

**MINUTES OF THE 81<sup>ST</sup> MEETING OF DRUGS TECHNICAL ADVISORY BOARD  
HELD ON 29<sup>TH</sup> NOVEMBER, 2018 AT DGHS, NIRMAN BHAWAN, NEW DELHI**

**PRESENT**

- |   |                  |
|---|------------------|
| 1. Dr. S. Venkatesh<br>Director General of Health Services,<br>Nirman Bhawan, New Delhi                                 | Chairman         |
| 2. Dr. S. Eswara Reddy<br>Drugs Controller General (India),<br>FDA Bhawan, New Delhi                                    | Member Secretary |
| 3. Shri C. Hariharan<br>Director (In-charge),<br>Central Drugs Laboratory, Kolkata                                      | Member           |
| 4. Dr. A. K. Tehlan<br>Director, Central Research Institute,<br>Kasauli, Himachal Pradesh                               | Member           |
| 5. Dr. Reena Nayyar<br>Additional Secretary, Medical Council of India,<br>New Delhi                                     | Member           |
| 6. Dr. Pallavi Jain Govil<br>Commissioner, Food Safety and Controller,<br>Food and Drugs Administration<br>Bhopal (M.P) | Member           |
| 7. Shri. Pankaj Patel<br>Chairman and Managing Director,<br>Zydus Cadila Group,<br>Ahmedabad, Gujarat                   | Member           |
| 8. Dr. Nilima Kshirsagar<br>Chair in Clinical Pharmacology,<br>ICMR, Mumbai   | Member           |
| 9. Shri. M.S Lokesh Prasad<br>Scientific Officer & Govt. Analyst,<br>Bengaluru, Karnataka                               | Member           |
| 10. Dr. Vaishali N Patel<br>Govt. Analyst, Food & Drugs Laboratory,<br>Vadodara, Gujarat                                | Member           |

The Director, Indian Veterinary Research Institute, Izatnagar; President, Pharmacy Council of India, New Delhi; Director, Central Drug Research Institute, Lucknow; Drug Controller, Assam; Prof. M. D. Karvekar (elected member by PCI) Bengaluru, Karnataka; Elected member by MCI; Honorary Secretary General, Indian Medical Association, New Delhi; President, Indian Pharmaceutical Association, Bengaluru could not attend the meeting because of their other commitments.

Special Invitees are also invited for deliberation on specific agenda as detailed below:

<b>S. No.</b>	<b>Name and Address of Special Invitees</b>	<b>Deliberation on Agenda No.</b>
1.	Dr. Praveen Malik Director(NIAH), Baghpat, UP	Agenda No. 4
2.	Dr. Vijay Pal Singh Dy, Director, QA, FSSAI, New Delhi	
3.	Dr. ShobiniRajan Assistant Director General (Blood Safety) & Director (NBTC), New Delhi	Agenda No. 11
4.	Dr. Renuka Malik Professor, Dept. of Obstetrics & Gynaecology, RML Hospital, New Delhi	Agenda No. 15
5.	Dr. Seema Singhal Assistant Professor, Dept, of Obstetrics & Gynaecology, AIIMS, New Delhi	
6.	Dr. R K Manchanda Director General, Central Council of Research in Homoeopathy, New Delhi.	Agenda No. 17
7.	Dr. S.R. Chinta Assistant Adviser (H), Ministry of AYUSH, New Delhi	

Dr. S. Venkatesh, Director General of Health Services & Chairman DTAB welcomed the Board members and special invitees. The Chairman in his opening remarks appreciated the efforts made by Dr. S. Eswara Reddy, DCG(I) with respect to ease of doing business in India. He also appreciated Dr. Nilima Kshirsagar, Chairman of the Sub-Committee and other members for handling issues related to FDCs in light of directions of Hon'ble Supreme Court for examining the issue in time bound manner. Thereafter, he requested DCG(I) to initiate the proceedings after brief round of introduction by all members.

Dr. S. Eswara Reddy, DCG(I), Member-Secretary, stated that this is the fourth meeting of DTAB in the year, 2018 in which several important agenda were going to be deliberated. Such frequent meetings reflect the commitment of the Board for taking initiatives to strengthen the drug regulatory system in the Country. Thereafter, DCG(I) explained briefly about Action Taken Reports on previous DTAB recommendations along with the agenda.

## **AGENDA NO.1**

### **ACTION TAKEN REPORT (ATR) FOR 80<sup>th</sup> DTAB MEETING HELD ON 25.07.2018**

The Action Taken Report (ATR) on the recommendations of DTAB in 80<sup>th</sup> meeting was approved by the Board.

## **AGENDA NO. 2**

### **CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 FOR DECLARING THE NOT OF STANDARD QUALITY (NSQ) DRUGS UNDER DIFFERENT CATEGORIES FOR TAKING REGULATORY ACTION**

DTAB was apprised that,earlier guidelines were issued to all the State Drugs Controllers for taking action on samples of drugs declared spurious or Not of Standard Quality(NSQ) in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008. The guidelines divided the defects in different categories depending upon the gravity of the defects and the action proposed to be taken in each category was specified.

As the guidelines are not part of the Rules and their implementation varies from State to State, the proposal to revise these guidelines and bring under the purview of Drugs & Cosmetics Rules to ensure uniform implementation is under consideration for quite some times now.

DTAB in its 79<sup>th</sup> meeting held on 16.05.2018, deliberated the proposal. The Board considered these issues and recommended to include the said guidelines as part of the Rules.

However, while preparing the draft for making the said guidelines as part of the Drugs & Cosmetics Rules, 1945 it was observed that the guidelines need to be further updated/ modified to bring more clarity as well as make it contemporary for effective and uniform implementation by the Regulatory Authorities. NSQ drugs which don't fall under section 27(a), 27(b), 27(c) of the Drugs and Cosmetics Act, 1940 may be dealt separately to take prompt action by having provisions for imposition of fine along with other regulatory measures to ensure the quality of the drugs manufactured in the Country.

Accordingly draft rules for amendment of the Drugs & Cosmetics Rules were placed before the DTAB for deliberation.

DTAB deliberated and agreed to the proposal for declaring the Not of Standard Quality (NSQ) drugs under different categories for taking regulatory action by incorporating the said draft rules as Schedule K1 to the Drugs and Cosmetic Rules, 1945.

### **AGENDA NO.3**

#### **CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF RULES AND SCHEDULE IN DRUGS & COSMETICS RULES, 1945 ON GOOD DISTRIBUTION PRACTICES (GDP) OF PHARMACEUTICAL PRODUCTS**

Good Distribution Practices (GDP) in the supply chain is of paramount importance to ensure the quality, safety and efficacy of the drugs. The DTAB was appraised that the proposal for preparation of Guidelines on Good Distribution Practices (GDP) was deliberated earlier in 47<sup>th</sup> Drugs Consultative Committee (DCC) held on 30.07.2014 and 31.07.2014 and as per the recommendation of the DCC, a Sub-Committee was constituted for preparation of Guidelines on GDP of Pharmaceutical Products.

The Sub-Committee submitted its report along with GDP guidelines and the matter was again deliberated in 54<sup>th</sup> meeting of DCC held on 30.07.2018. The DCC recommended to incorporate the guidelines in the Drugs & Cosmetics Rules, 1945 as a separate Schedule.

As per the recommendation of the DCC, the guidelines were placed before the DTAB for deliberation.

DTAB after detailed deliberation agreed to the proposal for inclusion of the Good Distribution Practices (GDP) guidelines of pharmaceutical products as a separate Schedule to the Drugs & Cosmetics Rules, 1945.

#### **AGENDA NO.4**

### **CONSIDERATION OF THE PROPOSAL FOR RESTRICTING/ PROHIBITING COLISTIN AND ITS FORMULATIONS FOR USE IN FOOD PRODUCING ANIMALS, POULTRY AND AQUA FARMING AS WELL AS ANIMAL FEED SUPPLEMENTS**

The Board was apprised about the various regulatory measures taken for ensuring judicious use of anti-microbials in human and as well as animals to contain the problem of anti-microbial resistance.

In this regard, recently a representation has been received from the Coordinator, Chennai declaration on antimicrobial resistance, Technical Advisory Member, National Antibiotic Policy, requesting urgent ban of growth promotional use of Colistin in poultry and aqua farming.

Subsequently, CDSCO had forwarded the same to Department of Animal Husbandry, Dairying and Fisheries (DADF), Ministry of Agriculture & Farmer's Welfare and Food Safety and Standards Authority of India (FSSAI), MoHFW for examination. After examining the matter DADF has informed that Colistin sulphate cannot be used as feed premix/feed supplement. The representation was placed before the Board.

DTAB deliberated in detail on the need of restriction on growth promotional use of Colistin and recommended for prohibiting Colistin and its formulations for use in food producing animals, poultry and aqua farming as well as animal feed supplements.

## **AGENDA NO.5**

### **CONSIDERATION OF THE PROPOSAL TO DEVISE A MECHANISM UNDER THE DRUGS AND COSMETICS RULES, 1945 TO AVOID SAME TRADE NAME FOR DIFFERENT DRUGS**

DTAB was apprised that, the Hon'ble High Court of Delhi in the matter of M/s.Curewell Drugs & Pharmaceuticals Pvt. Ltd & Anr. Vs Ridley Sciences Pvt. Ltd, CS (COMM)1071/2018, has issued order dated 14.08.2018 that the DCG(I) and the state FDAs ought to implement an action plan in which drugs with identical or near identical brand names or marks are not given licenses, so as to ensure that no confusion is created amongst doctors, chemists and patients. Moreover, the manner in which identical packaging is also being used is a cause for concern.

The court has also highlighted the judgment of the Supreme Court in Cadila Health Care Ltd. v. Cadila Pharmaceutical Ltd. (2001) 5 SCC 73, in which the Supreme Court had directed as under:

“34. Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which inter alia indicates that an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a drug under a brand name the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark Office pertaining to the trade mark in question which will enable the Drug Authority to arrive at a correct conclusion.”

Accordingly the court has directed the Government to ensure that an action plan is prepared to ensure that identical brand names are not allotted to multiple parties and such confusion is avoided.

Subsequently, in compliance with the order/ direction of the Hon'ble High Court of Delhi, a meeting was held under the chairmanship of Additional Secretary & Director General(CGHS), Ministry of Health & Family Welfare on 13.11.2018.

During the meeting it was discussed that the brand name/trade name in case of pharmaceuticals is neither controlled by the Licensing Authority under the Drugs and Cosmetic Act 1940 & Rules 1945, nor the Trademarks office at present which leave scope for having same trade names for different drugs manufactured and sold in the Country, which may create a situation which is very detrimental to patient safety and the trade names which are not registered and repeated for different drugs can create confusion. Therefore, the Drugs and Cosmetic Rules 1945 may be amended to include the provisions for regulating brand names/ trade names by the Central and State Licensing Authorities.

DTAB after detailed deliberation, recommended for devising a mechanism under the Drugs and Cosmetic Rules 1945 to include provisions for regulating the brand names/ trade names of Pharmaceutical products.

## **AGENDA NO.6**

### **CONSIDERATION OF THE PROPOSAL FOR ALLOWING DRUG SUBSTITUTION FOR JAN AUSHADHI STORES UNDER PMBJP FOR PROMOTION OF QUALITY GENERIC MEDICINES AT AFFORDABLE PRICES**

Government has launched Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana under which there are about 4041 Pradhan Mantri Jan Aushadhi Kendra in the country to promote generic medicines at affordable price.

DTAB was apprised that, the rule 65(11A) of the Drugs and Cosmetics Rules, 1945 provides that, no person dispensing a prescription containing substances specified in Schedule H and Schedule H1 or X, may supply any other preparation, whether containing the same substance or not, in lieu thereof. Thus, the pharmacies including the Jan Aushadhi Kendras are not allowed to substitute medicines while dispensing prescription drug.

Therefore, with a view to improve the effectiveness of the Jan Aushadhi Scheme through promotion of generic medicines, the rule 65(11A) may be amended to allow only the Jan Aushadhi Kendras for substitution of medicines while dispensing a prescription containing substances specified in Schedule H and Schedule H1 or Schedule X.

DTAB deliberated the proposal in detail and agreed to amend rule 65(11A) of the Drugs and Cosmetic Rules 1945 for allowing substitution of drugs specified in Schedule H, Schedule H1 or Schedule X with drugs containing same substance, strength and dosage form only in Jan Aushadhi stores under Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) for promotion of quality generic medicines at affordable prices.

## AGENDA NO.7

### CONSIDERATION OF THE PROPOSAL TO EXPLORE THE FEASIBILITY OF PROVIDING A SEPARATE SHELF/RACK FOR GENERIC MEDICINES IN PHARMACY

DTAB was apprised that, to promote the availability of generic medicines, provision of keeping a separate shelf/ rack of generic medicines in every pharmacy was deliberated in 52<sup>nd</sup> meeting of DCC held on 18.09.2017 and subsequently in 78<sup>th</sup> meeting of the Board held on 12.02.2018 and agreed for amendment in the Drugs & Cosmetics Rules, 1945 for incorporating such provision.

Ministry is, however, of the opinion that the proposal to provide a separate shelf/ rack reserved exclusively for stocking of generic medicines in the licensed premises separated from other medicines, which shall be visible to the consumers, may not be effective to bring in the desired impact with regards to the promotion of Generic Medicine and therefore the Ministry has requested to re-examine the matter and explore better ways to boost the use of generic medicines.

Therefore, a proposal to have a requirement to display the sign board in the retail pharmacies that generic medicines in proper name are also available, in addition to the proposal to have a separate shelf/ rack was placed before the Board for deliberation. Accordingly, the following draft rule to be incorporated under Rule 65 of the Drugs and Cosmetics Rules, 1945 was placed before the Board.

*“(22) The licensee shall maintain a separate rack / shelf reserved solely for the storage of “Generic Medicines sold in proper name” in a part of the premises separated from other medicines and shall display the following words in conspicuous manner in prominent place in their licensed premises*

**‘GENERIC MEDICINES IN PROPER NAME ARE ALSO AVAILABLE’.**”

DTAB after deliberation recommended to amend the Drugs and Cosmetic Rules 1945 for provision of displaying in a sign board in conspicuous manner with the words “GENERIC MEDICINES ARE ALSO AVAILABLE” in prominent place in both English and regional language in addition to have separate shelf/rack for generic medicines in retail pharmacies. The Board further recommended to include a definition for Generic Medicine under Drugs and Cosmetic Rules, 1945 since it is currently not defined.

## **AGENDA NO.8**

### **REVIEW ORDER OF HON'BLE HIGH COURT OF KARNATAKA DATED 24.07.2017 IN BAN OF FIXED DOSE COMBINATION OF FLUPENTHIXOL + MELITRACEN FOR HUMAN USE BANNED VIDE G.S.R. 377(E) DATED 18.6.2013 AND G.S.R. 498(E) DATED 11.07.2014**

DTAB was apprised that, the Deanxit (FDC of Flupenthixol 0.5mg + Melitracen 10mg tablet) was approved on 28.10.1998 for manufacture and marketing in country. Parliament Standing Committee in its 59<sup>th</sup> report raised issue over approval of the FDC. Subsequently, the matter was examined in DTAB Sub-Committee/Expert Committee and Central Government vide G.S.R. 377(E) dated 18.06.2013 suspended the manufacturing and marketing of FDC of Flupenthixol + Melitracen.

The firm, M/s. Lundbeck India filed writ petition in Hon'ble High Court of Karnataka. The Single bench of Karnataka High Court in W.P. No. 28354/2013 vide its final order dated 14.08.2013 had inter alia held that the recommendation dated 11.05.2013 of New Drug Advisory Committee and the notification vide G.S.R. 377(E) dated 18.06.2013 issued by the Ministry of Health and Family Welfare stand quashed subject to the observation and liberty granted to the respondent to reconsider afresh and take a decision one way or other in accordance with the law.

Thereafter, the matter was again examined by the expert committee on 26.08.2013. The matter was placed before DTAB in its meeting held on 25.11.2013. DTAB agreed with the recommendation that the use of drug should be discontinued from the country.

Based on recommendation of DTAB & Expert Committee, Central Government had again prohibited the said FDC on 11.07.2014 vide G.S.R. 498(E).

Subsequently, the firm had filed the petition before the Hon'ble High Court of Karnataka. The Hon'ble High Court of Karnataka has issued order dated 24.07.2017 that petitions are accordingly allowed and the matter is again remanded to the respondents to comply with the terms of the directions given by the learned Judge and consider the case of the petitioners afresh in full compliance of the same, failing which, contempt action be initiated against them.

Subsequently, CDSCO had asked the petitioner to submit technical literature to the Directorate in order to examine the matter in the Subject Expert Committee (SEC).

M/s. Lundbeck India has submitted a letter wherein they stated that they no longer wish to commercialize Deanxit in India. However, M/s. Mankind Pharma had presented their proposal before 35<sup>th</sup> SEC (Neurology and Psychiatry) meeting held on 11.05.2018. The committee recommends that the firm should revise the Phase IV trial protocol as under:-

1. The study should be randomized, double blind, double dummy non inferiority design.
2. Sample size should be properly calculated based on statistical parameters and same should be mentioned in the protocol.
3. Detailed safety and efficacy assessment criteria should be clearly defined in the protocol.

4. Dose of the Clonazepam in comparator product should be 0.25mg.
5. ICD-10 should be used for diagnosis.
6. Details of the study sites along with undertaking by the investigators as per the Schedule-Y of Drugs & Cosmetics Rules 1945 should be submitted. Accordingly, the firm should submit the revised protocol within 6 weeks for review by the committee for further consideration in the matter.

DTAB deliberated the matter in detail and recommended to constitute a Sub-Committee under the Chairpersonship of Dr. Nilima Kshirsagar, Chair in Clinical Pharmacology, ICMR, Mumbai with following members to examine the issue and submit report for further consideration of the Board.

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|---|---------------|
| 1. Dr. Nilima Kshirsagar<br>Chair in Clinical Pharmacology,<br>ICMR, Mumbai                           | - Chairperson |
| 2. Dr. Smitha Deshpandey<br>Consultant, Department of Psychiatry,<br>RML Hospital & PGIMER, New Delhi | - Member      |
| 3. Dr. Shruti Srivastava<br>Professor, Department of Psychiatry,<br>UCMS, New Delhi                   | - Member      |
| 4. Dr. Ajit Awasthi<br>Professor of Psychiatry, PGIMER, Chandigarh                                    | - Member      |
| 5. Shri. Sanjeev Kumar<br>DDC(I), CDSCO(HQ), New Delhi  | - Convener    |

The Chairperson of the Sub-Committee may co-opt other experts from relevant field as deemed necessary for the purpose.

## **AGENDA NO.9**

### **CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 WITH RESPECT TO GLUTEN FREE MEDICINES**

DTAB was apprised that, a proposal has been received from the Department of Physical Medicine & Rehabilitation, AIIMS, New Delhi requesting to make provisions under Drugs and Cosmetics Rules, 1945 so that the manufacturers of drug products declare on their packing, if any of the contents of the drug product do or do not contain any ingredients having gluten and to enforce a law to avoid using Gluten containing agents as a bulk forming agent as a general principle.

DTAB deliberated that starch from corn and potato is more commonly used in pharmaceutical products and wheat starch may be used only very rarely. There may be possibility that only very small amount of wheat Gluten may be present in starch derived ingredients if wheat starch is used as the starting material. DTAB, however, after detailed deliberation deferred the proposal.

## AGENDA NO.10

### AGENDA RELATED TO AMENDMENT OF MEDICAL DEVICES RULES (MDR), 2017

#### 10.1. CONSIDERATION OF THE PROPOSAL TO AMEND MDR, 2017 TO INCLUDE PROVISIONS FOR COMPENSATION IN CASE OF INJURY OR DEATH DUE TO ANY MEDICAL DEVICE FOUND MALFUNCTIONING/ FOUND UNSAFE/ NOT IN COMPLIANCE WITH THE CONDITIONS OF THE LICENCE

The Ministry of Health & Family Welfare, Government of India has notified the Medical Devices Rules 2017 vide G.S.R. 78(E) dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940.

Said rules are effective from 01.01.2018 to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the notified medical devices in the country.

The Board was apprised that, the issue of having regulatory provision for payment of compensation by the manufacturer/ importer in case of injury or death of patient for use of notified medical device found malfunctioning/ found unsafe/ not in compliance with the conditions of the licence has been under consideration for quite some time now.

In said rules, there is no provision for payment of compensation in such scenario.

Therefore, following draft rules for incorporation the MDR, 2017 were placed before the Board:

*“98. (1) Without prejudice to any other provisions of these rules, where a medical device is found malfunctioning or unsafe or not in compliance with the conditions of the licence granted by the Central Licensing Authority or State Licensing Authority, as the case may be and has caused injury or death of the person on whose body such medical device was used,-*

- a. the manufacturer or importer shall provide medical management or compensation or both to such person.*
- b. the amount of compensation shall be determined in such manner and in accordance with the formula as prescribed in the New Drugs and Clinical Trials Rules, 2018.*
- c. the obligation under these rules shall be in addition to the action taken in terms of other provisions of the Act.”*

DTAB deliberated the matter that regulation of Medical Device is a vast and evolving field and often complicated due to legal technicalities. DTAB after detailed deliberation recommended to constitute a Sub-Committee comprising following members to examine the issue and to submit report for further consideration of the Board.

1. Dr. B. D.Athani - Chairperson  
Principal Consultant,  
Directorate General of Health Services,  
MoHFW, Nirman Bhawan, New Delhi
2. Dr. Y. K. Gupta -Co-Chairperson  
Former Professor & Head,  
Department of Pharmacology, AIIMS  
New Delhi
3. Dr. Rajesh Malhotra - Member  
Professor & Head,  
Department of Orthopedics,  
AIIMS, New Delhi
4. Dr. Ramesh Chander - Member  
Head, Central Institute of Orthopedics,  
Safdarjung Hospital & VMMC, New Delhi
5. Shri. N.K. Ahooja, - Member  
Drugs Controller, Haryana
6. Mr. Bejon Mishra, Consumer Expert - Member
7. Shri. Pavan Choudary, - Member  
Chairman& Director General,  
Medical Technology Association of India (MTAI),  
Haryana
8. Shri. Rajiv Nath, Forum Coordinator - Member  
Association of Indian Medical Device Industry  
(AIMED),New Delhi
9. Shri. Rishi Kant Singh - Member  
Legal Advisor  
New Delhi
10. Dr. Ravi Kant Sharma - Convener  
DDC(I) (I/C), CDSCO(HQ), New Delhi

The Chairperson of the Sub-Committee may co-opt other experts from relevant field as deemed necessary for the purpose.

## **10.2. CONSIDERATION OF THE PROPOSAL TO INCLUDE PROVISION FOR SUSPENSION AND CANCELLATION OF IMPORT LICENCE IN MDR, 2017**

The Board was apprised that, Chapter V of the Medical Devices Rules, 2017 specifies the provisions relating to import of medical devices. As per rule 34 in the MDR, 2017 an authorized agent having licence to manufacture for sale or distribution or wholesale licence for sale or distribution under these rules, shall make an application for grant of import licence for medical device to the Central Licensing Authority.

As per rule 36 in the MDR, 2017, the Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

However, there is no provision under the said rules for suspension and cancellation of Import licence of the medical devices in case of non-compliance with the regulatory provisions.

Therefore, following draft provisions were placed before DTAB for considering incorporation of the same under the MDR, 2017:

Suspension and cancellation of licence.—

- (1) Where the licensee contravenes any provision of the Act and these rules, the Central Licensing Authority, shall, after giving the licensee an opportunity to show cause as to why such an order should not be passed, shall by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary either wholly or in respect of any of the medical device or cancel the import licence.
- (2) A licensee whose import licence has been suspended or cancelled by the Central Licensing Authority, under sub-rule (1), may within forty-five days of the receipt of a copy of the order by such authority, prefer an appeal to the Central Government and the Central Government, shall after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.
- (3) The Central Licensing Authority may revoke suspension order issued under sub-rule (2) for reasons to be recorded in writing.
- (4) Orders of suspension issued or revoked; or cancellation of licence shall be duly published on the concerned websites of the Central Licensing Authority.

DTAB after deliberation agreed to incorporate the above provisions relating to suspension and cancellation of import licence in the MDR, 2017.

**10.3. CONSIDERATION OF THE PROPOSAL TO AMEND ANNEXURE ‘A’ OF FIFTH SCHEDULE IN MDR, 2017 IN RESPECT OF ENVIRONMENTAL REQUIREMENTS FOR CATHETERS/ ABLATION DEVICE/ INTRAVENOUS (IV) CANNULAE/ SCALP VEIN SET/ HYPODERMIC SYRINGES/ HYPODERMIC NEEDLES/ PERFUSION SETS**

The Board was apprised that, Fifth Schedule of the Medical Device Rules, 2017 specifies the Quality Management System for Medical Devices and in vitro diagnostic medical devices. Annexure A in said schedule specifies the environmental requirements for medical devices and *in-vitro* diagnostic medical devices.

To further streamline the requirements, Annexure A of the Fifth Schedule of said rules in respect of Catheters/Ablation Device/ IV Cannulae/ Scalp Vein Set/ Hypodermic Syringes/ Hypodermic Needles/ Perfusion Sets may be amended as under.

In Annexure A of the Fifth Schedule, for the words (mentioned in 1<sup>st</sup> column, 8<sup>th</sup> Row) i.e.

“

<b>Name of Device</b>	<b>Type of Operation</b>	<b>ISO Class (at rest)</b>
Catheters/Ablation Device/ IV Cannulae/ Scalp Vein Set/ Hypodermic Syringes/ Hypodermic/Needles / Perfusion Sets	Assembly, Coating, Wrapping and Packing	7
	Component Preparation and Cleaning	8
	Moulding	9

”

following shall be substituted:

“

<b>Name of Device</b>	<b>Type of Operation</b>	<b>ISO Class (at rest)</b>
Catheters/ Ablation Device/ IV Cannulae/ Scalp Vein Set/ Hypodermic Syringes/ Hypodermic/Needles/ Perfusion Sets, intended to be used as sterile.	Assembly, Coating, Wrapping and Packing	7
	Component Preparation and Cleaning	8
	Moulding	9

”

DTAB after detailed deliberation opined that such provision already exists in Rule 7.5.1.2.1(b) of Medical Device Rules, 2017. However, the Board recommended that a clarification from DCG(I) may be issued in this regard.

#### **10.4. CONSIDERATION OF THE PROPOSAL TO AMEND THE REQUIREMENT OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (TSEs) OR BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) CERTIFICATE IN THE MDR, 2017 AND ESSENTIAL PRINCIPLES FOR SAFETY AND PERFORMANCE OF MEDICAL DEVICES GUIDELINES 2018**

The Board was apprised that, Appendix II of Part III in fourth schedule of the Medical Device Rules, 2017 specifies the requirement of Device master file for Medical devices other than IVD.

Fourth Schedule, Part III, Appendix II, 7.4 specifies the requirements for Biological safety as under:

- (ii) The dossier should contain a list of all materials of animal or human origin used in the device. For these materials, detailed information should be provided concerning the selection of sources or donors; the harvesting, processing, preservation, testing and handling of tissues, cells and substances of such origin should also be provided. Process validation results should be included to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. Transmissible Spongiform Encephalopathies (TSEs) or Bovine Spongiform Encephalopathy (BSE) Certificates should also be submitted.

Also, as per clause 5.4.2 in Essential principle for safety and performance of medical device guidelines -

‘Veterinary control shall also include that an animal source should be tested and to be free from Transmission Spongiform Encephalopathies (TSEs) and Bovine spongiform Encephalopathy (BSE).’

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) has made a representation to CDSCO that India is recognized among countries of negligible BSE risk category and is compliant with safety conditions according to the World Organization of Animal Health, an intergovernmental organization that is responsible for animal health. Regulators such as USFDA has provision for allowing devices made of materials of cattle origin from countries which have no incidence of TSEs/BSE. Considering the fact that India is not included in the list of countries codified under FDA and has no reported incidence of TSEs/BSE, it can be surmised that medical devices made of cattle materials of Indian Origin can be used in Medical Devices.

Further, SCTIMST has proposed that the clause 5.4.2 may be rephrased as under:

*“The animal source from a country of origin other than one recognized as having negligible BSE risk including India (in accordance OIE recommendations), should be tested and be free from Transmission Spongiform Encephalopathies (TSEs) and Bovine spongiform Encephalopathy (BSE).”*

Accordingly, following amendments have been proposed:

- 1) To amend sub clause (i) in 7.4 of Appendix II, Part III in Fourth Schedule, in MDR, 2017.
- 2) To rephrase the clause 5.4.2 in Essential principle for safety and performance of medical device guidelines.

DTAB deliberated the proposal and agreed to amend sub clause (i) in 7.4 of Appendix II, Part III in Fourth Schedule, in MDR, 2017 and to rephrase the clause 5.4.2 in Essential principle for safety and performance of medical device guidelines.

#### **10.5. CONSIDERATION OF PROPOSAL FOR EXEMPTION OF STATE GOVERNMENT/CENTRAL GOVERNMENT TESTING LABS FROM NABL ACCREDITATION UNDER MEDICAL DEVICES RULES, 2017 FOR TWO YEARS**

The Board was apprised that as per Rule 19 of the Medical Device Rules, 2017 no medical devices testing laboratory shall be established as designated Central medical device testing laboratory for Testing and Calibration Laboratories unless it has been duly accredited by the National Accreditation Body.

It was proposed to provide exemption from mandatory NABL accreditation under rules to State government/Central Government testing laboratories for two years, as there are some laboratories which are already involved in testing of medical devices like Surgical Dressings, Absorbent Cotton, Catheters etc. prior to these rules, under Medical Devices Rules, 2017, which are not NABL accredited.

DTAB deliberated the proposal and agreed for amendment in the Medical Devices Rules, 2017 to provide exemption for two years from mandatory NABL accreditation under these rules to State government/Central Government testing laboratories.

## AGENDA NO.11

### CONSIDERATION OF THE RECOMMENDATIONS OF EXPERT WORKING GROUP CONSTITUTED BY NBTC ON 'REVIEW AND RECOMMENDATIONS OF MANPOWER NORMS FOR BLOOD BANKS'

The Board was apprised that, the National Blood Transfusion Council (NBTC), MoHFW had constituted an Expert Working Group under Chairmanship of Special Director General of Health Services to review & revise the norms for technical manpower in blood banks. The report on 'Review and Recommendations of manpower norms for Blood Banks' was approved in the meeting of Governing Body of NBTC in 27<sup>th</sup> meeting held on 30.01.2018.

The recommendations includes staffing pattern & number of personnel in blood bank for amendment in the Part XIIB of Schedule F of Drugs & Cosmetics Rules, 1945 so as to ensure that all licensed blood banks deploy adequate, qualified and trained human resources to ensure availability and accessibility of safe and quality blood and blood components to the people of country.

The recommendations on staffing pattern and number of personnel in blood bank are as under:

#### Staffing pattern & numbers:

- (i) For Whole Human Blood (24 hours operations, blood collection/Processing in routine working hours, cross match and issue 24/7).

Staff required	Annual blood collection (units)				
	Up to 5000	Up to 10000	Up to 20000	>20000	>50000
Medical Officer In-charge /Medical Personnel	2	3	5	7	8
Counsellor/ Medical Social Worker	1	2	2	2	4
Registered Nurse	1	2	3	4	8
Blood Centre Technician	5	8	11	13	22

**Note:** For Blood Centre's collecting less than 3000 units per annum, the Counsellor or Medical Social Worker can be part time and shared with the institution.

- (ii) For outdoor blood donation camps/ blood mobile Van collection (additional minimum staff required to collect 50-120 blood units per camp).

Additional staff required Numbers	Numbers
Medical personnel	1
Counsellor/ Medical Social Worker	2
Registered Nurse	2
Blood Centre Technician	3

**Note:** The Medical Officer/ residents undergoing post graduate training, having minimum qualification of MBBS can attend Blood Donation Camps under the supervision of trained Medical Officer of the blood centre.

(iii) For Blood Component separation

<b>Additional staff required</b>	<b>Annual blood collection (units)</b>				
	<b>Up to 5000</b>	<b>Up to 10000</b>	<b>Up to 20000</b>	<b>&gt;20000</b>	<b>&gt; 50000</b>
<b>Blood Centre Technical Supervisor</b>	1	1	1	1	1
<b>Blood Centre Technician</b>	1	2	3	3	4

(iv) For Aphaeresis (additional minimum staff required to conduct 20 Aphaeresis per month)

<b>Additional staff required</b>	<b>Number</b>
<b>Medical personnel</b>	1
<b>Nurse/ Technologist</b>	1

DTAB deliberated the recommendations of Expert Working Group constituted by NBTC, MoHFW and opined that public notice may be issued by CDSCO for seeking comments/ suggestions on the above recommendations on staffing pattern & number of personnel in blood banks for further consideration.

## AGENDA NO.12

### CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF THE DRUGS AND COSMETICS RULES, 1945 BY INTRODUCING REGULATORY PROVISIONS FOR SALE OF DRUGS BY E-PHARMACY AS PART VIB

DTAB was apprised that, the Department of Health & Family Welfare had published draft vide G.S.R. 817(E) dated 28.08.2018 further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board.

The new set of rules/Forms mainly consists of the following sub-headings:

<b>RULE / FORM</b>	<b>TITLE</b>
67 I	Definitions
67J	Registration of e-pharmacy
67K	Disclosure of information generated through e-pharmacy portal
67L	Application for registration of e-pharmacy
67M	Conditions of registration of e-pharmacy
67N	Grant of registration of e-pharmacy
67O	Periodic Inspection of e-pharmacy
67P	Procedure for distribution or sale, of drugs through e-Pharmacy
67Q	Validity of registration of e-pharmacy
67R	Renewal of Registration of e-pharmacy
67S	Prohibition of advertisement of drugs through e-pharmacy
67T	Suspension or cancellation of registration
67U	Complaint Redressal mechanism
67V	Monitoring of e-pharmacy
67W	Mode of payment of fee
FORM 18AA	Application for grant of Registration or Renewal to distribute and sell, stock or exhibit or offer for sale, drugs through e-pharmacy
FORM 21AA	Registration to distribute and sell, stock or exhibit or offer for sale, drugs through e-pharmacy

The Ministry in its draft notification invited objections and suggestions from public within the specified period and comments received are under considered by the Central Government for finalization.

DTAB agreed on the need for amending the Drugs and Cosmetics Rules, 1945 for regulation of sale of drugs by E-Pharmacy and asked CDSCO to bring the final version of the draft notification to DTAB for review.

### **AGENDA NO.13**

#### **CONSIDERATION OF THE PROPOSAL FOR NOTIFICATION AND RECOGNITION OF THE CHAUDHARY CHARAN SINGH NATIONAL INSTITUTE OF ANIMAL HEALTH (CCSNIAH), BAGHPAT, U.P. AS CENTRAL DRUGS LABORATORY (CDL) FOR QUALITY CONTROL (QC) TESTING OF VETERINARY BIOLOGICALS**

DTAB was apprised that, the Department of Health & Family Welfare had published draft vide G.S.R. 654 (E) dated 17.07.2018 further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 6, section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation after publication with the Drugs Technical Advisory Board, for including the functions of the Chaudhary Charan Singh National Institute of Animal Health, Baghpat, Uttar Pradesh and its Director in respect of quality control testing of two veterinary vaccines namely, Haemorrhagic Septicaemia vaccine and Ranikhet Disease vaccine.

Ministry of Agriculture and Farmers Welfare, Department of Animal Husbandry, Dairying and Fisheries and Chaudhary Charan Singh National Institute of Animal Health (CCSNIAH) had requested for the recognition of CCSNIAH, Baghpat, U.P. as Central Drugs Laboratory (CDL) for QC testing of Veterinary Biologicals, in the first phase, testing of vaccines for Haemorrhagic Septicaemia (HS), Black Quarter (BQ), Peste des Petits Ruminants (PPR), Goat pox and Ranikhet Disease.

The facility was jointly inspected along with expert from Indian Veterinary Research Institute (IVRI), Izzatnagar and recommended to consider for recognition of the CCSNIAH, Baghpat as CDL initially for HS Vaccine and Ranikhet disease Vaccine under the Drugs & Cosmetics Rules, 1945. The proposed lab was advised for complete QC testing of minimum 5 batches of HS vaccine and Ranikhet disease Vaccine and directed to submit the data for verification. Accordingly, the inspection team verified the non-compliances noted earlier and recommended for the notification of CCSNIAH as Central Drugs Laboratory for HS vaccine and Ranikhet Disease vaccine only.

DTAB deliberated the proposal and agreed for amendment in the D&C Rules, 1945 to consider the Chaudhary Charan Singh National Institute of Animal Health, Baghpat, Uttar Pradesh as Central Drugs Laboratory (CDL) in respect of quality control testing of two veterinary vaccines namely, Haemorrhagic Septicaemia vaccine and Ranikhet Disease vaccine.

## **AGENDA NO. 14**

### **CONSIDERATION OF THE PROPOSAL FOR NOTIFICATION AND RECOGNITION OF THE INDIAN INSTITUTE OF INTEGRATIVE MEDICINE (IIIM), JAMMU AS CENTRAL DRUGS LABORATORY (CDL) FOR TESTING OF PHYTOPHARMACEUTICAL CLASS OF DRUGS**

DTAB was apprised that, the Drugs and Cosmetics Rules, 1945 has already been amended vide G.S.R. 918(E) dated 30.11.2015 incorporating the detailed guidelines and requirements for approval of new Phytopharmaceutical drugs.

A request was received from Indian Institute of Integrative Medicine (IIIM), CSIR, Jammu, to declare the institute as CDL for testing of Phytopharmaceutical drugs under the provisions of the Drugs & Cosmetics Rules, 1945.

In order to assess the eligibility of the institute as notified Government laboratory for testing of Phytopharmaceutical class of drugs, an Expert Committee was constituted in August 2016 with the following members:

1. Prof. C. K. Kokate, Vice Chancellor, KLE University, Belgaum, Karnataka
2. Dr. D. B. Anantha Narayana, Chairman, HPCDC-IPC
3. Dr. Parthajyoti Gogoi, Director, RDTL, Guwahati

The Expert Committee inspected and recommended that IIIM, Jammu may be considered for notification as Central Drugs Laboratory for testing of Phytopharmaceutical drugs.

Considering the recommendation of the Expert Committee, the proposal of considering the IIIM, Jammu as Central Drugs Laboratory for testing of Phytopharmaceutical drugs under the provisions of Drugs and Cosmetics Rules, 1945 was placed before the Board.

DTAB deliberated the proposal and agreed for notification of Indian Institute of Integrative Medicine (IIIM), Jammu as Central Drugs Laboratory (CDL) for testing of Phytopharmaceutical drugs under the provisions of Drugs and Cosmetics Rules, 1945 subject to the condition that the institute should provide dedicated lab facility to act as an independent laboratory as CDL separated from the research and manufacturing facilities of the institute.

## **AGENDA NO.15**

### **CONSIDERATION OF THE PROPOSAL FOR WITHDRAWAL OF NOTIFICATION G.S.R 743(E) DATED 10.08.1989 ISSUED UNDER SECTION 26A FOR ALLOWING MANUFACTURING AND MARKETING OF FIXED DOSE COMBINATION OF INJECTABLE PREPARATIONS CONTAINING SYNTHETIC OESTROGEN AND PROGESTERONE**

It was informed that, the Board in its 78<sup>th</sup> meeting held on 12.02.2018 deliberated the matter of lifting the ban imposed on Fixed Dose Combination injectable preparation of synthetic Oestrogen and Progesterone prohibited under Section 26A vide G.S.R 743(E) dated 10.08.1989, in the light of the clinical trials conducted with Cyclofem and Norethisterone Enanthate (NET-EN) by the ICMR. Accordingly, DTAB had constituted a Sub-Committee under the Chairmanship of Dr. Nilima Kshirsagar to examine the matter.

The Sub-Committee after examination of the matter concluded that:

1. There is enough evidence available regarding the safety and efficacy of the injectable FDC consisting of Medroxyprogesterone acetate 25 mg + Estradiol cypionate 5mg
  - The study conducted by the ICMR
  - The FDC is approved for marketing and is in use in several countries
  - The FDC is included in the list of Essential Medicines of the World Health Organization (20<sup>th</sup> Edition, 2017)
2. There is a need for expanding the choices of injectable contraceptives available to Indian women.

Sub-Committee recommended for denotification of the ban imposed on Fixed Dose Combination of injectable preparation of synthetic Oestrogen and Progesterone and consideration of approval of Medroxyprogesterone acetate 25 mg + Estradiol cypionate 5mg injection for prevention of pregnancy.

The Sub-Committee noted that the FDC of Medroxyprogesterone acetate 25mg + Estradiol cypionate 5mg injection has never been marketed in the country. Therefore, it should be considered as a New drug as per the provisions of the Drugs and Cosmetics Rules, 1945.

DTAB examined the report of the Sub-Committee and agreed to the recommendation for withdrawal of notification of the ban imposed on Fixed Dose Combination of injectable preparation of synthetic Oestrogen and Progesterone. As this FDC has never been marketed in the country, the FDC of synthetic Oestrogen and Progesterone should be considered as a new drug as per provisions of Drugs and Cosmetics Rules, 1945. However, the applicants should obtain new drug approval for FDC of Medroxyprogesterone acetate 25 mg + Estradiol cypionate 5mg injection.

## **AGENDA NO.16**

### **CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 CONSEQUENT TO G.S.R 1337(E) DATED 27.10.2017 FOR HAVING EFFECTIVE IMPLEMENTATION OF PERPETUITY OF LICENCES**

The Board was apprised that, the Drugs and Cosmetics rules, 1945 were amended vide G.S.R. 1337(E) dated 27.10.2017 after consultation with DTAB providing that the manufacturing and sale licences of drugs shall remain valid if licensee deposits licence retention fee every five years, unless the licences are suspended or cancelled by the Licensing Authority. In the case of manufacturing licences, the premises shall be inspected jointly by the Central and State Drugs Inspectors at least once in three years or as required as per the risk based approach. With this requirement of renewal of manufacturing and sale licences were removed for ease of continuation of business.

Representations were also received from various State Licensing Authorities regarding certain anomalies in the published rules which were causing difficulties at the implementation level. Accordingly, the Rules and Forms have to be amended as given below:

(A) For omission from the rules:

1. Rule 150J. Renewal
2. Form 26J i.e. "Certificate of renewal of loan licence to manufacture for sale of Large Volume Parenterals or Sera and Vaccine or recombinant DNA (r-DNA) derived drugs specified in Schedule C and C-1 excluding those specified in Schedule X"

(B) For amendment of the rules:

1. Rule 150E. Condition of approval
2. Form 37. Approval for carrying out tests on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs /cosmetics.

DTAB deliberated and agreed for amendment of Drugs & Cosmetics Rules to streamline the procedure in line with the G.S.R 1337(E) for effective implementation of perpetuity of licences.

## AGENDA NO.17

### CONSIDERATION OF THE RECOMMENDATIONS OF THE SUB-COMMITTEE OF DTAB ON HOMEOPATHY FOR AMENDMENT OF DRUGS AND COSMETICS RULES, 1945

It was informed that, as per recommendation of DTAB in its 78<sup>th</sup> meeting held on 12.02.2018, Sub-Committee of DTAB on Homeopathy was reconstituted to deliberate technical matters relating to Homeopathy and give its recommendations.

The Sub-Committee in its 16<sup>th</sup> meeting held on 30.05.2018 has made certain proposals for amendment of Drugs and Cosmetics Rules, 1945 for consideration of the DTAB.

DTAB deliberated the recommendations of the Sub-Committee in detail. The recommendations of the Board on each recommendation of the Sub-Committee are as under:

1. The list of authoritative text books on Homoeopathy to be included in Drugs & Cosmetics Rules, 1945 as a separate Schedule i.e., Schedule Z.

**Recommendation:** Recommended to include authoritative text books on Homoeopathy in First Schedule of Drugs & Cosmetics Act, 1940 instead of including a separate Schedule.

2. Inclusion of French Homeopathic Pharmacopoeia and European Pharmacopoeia in clause 4A(b) & (c) of the Second Schedule to the Drugs & Cosmetics Act, 1940.

**Recommendation:** Agreed for the proposal to amendment of Second Schedule of Drugs & Cosmetics Act, 1940.

3. To amend the existing definition of Rule 2(dd) of Drugs & Cosmetics Rules 1945, so as to clarify the veterinary use of Homoeopathic Medicines.

**Recommendation:** DTAB deliberated the proposal and opined that such provision already exists in Rule 2(dd) and there is no need to specify Homoeopathic Medicines for veterinary use. However, the Board recommended that a clarification from DCG(I) may be issued in this regard.

4. Certain amendment in Rule 30AA for New Homoeopathic Medicines and Combination.

**Recommendation:** Agreed for the proposal to amend Rule 30AA for inclusion of provisions regarding New Homoeopathic medicines and its combinations.

5. To delete the provision of sub-rule (1) of Rule 67F of Drugs & Cosmetics Rules 1945 so as to enable Homoeopathy Physicians to practice in the premises having sale licence where Homeopathy Medicine are sold.

**Recommendation:** Deferred the proposal and recommended that a clarification from DCG(I) may be issued in this regard.

6. Inclusion of graduate in Science with Botany, Chemistry and Zoology as a subject under Rule 85E(1) of Drugs & Cosmetics Rules, 1945.

**Recommendation:** Agreed for the proposal to amend Rule 85E(1) of Drugs & Cosmetics Rules, 1945.

## **AGENDA NO.18**

### **CONSIDERATION OF PROPOSAL TO AMEND RULE 43-A OF THE DRUGS AND COSMETICS RULES TO NOTIFY DEVI AHILYABAI HOLKER AIR PORT, INDORE AS PORT OF ENTRY FOR DRUGS/PHARMACEUTICALS**

DTAB was apprised that, a representation had been received from the Commissioner, Food and Drugs Administration, MP regarding problems raised by pharma sector of Madhya Pradesh during the workshop “Enhancing Exports from Pharma Sector in Madhya Pradesh” on 04.10.2018 at Indore related to import of drugs/pharmaceuticals to Madhya Pradesh from sea ports and air ports located in other States which are too far and it is more time consuming.

To support the pharma sector of MP, the Commissioner, FDA, MP has requested to pursue the issue for notification of “Devi Ahilyabai Holker Air Port, Indore, Madhya Pradesh” as port of entry for Drugs/Pharmaceuticals under Rule 43-A of the Drugs and Cosmetics Rules, 1945.

Rule 43-A of the Drugs and Cosmetics Rules permits the import of drugs into the country through notified ports only.

DTAB deliberated the proposal and recommended to notify Indore as Inland Container Depot under Rule 43-A of the Drugs and Cosmetics Rules, 1945.

## AGENDA NO.19

### **CONSIDERATION OF THE PROPOSAL FOR RECONSTITUTION OF A STANDING COMMITTEE OF DTAB FOR PERIODIC REVIEW OF THE MARKETING DRUGS IN RESPECT OF THEIR INCLUSION/ DELETION IN SCHEDULE-H OF THE DRUGS AND COSMETICS RULES, 1945**

It was informed that, DTAB in its 77<sup>th</sup> meeting held on 16.06.2017 deliberated the proposal to amend Schedule H to include certain steroid preparations which are misused mainly as topical steroids leading to extensive tinea infections and agreed. The Board further recommended to constitute a Standing Committee for periodic review of the marketed drugs in respect of their inclusion/deletion in Schedule-H of the Drugs and Cosmetics Rules, 1945.

The meeting of Standing Committee could not convene due to unavoidable circumstances. Now the Board may reconsider the matter for recommendation.

DTAB deliberated the matter and recommended to constitute a Sub-Committee in place of Standing Committee comprising following members for periodic review of the marketed drugs in respect of their inclusion/ deletion in Schedule-H of the Drugs and Cosmetics Rules, 1945.

- |  |                  |
|--|------------------|
| 1. Dr. A.K.Gadpayle<br>Addl.DGHS, Ministry of Health & Family Welfare,<br>Nirman Bhawan, New Delhi   | - Chairperson    |
| 2. Dr. Y.K. Gupta<br>Former Professor & Head, AIIMS, New Delhi   | - Co-Chairperson |
| 3. Dr. Harmeet Singh Rehan<br>Professor & Head, Dept. of Pharmacology,<br>Lady Harding Medical College, New Delhi                            | - Member         |
| 4. Dr. Santanu Kumar Tripathi<br>Professor & Head,<br>Dept. of Clinical & Experimental Pharmacology,<br>School of Tropical Medicine, Kolkata | - Member         |
| 5. Dr. B.Gupta<br>Professor & Head, Dept. of Medicine,<br>NDMC Medical College & Hindu Rao Hospital,<br>New Delhi                            | - Member         |
| 6. Shri. Kasireddy V.R.N. Reddy, IPS<br>DG Drugs & Copyright, Andhra Pradesh   | - Member         |
| 7. Shri. A. K. Pradhan<br>DDC(I), CDSCO(HQ), New Delhi   | - Convener       |

The Chairperson of the Sub-Committee may co-opt other experts from relevant field as deemed necessary for the purpose.

## **AGENDA NO.20**

### **CONSIDERATION OF THE PROPOSAL FOR RECONSTITUTION OF A SUB COMMITTEE OF DTAB TO EXAMINE CONTINUED MARKETING OF THE DRUG BUCLIZINE FOR INDICATIONS OTHER THAN APPETITE STIMULANT**

It was informed that, DTAB in its 72<sup>nd</sup> meeting held on 27.06.2016 deliberated the proposal to prohibit the manufacture for sale or for distribution of the drug Buclizine as appetite stimulant under the provisions of section 26A of Drugs and Cosmetics Act, 1940 in public interest. The board recommended to constitute a Sub-Committee to examine continued marketing of the drug, 'Buclizine' for indications other than appetite stimulant.

The meeting of Sub-Committee could not convene due to unavoidable circumstances. Now the Board may reconsider the matter for recommendation.

DTAB deliberated the matter and recommended to re-constitute a Sub-Committee comprising of following members to examine the issue and to submit the report for further consideration.

- |  |               |
|--|---------------|
| 1. Dr. Nilima Kshirsagar<br>Chair in Clinical Pharmacology, ICMR, Mumbai                             | - Chairperson |
| 2. Dr. Sanjeev Sinha<br>Professor, Department of Medicine,<br>AIIMS, New Delhi                       | - Member      |
| 3. Dr. V. M. Motghare<br>Professor and Head, Dept. of Pharmacology,<br>Govt. Medical College, Nagpur | - Member      |
| 4. Shri. R. Chandrashekar<br>DDC(I), CDSCO(HQ), New Delhi  | - Convener    |

The Chairperson of the Sub-Committee may co-opt other experts from relevant field as deemed necessary for the purpose.

## **AGENDA NO. 21**

### **CONSIDERATION OF THE PROPOSAL FOR DESIGNATING CDTL, CHENNAI AND CDTL, MUMBAI AS APPELLATE LABORATORIES FOR DRUGS AND COSMETICS**

It was informed that, DTAB in its 80<sup>th</sup> meeting held on 25.07.2018 deliberated the proposal for designating CDTL, Mumbai and CDTL, Chennai as appellate laboratories for all classes of drugs and cosmetics except vaccines, sera, r-DNA products, Blood products, Phytopharmaceuticals and *in-vitro* diagnostics.

The Board recommended to assess the testing capacities of CDTL-Chennai, CDTL-Mumbai along with CDL-Kolkata for various categories of drugs including microbiology and their accreditation status.

Accordingly, a team of experts was constituted to assess the laboratories. The expert team audited all three laboratories and submitted its report for further consideration by the Board.

DTAB deliberated the report submitted by expert team and recommended CDSCO to take following actions on priority:

1. To initiate process for redistributing the man power in all Central Laboratories.
2. To develop a mechanism for designating other Central Drugs Testing Laboratories as appellate laboratory along with CDL Kolkata.
3. To review the procedures being followed in all the laboratories for testing.

The Board recommended CDSCO to report progress at the next DTAB meeting.

## **AGENDA NO. 22**

### **CONSIDERATION OF THE PROPOSAL TO AMEND RULE 96 OF DRUGS AND COSMETICS RULES, 1945 CONSEQUENT TO G.S.R 222(E) DATED 13.03.2018 WITH RESPECT TO LABELLING REQUIREMENTS OF DRUGS**

The Board was apprised that, Rule 96 of the Drugs and Cosmetics Rules, 1945 had been amended vide G.S.R. 222(E) dated 13<sup>th</sup> March 2018 effective prospectively from 13<sup>th</sup> day of September, 2018 providing that the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be in the same font but at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written in brackets below or after the proper name.

Concerns have been received from Indian Drug Manufacturers' Association (IDMA) that printing brand name in brackets as provided in the above said amendment does not provide any additional benefit, but may be a violation of Trademark Rules. Hence, the IDMA has requested to omit the provision to write brand name in brackets.

Since, the matter is related to writing brand name on the label, it needs to be deliberated in the context of initiatives of the Government for promotion of generic medicines to improve its accessibility and affordability to the public.

DTAB deliberated the matter and agreed to amend Rule 96 of the Drugs and Cosmetics Rules, 1945 for omitting the provision of writing brand name or the trade name in brackets on the label of drug products in the labelling requirements specified recently vide G.S.R 222(E) dated 13.03.2018. However, the brand name and trade name if any shall be mentioned in accordance with the provisions of the rules except writing them in brackets.

## **ADDITIONAL AGENDA NO. S-1**

### **CONSIDERATION OF THE PROPOSAL TO AMEND ENTRY NO.33 OF SCHEDULE K TO INCLUDE NICOTINE ORALLY DISINTEGRATING STRIPS ALONG WITH NICOTINE GUMS AND LOZENGES FOR EXEMPTION FROM THE PROVISION OF SALE LICENCE**

DTAB was apprised that, as per Schedule K to the Drugs and Cosmetics Rules, under entry no. 33 provided exemptions for nicotine gum and lozenges containing 2mg of nicotine to be exempted from the provisions of sale licence subject to the condition that such a product has been manufactured under a valid drug manufacturing licence.

CDSCO had received application for permission to manufacture and market Nicotine Polacrilex orally disintegrating strips 2mg/4mg for the indication to reduce the withdrawal symptoms, including nicotine craving, associated with quitting the smoking and quitting chewed tobacco and gutkha containing tobacco. Based on recommendation of the Subject Expert Committee and the data generated by the applicant, CDSCO has granted the permission to manufacture and market Nicotine Polacrilex orally disintegrating strips 2mg/4mg to above indication with the condition, "Warning : To be sold by retail on the prescription of RMP only".

Now, the firm had requested to grant OTC (Non-Prescription) status for Nicotine Polacrilex orally disintegrating strips 2mg for the sake of convenience of patients and advantages over the existing product and for a tobacco free society.

As orally disintegrating strip is a type of formulation which acts in the same way as that of gums and lozenges. It is therefore, proposed to include orally disintegrating strip containing 2 mg of nicotine also under the said entry.

DTAB deliberated the proposal and agreed to amend the entry No.33 in Schedule K for providing exemption for all nicotine oral formulations containing 2mg of nicotine.

## **ADDITIONAL AGENDA NO.S-2**

### **CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 TO PROHIBIT ADVERTISEMENTS OF DRUGS SPECIFIED IN SCHEDULE G**

The DTAB apprised that, Representation has been received from the Director, Food and Drugs Administration, Goa regarding prohibition of advertisement of drugs specified in Schedule G under Drugs and Cosmetics Rules, 1945.

The Rule 74 & Rule 78 under Drugs & Cosmetics Rules, 1945 states that “No advertisement of the Drugs specified in schedule H, schedule H1 & schedule X shall be made except with previous sanction of the Central Government”. For the drugs specified in Schedule G, there is no provision for prohibition of advertisements which may lead to self-medication.

Therefore, it is proposed to amend the conditions of licence for manufacture of drugs prescribed under Drugs& CosmeticsRules, 1945 to prohibit the advertisement of drugs specified in Schedule G.

DTAB deliberated the proposal and agreed to prohibit the advertisements of drugs specified in Schedule G under Drugs& CosmeticsRules, 1945. Further the Board recommended that the Sub-Committee constituted under Agenda No. 19for periodic review of Schedule H should also examine the requirement of Schedule G as a separate Schedule and whether the drugs included in Schedule G can be shifted to Schedule H and submit report for further consideration.

The meeting ended with the vote of thanks to the Chair.

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