MINUTES OF THE 78th MEETING OF DRUGS TECHNICAL ADVISORY BOARD
HELD ON 12TH FEBRUARY, 2018 AT DGHS, NIRMAN BHAWAN, NEW DELHI

PRESENT

1. Dr. B.D. Athani, Chairman
   Director General of Health Services,
   Nirman Bhawan, New Delhi.

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

3. Shri C. Hariharan, Member
   Director in-charge,
   Central Drugs Laboratory, Kolkata

4. Dr. A. K. Tahlan, Member
   Director, Central Research Institute,
   Kasauli, Himachal Pradesh

5. Dr. Alok Dhawan, Additional Director, Member
   Central Drugs Research Institute,
   Lucknow-226001

6. Dr. Muzaffar Ahmad, Member
   Rep. President, Medical Council of India,
   New Delhi

7. Mrs. Archana Mudgal, Member
   Rep. President, Pharmacy Council of India,
   Combined council Building, Temple lane,
   Kotla Road, P.B.No.7020, New Delhi

SPECIAL INVITEES

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

2. Dr. H. G. Koshia,
   Commissioner, FDCA,
   Gujarat, Block No.8, Dr. J. M. Bhawan, Gandhinagar, Gujarat

3. Dr. Nilima Kshirsagar,
   Chair in Clinical Pharmacology, ICMR
   181 buena vista, J. Bhosale marg, Mumbai
4. Prof. M. D. Karvekar,
   #1449, Sector, 7, 4th Main
   21st Cross, HSR Layout, Bangalore

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

6. Dr. R.N. Tandon,
   Honorary Secretary General,
   Indian Medical Association, New Delhi-110002

7. Shri Sheju Purushothaman, Government Analyst,
   Regional Drug Testing Laboratory, Kakanad, Ernakulum- 682030, Kerala

8. Dr. Amit Misra, Deputy Director, Central Drugs Research Institute,
   Lucknow-226001

   The Director, Indian Veterinary Research Institute could not attend the meeting
   because of his other commitments.

   Dr. G. N. Singh, Member-Secretary DTAB welcomed the members and special
   invitees. The members were introduced to the Chairman, Dr. B. D. Athani, DGHS as it was
   the first meeting of the Board under his Chairmanship. The Chairman then requested DCG(I)
   to initiate the proceedings. Dr. G. N. Singh, then explained briefly about DTAB Agenda along
   with Action Taken Reports on previous DTAB recommendations.

   AGENDA NO.1

   ACTION TAKEN REPORT FOR 77th DTAB MEETING HELD ON 16.06.2017

   The Action Taken Report (ATR) on the recommendations of DTAB in 77th meeting was
   approved. However, following agenda items were taken up for reconsideration by the Board.

   A. (Agenda No. 3) 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 matter was reconsidered by the DTAB and it recommended that a sub-
      committee under chairmanship of Dr. R.N. Tandon comprising following members of
      DTAB should be constituted for revision of the provisions related to labelling of drugs
      under Rule 96 of the Drugs and Cosmetics Rules, 1945.

      1) Dr. R. N. Tandon, Honorary Secretary General, Indian Medical
         Association, New Delhi, Chairman
      2) Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian
         Council of Medical Research (ICMR), Mumbai
3) Shri O. S. Sadhwani, Joint Commissioner, Food & Drugs Administration, Mumbai

If needed the Chairman of sub-committee may seek the inputs from relevant members.

The committee shall give recommendations to streamline the labelling requirements so as to provide requisite information to the consumer.

The committee shall submit the recommendation to DTAB within 15 days for consideration.

B. (Agenda No. 4) 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 after reconsideration recommended that since some clinical batches have short expiry, the approval should be given on case to case basis. Clinical batches with the shelf life of less than 6 months should not be permitted to be sold / distributed.

C. (Agenda No. 8) Consideration of the proposal for making the engagement of pharmacist having relevant qualification mandatory for blood banks/blood storage centres

and

D. (Agenda NO. 9) 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

and

E. (Agenda No. 10) 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

The members desired that the above agenda may be taken up for discussion in the next DTAB for detailed deliberations.

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 SIX MONTHS FROM THE DATE ON WHICH THIS JUDGMENT IS RECEIVED BY THE DTAB

The members of DTAB deliberated the matter in detail in the light of the directions of the Hon'ble Supreme Court of India. DTAB recommended constituting a sub-committee
under the Chairmanship of Dr. Nilima Kshirsagar to examine the banned 344 FDC + 5 FDCs. The members of the Sub-Committee shall be as follows.

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairman)
2. Dr. Rao V. S. V. Vadlamudi, President, Indian Pharmaceutical Association, Telangana. (Member)
3. Shri O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member)
4. One representative from Indian Medical Association, New Delhi (Member)
5. One representative from Indian Medical Association, Mumbai (Member)
6. One Clinical Pharmacologist (Member)
7. Shri. Sanjeev Kumar Gupta, DDC (I) CDSCO (HQ) (Convener)

The committee may co-opt subject experts as and when required.

Sub-Committee shall submit the report in three months for consideration of the DTAB.

**AGENDA NO. 3**

**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**

The DTAB deliberated the matter and did not agree to the proposal.

**AGENDA NO. 4**

**CONSIDERATION OF THE PROPOSAL FOR NOTIFYING (I) KAMARAJAR PORT LTD., CHENNAI, TAMILNADU AND (II) MUNDRA PORT, KUTCH, GUJARAT; FOR IMPORT/EXPORT OF DRUGS/PHARMACEUTICALS**

The members of DTAB deliberated the matter and agreed in principle for the amendment of Rule 43A of the Drugs and Cosmetics Rules, 1945 for inclusion of Kamarajar Port Ltd., Chennai and Mundra Port Ltd. Kutch, Gujarat to facilitate the import and export of Drugs, Pharmaceuticals and Cosmetics from these ports. DTAB further recommended that the notification of the ports may be done on the basis of satisfactory inspection reports and availability of requisite man power.
AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL FOR EXEMPTION UNDER PARA 15 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.

The members of DTAB deliberated the matter and opined that clarification may be sought from manufacturers whether the exemption is needed on brand name or generic name of the drug.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL REGARDING INCLUSION OF SEPARATE FORM FOR ISSUING TEST REPORTS TO OTHER THAN MANUFACTURERS LIKE THE PROCUREMENT AGENCIES AND OTHERS

The members deliberated the matter and agreed for introduction of an enabling provision and a separate Form for issue of test report on sample received from an individual or an organisation.

AGENDA No. 7

CONSIDERATION OF THE PROPOSAL TO INCLUDE ORGAN PRESERVATIVE SOLUTION, ULTRASOUND EQUIPMENTS AND SIMILAR IMAGING EQUIPMENTS UNDER THE PURVIEW OF SECTION 3 (b) (iv) OF THE DRUGS AND COSMETICS ACT, 1940 AS MEDICAL DEVICES

The members of DTAB deliberated the matter and agreed to include organ preservative solution, ultrasound equipments and similar imaging equipments under the purview of section 3 (b) (iv) of the Drugs And Cosmetics Act, 1940 as medical devices, with a aim to regulate its import, manufacturing, distribution and sale.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS & COSMETICS RULES TO HAVE SINGLE LICENSING AUTHORITY INSTEAD OF MULTIPLE LICENSING AUTHORITIES HAVING EXPERIENCE IN MANUFACTURE OR TESTING OF DRUGS OR ENFORCEMENT OF PROVISIONS OF THE ACT FOR A MINIMUM PERIOD OF 10 YEARS

The members of DTAB deliberated the matter and agreed to the minimum experience required for Licensing Authority related to manufacturing and sale of drugs to be raised to minimum of 10 years regulatory experience instead of existing 5 years experience. Members also opined that there should be stringent and uniform licensing procedures among various State Licensing Authorities.
AGENDA NO. 9

RECONSTITUTION OF SUB-COMMITTEE OF DRUGS TECHNICAL ADVISORY BOARD ON HOMEOPATHY

The members deliberated the matter and agreed to re-constitute / extend the validity of the existing sub-committee of DTAB on Homeopathy for two years.

AGENDA NO. 10

CONSIDERATION OF THE PROPOSAL TO CLARIFY WHETHER THE CENTCHROMAN (30MG) TABLETS TO BE EXEMPTED FROM THE PROVISIONS OF CHAPTER IV OF THE D& C ACT AND RULES UNDER SCHEDULE K OR TO SELL THE REMAINING STRENGTHS UNDER SCHEDULE H OF D& C RULES

The members deliberated the matter and recommended that opinion from renowned gynaecologists may be sought along with details of Serious Adverse Events (SAEs) reported to PvPI for further consideration.

AGENDA NO. 11

CONSIDERATION OF THE PROPOSAL FOR DENOTIFICATION OF G.S.R 743(E) DATED 10.08.1989 ISSUED UNDER SECTION 26A FOR PROHIBITION OF ALL FIXED DOSE COMBINATION INJECTABLE PREPARATIONS CONTAINING SYNTHETIC OESTROGEN AND PROGESTERONE

The members of DTAB deliberated the matter and opined that since these FDCs were banned in 1989, a sub-committee which formed under the Chairmanship of Dr. Nilima Kshirasagar to examine the 349 FDCs shall also review this matter and give its recommendation for further consideration.

AGENDA NO. 12

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

The members of DTAB deliberated the matter and agreed to keep a separate rack / shelf reserved solely for the storage of “Generic Medicines” in a part of the premises separated from other medicines, which shall be visible to the consumers.

AGENDA NO. 13

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF RULE 127(2) OF THE DRUGS AND COSMETICS RULES, 1945, SO AS TO REMOVE THE AMBIGUITY AND SCOPE OF DIFFERENT INTERPRETATIONS IN CASE OF USE OF COLOURS IN EMPTY GELATINE CAPSULES (HARD AND SOFT)

The members of DTAB deliberated the matter and agreed that in the manufacture of gelatine capsule approved/permitted colours shall be used and drug label containing
gelatine capsules need not indicate the name of colour added as more than one colour are quite often used.

AGENDA NO. 14

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE D OF THE DRUGS AND COSMETICS RULES, 1945 TO PROVIDE EXEMPTION FOR RADIOPHARMACEUTICALS FROM THE PROVISIONS OF THE CHAPTER III OF THE DRUGS AND COSMETICS ACT, 1940

The members of DTAB deliberated the issue providing exemption for import of radiopharmaceuticals under Schedule D of Drugs and Cosmetics Rules, 1945 and did not agree for the proposal. Members also opined that all indigenous manufacturers of radiopharmaceuticals, radio labelled drugs / molecules shall be brought under regulation of the Drugs and Cosmetics Act and Rules made thereunder. CDSCO office shall also have a full fledged wing for regulation of radiopharmaceuticals. These products shall however have to be under the dual control of Department of Atomic Energy and CDSCO.

AGENDA NO. 15

CONSIDERATION OF THE PROPOSAL FOR REVIEW OF PROPHYLACTIC DOSES MENTIONED UNDER SCHEDULE ‘V’OF DRUGS AND COSMETICS RULES VIS A VIS THE DOSES PRESCRIBED UNDER FSS ACT

The members of DTAB deliberated the matter and opined that the matter may be referred to DG, ICMR for their recommendations.

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

The members deliberated the matter and opined that the matter may be referred to the Department of Biotechnology for their recommendations in respect of the effect on the product quality and shelf-life. Dr. A. K. Tahlan shall be the coordinator for deliberations with the Department of Biotechnology.

AGENDA NO. 17

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

The members deliberated the matter and opined that matters relating to medical devices may be placed before the Board in a separate meeting for consideration in detail.
ADDITIONAL AGENDA - S1

CONSIDERATION OF PROPOSAL TO PROHIBIT IMPORT OF OXYTOCIN UNDER DRUGS & COSMETICS ACT, 1940 TO PREVENT MISUSE OF THE DRUG AS ALL BONAFIDE REQUIREMENTS OF OXYTOCIN WOULD BE MET BY INDIGENOUS PRODUCTION

The members of DTAB deliberated the matter and agreed to prohibit the import of the Oxytocin and its formulations for human use as well as animal use under section 10A of the Drugs and Cosmetics Act, 1940.

ADDITIONAL AGENDA - S2

CONSIDERATION OF PROPOSAL TO RESTRICT SUPPLY OF OXYTOCIN FORMULATIONS FOR HUMAN USE ONLY TO THE REGISTERED HOSPITALS AND CLINICS IN PUBLIC AND PRIVATE SECTOR TO PREVENT MISUSE OF THE DRUG

The members deliberated the matter and agreed on a draft notification for regulating, restricting the Oxytocin formulations for human use to be supplied only to registered hospitals and clinics in public and private sector.

ADDITIONAL AGENDA - S3

CONSIDERATION OF PROPOSAL FOR ENSURING THAT BARCODING PRACTICE IS ADOPTED IN MANUFACTURING OF OXYTOCIN FORMULATION

The members deliberated the matter and agreed in principle on the proposal to amend rule 96 of the Drugs and Cosmetics Rules, 1945 to ensure that barcoding system is adopted for manufacture of Oxytocin formulations so as to ensure track and traceability of the product to avoid its misuse. It may however be ensured that there is no shortage of the drug in the country.

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

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