MINUTES OF THE 80TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 25TH July, 2018 AT DGHS, NIRMAN BHAWAN, NEW DELHI

PRESENT

1.	Dr. S. Venkatesh Director General of Health Services Nirman Bhawan, New Delhi	Chairman
2.	Dr. S. Eswara Reddy Drugs Controller General (India) FDA Bhawan, New Delhi	Member Secretary
3.	Shri C. Hariharan Director (In-charge) Central Drugs Laboratory, Kolkata	Member
4.	Dr. A. K. Tehlan Director, Central Research Institute, Kasauli, Himachal Pradesh	Member
5.	Dr. Jayshree Mehta President, Medical Council of India New Delhi	Member
6.	Dr. Pallavi Jain Govil Commissioner, Food Safety and Controller Food and Drugs Administration Bhopal (M.P)	Member
7.	Prof. M. D. Karvekar Pharmacy Council of India	Member
8.	Dr. G. B. Gupta Vice-Chancellor Pt. Deendayal Upadhyaya Memorial Health Sciences and Ayush University of Chhattisgarh, Raipur	Member
9.	Shri. Pankaj Patel Chairman and Managing Director, Zydus Cadila Group, Ahmedabad, Gujarat	Member
10.	Dr. Nilima Kshirsagar Chair in Clinical Pharmacology ICMR, Mumbai	Member

11. Dr. R.N. Tandon — Member
Honorary Secretary General
Indian Medical Association, New Delhi

12. Shri. M.S Lokesh Prasad, — Member
Scientific Officer & Govt. Analyst
Bengaluru, Karnataka

13. Dr. Vaishali N Patel, — Member
Govt. Analyst, Food & Drugs Laboratory
Vadodara, Gujarat.

The Director, Indian Veterinary Research Institute, Izatnagar; President, Pharmacy Council of India, New Delhi; Director, Central Drug Research Institute, Lucknow; Drug Controller, Assam; President, Indian Pharmaceutical Association, Bengaluru could not attend the meeting because of their other commitments.

Dr. S. Eswara Reddy, Member-Secretary, DTAB welcomed the Board members under the supervision of new chairman Dr. S. Venkatesh, DGHS. All members were introduced to the Chairman. The Chairman then requested DCG (I) to initiate the proceedings. Dr. S. Eswara Reddy, DCG (I) then explained briefly about DTAB Agenda along with Action Taken Reports on previous DTAB recommendations. Dr. Nilima Kshirsagar as Chairman of the sub-committee gave presentation on the sub-committee report with respect to banning of Fixed Dose Combinations (FDCs) consequent to the Hon'ble Supreme Court's directions.

AGENDA NO.1

ACTION TAKEN REPORT (ATR) FOR 79th DTAB MEETING HELD ON 16.05.2018

The Action Taken Report (ATR) on the recommendations of DTAB in 79th meeting was approved by the Board.

AGENDA NO. 2

CONSIDERATION OF REPORT OF SUB-COMMITTEE OF DTAB IN RESPECT OF THE DIRECTIONS OF HON'BLE SUPREME COURT OF INDIA IN THE CASE OF 344 FDCS + 5 FDCS PROHIBITED VIDES S.O. NO. 705 (E) TO 1048 (E) DATED 10.03.2016 AND S.O. NO. 1851 (E) TO 1855 (E) DATED 08.06.2017 OF THE MINISTRY OF HEALTH & FAMILY WELFARE

DTAB examined and agreed to the report submitted by the sub-committee and recommended for further action as per the report in the light of Hon'ble Supreme Court's order. Further Committee recommended that guidance and training material on FDCs may be prepared for applicants & stakeholders.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSALTO INCORPORATE PROVISIONSWITH RESPECT TO BIOLOGICAL PRODUCTS IN "NEW DRUGS AND CLINICAL TRIALS RULES, 2018" PUBLISHED AS DRAFT RULES VIDE G.S.R 104 (E) DATED 01.02.2018

DTAB deliberated and agreed to the proposal to incorporate provisions with respect to biological products in "New Drugs And Clinical Trials Rules, 2018" published as draft rules vide G.S.R 104 (E) dated 01.02.2018 during the finalization of draft rules as suggested by the Board members.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL FOR SEPARATE FEES FOR EACH DOSAGE /DOSAGE FORM/ROUTE OF ADMINISTRATION /INDICATION

DTAB deliberated and agreed for the proposal for separate fees for each dosage /dosage form/route of administration /indication.

The Board recommended for amendments of rule 122A and 122B of the Drugs & Cosmetics Rules, 1945 to include separate fee for each dosage /dosage form/route of administration /indication. Subsequently the same amendments shall be considered during finalization of the New Drugs and Clinical Trials Rules, 2018 published vide G.S.R 104(E) dated 01.02.2018.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN FORM 45 AND FORM 46 OF SCHEDULE-A CONSEQUENT TO THE AMENDMENT OF RULE 96 AND RULE 97 VIDE G.S.R 408 (E) AND G.S.R 222(E)

DTAB deliberated and agreed to the proposal for amendment in Form 45 and Form 46 of Schedule-A consequent to the amendment of Rule 96 and Rule 97 vide G.S.R 408 (E) dated 26.04.2018 and G.S.R 222(E) dated 13.03.2018.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL FOR UNIFORM IMPLEMENTATION DATE OF ALL GAZETTE NOTIFICATIONS REGARDING AMENDMENT OF RULE 96 AND RULE 97 OF D & C RULES, 1945

DTAB deliberated and agreed to the proposal for uniform implementation date of all gazette notifications regarding amendment of Rule 96 and Rule 97 of Drugs and Cosmetics Rules, 1945.

The Board recommended having 1st April, 2019 as the implementation date for G.S.R 408 (E) dated 26.04.2018, G.S.R 222(E) dated 13.03.2018 and G.S.R. 277(E) dated 23.03.2018.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL TO REPLACE THE STATE LICENSING AUTHORITY AS ISSUING AUTHORITY IN FORM MD-10 WITH CENTRAL LICENSING AUTHORITY TO STREAMLINE THE PROCEDURE BY AMENDING THE MEDICAL DEVICE RULES, 2017

DTAB deliberated and agreed to the proposal to replace the State Licensing Authority as Issuing Authority in Form MD-10 with Central Licensing Authority to streamline the procedure by amending the Medical Device Rules, 2017.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL TO AMEND NOTE APPENDED TO SCHEDULE H OF DRUGS AND COSMETICS RULES, 1945 TO CURB THE MISUSE OF PREPARATION CONTAINING HYDROQUINONE

DTAB deliberated and agreed to the proposal to amend Note appended to Schedule H of Drugs and Cosmetics Rules, 1945 to curb the misuse of preparation containing Hydroquinone.

In view of the above, the Paragraph 4 in the Note appended to Schedule H, shall be substituted as follows:

"*4. The salts, esters, derivatives and any preparations containing steroids and/ or Hydroquinone for topical or external use shall also be covered by this Schedule.*"

AGENDA NO. 9

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

DTAB deliberated the matter and suggested to assess the capacity of testing of the said Central Drugs Testing Laboratories including CDL Kolkata for various categories of drugs including microbiology and accreditation status.

AGENDA NO. 10

CONSIDERATION OF THE PROPOSAL FOR NOTIFICATION OF BLOOD PRESSURE MONITORING DEVICES, DIGITAL THERMOMETER AS DEVICES UNDER SECTION 3(b)(iv) OF THE DRUGS AND COSMETICS ACT, 1940

DTAB deliberated and agreed to the proposal for notification of Blood Pressure Monitoring Devices, Digital Thermometer as Devices under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940. In addition to the said devices, the Board also agreed to notify Nebulizer and Glucometer as devices under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940.

AGENDA NO. 11

CONSIDERATION OF THE PROPOSAL FOR EXEMPTION UNDER SECTION15 OF DMR(OA), 1954 TO COMMUNICATE "FEVER" FOR CREATING PUBLIC AWARENESS ON MANAGEMENT OF FEVER ASSOCIATED WITH COMMON SELF-LIMITING CONDITIONS SUCH AS FEVER ASSOCIATED WITH COMMON COLD AND FLU, DENGUE, CHIKUNGUNYA, FEVER ASSOCIATED WITH VACCINATION ETC.

DTAB deliberated and agreed to the proposal for exemption under Section 15 of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 to communicate "Fever" for creating public awareness on management of fever associated with common self-limiting conditions such as fever associated with Common Cold and Flu, Dengue, Chikungunya, fever associated with vaccination etc.

The Board further clarified that the exemption under Section 15 of DMR (OA) shall be provided for generic name of Paracetamol to communicate fever and not for Brand name.

AGENDA NO.S-1

CONSIDERATION OF THE PROPOSAL TO AMEND THE MEDICAL DEVICES RULES, 2017 TO ALLOW AUDIT OF THE MANUFACTURING SITE OF CLASS B, AFTER GRANT OF THE LICENSE TO MANUFACTURE, AS IN CASE OF CLASS A MEDICAL DEVICES

DTAB deliberated and agreed to the proposal to amend the Medical Devices Rules, 2017 to allow audit of the manufacturing site of Class B, after grant of the licence to manufacture, as in case of Class A medical devices.

AGENDA NO.S-2

CONSIDERATION OF THE PROPOSAL TO AMEND THE SECOND SCHEDULE FOR FEES OF FREE SALE CERTIFICATE IN THE MEDICAL DEVICES RULES, 2017 AS PER LICENSING PRACTICES

DTAB deliberated and agreed to issue Free Sale Certificate by State Licensing Authority for Class A & B Medical devices & by Central Licensing Authority for Class C &D Medical devices. Further committee also recommended that, fees of 1000 rupees shall be prescribed for each 'Category of medical devices' e.g. orthopaedic implants, cardiac stents, catheters etc. instead of 'each distinct medical device'.

AGENDA NO.S-3

CONSIDERATION OF THE PROPOSAL TO AMEND THE RULE 97 IN MEDICAL DEVICES RULES, 2017

DTAB deliberated and agreed to the proposal to amend the Rule 97 in Medical Devices Rules, 2017 as follows:

"The licence or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be deemed to be valid till its expiry or for a period of thirty months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules, provided the licence holder has applied for continuation of the license, on due dates."

AGENDA NO.S-4

CONSIDERATION OF THE PROPOSAL TO AMEND THE PART II IN FOURTH SCHEDULE IN THE MEDICAL DEVICES RULES, 2017

DTAB deliberated and deferred the proposal.

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

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