MINUTES OF THE 79th MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 16TH MAY, 2018 AT DGHS, NIRMAN BHAWAN, NEW DELHI

PRESENT

1.	Dr. Promila Gupta 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. Tahlan, 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.	Shri. Pankaj Patel, Chairman and Managing Director, Zydus Cadila Group, Ahmedabad, Gujarat	Member
8.	Dr. Nilima Kshirsagar, Chair in Clinical Pharmacology, ICMR, Mumbai	Member
9.	Shri. M.S Lokesh Prasad, Scientific Officer & Govt. Analyst Bengaluru, Karnataka	Member
10.	Dr. Vaishali N Patel, Govt. Analyst, Food & Drugs Laboratory Vadodara, Gujarat.	Member

SPECIAL INVITEES

1. Dr. Amit Misra,
Senior Principal Scientist & Head
Pharmaceutics & Pharmacokinetics
Central Drug Research Institute, Lucknow

2. Dr. V.K Monga,
Honorary Finance Secretary,
Indian Medical Association,
New Delhi -110002

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, Bengaluru, elected member by the Pharmacy Council of India from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy; Dr. G.B. Gupta, Vice Chancellor, Chhattisgarh, elected member by the Medical Council of India, from among teachers in medicine or therapeutics; Dr. R.N. Tandon, Indian Medical Association, New Delhi; Prof. Dr. T.V. Narayana, President, Indian Pharmaceutical Association, Bengaluru; could not attend the meeting because of their other commitments.

Dr. S. Eswara Reddy, Member-Secretary DTAB welcomed the newly constituted board members and special invitees under the supervision of new chairman Dr. Promila Gupta, 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.

AGENDA NO.1

ACTION TAKEN REPORT (ATR) FOR 78thDTAB MEETING HELD ON 12.02.2018

The Action Taken Report (ATR) on the recommendations of DTAB in 78th meeting was approved by the board with clarifications in respect of following agenda items:

Agenda No.2 : *Consideration of the proposal for examination of cases of banning of 344 FDCs + 05 FDCs by DTAB/ sub-committee and send report to the Central Government as directed by the Hon'ble Supreme Court of India within 6 months from the date on which this judgment is received by the DTAB.*

Board constituted a sub-committee under Chairmanship of Dr. Nilima Kshirsagar with other members to re-examine the issue and to submit the report in 3 months.

Dr. Nilima Kshirsagar requested the chairman for extending the time period till first week of July 2018 as the time given is not sufficient for completion of the report of all 344 FDCs + 05 FDCs. The Chairman agreed for

extension of time and informed to stick to the time-line given by the Hon'ble Supreme Court of India.

Agenda No.16 : *Consideration of the proposal for amendment of Para 10.9 of Schedule 'M' of Drugs and Cosmetics Rules, 1945 for waiver of requirement for vaccines manufactured using less than 60% residual shelf-life period in the country*

Dr. A.K Tahlan who was requested to coordinate with DBT informed that DBT is in the process of reviewing the provision and will be submitting their opinion shortly.

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 49 OF DRUGS AND COSMETICS RULES, 1945 RELATING TO THE QUALIFICATIONS OF INSPECTORS

The Board agreed for the proposal to amend Rule 49 of Drugs & Cosmetics, Rules, 1945 to include the qualification of "*Doctor in Pharmacy (Pharm. D.)*" and to remove proviso relating to experience under Rule 49 (i), (ii) and (iii) of Drugs & Cosmetics, Rules, 1945.

With regards to the proposal of omitting qualification "*Medicine with specialisation in Clinical Pharmacology or microbiology",* the Board did not agree for the same.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 TO MAKE MANDATORY SUBMISSION OF DATA WITH RESPECT TO LICENSED MANUFACTURING UNITS AND MEDICAL PRODUCTS BY SELF DECLARATION BY THE MANUFACTURERS

The Board agreed for the proposal to amend Drugs & Cosmetics Rules, 1945 for mandatory submission of the data with respect to the licensed manufacturing units and medical products by self declaration by the manufacturers on the online portal of SUGAM (www.cdscoonline.gov.in) through software for data management developed by MoHFW.

The drug manufacturers licensed to manufacture drugs in the country are required to upload on the SUGAM portal details of their manufacturing licences along with the list of licensed products for having up to date information of drugs manufactured in the country. This information is required to be verified by the concerned State Licensing Authority for confirmation.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 FOR USAGE OF DRUGS AFTER THEIR SHELF LIFE ON THE LABEL

DTAB deliberated and deferred the matter.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL TO USE THE QUALITY CONTROL LABORATORY FACILITIES OF PRIVATE LICENCED MANUFACTURERS FOR TESTING OF CERTAIN DRUGS FOR WHICH THE FACILITIES ARE NOT AVAILABLE IN GOVERNMENT LABORATORIES FOR SPECIFIC CATEGORIES OF DRUGS

DTAB deliberated and deferred the matter.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 FOR INCLUDING THE PROVISIONS FOR RESPONSIBILITY TO THE PERSONS WHO ARE ONLY MARKETING THE DRUGS WITHOUT HAVING ANY MANUFACTURING FACILITY USING LICENCED FACILITIES OF MANUFACTURERS

The DTAB deliberated the matter and agreed for the proposal to make the provisions under the Drugs and Cosmetics Rules in addition to the existing provisions for fixing the responsibility to persons who are marketing the drugs without having any manufacturing facility using licenced facilities of manufacturers. The Board however, clarified that the persons involved in any distribution channel should not be affected. The marketing firm should be treated as an agent of the manufacturer and no plea under Section 19 of the D&C Act 1940 should be applicable to it.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL FOR INTRODUCTION OF TRACE AND TRACK FOR MOST POPULAR OR TOP 300 PHARMACEUTICAL BRANDS AVAILABLE IN INDIAN MARKET AS TEST TRIAL ON VOLUNTARY BASIS BY THE MANUFACTURERS

The DTAB deliberated the matter and agreed for introduction of trace and track mechanism for major 300 pharmaceuticals brands on voluntary basis. The Board informed that an order may be issued by DCG (I) to all the concerned to this effect.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS & COSMETICS RULES, 1945 FOR MANDATING INDICATION OF RED/BROWN OR GREEN DOT ON EVERY PACKAGE OF SOAPS, SHAMPOOS, TOOTHPASTES AND OTHER COSMETICS AND TOILETRIES FOR NON-VEGETARIAN OR VEGETARIAN ORIGIN

The DTAB deliberated the matter and agreed to the proposal for mandating the indication of green or red /brown dot on every package of soaps, shampoos, tooth paste & other cosmetics & toiletries for vegetarian/non-vegetarian respectively in the Drugs and Cosmetics Rules.

However, opinion from stakeholders and public may be obtained before taking action in the matter.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 FOR INCLUDING MANDATORY PROVISION OF PHARMACEUTICAL COMPANIES TO SPEND AT LEAST ONE PER CENT OF THEIR NET PROFIT FOR PROVIDING FREE MEDICINES IN MEDICINE BANK TO BE USED BY THE CENTRAL GOVERNMENT DURING HEALTH EMERGENCIES, DISASTER OR ANY OTHER CIRCUMSTANCES CONSIDERED NECESSARY BY THE CENTRAL GOVERNMENT AS PART OF CORPORATE SOCIAL RESPONSIBILITY (CSR)

DTAB deliberated the matter and agreed initially on voluntary basis.

AGENDA NO. 10

CONSIDERATION OF THE PROPOSAL TO AMEND THE MEDICAL DEVICES RULES, 2017- ISSUES GENERAL CLARIFICATION ETC. FOR SMOOTH AND UNIFORM IMPLEMENTATION

The Medical Devices Rules, 2017 was published vide G.S.R. 78(E) dated 31.01.2017 under the provisions of Drugs and Cosmetics Rules by the MoHFW. These rules were made effective from 01.01.2018 to regulate the Clinical Investigation, Manufacture, Import, Sale & Distribution of Medical Devices in the country.

The Board considered the representations received from the industry/ stakeholders/ associations for amending the Medical Devices Rules, 2017 and the details are as follows:

10.1 CONSIDERATION OF THE PROPOSAL TO AMEND ENVIRONMENTAL REQUIREMENTS IN RESPECT OF MANUFACTURING FACILITY AS SPECIFIED IN THE FIFTH SCHEDULE OF MEDICAL DEVICES RULES, 2017

The DTAB deliberated the matter and recommended for the amendment of Medical Devices Rules, 2017 in respect of environmental requirements for the final packing of sterile surgical dressings and also for final packing of condoms at Annexure A in the 5th Schedule as detailed below:

"a) Annexure A of the Fifth Schedule of said rules may be amended as follows:

I. Environmental conditions for weaving and assembly and gauzing should be deleted and only final primary packing for sterile surgical dressings should be included, accordingly, for sterile surgical dressings, Annexure A should be amended and the provision should be substituted with following:

Name of the device	Type of operation	ISO Class (At rest)
Sterile Surgical Dressings	Final primary packing	9

II. Similarly, for condoms neat & clean environment free from dust etc. shall be replaced instead of 5 μ filter."

10.2 CONSIDERATION OF THE PROPOSAL TO ADD PROVISIONS IN RESPECT OF THE WAIVER OF CLINICAL PERFORMANCE EVALUATION FOR IVDs, IN-LINE WITH WAIVER GIVEN FOR MEDICAL DEVICE UNDER RULE 63 OF MEDICAL DEVICES RULES, 2017

The Board deliberated the matter and agreed for the proposal to amend the provisions in Rule 64 making it identical for waiver of clinical performance evaluation of *in-vitro* Diagnostic medical devices in-line with waiver given for medical devices under Rule 63 of the Medical Device Rules 2017.

10.3 WHEN MEDICAL DEVICES WHICH ALREADY EXIST IN THE INDIAN MARKET FOR USE ARE BROUGHT IN FUTURE UNDER REGULATION, THEN SUCH DEVICES SHALL NOT BE A NEW MEDICAL DEVICE

DTAB deliberated and recommended with condition that the applicant need to provide evidences of safety, performance & effectiveness.

10.4 CONSIDERATION OF THE PROPOSAL FOR ENABLING NABL ACCREDITED LABORATORIES FOR ISSUING PERFORMANCE EVALUATION REPORT UNDER MEDICAL DEVICES RULES, 2017

The Board deliberated the matter and agreed for the proposal for enabling NABL accredited laboratories or by any hospital accredited by national accreditation board for hospitals and health care providers (NABH) for issuing performance evaluation report under Medical Devices Rules, 2017 to harmonize the requirements at par with the international rules and accordingly, the requirements specified in sub-clause (h) of clause (ii) of Part II of the Forth Schedule may be amended.

10.5 CONSIDERATION OF THE PROPOSAL TO INCLUDE ALL IMPLANTABLE MEDICAL DEVICES AND OTHER HIGH END EQUIPMENT UNDER THE PURVIEW OF SECTION 3 (B) (IV) OF THE DRUGS AND COSMETICS ACT, 1940 AS MEDICAL DEVICES

The Board deliberated the matter and agreed for the proposal to include the following medical devices and other high end equipments under the purview of Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 :

1. All implantable medical devices
2. CT scan equipment
3. MRI equipment
4. Defibrillators
5. Dialysis Machine
6. PET equipment
7. X-Ray Machine

10.6 CONSIDERATION OF AGENDA TO INCORPORATE PHARMACY DEGREE/ POST GRADUATION AS A QUALIFICATION IN MEDICAL DEVICES RULES, 2017

The Board deliberated the matter and agreed for the proposal to incorporate pharmacy degree/ post graduation as a qualification in Medical Devices Rules, 2017.

10.7 ACCEPTANCE OF EIFU AS OPTION IN PLACE OF TRADITIONAL PAPER IFU

The Board deliberated the matter and agreed for the proposal to accept the eIFU as an option in place of traditional paper IFU.

10.8 CONSIDERATION OF THE PROPOSAL FOR ENABLING SALE OF *in-vitro* DIAGNOSTIC DEVICES PRODUCTS BY WHOLE SALE LICENSE HOLDER

The Board deliberated the matter and recommended for the sale of *in-vitro* Diagnostic products shall be undertaken by a valid, whole license holder to Hospitals, Pathology Laboratories, Blood Banks & other such institution, based on requisition for such products, & the records of which shall be maintained.

In case an *in-vitro* Diagnostic product is to be sold directly to the consumer, it shall be supplied through a valid license holder, for sale on retail for such products.

10.9 CONSIDERATION OF THE PROPOSAL FOR NOTIFICATION OF BONE MARROW CELL SEPARATOR AS A MEDICAL DEVICE UNDER SECTION 3(b) (iv) OF THE DRUGS AND COSMETICS ACT, 1940

The Board deliberated the matter and agreed for the proposal for notification of bone marrow cell separator as a medical device under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940**.**

10.10 CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF CDSCO LOGO ON MEDICAL DEVICES LABELS

The Board deliberated the matter and agreed for the proposal that inclusion of medical devices approved by Licensing Authority under Drugs & Cosmetics Rules, 1945 may bear CDSCO logo on its labels**.**

10.11 CONSIDERATION OF THE PROPOSAL TO AMEND MEDICAL DEVICES RULES, 2017 TO AMEND THE DEFINITION AND APPLICABILITY CLAUSE FOR THE INCLUSION OF DISINFECTANTS

The Board deliberated the matter and recommended for amendment of the definition of medical device in clause (ii) of rule 2 and clause (ii) of rule 3(zb) as under:

For the words "substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); following is proposed to be substituted:

"disinfectants that are used to pre-clean or decontaminate medical devices prior/after to patient use and substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), notified under sub-clause (ii)".

Further, the Board also recommended for allied amendments in preamble/scope in the rules.

AGENDA NO. 11

CONSIDERATION OF THE PROPOSAL FOR GRANT OF PERMISSION FOR MANUFACTURE OF DRUGS WHICH ARE UNAPPROVED OR PROHIBITED FOR MANUFACTURE AND SALE UNDER THE ACT, DIRECTLY BY THE STATE LICENSING AUTHORITIES FOR THE PURPOSE OF EXPORT ONLY WITHOUT REQUIREMENT OF PRIOR NOC FROM CDSCO

DTAB deliberated the matter and agreed to delegate the power for grant of permission for manufacture of drugs which are unapproved or prohibited for manufacture and sale under the act, directly by the state licensing authorities for the purpose of export only without requirement of prior NOC from CDSCO.

However, the Board informed that the State Licencing Authorities should share the information online with CDSCO for all such export licences with quantities and the names of the countries exported.

AGENDA NO. 12

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF THE PROVISIONS INTRODUCED UNDER THE DRUGS AND COSMETICS RULES VIDE G.S.R 1337(E) DATED 27.10.2017 REGARDING PERPETUITY OF LICENCE AND INSPECTIONS TO ENSURE COMPLIANCE

DTAB deliberated the matter and agreed for amendment of the provisions introduced under the Drugs and Cosmetics Rules, 1945 vide G.S.R 1337(E) dated 27.10.2017 providing that the manufacturing and sale licences shall remain valid forever, if licencee deposits licence fee every five years, unless the licences are suspended or cancelled by the Licencing Authority.

In light of the representations received regarding certain anomalies and consequential changes in the published Rules, the Board agreed for introduction of new rules i.e. 77A and 83AB in respect of duration of licence in Forms 28, 28B & 28D and in respect of loan licence in Forms 28A and 28DA respectively to streamline the procedure in line with the G.S.R 1337 (E).

AGENDA NO. 13

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

DTAB deliberated the matter and agreed to amend Drugs & Cosmetics Rules, 1945 for categorizing the Spurious, Adulterated & Not of Standard Quality drugs for the purpose of taking action in this regard.

The Board considered the issues and recommended to include the guidelines on the action to be taken for samples of drugs declared Spurious, Adulterated & Not of Standard Quality as part of the Rules.

AGENDA NO. 14

CONSIDERATION OF THE PROPOSAL FOR UNIFORM RENAMING OF ALL CENTRAL DRUGS TESTING LABORATORIES AND HAVING UNIFORM RECURITMENT RULES FOR APPOINTMENT OF OFFICERS

DTAB deliberated the matter and agreed for the proposal to rename the Regional Drug Testing Laboratories at Guwahati and Chandigarh as Central Drug Testing laboratories for maintaining the uniformity in the names.

The Board also agreed to have uniform recruitment rules for appointment of officers in all Central Drugs Testing Laboratories for the purpose of interchangeability and uniformity of standard practices in testing of drugs.

AGENDA NO. 15

CONSIDERATION OF THE PROPOSAL FOR EXTENSION OF VALIDITY OF GMP CERTIFICATE AS PER WHO-GMP GUIDELINES FROM 2 YEARS TO 3 YEARS

DTAB deliberated the matter and agreed to the proposal for extension of duration of validity of GMP certificate as per WHO-GMP guidelines from 2 years to 3 years.

AGENDA NO. 16

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 FOR INTRODUCTION OF MANDATORY REQUIREMENT OF PACKAGE INSERT FOR NEW DRUGS

DTAB deliberated the matter and agreed to amend Drugs and Cosmetics Rules, 1945 for introduction of mandatory requirement of package insert for new drugs.

AGENDA NO. 17

CONSIDERATION OF THE PROPOSAL TO EMPOWER DCG(I) FOR PRESCRIBING DRUGS SPECIFIC LABELLING REQUIREMENTS AFTER COMPLETION OF NEW DRUG STATUS AT THE END OF FOUR YEARS FROM THE DATE OF APPROVAL

DTAB deliberated the matter and agreed to the proposal. DCG (I) grants permission/approval for manufacture of new drug formulations in Form-46 subject to certain conditions which involve requirements of its classification as a Scheduled drug or any other specific requirement mentioned as condition of permission.

However, after four years of approval of any new drug, the State Licensing Authorities grant licence to manufacture without putting any such conditions in

respect of its sale and the drug may be available in the market as non prescription drug.

Therefore, the Board recommended to empower DCG (I) for issuing drugs specific labelling requirements after completion of New Drug status at the end of four years from the date of approval and forward the information to the State Drug Controllers along with the specific labelling requirements which they may incorporate as condition of license so as to ensure that the drug is not sold as non schedule drug till such time it is included in the schedule H, H1 or X.

AGENDA NO. 18

CONSIDERATION OF THE PROPOSAL TO PUBLISH THE COSMETICS RULES, 2018 IN PUBLIC DOMAIN

DTAB deliberated the matter and agreed to forward the draft Cosmetic Rules to the Ministry of Health and Family Welfare for notification.

AGENDA NO. 19

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF DRUGS & COSMETICS RULES, 1945 WITH RESPECT TO LABELLING REQUIREMENT FOR TOOTHPASTE CONTAINING FLUORIDE FOR CHILDREN'S USE

DTAB deliberated the matter and agreed to amend provisions of Rule 149A of Drugs & Cosmetics Rules, 1945 to incorporate the labelling requirement for toothpaste containing fluoride for children's use namely:

i. Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton
ii. Date of expiry should be mentioned on tube and carton.

AGENDA NO. 20

CONSIDERATION OF THE DIRECTIONS OF HON'BLE SUPREME COURT OF INDIA IN THE CASE OF 344 FDCS + 5 FDCS PROHIBITED VIDE 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 AND CONSTITUTION OF DTAB SUB-COMMITTEE FOR HAVING A RELOOK IN THESE CASES

Dr. Nilima Kshirsagar, the sub-committee chairman for FDC issue, informed about the progress of the meetings held since March 2018.

Dr. Nilima Kshirsagar informed that the convenor of the sub-committee issued a notice to all appellant including 'All India Drugs Action Network' (AIDAN), to submit the desired information in the prescribed format in both hard and soft copies before 7th April 2018 enabling the sub-committee to complete its report for fulfilling the Honourable Supreme Court order.

She also informed that the sub-committee requested / co-opted experts in relevant field for reviewing the information submitted by the manufacturers. The sub-committee has so far completed more than 150 FDCs out of 349, with nearly 300 applications of manufacturers, out of 800 applications received till date, in the meeting held since 7th May 2018.

Dr. Nilima Kshirsagar requested the chairman for extending the time period till first week of July 2018 as the time given is not sufficient for completion of the report on all 349 FDCs since the appellant (AIDAN) has asked for more time for submitting their reply / information. The chairman agreed for extension of time.

The various representations submitted to the sub-committee from associations like AIDAN, FOPE, IDMA, IADBL & Abbott Health Care Pvt. Ltd, were reviewed by DTAB members.

The representations submitted by AIDAN & FOPE requesting to extend the deadline for submission of information on impugned FDCs was considered by the board and agreed to extend the time for submitting the information in prescribed format up to 4th June 2018. However, the representation submitted by AIDAN & Abbott Health Care Pvt. Ltd for not considering the representatives from IPA and IDMA was deliberated by the board and not agreed for removing them from the sub-committee as no conflict of interest was involved as these members were from professional associations and didn't require any criteria of expertise of Prof. Kokate Committee.

The representations of M/s Abbott Health Care Pvt. Ltd. requesting to exclude 15 FDCs approved prior to 1988 and 17 FDCs which were approved by DCG(I) from the list of FDCs in the purview of sub-committee constituted for the purpose as per the directions contained in the Honourable Supreme Court judgement were also deliberated by the DTAB.

However, the DTAB members deliberated the issues and were of the view that the sub-committee shall submit the report of all (344 + 05) FDCs again as per the directions from Honourable Supreme Court judgement which also includes the 15 FDCs approved prior to 1988 and 17 FDCs approved by DCG(I). Accordingly, the decision after submission of the report by the sub-committee would be conveyed to the Ministry of Health and Family Welfare.

The Board deliberated other issues submitted by appellate bodies and other associations of FOPE, IDMA & IADBL and confirmed that the decision would be followed as per the Honourable Supreme Court judgement.

AGENDA NO. 21

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 96 OF DRUGS AND COSMETICS RULES, 1945 FOR PROVIDING THE PROPER NAME OF THE DRUG IN A CONSPICUOUS MANNER

DTAB deliberated the matter and agreed to amend Rule 96 of Drugs and Cosmetics Rules, 1945 for providing the proper name of the drug in a conspicuous manner than the trade name under the labelling requirements specified recently vide G.S.R 222(E) dated 13.03.2018.

AGENDA NO. 22

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 TO INCORPORATE A PROVISION OF APPROVAL OF THE LAYOUT PLAN OF MANUFACTURING SITE BEFORE GRANT OF LICENCE FOR THE SITE TO MANUFACTURE FOR SALE OF DRUGS

DTAB deliberated the matter and agreed to have a provision in Drugs & Cosmetics, 1945 for making provisions with respect to the pre-approval of the requirement of layout plan of manufacturing facilities before grant of new licences.

AGENDA NO. 23

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF RULE 96 UNDER DRUGS & COSMETICS RULES, 1945 FOR DISCLOSURE OF PRICES AT FIRST POINT OF SALE/PRICE TO TRADE (PTT)/ EX-FACTORY PRICE OR IMPORT PRICE ALONG WITH MRP

DTAB deliberated and deferred the matter.

AGENDA NO. 24

CONSIDERATION OF PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945, PERTAINING PART XB– REQUIREMENTS FOR THE COLLECTION, STORAGE , PROCESSING AND DISTRIBUTION OF WHOLE HUMAN BLOOD , HUMAN BLOOD COMPONENTS BY BLOOD BANKS & PART XII B- REQUIREMENTS FOR THE FUNCTIONING AND OPERATION OF A BLOOD BANK AND/OR FOR PREPARATION OF BLOOD COMPONENTS

DTAB deliberated the matter and agreed for the proposal to amend Drugs and Cosmetics Rules, 1945 with respect to Part XB – Requirements for the collection, storage, processing and distribution of Whole Human Blood, human blood components by blood banks & Part XII B - Requirements for the functioning and operation of a blood bank and/or for preparation of blood components which are as under:

1. Change in name of blood bank to blood centre,
2. Inclusion of new definitions,
3. Addition of certain qualification of medical officers,
4. Addition of certain qualification of lab technicians,
5. Addition of certain specific blood components (which are usually prepared but not existing presently in rules).
6. Change in donor selection criteria,
7. Inclusion of therapeutic aphaeresis activity,
8. Addition of post of counsellor / medical social worker (if camps are organized).

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

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