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)/2/2026-eoffice **Dated: 16.09.2026**
Comp. No. 38596

To

All Members of DTAB

Subject: Minutes of the 94th meeting of the Drugs Technical Advisory Board (DTAB) held on 27.08.2026 through Hybrid mode.

Sir/Madam,

The 94th meeting of the Drugs Technical Advisory Board was held on 27.08.2026 in hybrid mode.

The minutes of the meeting, duly approved by the Chairperson, are enclosed for your information and record, please.

Yours faithfully,

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

Encl: Minutes of the 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 94th MEETING (HYBRID MODE) OF DRUGS TECHNICAL ADVISORY BOARD (DTAB)

HELD ON 27th Aug 2026 AT ROOM NO. 12072, DGHS ROOM, KARTAVYA BHAWAN, NEW DELHI-110001

INAUGURAL DELIBERATIONS

Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) DCG(I) and Member-Secretary, DTAB, welcomed the Chairperson of the Board, Dr. Loveneesh G. Krishna, Director General of Health Services (DGHS), as well as all the esteemed members participating through physical and online modes for sparing their valuable time. The DGHS requested all members to actively participate in the discussions to ensure meaningful and productive deliberations.

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 93rd DTAB meeting held on 16.02.2026

The Action Taken Report (ATR) on the recommendations of DTAB in the 93rd meeting was approved by the Board.

AGENDA NO. 1A

The below-mentioned proposals at (i), (ii), (iii) and (iv) were recommended by DTAB by way of circulation and presented here for record.

(i) Agenda pertaining to National Commission for Protection of Child Rights (NCPCR)

PROPOSAL- A

Consideration of the proposal to examine the installation of CCTV at sales premises and tracking and tracing of all NDPS Drugs in the supply chain**.**

PROPOSAL- B

Consideration of the proposal for listing of certain drugs to Schedule H1 and Schedule X of Drugs Rules, 1945 in light of misuse and intoxication.

(ii) Consideration of the proposal to amend Rule 31 of Drugs Rules, 1945 for import of Drugs having residual shelf life less than 60%.

(iii) Consideration of the Proposal for notification of Chaudhary Charan Singh National Institute of Animal Health (CCS-NIAH), Baghpat, Uttar Pradesh as a Central Drugs Laboratory (CDL) for Veterinary Vaccines, under the Drugs Rules, 1945.

(iv) Consideration of the Proposal for Gazette Notification of Navi Mumbai International Airport (NMIA) as authorized Airport for Drug Import and Export under Rule 43A of Drugs Rules 1945.

AGENDA NO. 1B

The below-mentioned proposals (i) and (ii) were presented for *ratification.*

(i) Consideration of the proposal to include required qualifications for Inspector (Medical Devices) to designate them as Medical Device Officer under MDR, 2017.

The Board was apprised of the draft GSR 748 (E) and final GSR 165 (E) published on 10.10.2025 and 02.03.2026, respectively, by the Central Government regarding amendments under the provisions of the Medical Devices Rules, 2017, in line with the qualifications prescribed for Medical Device Officers. DTAB deliberated on the matter and ratified the said notification.

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

The Board was apprised of the draft G.S.R. 927 (E) dated 29.12.2025 and final GSR 477(E) dated 09.06.2026 published by the Central Government regarding deletion of the exemption provided for the sale of Syrups for cough from Schedule K in view of the recent incidents due to contaminated cough syrup. The matter was previously discussed in the 67th DCC meeting dated 17.11.2025. DTAB deliberated on the matter and ratified the said notification.

AGENDA NO. 2

Consideration of the Sub-Committee Report to examine the matter regarding the proposal for withdrawal of the Notification published vide G.S.R. 220 (E) dated 26.03.2020 for doorstep delivery of certain medicines.

The Board was apprised about the representation received from the All India Organisation of Chemists & Druggists (AIOCD) association wherein it was requested to withdraw the said Notification, G.S.R. 220(E), dated March 26, 2020. The matter was deliberated during the 92nd DTAB meeting under Agenda Item No. 3, held on

24.04.2025. The Board recommended constituting a sub-committee to examine the matter in detail before considering the withdrawal of the notification.

The report of the DTAB sub-committee was placed before the Board.

DTAB deliberated the matter in detail and recommended that the sub-committee shall revisit the matter again in the present context and, if required, may also hear the association(s) before finalization.

AGENDA NO. 3

Proposal to amend Rule 43A of Drugs Rules, 1945 to include various ICDs/Port/SEZs for the import of Drugs/ Medical Devices/ Cosmetics in India

The Board was apprised about various representations requesting to notify the below-mentioned Ports/ ICDs/ SEZs for the import of Drugs/ Medical Devices/ Cosmetics in India:

1. Inland Container Depot (ICD), Sanath Nagar, Hyderabad
2. Inland Container Depot (ICD), Thimmapur, Hyderabad
3. Inland Container Depot (ICD), Gandhidham / Mundra, Gujarat
4. Inland Container Depot (ICD), Sonipat, Haryana
5. Inland Container Depot (ICD), Dadri, U.P.
6. Noida International Airport, U.P.
7. ICD Garhi Harsaru, Haryana
8. ICD Piyala, Haryana
9. ICD, Whitefield, Bengaluru
10. SEZ Bommasandra, Karnataka

DTAB deliberated the matter and recommended amending Rule 43A of the Drugs Rules, 1945 to include the above-mentioned Port/ ICDs/ SEZs for fast clearance of the consignments.

AGENDA NO. 4

Inclusion of provision of "prior intimation" for Import of New Drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis (Form CT-16, 17)

The Board was apprised about the proposal to examine Rules 67, 68, 69 and 70 of NDCT 2019 (Form CT-16, 17), in line with the GSR 46(E) dated 20.01.2026.

DTAB, after deliberation, recommended that the provision of "prior intimation" shall be included in the case of import of a new drug for analytical and non-clinical testing purposes only (excluding the new drug and investigational new drug of the category of sex hormones, cytotoxic, beta-lactam, vaccines, Cell and Gene therapy products, biologics with live microorganisms and narcotics and psychotropic drugs).

Further, the Board also recommended reducing the timeline for issuance of Form CT-17 from 90 working days to 45 working days, in line with the GSR 46(E) dated 20.01.2026.

AGENDA NO. 5

Consideration of the proposal to review the regulatory GMP requirements to manufacture for testing and analysis for the conduct of non-clinical studies and clinical studies.

The Board was apprised of the proposal that the present system of manufacturing trial batches does not differentiate the GMP requirements for clinical as well as non-clinical purposes.

Accordingly, DTAB, after detailed deliberation, recommended that rule 55 and rule 63 of NDCT Rules, 2019 may be amended as under for better clarity:

55. Condition of permission— The grant of permission under rule 53 in Form CT-11 shall be subject to the following conditions, namely: —

(ii) the permission holder shall manufacture new drugs for the purposes of clinical trial or bioavailability and bioequivalence study in small quantities in accordance with the provisions of these rules and at places specified in the permission and in the facility complying with the Good Manufacturing Practices as provided under Drugs Rules, 1945;

Provided that the permission holder may also manufacture new drugs for analytical and non-clinical testing purposes in accordance with the principles of Good Manufacturing Practices, with proper traceability.

63. Conditions of permission— The permission granted under rule 60 in Form CT-14 or Form CT-15 shall be subject to the following conditions, namely: —

the permission holder shall manufacture such active pharmaceutical ingredient or its pharmaceutical formulation for the purposes as specified in permission in accordance with the provisions of these rules and at places referred to in such permission and, in case, the manufacture of such drugs is for clinical trial or bioavailability and bioequivalence study, it should be manufactured in the facility complying with the Good Manufacturing Practices as provided under Drugs Rules, 1945

Provided that the permission holder may also manufacture such active pharmaceutical ingredient or its pharmaceutical formulation for analytical and non-clinical testing purposes in accordance with the principles of Good Manufacturing Practices, with proper traceability.

AGENDA NO. 6

Consideration of proposal for introducing a system of "prior intimation" for certain category of new drugs for conduct of "BA-BE studies" for the approval of new drug in India.

The Board was apprised about the system of prior intimation which has been introduced vide GSR 50 (E) dated 21.01.2026 to streamline the processing and approval of BA-BE study applications for export purposes for certain categories of drugs under certain conditions.

DTAB after deliberations, recommended that the same system of notification may also be extended for the conduct of BA-BE studies for the approval of New Drugs in India (domestic purpose) to have a level playing field.

AGENDA NO. 7

Redeliberation on the proposal to amend Rule 64 of the Drugs Rules, 1945 in respect of qualification of the competent person for wholesale licenses

The Board was apprised of the agenda for amendment in the qualification of a competent person for a wholesale license in Form 20B & 21B as per Rule 64 of the Drugs Rules, 1945.

The Board noted that the Central Govt had published a draft G.S.R 1179(E) dated 28.12.2016 for amendment of Rule 64 wherein the qualification of a competent person for a wholesale license in Form 20B & 21B was proposed as Registered Pharmacist only. However, the draft notification could not be finalised within the stipulated time due to the large number of issues raised by the stakeholders.

Thereafter, the said proposal was deliberated again in the 91st DTAB meeting held on 14.08.2024. DTAB, after deliberation, again recommended the finalization of the Draft G.S.R. 1179(E) dated 28.12.2016 for amendment of Rule 64 to strengthen the supply chain for ensuring the quality, safety and efficacy of drugs.

Further, 93rd DTAB in its meeting dated 16.02.2026, as desired, deliberated again on the proposal and recommended for amendment of rules that the qualification of the competent person (for Wholesale license in Form 20B or 21B) may be a registered

pharmacist or a degree in Science with two years' experience in dealing with drugs, including six months online certificate course recognised by PCI, NIPER, Skill

Development Council etc., for the purpose. However, a large number of representations were received on the said recommendations of the DTAB.

DTAB re-deliberated the proposal in detail and recommended that, considering the fact that a large number of pharmacists are available in the country, the qualification of a competent person shall be a registered pharmacist.

Accordingly, the rules may be amended suitably for qualification of competent person under rule 64 of Drugs Rules, 1945 and draft notification G.S.R. 1179(E) dated 28.12.2016 may be finalized.

AGENDA NO. 8

Consideration of the proposal for discussion on Nicotine Products.

The Board was apprised that CDSCO has been receiving applications for the grant of permissions for manufacture, import and marketing of nicotine pouches in strengths of 2 mg, 4 mg and 6 mg. These products contain different nicotine salts, including nicotine dihydrate ditartrate and nicotine polacrilex, and are proposed for use in smoking cessation and for the relief of nicotine-withdrawal symptoms. The matter was also referred to the programme division of the National Tobacco Control Programme (NTCP).

In its response, NTCP stated that nicotine pouches are addictive, pose independent health risks and have not been established as effective smoking-cessation aids. NTCP emphasised that evidence-based tobacco-cessation interventions should be prioritised over nicotine pouches and recommended that licences for new nicotine formulations should not be granted.

The Board also took note of the various nicotine formulations approved by CDSCO till date. Further, the Board was apprised of its recommendations dated 16.02.2026 regarding amendment of Schedule K to the Drugs Rules, 1945.

During the deliberations, the Board observed that the ultimate objective of tobacco-control and cessation measures is de-addiction. In view of the above, the Board, after detailed deliberations, recommended that no new nicotine formulation be approved henceforth in public interest.

AGENDA NO. 9

Redeliberation of the proposal for exemption for the requirement of a wholesale licence for liquid antiseptic in Schedule K of the Drug Rules, 1945.

The Board was apprised that the proposal was previously deliberated in its 91st Meeting held on 14.08.2024. Accordingly, a draft notification was published by the Ministry of Health and Family Welfare vide G.S.R. 759(E) dated 16.10.2025**.**

DTAB noted that several comments had been received on the draft G.S.R. and recommended that the Rules may be amended accordingly, as follows, in order to avoid any ambiguity:

Class of drugs	Extent and conditions of exemptions
39. Liquid Antiseptics	The provisions of Chapter IV of the Act and rules made thereunder, which require them to be covered with a sale license, subject to the following conditions, namely: ─ (a) the drugs are manufactured by licensed manufacturers; (b) the drugs do not contain any substance specified in Schedule G, H, H1 or X; (c) the drugs are sold in the original unopened containers of the licensed manufacturer;

AGENDA NO. 10

Deliberation on Proposal for Inclusion of all sterile drug products under the CLAA scheme.

The Board was apprised of the proposal to bring all sterile drug products, irrespective of category, within the purview of the Central Licensing Approving Authority (CLAA) to enable more effective monitoring.

Considering the importance of the matter, the DTAB recommended that it may first be deliberated in the Drugs Consultative Committee (DCC).

AGENDA NO. 11

Proposal for incorporation of statutory provisions under the Drugs Rules, 1945 for Mandatory e-RaktKosh registration, and Biometric Authentication of blood donors

The Board was apprised about the directions of the national review meeting to develop a process to enable all Blood Centres to upload the various data of collection, testing, and issuance of Blood on the e-RaktKosh portal and to integrate with ABDM (Ayushman Bharat Digital Mission) ID / or Aadhaar linked OTP verification for traceability and follow-up of the Blood Donors in the country.

The Board noted the importance of bringing an amendment which aims to enforce the mandatory authentication of all blood donors using their ABDM (Ayushman Bharat Digital Mission) ID / or Aadhaar-linked OTP verification for traceability and follow-up of the Blood Donors in the country. This systemic upgrade will enable robust donor traceability, comprehensive post-donation follow-ups, and prevent high-risk or deferred donors from immediate multi-site donations.

The Board was apprised that the matter was initially deliberated as Agenda 04 of the 69th DCC held on 24.06.2026. DCC, after detailed deliberation, recommended making necessary provisions under the Drugs Rules for mandating the registration of blood centres on the e-Raktkosh portal and uploading the data.

DCC also recommended the constitution of a sub-committee to discuss the modalities of biometric authentication of the Blood donors in the Blood Centres/camps.

In this regard, the sub-committee constituted has recommended Donor Authentication with ABDM (Ayushman Bharat Digital Mission) ID / ABHA or Aadhaar-linked OTP verification for traceability and follow-up.

DTAB, after deliberation, recommended making necessary provisions under the Drugs Rules for:

1. Mandating the registration of blood centres on the e-Raktkosh portal and uploading the data; and
2. Donor Authentication with ABDM (Ayushman Bharat Digital Mission) ID / ABHA or Aadhaar-linked OTP verification for traceability and follow-up.

AGENDA RELATED TO MEDICAL DEVICES

AGENDA NO. 12

Consideration of the proposal to amend Rule 31 of the Medical Device Rules, 2017, for granting exemption from the requirement of Test License for manufacturing Medical Devices.

DTAB noted that the proposal has been previously discussed in the 93rd DTAB meeting dated 16.02.2026, wherein it was opined that this may be deliberated initially at the CDSCO level for further consideration. Therefore, the proposal was placed before the Technical Committee of CDSCO dated 01.06.2026, wherein the matter was discussed and recommended for granting exemption from the requirement of obtaining a Test Licence for manufacturing medical devices for the purpose of test, examination, evaluation, demonstration or training only.

DTAB agreed with the recommendations of the Technical Committee of CDSCO and recommended that the Rules may be amended accordingly. The Board also recommended that all the consequential changes shall also be made appropriately.

AGENDA NO. 13

Consideration of the report of the Sub-committee constituted to examine the issues related to the proposal to amend rule 59 (3) (i), seventh schedule (1) (iii), table-2 (iii) of Medical Device Rules, 2017 to replace the words "Schedule Y" with the words "New Drugs and Clinical Trials Rules, 2019"

The Board was apprised of the proposal. DTAB noted that the matter was previously deliberated in its 91st meeting held on 14.08.2024, on a proposal to streamline the Medical Device Rules, 2017 by amending/replacing the reference to 'Schedule Y' in line with the New Drugs and Clinical Trials Rules, 2019.

DTAB deliberated the matter and opined that there could be medical devices for veterinary use and further the proposal may have wider implications and need to be reviewed in detail by a sub-committee in light of the consequential changes required in other rules, namely Drugs Rules, etc.

Accordingly, a Sub-committee as recommended by the DTAB was constituted to examine the issue and give its recommendation. The report of the sub-committee was placed before the DTAB for its consideration.

DTAB agreed with the recommendations of the sub-committee and opined that rules may be amended accordingly.

AGENDA NO. 14

Part-(A)

Consideration of the proposal to amend the Eighth Schedule (exemptions) with respect to the sale of absorbent cotton wool, bandages, absorbent gauze and adhesive plaster, home use devices viz. pulse oximeter, BP monitor, thermometer and pregnancy test kit, under the Medical Devices Rules, 2017.

The Board was apprised that representations have been received from stakeholders requesting exemption of such devices under Chapter XI of the Medical Devices Rules, 2017.

DTAB also noted that the proposal was deliberated during the meeting of the Medical Device Technical Advisory Group (MDTAG) held on 14th May 2026.

DTAB recommended incorporating the following amendments in the Eighth Schedule (Exemptions) of MDR-2017:

"**In the Eighth Schedule, at S. No. 2, Class of medical devices, the following shall be substituted, namely –**

(i) Medicated dressings and bandages for first aid kits containing bandages, cotton gauze, resuscitation mask, adhesive tape, thermometer

(ii) Absorbent cotton wool, bandages, absorbent gauze, adhesive plaster and other self-test medical devices such as Pulse Oximeter, Blood Pressure monitor, thermometer, Urine pregnancy test kit, Glucometer

(iii) **Small quantities of the medical devices which are placed in the exhibitions for display and demonstrations"**

Part-(B)

Consideration of the proposal to amend Eighth Schedule (exemptions) with respect to import of first aid kits for captive consumption by industries other than healthcare providers viz. automobile industry and hospitality industry

The Board was apprised that representations have been received from stakeholders requesting exemption of such devices under Chapter XI of the Medical Devices Rules, 2017.

DTAB also noted that the proposal was deliberated during the meeting of the Medical Device Technical Advisory Group (MDTAG) held on 14th May 2026.

DTAB opined that, in order to ease the process of import of these first aid kits from the point of view of Ease of Doing Business, such kits may be exempted from the requirements of Chapter V of the Medical Devices Rules, 2017, which require them to be covered by a license for import, as well as the requirements of Chapter XI of these Rules, which require them to be covered by a sale license, provided that the kits shall not have a residual shelf life of less than sixty percent and the kits shall meet the applicable standards as prescribed. Also, such imported kits should not be re-sold or distributed.

AGENDA NO. 15

Consideration of the proposal to amend the Second Schedule of the Medical Devices Rules, 2017 for fees of free sale certificate issued under the said rules.

The Board was apprised that the existing provision related to fees to be paid for a Free Sale Certificate issued under the MD Rules, 2017 is for each category of medical device, which creates ambiguity and repeated queries related to fee payment.

DTAB also noted that the proposal was deliberated during the meeting of the Medical Device Technical Advisory Group (MDTAG) held on 14th May 2026.

DTAB opined that, in order to have clarity and to avoid repeated queries related to fee payment for the issue of a free sale certificate, the provision to pay the fee as per the category of the device may be changed to the payment of the fee as per the medical devices under each manufacturing license.

Accordingly, DTAB recommended amending the rules accordingly.

AGENDA NO. 16

Consideration of the proposal to amend the Form MD-39 and Form MD-40 of the appendix to the Medical Devices Rules, 2017 to incorporate detailed information on the testing of the medical devices by a laboratory.

The Board was apprised that the existing input form i.e. Form MD-39 (Application for grant of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of the manufacturer) and output form i.e. Form MD-40 (Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of the manufacturer), does not incorporate adequate information on the discipline/group, material/products tested, specific test parameters and reference standards related to the testing of medical device carried out by Medical Device Testing Laboratory on behalf of manufacturer.

DTAB also noted that the proposal was deliberated during the meeting of the Medical Device Technical Advisory Group (MDTAG) held on 14th May 2026.

DTAB opined that in order to incorporate adequate information on the discipline/group, material/products tested, specific test parameters and reference standards related to the testing of medical device carried out by Medical Device Testing Laboratory on behalf of manufacturer, in the existing input form i.e. Form MD-39 (Application for grant of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer) and output form i.e. Form MD-40 (Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer), it is necessary to amend the form MD-39 and form MD-40 of the appendix to the medical devices rules, 2017.

Accordingly, DTAB recommended amending the rules accordingly.

AGENDA NO. 17

Consideration of the proposal to amend Rule 63 of the Medical Devices Rules, 2017, to include provisions related to post-marketing clinical investigation in Form MD-22 with the fee and document as specified in the Medical Device Rules, 2017.

The Board was apprised that the provision relating to the submission of the post-marketing clinical investigation application in Form MD-22, and the fee to be accompanied therewith, is not specified in the said rule.

DTAB also noted that the proposal was deliberated during the meeting of the Medical Device Technical Advisory Group (MDTAG) held on 14th May 2026.

DTAB opined that it is necessary to incorporate the provision relating to the submission of the post-marketing clinical investigation application in Form MD-22, and the fee to be accompanied therewith in the said rule.

Accordingly, DTAB recommended for amending the rules as follows:

"**In the said rules, after clause (b) of the fourth proviso of sub-rule (1) of rule 63, the following clause shall be inserted, namely: —**

(c) The post-marketing clinical investigation application in Form MD-22 shall be accompanied with a fee as specified in the Second Schedule along with information as specified in the Seventh Schedule.

and

In the said rules, in the Second Schedule, —

(a) After S. No. 47, the following shall be inserted, namely: —

Sr. No.	Rule	Subject	In rupees (INR) except where specified in dollars ($)
(1)	(2)	(3)	(4)
47a	63(1)	Permission to conduct post-marketing clinical investigation	100000

AGENDA NO. 18

Consideration of the proposal to amend clause (zb) of Rule 3 of MDR, 2017 to include the definition of in vitro Diagnostic (IVD) Medical Device.

The Board was apprised that an internationally separate definition is available for MD (Medical Devices) and IVD (*in vitro* Diagnostic) Medical Devices. However, currently there is no clear definition under MDR-2017 for IVD.

DTAB also noted that the proposal was deliberated during the meeting of the Medical Device Technical Advisory Group (MDTAG) held on 14th May 2026.

DTAB opined that globally separate definitions are available for IVD and MD.

Accordingly, DTAB recommended amending the rules by incorporating an IVD definition that is harmonized with global regulatory standards as follows:

CURRENT RULE POSITION	PROPOSED (ADDITIONS HIGHLIGHTED)
Rule 3(zb) "medical device" means, - (A) substances used for *in vitro* diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bags with or without anticoagulant covered under sub-clause (i), (B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii), (C) devices notified from time to time under sub-clause (iv) of clause (b) of	Rule 3(zb) "medical device" means, - (A) substances used for *in vitro* diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bags with or without anticoagulant covered under sub-clause (i), (B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii), (C) devices notified from time to time under sub-clause (iv) of clause (b) of

section 3 of the Act; *Explanation*: For the purpose of these rules, substances used for *in vitro* diagnosis shall be referred as *in vitro* diagnostic medical device.	section 3 of the Act; *Explanation*: ***For the purpose of these rules, substances used for in vitro diagnosis shall be referred to as in vitro diagnostic medical device, and in vitro diagnostic medical devices include kit, reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or analysers or system or other articles, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human or animal body solely or principally used, for diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status with objective to provide information for diagnostic, monitoring or compatibility purposes.***

ADDITIONAL AGENDA S-1

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

The Board was apprised about OM no. F. No.06/17/2022-HSM dated 21.01.2025 issued from the Ministry of Environment, Forest and Climate Change, Govt of India referring the Stockholm Convention to protect human health and the environment from persistent organic pollutants (PoPs).

The Board noted that the matter w.r.t prohibition of Lindane was also deliberated in 92nd DTAB meeting held dated 24.04.2025.

After detailed deliberation, DTAB opined that Lindane lotion & other formulations have been discontinued by USFDA and are also not available in the TGA database of Australia.

Further, alternative therapeutic options for Lindane are available in India.

DTAB revisited the matter and recommended prohibition of the manufacture, sale and import of Lindane.

The meeting ended with vote of thanks to the Chair.

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LIST OF ATTENDEES

1.	**Dr. Loveneesh G. Krishna**, Director General of Health Services, Kartavya Bhawan, New Delhi	Chairman
2.	**Dr. Rajeev Singh Raghuvanshi**, Drugs Controller General (India), FDA Bhawan, New Delhi	Member-Secretary
3.	**Dr. Atul Kumar Nasa**, Member, Executive Committee, Pharmacy Council of India	Member
4.	**Shri. Sudarshan Jain**, Secretary General, Indian Pharmaceutical Alliance	Member
5.	**Dr Amarjit Kaur,** Director, Central Research Institute, Kasauli (*Attended Online*)	Member
6.	**Dr. Pronab Dhar**, Member Principal Scientist, IVRI, Bareilly, U.P. (*Attended Online*)	Member
7.	**Dr. Shanmukhappa**, Senior Advisor, On behalf of Chairman, National Medical Commission (*Attended Online*)	Member
8.	**Dr. Montu M. Patel**, President, Pharmacy Council of India (*Attended Online*)	Member

9.	**Smt. Shweta Dessai**, Director, Directorate of Food and Drugs Administration, Goa (*Attended Online*)	Member
10.	**Dr. Manish Kapoor**, State Drugs Controller, Drugs Control Administration, Himachal Pradesh (*Attended Online*)	Member
11.	**Dr. Jerin Jose Cherian**, Scientist E, Division of Basic Medical Sciences, ICMR (*Attended Online*)	Member
12.	**Dr. R. N. Gupta,** National President, Indian Pharmaceutical Association (*Attended Online*)	Member
13.	**Dr. Vijay Oza**, President, Post Graduate Medical Education Board (PGMEB), National Medical Commission (*Attended Online*)	Member
14.	**Shri P. Venkateswarlu**, Govt. Analyst, Drugs Control Laboratory, Vijayawada, Andhra Pradesh (*Attended Online*)	Member

Dr Radha Rangarajan, Director of Central Drug Research Institute, Lucknow, Shri. A L Srivastava, Govt. Analyst, Govt. Public Analyst Laboratory, Lucknow, U.P, Dr. Bhavesh Vyas, Assistant Professor, Department of Pharmacology, Narendra Modi Medical College, Ahmedabad, Gujarat and Dr Rakesh Kumar Rishi, Director-in-Charge, CDL, Kolkata, were not able to attend the meeting.

SPECIAL INVITEE:

1. **Dr Shashi Bhushan**
   Representative from Indian Pharmacopoeia Commission
   (*Attended Online*)

2. **Dr. L. Swasticharan,**
   Deputy Director General and Director (Emergency Relief),
   Tobacco Control Section
   Dte.GHS

CDSCO REPRESENTATIVES:

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

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

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

4 **Shri Dinesh Kumar,**
Assistant Drugs Controller (I), CDSCO (HQ), New Delhi

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