MINUTES OF THE 76th MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 31st January, 2017 AT DGHS, NIRMAN BHAWAN, NEW DELHI

PRESENT

1. Dr. Jagdish Prasad, — Chairman
Director General of Health Services,
NirmanBhawan, New Delhi.

2. Shri C. Hariharan — Member
Director in-charge,
Central Drugs Laboratory,
Kolkata-700016

3. Dr. A. K. Tehlan, — Member
Director, Central Research Institute,
Kasauli (HP) -173205

4. Dr. A.K. Tiwari, — Member
IVRI, Izatnagar, (U.P.)

5. Shri O. S. Sadhawani, — Member
Controlling authority & Joint Commissioner,
Food & Drugs Administration, Mumbai
Bandra Kurla Complex, Bandra (E)
Mumbai, Maharashtra – 400051

6. Dr. Muzaffar Ahmad, — Member
Medical Council of India,
40/222, FF, C.R. Park,
New Delhi-110019

7. Prof. M. D. Karvekar, — Member
#1449, Sector, 7, 4th Main
21st Cross, HSR Layout, Bangalore, 560102

8. Dr. B.Suresh,
President, Pharmacy Council of India, — Member
Combined council Building,
Temple lane, Kotla Road,
P.B.No.7020,
New Delhi – 110002

9. Dr.H.G.Koshia, Member
Commissioner, FDCA,
Gujarat, Block No.8,
Dr.J.M.Bhawan,
Gandhinagar,
Gujarat – 382010.

10. Shri Sudhir Mehta,
Chairman, M/S Torrent Pharmaceuticals Ltd., Member
Torrent house, Ashram Road,
Ahmedabad – 380009
Gujarat.

11. Dr.Nilima Kshirasagar, Member
Chair in Clinical Pharmacology,ICMR
181 buena vista, J.Bhosale marg,
Mumbai – 400021.

12. Dr. G. N. Singh, Member Secretary
Drugs Controller General (India)
FDA Bhawan, New Delhi-110002

The Director, Central Drug Research Institute, Lucknow, Government Analyst, Regional Drugs Testing Laboratory, Kerala, Dr. G. B. Gupta, Prof. and Head, Department of Medicine, Raipur, Dr. A Marthanda pillai, Ananthapuri Hospital and Res. Institute, Kerala and Dr. Rao V. S. V. Vadlamudi, Hyderabad could not attend the meeting because of their other commitments.

The DTAB after detailed deliberations gave the following recommendations in respect of the various agenda items placed before it for consideration.

AGENDA NO.1

ACTION TAKEN REPORT FOR 75th DTAB MEETING HELD ON 03.01.2017

Action Taken Report (ATR) on the recommendations of DTAB in 75th meeting was approved.

In respect of agenda item 8 relating to examination of the certain FDCs, it was further recommended that the committee constituted for the purpose may have a consultative mechanism so that the stakeholders have the opportunity to present their case.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF PROVISIONS REGARDING STEM CELLS AND CELL BASED PRODUCTS UNDER THE COMPREHENSIVE AND SEPARATE RULES FOR NEW DRUGS AND CLINICAL TRIALS UNDER THE DRUGS AND COSMETICS ACT, 1940

The DTAB after detailed deliberations recommended that a committee under the chairmanship of Director General Health Services with the following members may be constituted to examine the proposed regulatory provisions for stem cells and cell based products. The committee may also visit the countries like Japan and Korea, which are exercising regulatory control over such products, for studying the practices and the regulatory provisions followed by these countries in respect of these products. The Ministry of Health and Family Welfare may also be appraised for facilitating the visit of the committee to these countries.

The constitution of the committee shall be as under

1. DGHS - Chairman
2. Dr. Nilima Kshirasagar, - Member
   Chair in Clinical Pharmacology, ICMR
3. O. S. Sadhawani, FDA, Maharastra - Member
4. Representative of MCI - Member
5. Representative of CDSCO - Member

The committee shall give its report in three to four months.

AGENDA NO.3

CONSIDERATION OF THE PROPOSAL TO EXEMPT IMPORT OF REFERENCE STANDARDS, IMPURITY STANDARDS AND PHARMACEUTICALS RAW MATERIALS IMPORTED AS REAGENTS ONLY FROM THE REQUIREMENT OF FORM 11 OF THE DRUGS & COSMETICS RULES, 1945.

The DTAB did not agree to the proposed amendment as it was felt that some sort of regulatory control is required at the time of import of such products in the country.

AGENDA NO.4

CONSIDERATION OF THE PROPOSAL TO MAKE A PROVISION UNDER THE DRUGS AND COSMETICS RULES, 1945 FOR EXEMPTING MULTIPLE TESTING OF RAW MATERIALS MANUFACTURED IN THEIR OWN FACILITY BY THE 100% EOUs

The DTAB reiterated its earlier decision taken in its 68th meeting held on 16.02.2015 and did not agree to the proposed amendment as it is essential to maintain quality during manufacture by testing the raw materials to eliminate any deterioration in quality during transit.

AGENDA NO.5

CONSIDERATION OF THE PROPOSAL TO INCORPORATE OF A PROVISION UNDER THE DRUGS AND COSMETICS RULES, 1945 FOR LABELING OF CELLULOSE BASED CAPSULE WITH GREEN DOT TO INDICATE ITS VEGETARIAN ORIGIN TO DISTINGUISH FROM NORMALLY AVAILABLE CAPSULES WHICH ARE GELATIN BASED

The issue of labelling of cellulose based capsules with green dot was deliberated in detail and the DTAB after discussion reiterated its earlier decision taken in the 75th DTAB held on 03-01-2017 that the matter pertains not only to drugs but other products also and therefore this is beyond DTAB and drugs. Hence the Ministry of Health and Family Welfare may have consultation with other ministries for taking a policy decision. Members further felt that it also cannot be certified that the contents in the capsule are purely of vegetarian origin.

AGENDA NO.6

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.

DTAB recommended that as the issue involves of providing exemption for import of radiopharmaceuticals, the Atomic Energy Regulatory Board (AERB) may be consulted to have their comments in the matter for having holistic approach in the matter.

AGENDA NO.7

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 IN RESPECT OF IMPORT, MANUFACTURE AND LABELLING OF COSMETICS AND SCHEDULE M II RELATING TO REQUIREMENTS OF FACTORY PREMISES FOR MANUFACTURE OF COSMETICS.

DTAB after deliberations agreed that the regulations for import of cosmetics needs to be simplified by making it online and once the registration of cosmetics for import and marketing in India is done, the import may be allowed for such registration holders on the basis of registration certificate. Further, committee also recommended that for the subsequent importer it shall also be simplified and shall be permitted by taking undertaking from such importers, by port officer of CDSCO at the time of import that, the cosmetics imported by them are complying with the Drugs and Cosmetics Act and Rules and are manufactured by the manufacturer mentioned on the label of imported cosmetics. It agreed to the proposed amendments with these changes for harmonization of the rules relating to cosmetics for the purpose of publication of the draft rules.

Meeting ended with vote of thanks to the Chair.
