MINUTES OF THE FORTIETH DRUGS TECHNICAL ADVISORY BOARD MEETING HELD ON APRIL 22, 1988 AT NEW DELHI

The Chairman welcomed the members attending the meeting and stated that meeting of the Board could not be held after December, 1984 because then Drugs Controller (India), Dr. S.S. Gothoskar retired in November, 85 and it took sometime for Government to appoint new Drugs Controller (India). Thereafter the term of the elected and nominated members of the Board had expired and it took time to reconstitute the Board. Since the reconstituted Board is meeting for the first time, the Chairman requested all the members to introduce themselves. He requested them to give their valuable advice on the various important issues included in the agenda. He also requested the members to give special consideration to the following points while deliberating on various agenda items:-

1. Whether the sale of mechanical contraceptives like 'Today' could be permitted without requirement of a sales licence.
2. Combination drugs for asthama containing corticosteroids do not have a rationale for long duration treatment. These combinations will have serious side effects on long term use. Therefore, members may please consider whether such combinations should be continued to be permitted to be marketed.
3. It has been observed that some combination formulations have been permitted to be manufactured by State Drugs Controllers which are now considered to be irrational.
4. The observations of Lentin Commission that the enforcement machinery is not adequate, the concerned persons were directly responsible for the episode and that strict measures are necessary to guard public health.

Chairman regretted that since he is pre-occupied with some other important work, be would not be able to spend much time in the morning. He requested Dr. Prem K. Gupta, Member Secretary to carry on with the meeting and hoped that he would be able to join again as early as possible.

Dr. Prem K. Gupta, Member Secretary welcomed the members and thereafter the agenda items were taken up for consideration.

ITEM NO. 1

Confirmation of the minutes of the 39th meeting held in New Delhi on the 19th December, 1984.

Member Secretary, Dr. Prem K. Gupta, Drugs Controller (India), informed the members that no comments were received on the minutes of the last meeting and therefore the minutes are considered confirmed without any change.

ITEM NO. 2

Consideration of the questions arising out of the minutes of the 39th meeting.

Member Secretary informed the members that a "Statement of the action taken on the various decisions arrived at the last meeting of the DTAB" has already been circulated as part of the agenda. He informed that action on all the items has been taken and he would be glad to give clarification on any point desired by the members.

The members sought some clarifications and these were given.

ITEM NO. 3

Consideration of the Report of the Drugs Controller (India) in pursuance of the Order of the Hon'ble Chief Justice of Supreme Court of India to take a decision as to whether high dose formulations of oestrogens and progesterone should or should not be permitted to be marketed and frame the recommendations of the Board for onward transmission to the Government of India for further action.

Member Secretary introduced the subject. He informed the members that in 1982 Government had taken a decision that high dose combination products of oestrogen and progesterone should be banned.

Some manufacturers went to the Court and got a stay order and pending the stay orders, a Public Interest Litigation was filed by Mr. Panikulangara in the Supreme Court of India against the stay granted in different High Courts in the country.

The Supreme Court in its judgement in 1986 directed the Drugs Controller (India) to hold public hearings and decide whether or not the hing dose oestrogen and in 1986 directed the Drugs Controller (India) to hold public hearings and decide whether or not the high dose oestrogen and, progesterone combinations should be banned.

In 1987, the Drugs Controller (India) held four public hearings one each at Madras, Delhi, Calcutta and Bombay. During the hearings Drugs Controller (India) heard the views of Experts, Gynecologists, Consumers Organizations, Voluntary and Women Associations, Individuals. After examining the oral and written evidence and after consulting other bodies like ICMR and FDA USA, Drugs Controller (India) submitted his report to Supreme Court of India giving the following recommendation:-

"Based on benefit – risk considerations, the apparent trend of misuse of high dose oestrogen-progesterone preparations for diagnosis of pregnancy, advice of ICMR for banning of such preparations and the information obtained from FDA USA indicating that combination of oestrogen-progesterone (other than oral contraceptives) are not available in USA. Drugs Controller (India) is in favour of recommending withdrawal of high dose combination of oestrogen and progesterone containing per tablet oestrogen content of more than 50 mcg (equivalent to ethynyl estradiol and progesterone content of more than 3 mg. (equivalent to norethisterone acetate).

The Board unanimously approved that estrogen and progesterone combinations should be permitted for use as oral contraceptives only and all high dose combinations per tablet more than 50 mcg of estrogen (equivalent to ethynyl oestradiol) and progesterone content of more than 3 mg (equivalent to norethisterone acetate) should not be permitted.

ITEM NO. 4

Consideration of the Government of India, Ministry of Health and Family Welfare Gazette of India notification no. 777 (E), dated the 15/9/1987 containing a draft amendment to Schedule K of the Drugs and Cosmetics Rules for insertion of a new Entry No. 27 on Oral Rehyderation Salts (Manufactured as per WHO formula) for its acceptance so that further action can be taken.

The Board agreed to the proposal with the recommendation that the composition of ORS should be specified in the proposed entry to the Schedule K.

The Board also recommended that a monograph on Oral Rehydration Salt, should be included in IP.

ITEM NO. 5

Consideration of the Government of India, Ministry of Health and Family Welfare Gazette of India notification no. GSR 708 (E), dated the 13/8/1987 containing a new provision to be added for the display of a code number for drugs which are to be exported from India for its acceptance so that further action can be taken.

The Board agreed to the proposed amendment.

ITEM NO. 6

Consideration of the Government of India, Ministry of Health and Family Welfare Gazette of India notification no. GSR 603 (E) dated 26/6/1987 containing modifications in the standards of condoms as laid down in Schedule R, in respect of Water Leakage Test and Tensile Strength, and the changes made therein with a view of its finalization, for acceptance by the Board.

Member Secretary explained that the proposed amendment was applicable only to thin variety.

The Board agreed to the proposed amendment.

ITEM NO. 7

Consideration of the modification made in the existing entry no. 26 of Schedule K to the Drugs and Cosmetics Rules regarding free sale of 'Band Aid Medicated Dressings' by the Government of India Ministry of Health and Family Welfare Gazette of India notification no. GSR 848 (E) dated 12/10/1987 for its acceptance.

The proposal was agreed to by the Board.

ITEM NO. 8

Consideration of the proposal to amend the existing Entry no. 23 in Schedule K to the Drugs and Cosmetics Rules which now exempts multipurpose workers attached to Primary Health Centres and other disciplines from being covered by a sale licence, so that Aanganwadi workers are also exempted similarly under this entry.

The Board agreed to the proposed amendment. The Drugs Controllers of States/UTs to be informed immediately, pending notification being priority programme.

ITEM NO. 9

Consideration of a proposal for exempting the product "Today" a vaginal contraceptive marketed by M/s. Bliss Chemicals and Pharmaceuticals India Ltd., from being covered by a sale licence under the Drugs and Cosmetics Rules.

A doubt was expressed regarding quality of the products that may be available if there is no control at sale points. However, Member Secretary, explained that the purpose was to make such contraceptives freely available even in interiors of the country.

The Board agreed to the proposed amendment. The Drugs Controller of State/U.Ts to be informed about the decision immediately, pending notification of family welfare being priority programme.

ITEM NO. 10

Consideration of the draft amendments to the Drugs and Cosmetics Rules for control over New Drugs as published under Ministry of Health and Family Welfare notification with GSR No. 602 (E) dated the 26/6/1987 based on the "New Drugs Policy" announced by the Government of India for its acceptance.

Member Secretary as well as Dr. P. Das Gupta, Dy. Drugs Controller (India), explained the purpose of the amendment i.e. to modify the requirements of New Drug applications. They also explained certain changes that are proposed to be made in the already published draft amendment on the basis of comments received from different quarters.

Dr. Bannerjee, representative of IMA, pointed out that there are already large number of formulations available in the country and that proposed amendment may not add to the existing number of formulations.

Member Secretary explained that the number of New Drugs cleared in the country are not more than 15-20 in a year. Permission to manufacture a New Drug in no way adds to the problems of multiplicity of drug formulations in any significant way.

Dr. Gupta also informed the members for general information that a subcommittee of the DCC is already constituted to examine the rationality of combination formulations available in the country. On the basis of the recommendations of this subcommittee, 26 combination formulations have already been banned and the process of screening is continuous.

The Board unanimously agreed to the proposed amendment.

ITEM NO. 11

Proposal for inclusion of standards for (i) Disposable Perfusion Set, (ii) Disposable Hypodermic syringe (iii) Disposable Hyperdermic needle in the Drugs and Cosmetics Rules after notifying them 'drugs' under section 3 (b) (iv) of the Drugs and Cosmetics

Act, as amended by the Amendment Act of 1982, as recommended by the Drugs Consultative Committee.

The Board agreed to the proposal to notify (i) Disposable Perfusion sets (ii) Disposable Hypodermic Syringes and (iii) Disposable Hypordermic needles as 'drugs'.

ITEM NO. 12

Proposal for inclusion of specifications of seven finished cosmetics of ISI as standards for the purpose of the Drugs and Cosmetics Act, in Schedule S of the Drugs and Cosmetics Rules.

The Board agreed to the proposal for inclusion of ISI standards for following 7 types of cosmetics in Schedule S to the Drugs and Cosmetics Rules:-

1. Nail Polish.
2. After Shave Lotion.
3. Pomades and Brillantines.
4. Depilatories Chemical.
5. Shaving Creams.
6. Cosmetic Pencils.
7. Lipstick.

ITEM NO. 13(A)

Proposal for inclusion of names of colours which shall be permitted to be used in the manufacture of soaps, in addition to the colours permitted for use in cosmetics, as given in Schedule Q to the Drugs and Cosmetics Rules pursuant to the inclusion of soaps as 'Cosmetics' as under Section 3(a), as amended by the Drugs and Cosmetics Amendment Act of 1982.

The Board agreed to the proposal of including 10 proposed colours for toilet soaps in Schedule Q as Part III.

It was explained to the members that four colours are approved by FDA, USA and remaining six colours have been approved by EEC for use in soaps.

ITEM NO. 13(B)

Proposal to delete the colour 'Quinoline Yellow SS' from rule 127 of the Drugs and Cosmetics Rules.

The Board agreed to the proposal of deleting the colour Quinoline Yellow SS and inclusion of the colour Quinoline Yellow WS in rule 127 of the Drugs and Cosmetics Rules.

ITEM NO. 14

Consideration of the question as to whether Saccharin should or should not be permitted to be used in Oral Rehydration Salts marketed as proprietary products by different drug manufacturers.

After discussion, the Board agreed that the use of colouring and flavouring agents in Oral Rehydration Salts may be permitted provided that sweetening agent is not used as a substitute for glucose and it contains glucose in requisite quantity.

ITEM NO. 15

Consideration of the proposal for amalgamation of Schedule G and H of the Drugs and Cosmetics Rules, 1945.

Member Secretary explained that at the time of permitting the marketing of Azatadine Maleate as a New Drug, a condition was laid that it will be labeled to be sold "Under prescription of a RMP" as is the requirement for other Schedule H drugs.

At the time of amendment to Schedule H to the Drugs and Cosmetics Rules, this Drug was proposed to be included in Schedule H. The manufacturer pointed out that this drug is an anti-histaminic drug, and since all other anti-histaminic drugs are included in Schedule G to the Drugs and Cosmetics Rules, this drug should also be included in Schedule G. Therefore, inclusion of the drug Azatadine Maleate in Schedule H was not carried out in finalized amendment. However, this drug was also not included in Schedule G and status quo was maintained.

The members recommended that the drug should be included in Schedule G to the Rules.

The members also recommended that no other change is necessary for recasting Schedules G & H to the Rules.

ITEM NO. 16

Consideration of the recommendations of the subcommittee for weeding out of formulations which are considered harmful/irrational, as approved by the Drugs Consultative Committee.

The Board agreed to the weeding out of following combinations of drugs:-

1) Fixed dose combination of tranquillizers with analgesics – antipyretics.
2) Fixed dose combination of Pyrazinamide and other anti-T.B. drugs.
3) Fixed dose combination of anti-ulcer (H_2 receptor antagonist, such as Cimetidine, Ranitidine etc.) with other drugs.
4) Fixed dose combination of essential oils with alcohol with percentage higher than 20% proof.
5) Fixed dose combination of chloroform with other drugs.
6) Fixed dose combination of non-specific anti-diarrhoieals like pectin, kaolin with specific anti-amoebic and/or anti-bacillary drugs.

Mr. Raman bhai Patel, representative of IPA, did not agree to the total ban on this combination. He stated that he had evidence to show that kaolin and pectin play a role in absorption of salmonella toxins.

It was decided that Dr. Patel will submit the evidence to the Member Secretary for examination by the subcommittee of the DCC.

7) Fixed dose combination of recognized drugs of indigenous system of medicine with allopathic drugs.

The Members agreed to the proposal for the weeding out of the proposed combinations with a change in the wording by substituting the word "other" for the word "indigenous".

It was agreed that this point should also be referred to AUDTAB for their consideration and recommendations.

8) Fixed dose combination of sub-therapeutic drugs.

After discussion, there was a general feeling that the wording of the entry was not specific. Therefore, it was unanimously decided that subcommittee of the DCC should examine cases of sub-therapeutic combinations which should be recommended to be banned.

ITEM NO. 17(a)

Proposal for amendment of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 so that advertisements made for treatment of diseases by Medical Practitioners could be prohibited.

Member Secretary explained that a suggestion had come from Government of Maharashtra to include some provision in the Drugs and Magic Remedies (Objectionable Advertisement) Act to prevent advertisement by Medical Practitioners for treatment of diseases or disorders which are covered by provisions of the Act and Rules. Subsequently a panel of Indian Pharmaceutical Association, Delhi branch was requested to examine the matter. The report of this Committee as well as the report of Committee of Tamil Nadu Branch of IPA are the basis of the ITEM NO. under consideration. It was agreed that the Drugs and Magic Remedies (Objectionable Advertisement) Act should be suitably amended as per the recommendation received and the list of diseases given to the Schedule should be revised.

After discussion the Board constituted the following two subcommittee:-

1) Dr. Siddiqui	Convener
Dr. M.G. Garg, Past President	IMA

This subcommittee will draw out a revised list of diseases to be given in Schedule to the DR(OA) Act. The subcommittee can co-opt any other expert. This committee should submit their report within three months.

2) Dr. J.L. Kaul, Drugs Controller, Delhi	Convener
Dr. M.S. Qadri, Principal, Hamdard College of Pharmacy, Delhi	Member
Dr. Ramanbhai Patel	Member

This subcommittee would suggest suitable amendments to the various sections of DMR (OA) Act to achieve the purpose. The subcommittee should also consider the question of banning of advertisements on amniocentesis test.

ITEM NO. 17(b)

Consideration of Control measures for advertisements of OTC drugs on T.V. and Radio. Member Secretary also requested the members to consider the additional item suggested by the Ministry of Health and Family Welfare as to whether advertisements of OTC drugs could be banned on the television and radio.

The Board felt that advertisements of OTC drugs on T.V. and Radio should be banned and Health Ministry should take suitable steps in this direction.

ITEM NO. 18

Consideration of the report of the subcommittee of the Drugs Technical Advisory Board appointed for examining the provisions of Schedule X of the Drugs and Cosmetics Rules and difficulties faced by the Chemist and Druggists, patients and Doctors.

The Board unanimously decided that the six benzodiazepines presently being marketed in the country as well as the 7^{th} benzodiazepine viz. alprozelam which is being permitted to be marketed in the country for the first time should continue to remain in Schedule H to the Drugs and Cosmetics Rules as at present. It was also decided that the drug pentazocine should also continue to remain in Schedule H. The Board also decided that Phenobarbitone which is presently included in Schedule X to the Drugs and Cosmetics Rules should be removed from that Schedule and brought to Schedule H.

It was also agreed that for all these 8 drugs, some additional conditions may be prescribed in Drugs and Cosmetics Rules in order to check the misuse of these drugs.

ITEM NO. 19

Approval of the constitution of Homoeopathic subcommittee of the Drugs Technical Advisory Board with new members.

The Board approved the composition of Homoeopathic subcommittee of the Drugs Technical Advisory Board as proposed.

The Board recommended inclusion of Drugs Controller (India) in the subcommittee.

ITEM NO. 20

Consideration of the decision of the Drugs Consultative Committee on the question of showing the name and address of the manufacturer where the drug has been manufactured, on the label of the drug.

The Board was of the view that only the address of the manufacturing premises should be mentioned on the lable of the drug and the relevant rules should be amended accordingly.

ITEM NO. 21

Proposal to notify "Intra Ocular Lens (IOL) implantation for cataract" as drug under the Drugs and Cosmetics Act.

Member Secretary explained that the item IOL under consideration is controlled in USA. The Board formed the following subcommittee to work out standards for IOL:-

Dr. Madan Mohan, Adv. (Ophthalmology)	Chairman
Dr. J.L. Kaul, Drugs Controller, Delhi	Member
Dr. L.V. Kannan, DDC(I), New Delhi	Convener

ITEM NO. 22

Proposal to amend rule 3-A of the Drugs and Cosmetics Rules, 1945 so that the functions of the Central Drugs Laboratory in respect of IUD may be performed by the Department of Biotechnology, Indian Institute of Technology, Delhi.

The Board approved the proposal.

ITEM NO. 23

Consideration of the Report of the subcommittee of the Drugs Consultative Committee to lay down details of space, equipment etc. for the manufacture of Cosmetics, as approved by the Drugs Consultative Committee.

The Board approved the proposal.

ITEM NO. 24

Consideration of the draft amendment to the Drugs and Cosmetics Rules for abolition of Loan Licensing system as published under Ministry of Health and Family Welfare notification with GSR No. 996 (E), dated 21/12/1987, based on the "New Drug Policy" announced by the Government of India, for acceptance.

Member Secretary explained that according to Policy measures announced by the Government, the Loan Licensing system is to be abolished by 31/3/1990. Accordingly, the draft amendment was published for comments.

Some of the members expressed a feeling that such a sweeping amendment totally abolishing the loan licensing system may cause hardship to new entrepreneurs.

The Member Secretary explained that the comments/representations received will be examined by the Government before a final decision is taken.

The Board approved the draft amendment.

ITEM NO. 25

Review of fixed dose combination of chloramphenicol and streptomycin and fixed dose combination of corticosteroids with other drugs for systemic use.

The Board agreed that the fixed dose combination of chloramphenicol and streptomycin should not be allowed to be marketed.

After exchange of views amongst the members, it was agreed that the fixed dose combinations of corticosteroids with other drugs for use in asthma should be banned because asthma therapy is a long term therapy and corticosteroids, even in low dosage, when administered for longer periods are reported to cause more harm than good to the patients.

The Board approved that the entry No. 14 appearing in the notification GSR No. 578 (E) dated 23/7/1983 may be suitably amended.

ITEM NO. 26

Review of fixed dose combination of Analgin with other drugs.

The Board decided that decision on this item should be deferred till result of local studies being conducted on analgin combination drugs are made available.

ITEM NO. 27

Reviewing of the category Fixed dose combination of Anabolic Steroids with other drugs.

(a) The Board decided that case of Trinergic injections and Capsules should be re-examined by the subcommittee of DCC already in existence for screening of irrational and harmful combinations of drugs. If necessary, this subcommittee may consult other experts to help them to arrive at a decision. This subcommittee should again give a clear verdict on rationality or otherwise of this combination.
(b) In case of dexatopic cream and decabolin Injection which contain corticosteroids in combination with anabolic steroids, the Board decided that both the combinations should be permitted to be marketed and suitable changes in the notifications already issued may be made.

ITEM NO. 28

Any other item with the approval of the Chair. Proposal to amend the Drugs and Cosmetics Rules, 1945 so as to provide for colour coding of packages of drugs to differentiate products according to the degree of hazard.

The Board agreed to the proposal.

The Member-Secretary thanked the participants for attending the meeting and giving valuable suggestions. The meeting terminated with a vote of thanks to the chair.