MINUTES OF THE 61ST MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 24TH JULY, 2012 IN THE COMMITTEE ROOM, FDA BHAVAN, KOTLA ROAD, NEW DELHI – 110002

PRESENT

1. Dr. Jagdish Prasad, Chairman
   Director General of Health Services,
   Nirman Bhawan, New Delhi.

2. Dr. M.F.A. Beg, Member
   Director I/C, Central Drugs Laboratory,
   3, Kyd Street, Kolkata-700016

3. Dr. Sunil Gupta, Member
   Director, Central Research Institute,
   Kasauli, (HP) -173205

4. Dr. B.R. Jagashetty, Member
   Drugs Controller, Karnataka,
   Palace Road, Banalore-560001

5. Dr. B.P.S. Reddy, Member
   CMD, Hetero Drugs Pvt. Ltd.,
   Hyderabad

6. Dr. S. D. Seth, Member
   Advisor CTRI,
   National Institute of Medical Statistics,
   ICMR, Ansaari Nagar,
   New Delhi-110002

7. Dr. K. Chinnaswamy Member
   22-A, Vimal Residency, Vimal Nagar,
   Off Thondamuthur road Vadevalli,
   Coimbatore-643041, Tamil Nadu

8. Dr. J.K. Rajvaidya, Member
   Government Analyst,
   Drugs Testing Laboratory,
   Food and Drugs Administration M.P.,
   Idgah Hills, Bhopal-462001

9. Dr. A. K. Tiwari — Member
   Indian Veterinary Research Institute,
   Izatnagar-243122 (U.P)

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

11. Dr. J.A.S. Giri — Representative of
    815A, Road No. 41 — Indian Pharmaceutical Association
    Jublee Hills, Hyderabad-500033

CDSCO REPRESENTATIVES

1. Dr. V. G. Somani
   Deputy Drugs Controller (India)
   CDSCO, New Delhi

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

3. Shri Lalit Kishore
   Consultant, DCG(I)
   CDSCO, New Delhi

4. Dr. S.Eswara Reddy
   Assistant Drugs Controller (India)
   CDSCO, New Delhi

5. Shri A.K. Kukreti
   Assistant Drugs Controller (India)
   CDSCO, New Delhi

6. Shri Sanjeev Kumar
   Assistant Drugs Controller (India)
   CDSCO, New Delhi

Dr. T.K. Chakraborty, Director, CDRI, Lucknow; Prof. K.K. Talwar, Chairman, Board of Governors, MCI, New Delhi; Dr. B.R.Jagashetty, Drugs Controller, Karnataka, Dharam Prakash, Delhi, Dr. K.Chinnaswamy, Coimbatore, Dr. B.P.S.Reddy, Hyderabad, Dr. J.K. Rajvaidya, Bhopal and Shri Yatendra Raj Mehta, Drug Testing Laboratory, Jaipur could not attend the meeting because of their pre-occupation.

Dr. G. N. Singh, Drugs Controller General (India) and Member Secretary DTAB welcomed the Chairman and members of the Board and requested the Chairman to initiate the proceedings as the quorum was complete as per bye-laws.

AGENDA NO. 1

CONSIDERATION OF THE PROPOSAL TO INTRODUCE A SEPARATE SCHEDULE H1 UNDER THE DRUGS AND COSMETICS RULES, FOR REGULATING SALE OF ANTIBIOTICS, CERTAIN ANTI-TB DRUGS AND HABIT FORMING DRUGS

The Chairman briefed the members that the meeting has been convened to finalize the list of the drugs to be included under Schedule H1 in the light of the assurance made by the Hon'ble Union Minister of Health & Family Welfare for further review of the notification for introduction of a separate Schedule for regulating sale of antibiotics, certain anti-TB and Habit forming drugs. The notification was earlier published as draft rules vide Gazette notification G.S.R. 228 (E) dated 20-03-2012 for comments for the public before finalizing. Dr. Jyoti Mirdha, MP during a discussion in Lok Sabha on 30-11-2012 had suggested that it would have been worthwhile to properly monitor and audit 4th generation antibiotics and not all antibiotics under the Schedule.

A separate Schedule was proposed in the light of the recommendation of the Task Force set up by the Government of India under the Chairmanship of Dr. R.K. Srivastava, the then Director General of Health Services, to assess, review and suggest measures to contain antimicrobial resistance. The matter was also considered in the Drugs Consultative Committee Meeting held on 28th October, 2010 and it recommended

that certain Anti-TB drugs and Habit forming drugs which are commonly misused should also be included the Schedule. Central TB Division, DGHS in the meanwhile had also recommended that the following Anti-TB drugs need to be included in the revised Schedule H1.

1. Ethionamide
2. Cycloserine
3. Sodium Para –aminosalicylate
4. Rifabutin
5. Capreomycin
6. Clofazimine
7. Amoxyclav (Amoxycillin & Potassium Clavulanate)
8. Thiacetazone

DTAB after deliberation agreed that the Schedule H1 should have only 3rd and 4th generation antibiotics along with the Anti-TB drugs mention above and earlier included in the draft rules as well as Habit Forming Drugs in the draft rules .

It was further recommended that in order to keep a check or monitor the sale of such drugs, a condition should be incorporated under Rule 65 that the supply of any drug covered in the Schedule shall be recorded at the time of supply in a prescription registered specially maintained for the purpose giving the name and address of the prescriber and the patient and name of the drug and the quantity supplied, and the records shall be open for inspection..

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF ZINC SULPHATE TABLETS UNDER SCHEDULE K OF THE DRUGS AND COSMETICS RULES

The members were briefed that during 61st meeting of DTAB held on 24th July, 2012, it was recommended that Zinc Sulphate Tablets/Oral Solutions IP of 5mg and 10mg should be given exemption from the sale license under Schedule K of the Drugs & Cosmetics Rules for the purpose of controlling the childhood diarrhea. Prof.. S.D. Seth, Advisor, Clinical Trial Registry, wrote to the Member Secretary that in his opinion Zinc Tablets of 10mg/20mg should be approved rather than 5mg/10mg.

The Indian Pharmacopoeia in the monograph of Zinc Sulphate Dispensible Tablets gives the usual strength as 10mg/20mg of elemental Zinc (as Zinc Sulphate monohydrate).

The Board after deliberation agreed that the Zinc Sulphate Tablets/Oral Solutions giving 10mg;20mg of elemental Zinc (as Zinc Sulphate Monohydrate) may be given exemption from sale license under Schedule K of the Drugs and Cosmetics Rules in place of 5mg or 10mg as a recommended earlier.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE Y OF THE DRUGS AND COSMETICS RULES TO MAKE A PROVISION FOR AUDIO / VIDEO RECORDING OF THE INFORMED CONSENT AND ALSO TO ENSURE THAT THE SUBJECT IS ADEQUATELY INFORMED ABOUT THE FAILURE OF INVESTIGATIONAL PRODUCTS TO GIVE THERAPEUTIC EFFECT OR THE LACK OF EFFECT OF PLACEBO IN CERTAIN TRIALS

DCG(I) briefed the members that under Schedule Y to the Drugs and Cosmetics Rules, it is mandatory that a freely given informed, written consent is required to be obtained from each study subject before he is enrolled in a clinical trial. The investigator is required to provide information about the study verbally as well as using a patient information sheet in a language that is not technical and understandable by the study subject.

It is proposed that the investigator should make audio / video recording of the procedure of obtaining informed consent of the individual subject and maintain it for record. This will authenticate that at the time of enrollment proper care was taken to inform the subject about the pros and cons of the clinical trial and his participation was voluntary. A provision in this regard was proposed to be introduced under sub-para (4) related to 'Informed Consent', under para '2. Clinical Trials' under Schedule Y.

The Chairman stated that it is the duty of the investigator to adequately inform the trial subject about the essential elements of the study and that of the drug to be administered. The trial subject should be made aware that the drug is a new drug and is first time being administered, its therapeutic efficacy and serious adverse reactions have not yet been well documented. The research subject should also give his consent stating that he has understood the information provided by the investigator in respect of

the study and his participation in the trial is voluntary. The audio and video recording of this procedure of individual subject should be maintained by the investigator for record.

DCG(I) further stated that it was also proposed that the trial subject should also be made aware during informed consent process, that there may be a possibility of failure of investigational product to provide intended therapeutic effect and in the case of placebo controlled trial, the placebo administered would not have therapeutic effect.

The Board after deliberations agreed to the following amendments in Schedule Y.

(1) In sub-para (4) under the caption 'Informed Consent', under para 2. Clinical trial the following clause may be inserted.

> "An audio / video recording of the informed consent process of individual subject including procedure of providing information to the subject and his understood consent shall be maintained by the investigator for record."

(2) In Appendix V, under point '1.1 Essential Elements' the following clauses shall be inserted at appropriate places.

(i) That there is possibility of failure of investigational product to provide intended therapeutic effect,

(ii) in the case of placebo controlled trial, the placebo administered to the subjects would not have therapeutic effect.

The Drugs Controller, Karnataka stated that the State Drugs Control Authorities should be taken into confidence in respect of the trials permitted in his State. The Member Secretary informed that the Secretary Health and Family Welfare, Government of India has written to the State Health Secretaries for the creation of monitoring cells by the State Drugs Control Authorities. The information in respect of grant of permission for clinical trials would be communicated to the concerned States by the CDSCO. Apart from this DTAB had also earlier recommended amendments to the Drugs and

Cosmetics Rules, for inspection of clinical trial sites by CDSCO in consultation with the State Drug Control Authorities.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 FOR THE PURPOSE OF INTRODUCTION OF PHYTOPHARMACUETICALS AND TO PROVIDE GUIDELINES FOR PERMISSION FOR MANUFACTURE OF NEW PHYTOPHARMACUETICALS OR FOR THEIR CLINICAL TRIALS IN THE COUNTRY

DCG(I) briefed the members that Phytopharmaceutical products are drugs of plant origin having therapeutic effect. These are not single substances but comprise of standardized extracts or fractions of processed or unprocessed medicinal plants. These drugs are however, required to be evaluated for their safety and efficacy like other new drugs belonging to the modern system of medicines. The system adopted for evaluation of modern drugs like toxicity, safety and efficacy studies should be made applicable to this class of drugs also. This will help in creating scientific and authenticated data about their therapeutic efficacy and safety.

It was therefore proposed to amend the Drugs and Cosmetics Rules to have a separate definition of Phytopharmaceutical drugs and also its inclusion in the definition of new drug for the purpose of having a similar provisions for evaluating their safety and efficacy to authenticate the claims made for the Phytopharmaceutical drugs. A separate Appendix I-B was proposed to be incorporated under the Schedule Y for providing information specific to the Phytopharmaceutical products in regard to their origin, Pharmacognostic descriptions, quality specifications, process of extraction, stability data, safety and pharmacological information etc. along with the application to conduct clinical trial / import / manufacture of a Phytopharmaceutical drug in the country.

The matter was considered in the 60th meeting of DTAB held on 10th October, 2011 and it was agreed in principles to incorporate provisions relating to Phytopharmaceutical drugs under the Drugs and Cosmetics Rules.

The members welcomed the proposal as this will help in evaluation of many of the such drugs of Indian origin on the methods employed for modern medicines. The

DTAB however, recommended that repeat dose toxicity should be on two species of animals and one of them should be non-rodent as is under Schedule Y.

The Board after deliberations agreed to the proposed amendments.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL TO AMEND ENTRY NUMBER 27 OF THE LIST OF BANNED DRUGS UNDER NOTIFICATION GSR 578(E) DATED 23.07.83 RELATING TO FIXED DOSE COMBINATIONS OF INJECTABLE PREPARATIONS CONTAINING SYNTHETIC OESTROGEN AND PROGESTERONE

DCG(I) briefed the members that an application from ICMR to conduct a study on 'Pre-programme introduction of injectable contraceptive Cyclofem and NET-EN through District hospitals and NGO clinics- An ICMR Task Force Study' is pending with the CDSCO as the entry number 27 under the list of banned drugs under Section 26A of the Drugs and Cosmetics Act prohibits FDCs of oestrogen and progesterone in the country. The DTAB in its 48th meeting held on 8th July, 1999 had earlier agreed to the clinical trials of cyclofem injection by ICMR. Accordingly ICMR conducted the study and submitted the report. Further, ICMR has applied for another clinical trial of cyclofem injection and Net-EN injection.

M/s. Sun Pharma has also applied for permission for manufacture for sale of cyclofem (an FDC as an injectable suspension containing Medroxyprogesterone acetate 25 mg ad estradiol cypionate 5 mg per 0.5ml as injectable contraceptive). The office of DCG(I) has been informed that the injectable preparation containing Medroxyprogesterone acetate and estradiol cypionate (Clyclofem) are available in USA, Indonesia, Hongkong & Thailand. The preparation is also included in the WHO model list of Essential Medicines.

The Board after deliberations recommended that an expert committee consisting of Gynocologists, Pharmacologists may be constituted by the DCG(I) to examine the safety and efficacy of cyclofem especially in the lights of the fact that such contraceptive injections are prone to cause reduction in bone mineral density (BMD). The committee

may examine the overall safety and efficacy profile of the drug including assessment of the BMD, if any done by ICMR during the clinical trial. The proposals of ICMR to conduct the clinical trial would then be considered by DTAB in the light of the recommendations of the expert committee.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL TO EXAMINE THE RATIONALITY AND CONTINUED MARKETING OF ANALGIN IN THE COUNTRY

DCG(I) briefed the members that the Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report has examined the question of rampant use of pain killers without medical advice. The committee has observed that there is misuse and overuse of the drug analgin as it is not labeled properly. The approved indication of the drug is “severe pain or pain due to tumour and also for bringing down the temperature in refractory cases when other anti-pyretics fail to do so.” However, the product inserts of Baralgan-M and Novalgin do not give the full indication on the label.

The Board after deliberations recommended that the continued marketing of the drug may be examine by the Expert Committee in the context of present day knowledge on priority, while the manufacturers of analgin may be directed to market the product giving the full indications on the label approved earlier by DTAB as under.

> “severe pain or pain due to tumour and also for bringing down the temperature in refractory cases when other anti-pyretics fail to do so.”

The DTAB further recommended that the use of all analgesics with special reference to analgin should be placed under focused pharmacovigilance under Pharmacovigilance Programme of India. The safety data so collected should be properly analyzed so that suitable action could be taken on use of the such drugs.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE K OF THE DRUGS AND COSMETICS RULES IN RESPECT OF THE EXTENT OF CONDITIONS OF EXEMPTIONS IN THE CASE OF DRUGS FALLING UNDER THE DEFINITION OF THE TERM DRUG BUT NOT INTENDED FOR MEDICINAL USE

DCG(I) briefed the members that many of the products containing drugs are marketed as non-drug items under the exemption provided in Schedule K for drugs not sold for medicinal use or for use in the manufacture of medicines requiring only the container to be labelled with the words “NOT FOR MEDICINAL USE”. However, the provision is reported to be misused by the manufacturers especially in the case of multivitamin preparations.

The Chairman, National Pharmaceutical Pricing Authority (NPPA) had also written to the office of DCG(I) that vitamin tablets and capsules are being marketed in the country as dietary / food supplement to circumvent the Drugs Price Control Order.

In respect of import of substances not for medicinal use under the Drugs and Cosmetics Rules, DTAB had earlier recommended that an amendment in Schedule D may be made to the effect that permission / no objection certificate is required to be obtained from the licensing authority for import of drug substances for non medicinal use. The necessary amendment under Schedule D is being processed by the Ministry of Health and Family Welfare.

In view of the above proposed to incorporate a similar provision under Schedule K in item no. 1 also, to ensure that the drug substances manufactured for non medicinal use in the country should be with the permission / no objection

certificate from the concerned licensing authority. The following clause was proposed to be added in item 1 under Schedule K.

> 'Further, permission from the concerned licensing authority has been obtained for the exemption from the requirements of chapter IV of the Act for manufacture of the product containing the drug substance for non-medicinal use.'

Drugs Controller, Karnataka, informed the Board that the question of marketing of neutraceuticals especially vitamin formulations was examined by the Food Safety and Standards Authority of India (FSSAI) and it has asked the State Food Authorities to withdraw permissions granted to under the Food Safety and Standards Act, 2006 for vitamin formulations (as tablets / capsules) as food supplements.

The Chairman stated that as the vitamins for therapeutic and prophylactic use are covered under the Drugs and Cosmetics Rules, a sub-committee having representatives of DCG(I), State Drugs Control Authorities and FSSAI may be constituted by the Member Secretary to prepare a guidance document for licensing vitamin formulations as drugs in the country.

It was also agreed that the manufacturers intending to manufacture such formulations should be asked to provide the method of analysis or testing protocols for testing of the finished formulations to ensure that these formulations conform to the standards prescribed further.

DTAB after deliberations agreed to the proposed amendment as well as constitution of the committee to prepare the guidance document in this regard.

SUPPLEMENTARY AGENDA

AGENDA S-1

CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF ZINC SULPHATE TABLETS UNDER SCHEDULE K OF DRUGS AND COSEMTICS RULES

DCG(I) briefed the members that the use of Zinc tablets in childhood diarrhea has been considered essential and easily achievable public health goal in India. It has been recommended by the organizations like UNICEF, WHO, PATH, AIIMS. Like ORS, Zinc has the possibility of making a major impact on the health of children in India by controlling the childhood diarrhea.

An Expert Committee in 2006 and a conference organized by Clinical Development Service Agency (CDSA) and Department of Biotechnology (DBT) in 2011 had advocated for the inclusion of Zinc products under schedule K to ensure consistent and easy availability and promotion of these products.

The matter was also considered by the Drugs Consultative Committee in its 44th meeting held on 20th July, 2012 and it recommended that Zinc tablets of 5mg and 10mg should be granted exemption under Schedule K from the requirement of sale licence provided the drug has been manufactured under a valid licence.

In view of the above it is proposed to include Zinc sulphate tablets / oral solution IP of 5 mg and 10 mg under Schedule K for exemption from the sale licence provided the drug has been manufactured under a valid licence.

DTAB agreed to the proposed amendment.

AGENDA NO. S-2

CONSIDERATION OF THE RECOMMENDATION OF THE PARLIAMENTARY STANDING COMMITTEE OF THE MINISTRY OF HEALTH AND FAMILY WELFARE FOR MAKING A PROVISION UNDER THE DRUGS AND COSMETICS RULES, TO PROHIBIT ADVERTISEMENTS OF DRUG FORMULATIONS CONTAINING DRUGS COVERED UNDER SCHEDULE H

DCG(I) briefed the members that the Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report on the functioning of the Central Drugs Standard Control Organization has taken note that some manufacturers advertise prescription drugs (Schedule H) in the lay press. The committee apprehends that based on incomplete information patients tend to self medicate more so because such medicines are generally available without prescription. Such practices can adversely impact not only the health of individuals but even communities and countries. The committee had therefore recommended that apart from giving sharper teeth to the Drugs and Magic remedies (Objectionable Advertisements) Act, a provision should also be incorporated in the Drugs and Cosmetics Rules, ban such practices and penalize offenders.

The members opined that even though advertisements of drugs do not come under the purview of the Drugs and Cosmetics Act, 1940, it is however, necessary in public interest that the manufacturers do not indulge in advertisement of drugs included in Schedule H, H1 and X of the Drugs and Cosmetics Rules as self medication may lead to dangerous side effects.

The DTAB after deliberations recommended that a condition under the licence to manufacture drugs may be incorporated under the Drugs and Cosmetics Rules to the effect that the advertisement of drugs covered under Schedule H, H1 (proposed) and X are not permitted, except otherwise as permitted by the Government of India in public interest.

AGENDA NO. S-3

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS & COSMETICS RULES TO INTRODUCE CERTAIN AMENDMENTS RELATING TO MEDICAL DEVICES AND DIAGNOSTIC REAGENTS

DCG(I) briefed the members that the medical devices were notified under the Drugs and Cosmetics Rules in 2005 for regulating their quality in the country under the Drugs and Cosmetics Rules. However, the specific provisions in respect of medical devices for the manner of labeling, qualifications of competent person to manufacture and test these devices, shelf life, provisions for the standards to which these devices should adhere including quality management systems and exemptions for custom made devices for their import and manufacture are required to be incorporated under the Drugs and Cosmetics Rules for having proper quality control over medical devices. These issues were deliberated by a committee having experts from in the medical device industry, regulatory authorities and clinicians who use such devices. The committee had made recommendations in respect of amendments that are required to be made under the Drugs and Cosmetics Rules, so as to have an effective control over the quality of medical devices. It was proposed to incorporate these draft rules under the Drugs and Cosmetics Rules.

The Board agreed to the proposed amendments as these were required for regulating the quality of medical devices in the country and were prepared in consultation with a committee having experts from medical device industry. The members were however, further informed that the draft rules when published will remain in the public domain for comments.

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

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AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 FOR THE PURPOSE OF INTRODUCTION OF PHYTOPHARMACUETICALS AND TO PROVIDE GUIDELINES FOR PERMISSION FOR MANUFACTURE OF NEW PHYTOPHARMACUETICALS OR FOR THEIR CLINICAL TRIALS IN THE COUNTRY

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It was therefore proposed to amend the Drugs and Cosmetics Rules to have a separate definition of Phytopharmaceutical drugs and also its inclusion in the definition of new drug for the purpose of having a similar provisions for evaluating their safety and efficacy to authenticate the claims made for the Phytopharmaceutical drugs. A separate Appendix I-B was proposed to be incorporated under the Schedule Y for providing information specific to the Phytopharmaceutical products in regard to their origin, Pharmacognostic descriptions, quality specifications, process of extraction, stability data, safety and pharmacological information etc. along with the application to conduct clinical trial / import / manufacture of a Phytopharmaceutical drug in the country.

The matter was considered in the 60th meeting of DTAB held on 10th October, 2011 and it was agreed in principles to incorporate provisions relating to Phytopharmaceutical drugs under the Drugs and Cosmetics Rules.

The members welcomed the proposal as this will help in evaluation of many of the such drugs of Indian origin on the methods employed for modern medicines. The DTAB however, recommended that repeat dose toxicity should be on two species of animals and one of them should be non-rodent as is under Schedule Y.

The Board after deliberations agreed to the proposed amendments.

(Extract of the minutes of 61st meeting of DTAB held on 24th July, 2012)

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE K OF THE DRUGS AND COSMETICS RULES IN RESPECT OF THE EXTENT OF CONDITIONS OF EXEMPTIONS IN THE CASE OF DRUGS FALLING UNDER THE DEFINITION OF THE TERM DRUG BUT NOT INTENDED FOR MEDICINAL USE

DCG(I) briefed the members that many of the products containing drugs are marketed as non-drug items under the exemption provided in Schedule K for drugs not sold for medicinal use or for use in the manufacture of medicines requiring only the container to be labelled with the words "NOT FOR MEDICINAL USE". However, the provision is reported to be misused by the manufacturers especially in the case of multivitamin preparations.

The Chairman, National Pharmaceutical Pricing Authority (NPPA) had also written to the office of DCG(I) that vitamin tablets and capsules are being marketed in the country as dietary / food supplement to circumvent the Drugs Price Control Order.

In respect of import of substances not for medicinal use under the Drugs and Cosmetics Rules, DTAB had earlier recommended that an amendment in Schedule D may be made to the effect that permission / no objection certificate is required to be obtained from the licensing authority for import of drug substances for non medicinal use. The necessary amendment under Schedule D is being processed by the Ministry of Health and Family Welfare.

In view of the above proposed to incorporate a similar provision under Schedule K in item no. 1 also, to ensure that the drug substances manufactured for non medicinal use in the country should be with the permission / no objection

certificate from the concerned licensing authority. The following clause was proposed to be added in item 1 under Schedule K.

> 'Further, permission from the concerned licensing authority has been obtained for the exemption from the requirements of chapter IV of the Act for manufacture of the product containing the drug substance for non-medicinal use.'

Drugs Controller, Karnataka, informed the Board that the question of marketing of neutraceuticals especially vitamin formulations was examined by the Food Safety and Standards Authority of India (FSSAI) and it has asked the State Food Authorities to withdraw permissions granted to under the Food Safety and Standards Act, 2006 for vitamin formulations (as tablets / capsules) as food supplements.

The Chairman stated that as the vitamins for therapeutic and prophylactic use are covered under the Drugs and Cosmetics Rules, a sub-committee having representatives of DCG(I), State Drugs Control Authorities and FSSAI may be constituted by the Member Secretary to prepare a guidance document for licensing vitamin formulations as drugs in the country.

It was also agreed that the manufacturers intending to manufacture such formulations should be asked to provide the method of analysis or testing protocols for testing of the finished formulations to ensure that these formulations conform to the standards prescribed further.

DTAB after deliberations agreed to the proposed amendment as well as constitution of the committee to prepare the guidance document in this regard.

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The Board agreed to the proposed amendments as these were required for regulating the quality of medical devices in the country and were prepared in consultation with a committee having experts from medical device industry. The members were however, further informed that the draft rules when published will remain in the public domain for comments.

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