(Dr. G. N. Singh)
DRUGS CONTROLLER GENERAL (INDIA)

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F.No. **22-2/2017-DC**
Dated: **27.06.2017**

To

Members of DTAB,

Subject: Minutes of the 77th meeting of the Drugs Technical Advisory Board (DTAB) held on 16th June, 2017 at Nirman Bhavan, New Delhi.

Sir,

A copy of the minutes of the 77th meeting of Drugs Technical Advisory Board held on 16th June, 2017, duly approved by the Chairman, is annexed for your information and perusal please.

Yours faithfully,

(Dr. G. N. Singh)
Member Secretary (DTAB)

Encl:- Copy of the Minutes

MINUTES OF THE 77th MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 16TH JUNE, 2017 AT DGHS, NIRMAN BHAWAN, NEW DELHI

PRESENT

1.	Dr. Jagdish Prasad, Director General of Health Services, Nirman Bhawan, New Delhi.	Chairman
2.	Shri C. Hariharan Director in-charge, Central Drugs Laboratory, Kolkata	Member
3.	Dr. A. K. Tahlan, Director, Central Research Institute, Kasauli, Himachal Pradesh	Member
4.	Dr. P. Dhar, Indian Veterinary Research Institute, Izatnagar, Uttar Pradesh	Member
5.	Shri O. S. Sadhwani, Controlling authority & Joint Commissioner, Food & Drugs Administration, Mumbai Bandra Kurla Complex, Bandra (E) Mumbai, Maharashtra	Member
6.	Dr. B.Suresh, President, Pharmacy Council of India, Combined council Building,Temple lane, Kotla Road, P.B.No.7020, New Delhi	Member
7.	Dr.H.G.Koshia, Commissioner, FDCA, Gujarat, Block No.8, Dr.J.M.Bhawan, Gandhinagar, Gujarat	Member
8.	Dr.Nilima Kshirasagar, Chair in Clinical Pharmacology,ICMR 181 buena vista, J.Bhosale marg, Mumbai	Member
9.	Prof. M. D. Karvekar, #1449, Sector, 7, 4th Main 21st Cross, HSR Layout, Bangalore	Member

10. Dr. Rao V. S. V. Vadlamudi, Member
President, Indian Pharmaceutical Association
Hyderabad, Telangana.

11. Shri Sudhir Mehta, Member
Chairman, Torrent Pharmaceuticals Ltd.
Ahmedabad

12. Dr. G. N. Singh, Member Secretary
Drugs Controller General (India)
FDA Bhawan, New Delhi

President, Medical Council of India, New Delhi; Director, Central Drug Research Institute, Lucknow; Smt. Shushma M. Saptarshi, Asst. Director & Government Analyst, Drugs Control Laboratory, Mumbai; Dr. G. B. Gupta, Prof. and Head, Department of Medicine, Raipur; Dr. A Marthanda Pillai, Ananthapuri Hospital and Res. Institute, Kerala and Shri. Sheju Purushothaman, Government Analyst, Regional Drugs Testing Laboratory, Kerala could not attend the meeting because of their other commitments.

Dr. Jagdish Prasad, Chairman, DTAB welcomed all the members and special invitees and requested DCG (I) to initiate the proceedings. Thereafter, Dr. G. N. Singh, Member-Secretary, DTAB welcomed the chairman and members and informed them about the various steps taken by the Government for strengthening the drug regulatory system in the country. He explained briefly about DTAB Agenda.

Thereafter, chairman started discussion on the agenda items one by one.

AGENDA NO.1

ACTION TAKEN REPORT FOR 76th DTAB MEETING HELD ON 31.01.2017

Action Taken Report (ATR) on the recommendations of DTAB in 76th meeting was approved.

However, in respect of the proposal for inclusion of provisions regarding stem cells and cell based products the DTAB recommended that the draft already prepared should be presented in a meeting of following members for further consideration by the board:

1) Dr. B.Suresh, President, Pharmacy Council of India,
Combined council Building,Temple lane,
Kotla Road, P.B.No.7020, New Delhi

2) Dr.Nilima Kshirasagar,
Chair in Clinical Pharmacology,ICMR
Buena Vista, J.Bhosale marg, Mumbai

3) Shri O. S. Sadhwani,
Controlling authority & Joint Commissioner,
Food & Drugs Administration, Mumbai
Bandra Kurla Complex, Bandra (E), Mumbai, Maharashtra .

4) Dr V G Somani ,
Joint Drugs Controller,
CDSCO, HQ, New Delhi
(Representative of DCGI)

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL TO AMEND FORM 12-B OF THE DRUGS AND COSMETICS RULES FOR PERMIT TO IMPORT OF SMALL QUANTITIES OF DRUGS FOR PERSONAL USE FOR LONGER PERIODS INSTEAD OF SIX MONTHS IN CASE OF CHRONIC DISEASES

DTAB recommended that the Permit in Form 12B should remain valid the patient requires the drugs as per the prescription of the Registered Medical Practitioner. However, the permit holder should submit the details of the drugs imported, utilised etc. to the licensing authorities on yearly basis.

AGENDA NO.3

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE H TO INCLUDE CERTAIN STEROID PREPARATIONS WHICH ARE MISUSED MAINLY AS TOPICAL STEROIDS LEADING TO EXTENSIVE TINEA INFECTIONS

I. The DTAB recommended for inclusion of following corticosteroids in Schedule H of the Drugs and Cosmetics Rules, 1945.

1. Alclometasone
2. Beclomethasone
3. Betamethasone
4. Desonide

5. Desoximetasone
6. Dexamethasone
7. Diflorasone diacetate
8. Fluocinonide
9. Fluocinolone acetonide
10. Halobetasol propionate
11. Halometasone
12. Methylprednisone
13. Prednicarbate
14. Triamcinolone acetonide

II. It was also recommended that a Standing Committee under chairmanship of "Director General of Health Services" comprising following members of DTAB should be constituted for periodic review of the marketed drugs in respect of their inclusion/deletion in Schedule-H of the Drugs and Cosmetics Rule, 1945 and submits the recommendation to DTAB for consideration.

1. The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR)
2. The President, Pharmacy Council of India (PCI)
3. The President, Medical Council of India (MCI)
4. One In-charge of Drugs Controller in the States nominated to be member of DTAB.

AGENDA No.4

CONSIDERATION OF THE PROPOSAL TO LABEL IRON TABLETS AND POLIO DROPS DISTRIBUTED TO THE CHILDREN UNDER GOVERNMENT PROGRAMMES WITH NAME AND EXPIRY DATE IN HINDI ALSO

The DTAB recommended that the proposal is agreeable in principle and may be kept voluntary for multilingual labelling where ever practical. Committee further opined that the proposal needs to be considered in broader prospective for making provision under the Drugs and Cosmetics Rules, 1945 requiring the manufacturers of drugs to provide Patient Information with the drugs.

AGENDA NO.5

CONSIDERATION OF THE PROPOSAL TO MAKE A PROVISION UNDER THE DRUGS AND COSMETICS RULES, 1945 FOR PERMISSION TO SELL / DISTRIBUTE REMAINING QUANTITIES OF UNUSED CLINICAL TRIAL BATCH OF A BIOLOGICAL DRUG WITHIN ITS SHELF LIFE, IF RESULTS OF CLINICAL TRIAL HAVE BEEN FOUND SATISFACTORY

The DTAB agreed to the proposal and recommended that such applicant shall obtain manufacturing licence and conduct clinical trials on batches manufactured under the licence and only after submission of clinical trial results & obtaining New Drug Permission (in Form 46) from Licensing Authority, the drug shall be marketed within its shelf life.

AGENDA No.6

CONSIDERATION OF THE PROPOSAL TO EXEMPT UNDER SCHEDULE-K FOR MANUFACTURING OF OXYGEN 93%

DTAB agreed to the proposal and recommended that the amendment should be made both for Oxygen 93% as per IP as well as for Oxygen 93% supplied from liquid Oxygen.

AGENDA NO.7

CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF "STEM CELLS AND CELL BASED PRODUCTS"UNDER THE DEFINITION OF NEW DRUGS AND ITS REGULATION UNDER THE DRUGS AND COSMETICS RULES, 1945

As regards to inclusion of **"STEM CELLS AND CELL BASED PRODUCTS"** under the Definition of New drug (Rule 122-E) in Drugs and Cosmetic Rules, 1945, DTAB agreed for inclusion and recommended that committee proposed to be constituted under Agenda No. 1 shall consider the same.

As regards to removal of "Stem Cells and Tissue Based Products" from negative list of substances for use in cosmetics notified by the BIS; the DTAB recommended that the matter may be referred to BIS for consideration, as presently, BIS is setting Standards for Cosmetics falling under the Drugs & Cosmetic Rules, 1945.

AGENDA NO.8

CONSIDERATION OF REPORT OF SUB-COMMITTEE OF DTAB IN RESPECT OF THE DIRECTIONS OF THE HON'BLE HIGH COURT OF JUDICATURE OF PATNA FOR ANALYZING THE COMPONENTS OF INGREDIENTS AND THEIR EFFECT ON HUMAN BODY IF CONSUMED AS FOOD IN RESPECT OF THE NEUTRACEUTICAL PRODUCTS UNDER CONSIDERATION IN THE CASE OF CWJC OF 2425 OF 2006

The DTAB noted the report of the sub-committee and recommended that it should be presented to the Director General of Health Services for further consideration.

AGENDA NO.9

CONSIDERATION OF THE PROPOSAL FOR MAKING THE ENGAGEMENT OF PHARMACIST HAVING RELEVANT QUALIFICATION MANDATORY FOR BLOOD BANKS/BLOOD STORAGE CENTERS

The DTAB recommended that details giving full background objective of the agenda should be placed before the Board for consideration.

AGENDA NO.10

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

The DTAB agreed with the proposal and required that the Chairman may further discuss the issue with some experts in this field for further consideration of notification of draft rules.

AGENDA NO.11

CONSIDERATION OF PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 INCORPORATING A PROVISION FOR PHARMACOVIGILANCE FEE TO BE LEVIED ON THE MARKETING PERMISSION HOLDER OF NEW DRUGS AS WELL AS OTHER DRUGS

DTAB opined that the proposal does not come under their purview.

ADDITIONAL AGENDA NO. S-1

CONSIDERATION OF THE PROPOSAL TO PROHIBIT ANTIBODY DETECTION RAPID DIAGNOSTIC TESTS FOR ROUTINE DIAGNOSIS OF MALARIA TO MANUFACTURE/ IMPORT AND SALE OF IN INDIAN MARKET

The DTAB recommended to prohibit 'Antibody Detection Rapid Diagnostic Tests (RDTs) for routine diagnosis of Malaria'.

ADDITIONAL AGENDA NO. S-2

AMENDMENT IN NOTIFICATION OF BA/BE REQUIREMENT FROM FOR "ORAL DOSAGE FORM"TO "ORAL SOLID DOSAGE FORM"

DTAB recommended for the amendment of the provisions relating to Bioavailability-Bioequivalence Study notified vide GSR No. 327(E) dated 03.04.2017 substituting 'Oral Dosage Form' by 'Oral Solid Dosage Form'. Further, the DTAB recommended that 'Bioavailability-Bioequivalence Study' should also be conducted for already licensed 'Oral Solid Dosage Forms' of drugs specified under category II and category IV of Biopharmaceutical Classification System (BCS) within four years and the licence holders of such drugs shall submit the results of 'Bioavailability-Bioequivalence Studies' to Licensing Authority for continuation of manufacturing & marketing of these drugs.

ADDITIONAL AGENDA NO. S-3

MEASURES FOR UNIFORM IMPLEMENTATION OF PROVISIONS OF DRUGS & COSMETICS ACT AND RULES THROUGHOUT THE COUNTRY

The DTAB agreed following recommendations of the DCC for strengthening Drug Regulatory System in the Country to ensure effective and uniform implementation of the provisions of Act and Rules, 1945.

1) Cadre restructuring in State Drugs Controls for uniform implementation of provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945

   - The post of Drugs Inspectors should be re-designated as Drugs Control Officers.
   - The grade pay of Drugs Inspector should be raised to Rs.5400 in Pay Band-2.
   - The grade pay of Assistant Drugs Inspector should be raised to Rs.4800 in Pay Band-2.
   - All the other higher posts should accordingly be re-organized.

2) The Central Govt. should issue direction to the State Governments to ensure adequate regulatory officials which will be commensurate with the number of sale outlets and manufacturing units located in the respective States considering that there should be one official for every 200 sale outlets and one official for every 50 manufacturing units.

3) There should be provisions for deputation of State regulatory officials to the Central regulatory system and vice versa.

4) The minimum experience for Licensing Authorities (LA) relating to manufacturing and sale of drugs should be raised adequately.

5) The practice of having multiple LA in a State for regulation of manufacture of drugs may be replaced by a single LA with provision for delegation of powers to other regulatory officials.

6) Guidelines, directions as and when issued, should be communicated to the State Government and not to the State Drugs Controllers for ensuring effective uniform implementations of such guidelines directions.

7) It was suggested that Drugs Control Authority of each State should create an Intelligence cell with a Nodal Officer for market surveillance and conducting investigation in respect of Spurious, adulterated drugs in co-ordination with CDSCO.

8) Drugs samples from supply chain of procurement agencies needs focused monitoring for ensuring quality of the drugs.

9) The procurement agencies get their sample tested at approved private drug testing laboratories and obtain test reports in Form 39, which is supposed to be issued by such laboratories only to drug manufacturers who do not have testing facilities. The Drugs and Cosmetics Rules, 1945 should be amended to prescribe a separate Form for issuing test reports by such laboratories for procurement agencies.

10) The committee while appreciating the recently conducted National Drugs Survey, mentioned that a system should be put in place to address issue, if any, relating to the Survey, when brought to the notice of the authority.

11) Guidelines should be prepared for disposal of expired drugs - a committee comprising Drugs Controllers of Telangana, MP and DDC (I), Hyderabad zone should be constituted in this regard.

12) Weak areas of market identified on the basis of risk analysis and intelligence information shall be kept under active quality surveillance of GAP by conducting special operations.

13) Regulatory officials should not participate in the procurement activities as there may be conflict of interest.

14) Minutes of all DCC and DTAB meetings held so far should be compiled and uploaded in CDSCO website.

15) The Medical Device officers to be appointed under the Rules should have B. Pharm. / M. Pharm. Such officer should undergo training in medical device regulation under a training module being developed under joint collaboration between Delhi Pharmaceutical Science and Research University and IPC, Ghaziabad or any other institutions which deems fit for such activity.

16) Uniform nomenclature on the pattern of earlier proposal of naming CDSCO as Indian Drug Administration. Likewise, in the States whether they may be named as IDA (Name of the State/FDA/name of the institution).

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

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