MINUTES OF THE 75th MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 3rd January, 2017 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. A. Marthanda Pillai, Ananthapuri Hospital and Res. Instt., Chakka, Thiruvananthapuram - 659024 Kerala	Member
5.	Dr. A.K. Tiwari, Director, IVRI, Izatnagar, (U.P.)	Member
6.	Shri O. S. Sadhawani, Controlling authority & Joint Commissioner, Food & Drugs Administration, Mumbai Bandra Kurla Complex, Bandra (E) Mumbai, Maharashtra – 400051	Member
7.	Dr. Muzaffar Ahmad, Medical Council of India, Pocket 14, Sector-8, Dwarka- Phase I, New Delhi-110077	Member
8.	Prof. M. D. Karvekar, #1449, Sector, 7, 4th Main 21st Cross, HSR Lyt, Bangalore, 560102	Member
9.	Dr. G. N. Singh, Drugs Controller General (India) FDA Bhawan, New Delhi-110002	Member Secretary

The Director, Central Drug Research Institute, Lucknow, President, Pharmacy Council of India, Commissioner FDCA- Gujarat, Government Analyst, Regional Drugs Testing Laboratory, Kerala, Dr. G. B. Gupta, Prof. and Head, Department of Medicine, Raipur, Shri. Sudhir Mehta, Chairman Torrent Laboratories, Ahmadabad, Dr. Nilima Kshirsagar, Chair in Clinical Pharmacology, ICMR, Mumbai 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 74th DTAB MEETING HELD ON 15.11.2016

Action Taken Report (ATR) was approved

AGENDA NO.2

CONSIDERATION OF THE EXPERT COMMITTEE REPORT CONSTITUTED BY THE HON'BLE HIGH COURT OF MADRAS TO EXAMINE THE RESTRICTIONS OF PACK SIZE OF DICLOFENAC INJECTION FOR HUMAN USE

The DTAB accepted the report of the sub-committee under the Chairmanship of Dr. S D Seth, Advisor, CTRI, ICMR New Delhi.

The DTAB after deliberations agreed that restrictions of pack size of Diclofenac injection for human use under the Drugs and Cosmetics Rules, 1945 was justified as larger packing has the potential of misuse in vultures which is detrimental to environmental protection. Moreover in multi-dose vials, the drug is required to be withdrawn multiple times causing number of pricks, which may lead to development of infections including certain serious infections like HIV or Hepatitis. Single dose vials are therefore considered safe for human use.

AGENDA NO.3

CONSIDERATION OF THE PROPOSAL FOR RESCINDING OF NOTIFICATION GSR 752(E) DATED 12.01.2011 ISSUED UNDER SECTION 26 A FOR SUSPENSION OF MANUFACTURE AND SALE OF THE DRUG LETROZOLE FOR INDUCTION OF OVULATION IN ANOVULATORY INFERTILITY

In view of the report of ICMR expert committee forwarded by the Secretary, Department of Health Research, Ministry of Health and Family Welfare and Director General, ICMR; DTAB recommended that the notification under Section 26A for suspension of manufacture and sale of the drug Letrozole for induction of ovulation in anovulatory infertility may be revoked.

AGENDA NO.4

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF RULE 96 OF THE DRUGS AND COSMETICS RULES, 1945 FOR PROVIDING THE PROPER NAME OF THE DRUG LARGER THAN THE TRADE NAME IF ANY

The DTAB after deliberations agreed that the rule may be amended to have the proper or generic name of the drug in a font size which is two font sizes more than the trade name.

AGENDA NO.5

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 96 OF THE DRUGS AND COSMETICS RULES, 1945 TO LABEL CERTAIN CATEGORIES OF DRUG FORMULATIONS WITH A BAND NOT LESS THAN 5MM WIDTH IN WHICH WORDS "SCHEDULED DRUGS" IN BLACK COLOUR ARE OVERPRINTED

The DTAB after deliberations agreed that the Rule 96 may be amended to label certain categories of drug formulations with a band not less than 5 mm width in which words "Prescription Drug" overprinted in black colour.

AGENDA NO.6

CONSIDERATION OF THE PROPOSAL FOR MAKING SEPARATE RULES UNDER THE DRUGS AND COSMETICS ACT, 1940 FOR NEW DRUGS AND CLINICAL TRIALS INCLUDING STEM CELL AND CELL BASED PRODUCTS

The DTAB after detailed examination agreed to the various provisions now being incorporated under the rules for clinical trials and its requirement.

It however a recommended that for "accelerated approval process" for new drug, even before completion of Phase III trial in certain cases, where report of the Phase II clinical trial has been received and at least three institutions have given the certificate that there is un-met need of the drug.

DTAB further recommended that earlier decisions taken by DTAB in respect of clinical trials should be expedited for notification and not clubbed with the present notification and for stem cell and cell based products next DTAB meeting shall be called at earliest.

AGENDA NO.7

CONSIDERATION OF THE RECOMMENDATIONS OF THE COMMITTEE TO EXAMINE THE BENEFITS AND RISKS ASSOCIATED WITH THE USE OF DEXTROPROPOXYPHENE AND ITS FORMULATIONS WHOSE MANUFACTURE AND SALE PROHIBITED UNDER A NOTIFICATION G.S.R. 332(E) DATED 23.05.2013

DTAB after deliberations agreed to the recommendations of the expert group and recommended for revocation of suspension.

The drug Dextropropoxyphene and its formulations should be made available in the market with following conditions only:-

1. The package insert, promotional literature, labelling of the drug etc. should clearly mention the “Use of drug for cancer pain only”, and that the dose of the drug should not be more than 300mg per day.
2. The firm should sensitize doctors for use of drug in cancer pain only.

AGENDA NO.8

CONSIDERATION OF PROPOSAL TO EXAMINE CERTAIN FDCS PERMITTED BY THE OFFICE OF DCG (I) BUT CONSIDERED IRRATIONAL BY A COMMITTEE CONSTITUTED BY THE HON’BLE HIGH COURT OF BOMBAY, NAGPUR BENCH

DTAB after detailed examination recommended that scientific rationale of these combinations may be examined by a group of clinicians, surgeons, and microbiologists to evaluate scientifically the conditions where such drugs would be considered beneficial or otherwise for further consideration. The constitution of the committee is as under;

1) Dr. Parija, Department of Microbiology, JIPMER, Puducherry
2) Dr. Samantary or his representative, AIIMS, New Delhi
3) Prof. and Head of Department, Surgery, CMC, Vellore
4) Prof. and Head of Department, Surgery, Madras Medical College
5) Prof. and Head of Department, Medicine, PGI, Chandigarh
6) Prof. and Head of Department, Medicine, KEM Hospital, Mumbai
7) Dr. V.G. Somani, Joint Drugs Controller (India), CDSCO, FDA Bhawan, New Delhi

AGENDA NO.9

CONSIDERATION OF PROPOSAL FOR AMENDMENT OF RULE 37 OF THE DRUGS AND COSMETICS RULES, 1945 REGARDING PACKING OF PATENT & PROPRIETARY MEDICINES OR PHARMACOPEIAL MEDICINE, READY FOR INTERNAL OR EXTERNAL USE

DTAB agreed to the proposed amendment of Rule 37 so as to ensure that the conditions are equally applicable for both patent and proprietary and pharmacopoeial medicines.

AGENDA NO.10

CONSIDERATION OF PROPOSAL FOR AMENDMENT OF SCHEDULE D OF THE DRUGS AND COSMETICS RULES, 1945 FOR MAKING PROVISIONS FOR IMPORT OF MEDICINES FOR CHARITY PURPOSES AS GIFT / FREE DONATION/ HUMANITARIAN AID WITHOUT TAKING ANY COST OF DRUGS OR SERVICES BY SOCIAL ORGANIZATION/SOCIETIES AND NGOS, INVOLVED IN SUCH ACTIVITIES

The DTAB recommended that the term NGOs may be deleted from the proposed amendment. It further recommended that the condition that the drug shall not be sold at all should also be provided.

AGENDA NO.S-1

CONSIDERATION OF PROPOSAL TO REPLACE GELATIN CAPSULES WITH CELLULOSE BASED CAPSULES

The matter was discussed in DTAB. This pertains not only to drugs but to other products also, therefore, this is beyond the DTAB and drugs. Hence, Ministry of Health may have consultation with other ministries to take a policy decision.

AGENDA NO.S-2

CONSIDERATION OF PROPOSAL TO WAIVE CLINICAL TRIALS IN THE CASE OF THE DRUG ALREADY APPROVED IN ICH COUNTRIES

DTAB agreed to the inclusion of following two conditions for waiving of local clinical trials for approval of new drug approved by major ICH countries.

1. Inspection by CDSCO of Research and Development facilities for batches manufactured for regulatory approval of the drug
2. Bioavailability/Bioequivalence study for new drugs including parenteral preparations manufactured for the first time in India where local clinical trial has been waived off.

It may also be ensured that the drug is being marketed in the country of origin.

AGENDA NO.S-3

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

DTAB agreed to the various provisions being incorporated under the rules in respect of cosmetics in the country and recommended for publication of the draft rules.

Other Agenda Taken during Meeting

Member secretary proposed to change the name of Central Drugs Standards Control Organisation(CDSCO) to Indian Drugs Administration (IDA) to make it simple and befitting to its activities and DTAB after deliberations recommended the proposal .

Meeting ended with vote of thanks to the Chair.
