

MINUTES OF THE 51ST MEETING OF DRUGS TECHNICAL ADVISORY
BOARD HELD ON APRIL 11, 2002 IN THE COMMITTEE ROOM NO.
249, 'A' WING AT NIRMAN BHAWAN, NEW DELHI-110011.

PRESENT

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| 1. | Dr.S.P.Aggarwal, DGHS
Nirman Bhawan,
New Delhi. | Chairman |
| 2. | Shri P.D.Sheth,
President, Indian Pharmaceutical Association,
E-256, Greater Kailash, New Delhi-110048. | Member |
| 3. | Mr.R.Anandarajshekhar,
Drugs Controller (Karnataka), Drugs Control Deptt.
Palace Road, Bangalore-560001. | Member |
| 4. | Mr.S.S.Venkatakrishnan,
Drugs Controller (Kerala), Public Health Lab.
Campus, Red Cross Road, Thiruvananthapuram-
695037. | Member |
| 5. | Mrs. Kamala A.Kannan,
Govt.Analyst, Drugs Testing Laboratory,
Chennai-600 006. | Member |
| 6. | Mr.B.Mandal,
Director,
CDL,Kolkata. | Member |
| 7. | Dr.Usha Soren Singh,
Director,
CRI, Kausauli. | Member |
| 8. | Dr.U.C.Samal,
Medical Council of India,
Prof. of Cardiology, Patna Madical College,
Patna-800004. | Member |

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| 9. | Dr.Sanjiv Malik,
Hony.Secretary General,
IMA, New Delhi. | Member |
| 10. | Prof.C.K.Kokate,
President,
Pharmacy Council of India,
Kakatiya University, Warangal. | Member |
| 11. | Prof.S.D.Seth,
Chair in Clinical Pharmacology,
Indian Council of Medical Research,
N 14/D, Mandir Marg, Saket,
New Delhi-110017. | Member |
| 12. | Shri Ashwini Kumar
Drugs Controller General (India) | Member
Secretary |

Invities

13. Dr.S.P.Singh,Dy.Advisor (H),Deptt. of ISM&H,
New Delhi.
14. Dr.Vikramaditya,
Director, H.P.L., Gaziabad.(UP)
15. Dr.S.R.Gupta,
Joint Drugs Controller (I),
CDSCO, North Zone, Ghaziabad.

Director, CDRI, Lucknow, President, Medical Council of India, New Delhi;
Director, Indian Veterinary Research Institute, Izatnagar; Dr..D.P.Jindal, Panjab
University, Chandigarh; Mr.M.V.Kumar, M/s.TTK Pharma Ltd., Chennai and
Dr.Tupkari Suresh Vishnu, Govt. Analyst, Drugs Control Laboratory, Mumbai
could not attend the meeting because of their pre-occupation.

S/Sh. A.K.Ramteke, DDC(I); B.R.Wadhawan ,DDC(I); S.P.Das, DDC(I), R.Narayanaswamy, DDC(I), K.Thulsiraman, LO; S. D. Vijayaraghavan, ADC(I); Lalit Kishore, TO; A.K. Khanna, STA from Headquarter also attended the meeting.

After welcoming the members to the fifty first meeting of the Board, the Chairman mentioned that the present Board was notified on 21st October, 1999. The elected and nominated members will complete their statutory term of 3 years on April 20 2002. Fresh nominations have already been called for from Associations and Councils, and Board will be re-constituted soon.

The Chairman thanked the members of the present Board for their active participation, contribution and guidance in taking momentous decisions. During this period, landmark amendments to the Drugs & Cosmetics Rules were made like amendment of Schedule M to make Good Manufacturing Practices (GMPs) at par with International Standard, enhancing the licensing fees for manufacture and sale licenses granted by State Licensing authorities and increase in their validity period from 2 years to 5 years, prescribing evaluation fees for processing new drug application, introduction of registration system for import of drugs to monitor the quality of imported drugs specifying detail provisions regarding collection, storage and transportation of blood and blood banking. A comprehensive document on 'Guidelines on Good Clinical Practices' approved by the DTAB was officially released by the Hon'ble Minister of Health on 21st December 2001. These guidelines for biomedical studies aims to ensure that the studies are scientifically and ethically sound, properly documented and are at par with the international standards.

The present Board had also examined the list of drugs referred to it by the Hon'ble Supreme Court of India for their rationality. The recommendations of the Board were forwarded to the Hon'ble Court as per the direction of the court. Eight drug formulations recommended to be withdrawn were notified by the Ministry of Health for phasing out. In view of the prompt action taken by the Board, the court was satisfied and it disposed off long pending petitions filed by the Drug Action Forum.

The Board during this period constituted two sub-committees, One for examining the rationality of drug formulations referred to it, and the other to advise on matters related to homeopathy. These committees are functioning satisfactorily and have made significant recommendations after interacting with Pharma Industry, public health officials and public representatives. Because of other pressing engagements of DGHS, on the request of the Chairman, it was decided that Dr.S.D.Seth would preside over the meeting during his absence.

The Chairman then asked Member Secretary to proceed with the agenda.

AGENDA NO. (1)

ACTION TAKEN ON MATTERS ARISING OUT OF THE 50TH MEETING OF DTAB, HELD ON JUNE 21, 2001 AT NEW DELHI.

The follow up action taken by the office of DCG(I) in respect of various decisions arrived at in the 50th meeting was explained to the members. The Board observed that appropriate action has been taken in regard to matters arising out of the meeting of the Board. However, the subject of dress code as a mandatory requirement under the rules (item 1(11)) was sought to be discussed by some members.

Dr. Kokate stated that the question and requirement of dress code of registered Pharmacist should be viewed from the angle of enforcement of Good Pharmacy Practices. He felt that the consumer has a right to know whether the medicines purchased by him are being dispensed through the involvement of a professional person incharge of the shop or through someone else. He added that wearing of white coat would make the pharmacist easily identifiable.

Shri A. Rajshekhar, DC, Karnataka, supported the proposal mooted by Dr. Kokate. He felt that voluntary promotion of wearing the coat while discharging the duties at retail outlets would not serve the purpose and perhaps there is a need to make such a provision mandatory under the statute.

The Chairman stated that he appreciates the concern expressed by the members for ethical dispensing of medicines. However, the wearing of white coat alone would not solve the problem of identification of the pharmacists in a retail shop. This is because wearing of white coat by persons other than the registered pharmacists cannot be prohibited. Moreover, such a person could also be mistaken as a doctor by lay public. It would, therefore, be appropriate to have some sort of identity card or batch on the chest of the pharmacist for his identification while discharging the duties.

Shri P.D.Sheth stated that the role of pharmacist is much larger an issue. Good pharmacy practices are required to be developed and the pharmacists are required to be trained in not only dispensing of medicines and informing the consumer about the proper dose and precautions etc., but also in preserving the potency of drugs through proper storage. He however, agreed that for identification, wearing of identity card would suffice.

DC, Kerala stated that Chemists and Druggists Associations are strongly opposed to such a move. It is for the Pharmacy Council which registers Pharmacists, to devise ways and means by which it can ask the pharmacists to wear white coats and they would feel pride in identifying themselves as professionals and an important functionary in health care system.

Chairman further stated that the proposal is required to be examined from a broader perspective and as a part of whole system of health care and not in isolation. Once such a provision is made, punishments would also have to be specified in case of violation of dress code. This may create many complexities.

Member Secretary stated that the proposal was earlier considered and was withdrawn as the Act essentially deals with the regulation of quality of drugs manufactured and sold in the country and not the ethics of pharmacy. AIOCD also had expressed reservation about making it mandatory provision under the rules. Further, there is no system of issuing identity cards to the pharmacists by the Drugs Control Authorities.

The Board after discussion agreed that specifying a dress code is a matter of pharmacy ethics and thus the provision concerning it should be created under the Pharmacy Act and Rules thereunder. Identity cards for registered pharmacists could also be issued by the State Pharmacy Councils where the person is registered. Pharmacy Council may also consider for making a provision for awarding penalties in case of violation of the said provisions.

The members then approved the ATR report.

AGENDA NO. (2)

PROPOSAL TO CONSIDER REVISION OF SCHEDULE Y TO THE DRUGS AND COSMETICS RULES, 1945.

The Member Secretary explained to the Board that revision of Schedule Y relating to requirements and guidelines on clinical trials for import and manufacture of new drugs was deliberated in the last meeting of the Board. It was then agreed to that the proposal to revise Schedule Y may be considered by an expert committee like, Investigational New Drugs (IND) Committee, constituted by the Government, to evaluate the IND applications and which has members from ICMR, CDRI, medical institutions and medical specialists etc. The preliminary review of the existing Schedule Y was completed by a group of clinical scientists under Dr. Neelima Kshirsagar and a document proposed for amending the existing provisions was prepared. This draft was further improved upon in consultation with experts, for the consideration of IND Committee headed by DG, ICMR. The draft of revised Schedule Y, along with the recommendations of IND Committee, is now under further consideration of a group of experts under DG, ICMR for finalisation. A copy of the draft was circulated to the members of the Board.

He further informed the members that associations of various medical specialists including oncologists, pharmacologists, academicians, pharma industry etc., have expressed the need to review restrictive provision of permitting clinical trials at one phase below to the phase in other countries. These provisions hamper collaborative research under global trials as they do

not allow simultaneous clinical trials to be conducted in India. Therefore, there has been limited meaningful research in clinical area of new drug development and the existing rules rather encourage repetitive and confirmatory trials with new drug products which have been conducted in other countries. It was observed that most of the countries allow concomitant multicentric clinical trials. Countries like U.K. allow even phase I studies on new molecules based on the pre clinical data developed in other countries.

The Board noted that the Pharmaceutical Research & Development Committee headed by Dr. Mashelkar had recommended in its report that India has excellent expertise in developing new and innovative process for new molecules. Citing the unique opportunity for India to become a leading centre for clinical trials, the Committee has called for basic changes in the legislation allowing the import of animals, contract research, and a legal status for institutional animal ethics committee. Furthermore, establishment and operationalization of GMP, GLP and GCP monitoring authority has been recommended.

The safety of the patients and their human rights as well as the meaningful growth of research in clinical and pre-clinical areas of the drug development are the prime concerns in developing the guidelines so that ethical aspect of the clinical research is brought at par with developed countries.

Dr. S.D.Seth then highlighted the major changes proposed to be made in Schedule Y, which are enlisted below:

- 1) "Form 44" introduced recently under the Drugs & Cosmetics Rules, 1945 has been appropriately incorporated in the Schedule Y.
- 2) The phase lag in clinical trials has been omitted to allow simultaneous trials to be conducted in the country.
- 3) Extensive reference has been made to the Indian Good Clinical Practices requirements that were published by the CDSCO, Dte. General of Health Services, Ministry of Health & Family Welfare.
- 4) Ethical requirements to protect the safety and interest of the study subjects have been reinforced.
- 5) Responsibilities of the 'sponsor', 'ethics committee' and 'investigator' have been clearly stated.
- 6) The format for clinical trial report submission has been made more elaborate so that all the necessary data components – particularly adverse drug event/reaction data is made available to the licensing authority to facilitate informed decisions.
- 7) Definitions of clinical trial phases have been revised in accordance to the current scientific contexts.
- 8) An 'Investigator's Undertaking' has been prescribed so as to ensure patient's safety and credibility of the data.
- 9) Animal toxicity studies data requirements have been revised on the basis of current scientific contexts.

Shri P.D.Sheth desired that the provision should be made to involve "elderly patients" in the trials (p 5 of 22) and to add "storage conditions" under "data on formulation" (p 8 of 22).

The Board, after detailed deliberation agreed to the revision of Schedule Y on the lines proposed in the draft. It was, however, decided that since the expert group under DG, ICMR is preparing the final draft which may include some changes / corrections etc., the same may be further circulated to the members of the Board for comments. The Board authorized the Chairman for approval of the final version of proposed Schedule Y for necessary amendment in the Drugs & Cosmetics Rules, 1945.

AGENDA NO. (3)

CONSIDERATION OF PROPOSAL TO AMEND RULE 44 OF THE DRUGS & COSMETICS RULES TO CONSIDER THE EXPERIENCE OF TESTING OF DRUGS IN PRIVATE SECTOR ALSO FOR THE PURPOSE OF APPOINTMENT TO GOVERNMENT ANALYSTS.

Member Secretary invited the attention of the Board members to rule 44 of the Drugs & Cosmetics Rules, 1945 which prescribes "qualifications of Government Analyst" for person who can be appointed as a 'Government Analyst' under Section 20 of the Drugs and Cosmetics Act in respect of specified drugs or classes of drugs. Such person with prescribed qualification should also possess not less than 5 years experience, if he is a Graduate in Medicine or Science or Pharmacy or Pharmaceutical Chemistry, in the testing of drugs in a Lab. under the control of-

(i) a Government Analyst appointed under the Act;
or (ii) the head of the institution or testing lab. approved for the purpose by the approving authority;
or (iii) has completed 2 years training on testing of drugs including those stated in Schedule C in Central Drugs Laboratory.

In case the person possesses post-graduate degree, he ~~should~~ possess not less three years experience in the testing of drugs in the labs as stated above.

He further stated that difficulties were being faced by some of the State Drugs Control Authorities in the appointment of persons as Govt. Analysts in the State laboratories, who otherwise are well qualified and have experience and expertise but do not conform to the specific criteria of experience in testing as prescribed under the said rule. The experience under the rule is limited to certain specified laboratories only and excludes experience in private or approved laboratories. The problem is more acute when a new Govt. testing laboratory is to be established by the State or Central Govt. Even though a person appointed

may have adequate expertise in testing of specific categories of drugs, he cannot be notified as Govt. Analyst under the rules. Thus analysts working in the Govt. approved private testing laboratories or R & D wings of many pharmaceutical units who are capable of taking such assignments, cannot be appointed as Govt. Analysts.

The Board, after deliberations, observed that rule 44 also provides for recognizing experience of the person to be appointed as analyst who has experience under the control of the head of an institution or testing laboratory approved for the purpose by the appointing authority, and this provision should enable the Govt. to draw persons from such approved laboratories to be appointed as Govt. Analysts. It would, therefore, not be necessary to amend the said rule.

AGENDA NO. (4)

PROPOSAL TO CONSIDER TO MAKE AVAILABLE CERTAIN COMMONLY USED DRUGS (OTC DRUGS) WHICH COULD BE SOLD WITHOUT A SALE LICENCE UNDER THE DRUGS & COSMETICS RULES 1945.

The Member Secretary briefed the members that certain commonly used drugs, which are considered safe and are needed for symptomatic relief, may not be limited for their sale through the licensed outlets only and should be made available to the consumer at other sale outlets also. Such practice is prevalent in many countries where drugs have been classified as Prescription drugs and Over the Counter (OTC) drugs. The OTC drugs are further classified as Pharmacy only or Nonpharmacy drugs. In India a few class of drugs have been exempted under Schedule K to the Drugs & Cosmetics Rules, from the condition of sale licence under the said rules.

The proposal was also considered by the Drugs Consultative Committee in its 32nd meeting and a sub-committee was formed to consider the introduction of OTC drugs under the said rules. The committee had recommended that various class of drugs which have been exempted under Schedule K from time to time, should be clubbed together and the list should be enlarged to include more drugs which could be permitted to be sold without the condition of sale licence under the rules. The Drugs Consultative Committee (DCC) in its subsequent meeting agreed, in principle, for review of Schedule K on the lines suggested by the Sub-Committee. Sr. No. 13 of Schedule K lists certain household remedies which are permitted to be sold without a licence in a village having population not more than 1000 persons. Some of the drugs covered under this entry could also be included in the list for total exemption from the sale licence.

The board after deliberations opined that the list of drugs which could be exempted from sale licences should be examined by the Expert Committee (Sub-Committee of DTAB) and its report submitted for the consideration of the Board.

AGENDA NO. (5)

PROPOSAL TO CONSIDER AMENDMENT OF SCHEDULE F TO THE DRUGS & COSMETICS RULES, 1945 TO PERMIT USE OF RAPID TEST KITS FOR TESTING HIV ANTIBODIES BY THE BLOOD BANKS.

Member Secretary explained to the Board that one of the requirements of the licence for blood banks was to provide Elisa or RPHA test kits for screening blood units in respect of freedom from Hepatitis B, HIV I & II and HCV. However, small blood banks do not find it feasible to install Elisa test kits and it has been observed by NACO that Rapid Test Kits are considered as sensitive as Elisa kits. NACO has stated that the rapid kits are cheaper and quick in testing. Non installation of Elisa test kits by the blood banks could lead to administrative action like the refusal of licence or suspension of existing licence leading to shortage of blood supply in the particular area. Since the proposal was of immediate nature, the agenda item was circulated in December, 2001 to the members for their opinion. While the Drug Controller, Kerala, Karnataka and Dr. Kamla .A. Kanan agreed to the proposal, Director of CDL, Kolkata and CRI, Kasauli desired data to be made available to establish sensitivity of rapid test kits. Dr. P.D.Sheth, however, did not agree to the proposal as the rapid test kits available in the market may not be of reliable sensitivity.

Mr. Sheth agreed that as blood is a scarce commodity and with rapid advances in technology if satisfactory rapid test kits are available, there should not be any objection to their use.

Shri R. Narayanaswamy, DDC(I) informed that from the reports received from NIB, NOIDA, it is observed that rapid test kits are now as sensitive as Elisa for HIV I & II. However, Hb_sAg rapid devices do not pick up weak reactive sera. So no specific opinion about sensitivity of rapid test kits for testing Hb_sAg can be given.

Dr. Malik observed that India is a vast country and it is essential that blood supplied is safe for use. Kit might show false positive results or false negative results. If the kit shows false negative test, it might be viewed seriously and such kits should not be recommended for use by the blood banks. For false positive results, it is necessary to use another safeguard method for re-testing.

The Board, after deliberation, felt that kits which on evaluation have been found to be equally sensitive as Elisa for HIV I&II and HCV may be permitted to be used in blood banks. With regards to HbsAg, further opinion of NACO about its suitability as compared to Elisa test method may be obtained.

AGENDA NO.(6)

PROPOSAL TO CONSIDER THE AMENDMENT TO SCHEDULE M-III OF THE DRUGS & COSMETICS RULES, 1945 FOR DELETING THE TEST FOR PYROGENS AND ABNORMAL TOXICITY IN RESPECT OF MEDICAL DEVICES.

The Member Secretary explained that a need has been expressed to avoid use of animals wherever alternative tests are available or to dispense with animal experimentation, if not considered essential, in the context of scientific advances.

Proposals have been received to review the requirement for use of animals for performing test for pyrogens and abnormal toxicity on single use syringes, single use infusion sets and needles. The pyrogenicity and toxicity in medical devices normally occurs from the raw materials besides environmental conditions under which these devices are manufactured. Since the manufacturers of these devices use medical grade plastic and if the raw material is free from pyrogens and toxicity, the final product manufactured from there may not fail in respect of the above said tests.

The matter was referred to the Director, CIPL, Ghaziabad for his comments, and he informed that these tests have been replaced in the corresponding international standards (ISO) also. As the standards of these medical devices covered under the Drugs & Cosmetics Rules are as per the specifications laid down by BIS for the purpose, the BIS has been separately requested to take steps to make suitable amendments in the respective BIS standards in line with ISO. The matter is under active consideration of BIS.

The Member Secretary further stated that Schedule M III to the Drugs & Cosmetics Rules provides for requirements of "Factory premises for manufacture of medical devices" and "item 7" of the Schedule specify the testing facilities that should be set up for medical devices. It provides that the licensee shall provide testing facilities for sterility, pyrogen and toxicity. As animal tests for pyrogens and toxicity are proposed to be deleted in the BIS standards, it is proposed to amend the proviso of the said item so that the licensee is required to establish only those specific facilities which are required under the standards for testing the devices.

After deliberation, the Board agreed that the proviso to item 7 of Schedule M III should be amended by adding the word "wherever applicable" after the words sterility, pyrogens and toxicity, so that manufacturer is required to establish facilities for only those tests which are actually required to be performed.

AGENDA NO.(7)

PROPOSAL TO CONSIDER THE RE-CLASSIFICATION OF CLORAZEPATE DIPOTASSIUM FROM SCHEDULE 1 TO SCHEDULE II OF THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (NDPS) RULES.

Member Secretary explained to the Members that M/s. Ranbaxy Labs. Ltd. had made an application for manufacture of Clorazepate di-potassium, a psychotropic substance, for export purposes. The said drug was covered under Schedule I to the NDPS, Rules and was prohibited for import into India and export out of India as per said rules. The drug is similar to Diazepam on oral administration.

Even though the product is permitted in the international trade, its import and export is prohibited in India due to its inclusion in Schedule I of NDPS Rules. A proposal for re-classification of the said item was under consideration of the Ministry of Finance with a view to facilitate its export to other countries by the Indian manufacturers. Ministry of Finance have now amended the NDPS Rules, vide GSR No. 214 (E) dated 19th March, 2002, wherein a separate schedule for purpose of permitting export of controlled substances has been added. The product Clorazepate di-potassium has been included in it.

The Board noted the action taken by the Ministry of Finance to facilitate export of the said item by the Indian manufacturers. No further action is required in the matter.

AGENDA NO.(8)

CONSIDERATION OF PROPOSAL TO BRING RECOMBINANT DNA DERIVED THERAPEUTIC PRODUCTS WITHIN THE AMBIT OF "CENTRAL LICENSING APPROVING AUTHORITY (CLAA)" UNDER DRUGS AND COSMETICS RULES.

Member Secretary explained that manufacture of Recombinant DNA (r-DNA) products is a complex process as it involves specific methodology viz. characterization of host cells, gene and vector construction, plasmids, cloning procedure and transcription methods. The procedure also involves description on identity, physical, chemical, immunological and biological characterization. Further, a set of pre-chemical and clinical data is also required to be developed before large scale production of r-DNA products could be undertaken.

The expert committee constituted by Govt. to advise DCG(I) in evaluation and approval of r-DNA therapeutic products, has recommended that similar to other sensitive drugs like sera and vaccines, Large Volume Parenterals (LVPs) and blood and blood products, the licensing for these products should also be uniformly regulated in the country through the mechanism of Central Licence Approving Authority.

After deliberation, the Board agreed that these products should be regulated for their grant/renewal of manufacturing licences under the ambit of Central Licence Approving Authority (CLAA) and appropriate notification may be issued and necessary changes, if required, may be made under the Drugs and Cosmetics Rules, 1945

AGENDA NO.(9)

CONSIDERATION OF THE PROPOSAL FOR LABELLING OF COSMETICS AS VEGETARIAN OR NON-VEGETARIAN ORIGIN ON THE BASIS OF INGREDIENTS – MATTER ARISING OUT OF A PIL FILED IN THE HIGH COURT.

The Chairman briefed the members that the proposal for labelling of cosmetics as "vegetarian or non-vegetarian" is based on a PIL filed by Mr. Ozair Hussain (CWP 837/2001) in the High Court of Delhi, that the right of conscious consumers who do not consume products derived from animal origin are violated due to non-disclosure of the fact that the ingredients used in their production are of animal origin. The PIL covered food, drugs and cosmetics. In the case of drugs, the matter was earlier considered by DTAB in its 48th meeting and it was felt that as the drugs are not taken by choice and are required for saving the life of the patients, it was not necessary to label them as vegetarian or non-vegetarian. Regarding food, the Prevention of Food Adulteration Rules, 1955 have been amended to indicate by a symbol and colour code if an article of food contains whole or part of any animal including birds and fresh water or marine animals or eggs as ingredients.

In respect of cosmetics, the Hon'ble court during the course of hearing of the case, by its order dated 13.7.2001 directed the Govt. to grant an opportunity of hearing to the counsel of petitioners by the Sectional Committee of Bureau of Indian Standards (BIS) and its recommendations be considered by DTAB. Shri Raj Panjivani, counsel of the petitioners, was provided a hearing on 12.10.2001 in the meeting of the Sectional Committee (PCD 19) of BIS. The Committee while agreeing that the consumer has a right of informed choice between products made or derived from animal and non-animal ingredients, however, implementation of such a provision would be very difficult as the verification of authenticity of claims made would not be feasible. Identity of source of raw materials cannot be ascertained by testing. The matter of informing the consumer should, therefore, be in a positive way i.e. the manufacture would label only those cosmetics which do not have any raw material from animal origin as

'suitable for vegetarian' or any such similar mark. There will be no negative labeling.

The Chairman suggested that keeping in view the usage pattern of cosmetics as compared to medicines, it would perhaps be appropriate to keep them in a category similar to food for purpose of labeling with vegetarian or animal source. A provision similar to food, therefore, may be adopted in the case of cosmetics. Cosmetics containing ingredients of animal origin should display a symbol consisting of colour-filled-circle, having a minimum specified diameter, in a square to indicate their vegetarian or non-vegetarian origin. The "brown colour" in the circle may indicate the cosmetic having ingredients derived from "animal origin" and "green colour" for cosmetics having ingredients of "non-animal origin." The Drugs & Cosmetics Rules should be suitably amended to make provision for such labeling on every packet of cosmetic.

The Board, after deliberations agreed to the views of the Chairman for affecting suitable amendments in the Drugs & Cosmetics Rules as has been done in the case of food products.

AGENDA NO.(10)

PROPOSAL FOR RECONSTITUTION OF SUB-COMMITTEE OF DTAB ON HOMOEOPATHY

Member Secretary explained to the members that based on the recommendations of the Board, the Ministry of Health had constituted a sub-Committee of DTAB on Homoeopathy, in February 1999, to advise the Board on technical matters on homoeopathy arising out of the administration of Drugs and Cosmetics Act, 1940 and Rules thereunder. Deptt. of ISM&H informed that the term of the said sub-Committee, which has since expired on Jan 31, 2002, may be extended for another period of three years.

After deliberation, the Board gave its concurrence that the term of the said sub-Committee may be extended for another period of three years. The Board, however, recommended that the chairman of the said sub-Committee may also co-opt such other members to the committee whose contributions are considered essential to the proposals under consideration.