively of Medical Device Rules, 2017

The Board was apprised about the agenda and DTAB agreed for appropriate amendment in the Medical Device Rules, 2017.

Agenda No. 22

Consideration of the proposal to amend the clause (j) of rule 3 of MDR, 2017 to include the registration certificate holder and to include the definition of registration certificate after clause (y) of rule 3 of Medical Device Rules, 2017

The Board was apprised about the agenda and DTAB agreed for appropriate amendment in the Medical Device Rules, 2017.

Additional Agenda No. 1

Consideration of the proposal for suspension of product permission declared Not of Standard Quality Drug by a Government Analyst of Government Testing Laboratory.

The Board was apprised about the issue. The board noted that it is very important that once a drug is declared NSQ, the license of such product shall be suspended immediately in public interest unless a satisfactory corrective action and preventive action (CAPA) is submitted by such manufactures.

After detailed deliberation, DTAB recommended for the appropriate amendment in the Drug Rules in this regard and the suspension product license should be revoked only after route cause analysis and corresponding CAPA has been implemented.

Additional Agenda No. 2

Consideration of proposal for deliberation of matter pertaining to prohibition of manufacturing, import, sale and distribution of 37 Antimicrobials medicinal products (as laid down in the Commission Implementing Regulation (EU) 2022/1255 for Growth purpose or yield increase in the food producing animals which are reserved for treatment of certain infections in Humans.

The Board was apprised about the agenda. Board also noted that though these 37 antimicrobials have not been approved by CDSCO for veterinary use in treatment of various diseases, however these may be notified for prohibition in light of the request received from the Ministry of Commerce.

The representative from DAHD also explained the background on the issue. The Board noted that DAHD has no objection for reserving 34 antimicrobials only for human use.

After detail deliberation, DTAB recommended as under:

1. To prohibit manufacture, import, sale, distribution and use of 34 antimicrobials medicinal products as laid in EU regulation 2022/1255 except 3 antimicrobials viz Carboxypenicillins, Combinations of Cephalosporin's with beta-lactamase inhibitors and Phosphonic acid derivatives only, for animal use.

2. DAHD shall submit the report about these three antimicrobials at the earliest by providing the clear recommendations, which may be placed before the Chairman, DTAB for appropriate decision.

Additional Agenda No. 3

Proposal to incorporate system of notification for certain category of new drugs for conduct of "BA-BE Studies" for export purpose under Chapter V, New Drugs and Clinical Trials Rule, 2019

The Board was apprised about the agenda. After detailed deliberation, committee agreed for amendment in the NDCT Rules, 2019 with certain conditions based on study design for introducing a system of notification in the Rules w.r.t. certain categories of new drugs for conduct of "BA-BE Studies" for export purpose.

Meeting ended with the vote of thanks to the Chairman

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