MINUTES OF THE 74th MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 15th NOVEMBER, 2016 AT DGHS, NIRMAN BHAWAN, NEW DELHI

PRESENT

1.	Dr. Jagdish Prasad, Director General of Health Services, NirmanBhawan, New Delhi.	Chairman
2.	Shri C. Hariharan Director in-charge, Central Drugs Laboratory, Kolkata-700016	Member
3.	Dr. A. K. Tehlan, Director, Central Research Institute, Kasauli (HP) -173205	Member
4.	Dr. NilimaKshirasagar, Chair in Clinical Pharmacology, ICMR 1501-2, Datta Tower, Dr. Vijay Kumar Walimbe Marg, Mumbai – 400012	Member
5.	Dr. Rao V. S. V. Vadlamudi Flat F-6, Vora Towers, 8-3 – 224, Yousufguda road Madhuranagar, Hyderabad – 500038	Member
6.	Shri Sudhir Mehta, Chairman, M/s. Torrent Pharmaceuticals Ltd., Ahmedabad	Member
7.	Dr. A.K. Tiwari, Director, IVRI, Izatnagar, (U.P.)	Member
8.	Dr. G. N. Singh, Drugs Controller General (India) FDA Bhawan, New Delhi-110002	Member Secretary

CDSCO REPRESENTATIVES

1. Dr. S. Eswara Reddy,
   Joint Drugs Controller (India),
   CDSCO (HQ), New Delhi

2. Dr V. G. Somani,
   Joint Drugs Controller (India),
   CDSCO (HQ), New Delhi

3. Shri A. K. Pradhan,
   Deputy Drugs Controller (India)
   CDSCO (HQ), New Delhi

4. Shri R. Chandrasekhar,
   Deputy Drugs Controller (India)
   CDSCO (HQ), New Delhi

The Secretary, Medical Council of India, Shri, O.S. Sadhawani, Controlling Authority and Joint Commissioner, FDA Mumbai, Dr. A. Marthanda Pillai, Ananthapuri Hospital and Research, Kerala, Smt. Sushma M. Saptarshi, Assistant Director & Government Analyst, Drugs Control Laboratory, Mumbai, Dr. Anand Kulkarni, Director, CDRI Lucknow, Dr. B. Suresh, President, Pharmacy Council of India, New Delhi, DR. H.G. Koshia, Commissioner FDCA- Gujarat, Dr. M.D Karvekar, Bangalore, Shri Sheju Purushothaman, Government Analyst, Regional Drugs Testing Laboratory, Kerala and could not attend the meeting because of their other commitments.

Dr. G. N. Singh, Member-Secretary, DTAB welcomed the Chairman and members and briefed the DTAB Agenda. He then requested the Chairman to initiate the proceedings as the quorum was complete.

Thereafter, Dr. Jagdish Prasad, Chairman, DTAB welcomed all the members. He requested the members to deliberate the agenda in detail and express their views so that considered decision could be taken.

Thereafter, the Chairman started discussion on the agenda items one by one. The recommendations of the DTAB are as under.

AGENDA No. 1 – Action taken report on 73rd meeting

Recommendations:

- **Draize test:**

  In continuations to recommendations of earlier DTAB in this regard the committee further recommended that

  - Draize test should be discontinued with in a period of one year if the alternative Non-animal test methods have been developed.
  - A committee of experts should be constituted to examine the feasibility of prescribing specific non-animal test methods in the Schedule Y.

- **Amendments relating to clinical trials:**

  - In order to facilitate notification of rules considering the recommendation in timely manner, it was recommended that DTAB should be informed about the status of its recommendations for any amendments in the rules, as to whether the recommendations of the DTAB are being considered for framing suitable rules or not, within a period of thirty working days from the date of finalization of the minutes of DTAB. It was also opined that, in case the recommendation of the DTAB are not accepted it shall be placed for relooking before the DTAB.
  - Further, the Ministry may be requested to depute one of his senior officers for participating in the meeting of the DTAB, so that recommendations can be made considering the views of the Ministry.

AGENDA NO. 2

CONSIDERATION QF PROPOSAL FOR AMENDMENT IN DRUGS AND COSMETICS RULES, 1945 PROVIDING THAT THE LICENCES ONCE ISSUED, SHALL REMAIN VALID FOREVER, UNLESS SUSPENDED OR CANCELLED BY THE LICENSING AUTHORITY.

Recommendations:

- The committee agreed for the proposal that the manufacturing and sale licences once issued, shall remain valid forever, unless suspended or cancelled by the Licensing Authority subject to following condition that
    - Such inspection for grant of licence shall be carried jointly by State and Central involving relevant experts of respective area considering the category of the drug for GMP / GLP inspection.
    - Further the committee recommended for one time grant of licence the number of Drug inspectors and other regulatory officials in respective areas at the State and Central level shall commensurate with the number of manufacturing units in specific area / jurisdiction.
    - Such licensees shall be subjected to minimum of one annual inspection until unless justified otherwise on the basis of risk evaluation.
    - The observations of the inspection report shall be shared with the licensee or proposed licensee immediately after the inspection and the report of observation of the inspection shall be made available to public on website of State or Centre. The

recently published checklist by CDSCO on its website after for risk based GMP inspection may be used for inspection and publication of the report.

- State wise data about manufacturing units inspected and found satisfactory, should be maintained and uploaded on the website by State and Central drug regulatory authorities involved in issue of such licences.

AGENDA NO. 3

CONSIDERATION OF PROPOSAL FOR AMENDMENT IN DRUGS AND COSMETICS RULES,1945 FOR AMENDING THE DURATION FOR WHICH A NEW DRUG SHALLBE CONSIDERED AS NEW DRUG TO 10 YEARS IN PLACE OF THE PRESENT 4 YEARS

Recommendations

- The period of four years should continue however, the joint inspections shall be carried out and licence shall be granted. It shall be ensured by the Licensing Authority that proper development of product have been carried out in research / formulation and development facilities and bioequivalence studies of the products, wherever required based on scientific principles.

AGENDA NO. 4

CONSIDERATION OF PROPOSAL FOR AMENDMENT IN DRUGS AND COSMETICS RULES, 1945 TO UPGRADE AND SYNCHRONIZE THE SCHEDULE M SPECIFICATIONS WITH WHO-GMP COMPLIANCE STANDARDS

Recommendations:

- Agreed for amendment in the rules to upgrade the Schedule M to make it par with the WHO GMP as per the draft placed before the Board for further notification of draft rule, with consequential changes wherever necessary.

AGENDA NO. 5

CONSIDERATION OF PROPOSAL TO MAKE SEPARATE RULES UNDER THE DRUGS AND COSMETICS ACT, 1940 TO REGULATE MANUFACTURE, IMPORT, CLINICAL INVESTIGATION, SALE AND DISTRIBUTION OF COSMETICS IN THE COUNTRY

Recommendations:

- Agreed to have separate rules for cosmetics to be developed considering EU / ASEAN model.

AGENDA NO. 6

CONSIDERATION OF PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 TO DELETE THE REQUIREMENT OF SUBMISSION OF INFORMATION WITH REGARD TO PATENT STATUS OF DRUG, IN THE APPLICATION FOR GRANT OF PERMISSION TO IMPORT OR MANUFACTURE A NEW DRUG OR TO UNDERTAKE CLINICAL TRIAL IN FORM 44

Recommendations:

- Agreed for the amendment in the rules to delete the entry at point number 1(8) of the Form 44.

AGENDA No. 7

CONSIDERATION OF PROPOSAL FOR AMENDMENT IN DRUGS AND COSMETICS RULES, 1945 FOR INCLUSION OF THE DRUG OSELTAMIVIR AND ZANAMAVIR UNDER THE APPROPRIATE SCHEDULE OTHER THAN SCHEDULE X.

Recommendations:

- Both Oseltamivir and Zanamavir should be included in Schedule H1 subject to condition that
    - Details of the manufacture and sale of the drugs should be submitted by the manufacturers to the DCG(I) at regular interval.
    - DCG(I) should direct his enforcement officials to keep strong vigil on manufacture, sale of these drugs.

AGENDA NO. 8

CONSIDERATION OF PROPOSAL FOR AMENDMENT OF RULE 24 IN DRUGS AND COSMETICS RULES, 1945 THAT THE REGISTERED AGENT SHALL NOT OBJECT OR REJECT THE ISSUANCE OF FORM 9 UNDERTAKING WHEN THE IMPORTER APPLIES FOR LICENSE IN FORM 10

Recommendations:

- Rules should be amended to delete the requirement of undertaking in Form 9 from the authorised agent of the manufacturer in India with the condition that the applicant who wants to obtain the import licence in Form 10 shall give the notarised self declaration or undertaking to the registered agent and licensing authority under rule 21 (b) that he will abide by Drugs and Cosmetics Rules, 1945 and will be responsible for the business activities for the part of drugs imported by him under said licence.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL FOR AMMENDEMENT OF THE DRUGS & COSMETICS RULES PROVIDING THAT THE LICENSING AUTHORITY AS DEFINED UNDER RULE 21(b) i.e. DCG(I) MAY BY AN ORDER, IN WRITING DELEGATE THE POWER TO SIGN LICENSES, APPROVALS ETC ANY PERSON UNDER HIS CONTROL

Recommendations:

- DTAB may not have objection for such proposal. However, being the matter of Central Government, it was opined that the Ministry may take a considered decision in the matter.

Meeting ended with vote of thanks to the Chair.