MINUTES OF THE 56TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 16TH JANUARY, 2008 IN THE COMMITTEE ROOM NO. 249, 'A' WING AT NIRMAN BHAWAN, NEW DELHI - 110011

PRESENT

1. Dr. R. K. Shrivastava, DGHS — Chairman
   Nirman Bhawan,
   New Delhi.

2. Shri P. D. Sheth, — Member
   E-256, Greater Kailash,
   New Delhi - 110048

3. Sh. Satish Reddy, — Member
   Managing Director,
   Dr. Reddy's Lab., Hyderabad, A.P.

4. Mr R. Ranga Rao, — Member
   The Director,
   Drugs Control Administration, Drugs Control Bhawan
   Vengal Rao Nagar,
   Hyderabad - 500038

5. Sh. A. K. Pande, — Member
   Drugs Controller, Uttar Pradesh,
   Swasthya Sewa Mahanideshalaya (U.P.),
   Swasthya Bhawan, Aushadhi Kaksha,
   Lucknow – 6 (U.P.)

6. Dr. P. K. Guha — Member
   Director,
   Central Drugs Laboratory,
   3, Kyd Street, Kolkata - 700016

7. Dr. K. R. Mani, — Member
   The Director
   Central Research Institute,
   Kasauli (Himachal Pradesh) - 173205

8. Dr. Rishendra Verma, Member
   Head Division of Biological Standardization,
   IVRI, Izatnagar - 243122

9. Shri Subodh Priolkar, President, Member
   Indian Pharmaceutical Association
   Laxmi Towers, Bandra (E)
   Mumbai - 400051

10. Dr. B. Suresh, Member
    President
    Pharmacy Council of India,
    New Delhi.

11. Dr. M. Venkateswarlu Member Secretary
    Drugs Controller General (India)
    FDA Bhawan, New Delhi-110002

INVITEES

1. Dr. S. P. Singh, Adv (H)
   Chairman, Homeo Sub-Committee
   Deptt. Of ISM & H, New Delhi

2. Dr. S. N. Sahu,
   Dy. Advisor (H), Deptt. of ISM & H, New Delhi

3. Dr. P. C. Verma,
   Principal Scientist
   IVRI, Izatnagar

4. Shri Mahendra Pratap
   Under Secretary (Drugs)
   Ministry of Ministry of Health and Family Welfare,
   New Delhi

Director, CDRI, Lucknow, President, Medical Council of India, New Delhi; Prof. B. K. Gupta, Kolkata, Dr. Sanjiv Malik, Gurgaon, Dr. V. P. Singh, Patna, Dr. B. N. Patel, Food and Drugs Laboratory, VAdodara and Smt. Sudha Swamy, Drug Testing Lab, Banglaore could not attend the meeting because of their pre-occupation.

Sh. A. K. Ramteke, DDC(I); M. Mitra ADC(I); Janak Raj ADC(I), N. C Dawan DDG, Dr. C. Sokhey, Advisor WHO, Lalit Kishore WHO Consultant and A. K. Khanna, TO from Headquarter also attended the meeting.

Dr. M. Venkateswarlu, Drugs Controller General (India) and the Member Secretary DTAB welcomed the Chairman and Members of the Board and requested the Chairman to initiate the proceedings.

The Chairman in his address stressed the importance of this highest technical body and desired that due technical weightage should be given to the decisions taken by the Committee so that these do not face challenge or scrutiny at other fora. The decisions of the Board should be based on sound logic and recorded in a manner that their interpretations are beyond doubt.

The Chairman than requested the Members Secretary to take up the agenda items for discussion.

AGENDA NO. 1

ACTION TAKEN ON MATTER ARISING OUT OF THE 55TH MEETING OF DTAB HELD ON 6TH JULY, 2007 AT NEW DELHI

The Member Secretary briefed the members about the action taken on the recommendations of 55th meeting of DTAB held on 6th July, 2007.

The Board approved the ATR report.

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL TO INCLUDE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES UNDER THE LIST OF THE PRODUCTS TO BE LICENSED BY THE CENTRAL LICENSING APPROVING AUTHORITY (CLAA) AND DEVISING A SYSTEM FOR COLLECTING INFORMATION OF ANNUAL CONSUMPTION OF THESE DRUGS IN THE COUNTRY

Dr. M. Venkateswarlu, DCG(I) briefed the members that the matter was placed before DTAB in 55th meeting also that the Narcotic drugs and Psychotropic substances are required to be brought under the purview of Central Licensing Approving Authority (CLAA) as statistical information in respect of manufacture and sale of these drugs is required to be furnished to the INCB, Vienna, as an International obligation. The present system of obtaining the information from the State Drugs Control Authorities for onward transmission to the Narcotic Commissioner of India has not satisfactorily worked as states have not been able to provide the desired information. The DTAB agreed to the proposal in principal and desired that specific changes required under the rules may be placed before it in the next meeting. In view of this necessary Forms desired for licensing of these drugs have been placed before the Board. As the exercise is initiated for the purpose of collecting the information in respect of manufacture and sale of these drugs in the country, it is proposed that the continuation of the licence would be linked to the furnishing of desired statistics of manufactures and sale on annual basis by the manufacture4r to the designated authority. A condition will be introduced under the rules to the effect that non-compliance of annual furnishing of statistics of manufacture and sale would lead to the cancellation of the license. A separate notification declaring the Narcotic drugs and Psychotropic substances manufactured as ‘drugs’ as CLAA items would also required to be issued separately.

DTAB after deliberation agreed to the proposed amendments and notifications.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL TO RE-EXAMINE THE ENTRY NO. 55 IN THE LIST OF BANNED DRUGS REGARDING FIXED DOSE COMBINATIONS OF DEXTROPROPOXYPHENE – REGARDING

DCG(I) stated that the entry No. 55 in the list of banned drugs under section 26 A prohibits fixed dose combinations of dextropropoxyphene with any other drug other than anti-spasmodics and / or non-steroidal anti-inflammatory drugs (NSAIDs). The entry was introduced in 1995 on the basis of recommendations of DTAB. The relevant minutes of DTAB reveals that the intention was to prohibit the combination of dextroproxyphene with oxyphenbutazone or with phenylbutazone. The Board also took note of the fact that FDC of dextropropoxyphene with aspririn / Paracetamol is marketed in developed countries to combat severe pain. Under the present entry FDC of dextroproFDC of dextropropoxyphene with Paracetamol also stands prohibited while the drug is official in USP. The entry is therefore, required to be examined for its deletion or amendment.

Dr. S. D. Seth stated that the FDC of dextropropoxyphene with Paracetamol has been restricted in U.K. and it is necessary to examine all issues related to the entry and the matter may be referred to the sub-committee constituted in the last meeting for the purpose for examining the entry before the matter is considered by the Board.

DTAB agreed to the proposal of Dr. Seth for referring the proposal to the sub-committee for its opinion in the matter.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO EXAMINE THE RATIONALITY OF CERTAIN FIXED DOSE COMBINATIONS OF DRUG S MARKETED IN THE COUNTRY AND CONSIDERED BY EXPERTS AS 'ABSURD' FOR THE PURPOSE OF BANNING UNDER SECTION 26 A OF THE DRUGS AND COSMETICS ACT

DCG(I) briefed the members that the list of fixed dose combinations placed before the DTAB are the drug formulations considered 'absurd' by the pharmacologists and specialists in a workshop conducted as AIIMS as they appear to have no rationality at all. These formulations have been permitted by the State Licensing Authorities for marketing in the country. The brief background of the case was that on the basis of a complaint by an NGO, a list of 294 drugs was drawn whose rationality was either suspect or has not been evaluated as per provisions of the drugs and cosmetics rules. While majority of drug formulations were 'new drugs' whose rationality is required to be examined by the office of DCG(I) as per requirements of Schedule Y, certain formulations did not apparently have rationality at all or were coming under the category of banned drugs. The list of drug formulations was examined by the experts in the above workshop and it was opined that FDCs which have not been assessed for their safety and efficacy should be withdrawn from the market. The matter was considered by the Drugs Consultative Committee in its 38 and 39th meeting also. In the 39th meeting held on 26th and 27th October, 2007 it was decided that the State Drugs Controller will direct the manufacturers to stop manufacturing the FDCs under reference and in the case of combinations considered absurd or rejected the stocks may also be withdrawn from the market. Certain drug manufacturers associations have gone to the Court against the above decision and the matter is being pursued separately for vacation of the stay.

The matter was discussed in detail and after taking into account the views expressed by the members, the chairman desired that the matter should be examined by the sub-committee in totality; and as it is of urgent nature and has a bearing of

continued marketing of certain drug formulations whose safety and efficacy is suspect the list of the drugs should be examined on a fast tract basis.

The DTAB recommended that the list of 294 drugs under consideration may be placed before the sub-committee for its consideration alongwith the comments and the assessment made by the committee of pharmacologists and specialists. The sub-committee will examine the drug formulations in one month's time and the recommendations of the sub-committee may than be circulated to the members of DTAB for their approval.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL TO GRANT EXEMPTION UNDER SCHEDULE K FOR SALE OF HOMEOPATHIC HAIR OILS FROM GENERAL SALE OUTLETS

DCG(I) briefed the members that a representation was received that hair oils containing homeopathic medicines in small quantities may be exempted under Schedule K from the conditions of sale license so that these could be available from general outlets. The department of AYUSH, which was consulted in the matter agreed that homeopathic hair oils, whether it is in the name of Arnica Hair Oil or otherwise may be allowed to be sold from general outlets provided that these are safe for use.

DTAB after deliberations agreed that homeopathic hair oils may be exempted from the conditions of sale license under Schedule K provided it has less than 3 X potency.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL TO NOTIFY CENTRAL DRUG TESTING LABORATORY, CHENNAI TO FUNCTION AS CENTRAL DRUGS LABORATORY TO TEST CONDOMS, COSMETICS AND CHEMICALS TESTING OF ALL CATEGORIES OF DRUGS INCLUDING SCHEDULE 'C' AND 'C 1' EXCEPT SERA AND VACCINE e

DCG(I) briefed the members that the Central Drug Testing Laboratory, Chennai is presently engaged in the analysis of drug samples in south zone. The laboratory was inspected by an expert team which observed that it has adequate space equipments and experienced staff for chemical testing drugs. The lab has fully equipped section for testing rubber latex condoms.

The Director CDL, Kolkata was of the view that the laboratory should at present be notified under rule 3A of the Drugs and Cosmetics Rules to function as Central Drugs Laboratory to test condoms only.

DTAB after deliberations agreed to the above suggestion and recommended that CDTL, Chennai may be notified for testing of condoms only under rule 3A of said rules while it may continue to test other drugs and its Director declared as Government analyst for testing of samples of drugs forwarded to the laboratory.

AGENDA NO. 7

PROPOSAL TO CONSIDER CORRECTION IN THE TABLE ATTACHED TO SCHEDULE V OF THE DRUGS AND COSMETICS RULES IN RESPECT OF UNITS OF VITAMIN B12 – REGARDING

DCG(I) stated that Schedule V relating to standards for patent proprietary medicines prescribes standard for formulations containing vitamins for prophylactic, therapeutic or pediatric use. The table specifying limits of vitamins prescribes 'unit' in which these should be added. The unit for vitamin B 12 has been indicated as 'mg', while strength of B 12 is such combinations is prescribed in micrograms i.e. mcg. Entry appears to be a typographical error and may be amended to read as 'mcg'.

DTAB agreed to the proposed change in Schedule V to the Drugs and Cosmetics Rules.

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