MINUTES OF THE FORTY FIRST DRUGS TECHNICAL ADVISORY BOARD MEETING HELD ON MARCH 9, 1990.

The Chairman, Dr. A.K. Mukherjee, DGHS, welcomed the members attending the meeting and stated that the meeting of the Board could not be held in 1989 due to certain unavoidable circumstances. He expressed that a large number of agenda items are to be discussed by the highest Technical Body constituted under the provisions of Drugs and Cosmetics Act, 1940. He pointed out that the issues regarding usage and quality of drugs are important and come up at the national level in various foras as well as on the floor of the Parliament frequently. He, therefore, exhorted the members that they should give careful consideration to the complicated matters since the Government is giving lot of attention to the affairs related to drugs and allied subjects. The members introduced themselves after which the Chairman requested the Member Secretary to take up the agenda items for discussion.

Dr. Prem K. Gupta, Member Secretary of the Drugs Technical Advisory Board, welcomed the members and informed that Dr. M.A. Patel has been invited to attend the meeting as a Special Invitee, being Chairman of the subcommittee of the Drugs Consultative Committee for weeding out of irrational and harmful drugs.

Secretary (Health) had kindly agreed to address the members of the Board. He stated that strengthening of Drug Control set up in the country is under Consideration of the Govt. of India and it is hoped that money will be allocated in the 8th Five year plan for the purpose of creating more testing facilities and strengthening the Drugs Control Organizations at the Centre and the State level. He drew the attention of members for three basic issues namely, self-policing by the industry, policing by Government authorities and market surveillance by consumer. He was of the opinion that the Drugs and Cosmetics Act may have to be looked into to make it more effective in taking action against the erring manufacturers. He was of the view that the Government should set up about 8-10 laboratories under Central Government and augment the testing of samples by Drugs Inspectors in each State. The Secretary opined that State and Central Government should think of utilizing the existing facilities in medical colleges or other Institutions which can be made available for testing of statutory samples by the Drugs Control Authorities. He also stated that different laboratories in each State can be classified and assistance can be given to bring them to acceptable level.

Secretary (Health) also mentioned that Government should make arrangements for training of laboratory Analysts at various well equipped laboratories. He was of the opinion that Drugs Technical Advisory Board should meet at least once in a year and also invite persons from organizations like Voluntary Health Organisation for seeking their opinion on various issues.

Agenda items were then taken up for consideration.

ITEM NO. 1

Confirmation of the minutes of the 40th meeting held on 22nd April, 1988 at New Delhi.

Member Secretary informed that no comments have been received on the minutes of the last meeting except some observations made by Dr. N.C. Banerjee, to whom necessary clarification regarding the points raised was issued.

The Member Secretary explained that action on various decisions taken in the last meeting has either been completed or initiated on the basis of recommendations made by the Board. A statement on action taken is annexed alongwith the agenda.

ITEM NO. 2

Consideration of Government of India Ministry of Health proposed notification containing draft amendment to the Drugs and Cosmetics Rules inserting a new rule 149-A containing special provisions relating to toothpaste containing fluoride.

The member Secretary, Dr. Prem Kumar Gupta, Drugs Controller (India) informed about the concern expressed at various fora for controlling the content of fluoride in tooth paste. The Ministry of Health and Family Welfare had constituted a Committee of experts under the Chairmanship of Drugs Controller (India) to examine the matter and suggest measures to regulate the fluoride content in tooth pastes. The Committee gave its report to the Ministry of Health. Based on the recommendations made, a draft amendment incorporating Rule 149-A to the Drugs and Cosmetics Rules was sent for publication to the Gazette. The step was taken in public interest and the Board members are requested to approve the action taken.

The Board agreed to the proposal to amend the Drugs and Cosmetics Rules as per draft amendment.

ITEM NO. 3

Consideration of Government of India, Ministry of Health and Family Welfare notification containing draft amendment to Rule 3-A of the Drugs and Cosmetics Rules 1945 inserting a new sub-rule declaring laboratories for testing of Oral Polio Vaccines.

The Member Secretary explained that a need arose to identify more laboratories for testing Oral Polio Vaccines as CRI, Kasauli was having too much load of testing imported as well as indigenously manufactured OPV. Pasteur Institute of India, Coonoor and Enterovirus Research Centre, Bombay have adequate facilities and expertise to carry out testing of OPV. Circumstances had arisen which rendered it necessary to amend Rule 3-A of Drugs and Cosmetics Rules notifying these Labs. to carry out the functions of Central Drugs Laboratory in respect of OPV, without consulting the DTAB. The step was taken in public interest.

The Board may approve and give its concurrence for making the said Rule as proposed in draft amendment notification no. GSR 718 (E) dated 28/7/1989.

The Board gave its approval to notify the two laboratories for testing of OPV in addition to CRI Kasauli and agreed to the proposal draft amendment.

ITEM NO. 4

Consideration of the draft amendment to the Drugs and Cosmetics Rules, 1945 regarding the provisions to the Blood Banks from HIV antibodies.

Member Secretary informed that a situation had arisen in the public interest to make testing of each unit of blood against freedom from HIV antibodies statutory, urgently. The Drugs and

Cosmetics Rules were amended by notification GSR No. 691 (E) dated 11/7/1989 without consulting Drugs Technical Advisory Board.

Drugs Technical Advisory Board had earlier approved amendment of Drugs and Cosmetics Rules, 1945 regarding requirements for the collection, storage, processing and distribution of whole human blood and components. The draft amendment approved by the Board was slightly modified on the basis of technical advice and by incorporating test against freedom from HIV antibodies. The draft amendment has been published under GSR 899 (E) dated 17/10/1989.

The Board approved the said draft amendment dated 17/10/1989 including therein the test for freedom from HIV antibodies.

ITEM NO. 5

Consideration of the recommendations of the Committee constituted under the Chairmanship of Dr. M.D. Saigal to chalk out a plan of action for standardization of packing of drugs in the country.

Member Secretary explained that in pursuance of Drugs Policy 1986, stating that pack sizes would be standardized and made statutory, the Ministry of Health had set up a Committee under the Chairmanship of Dr. M.D. Saigal to give recommendations.

The Committee inter-alia gave recommendations for standard consumer packs under different sizes for different categories of drugs.

It was proposed to add a new schedule giving details of pack sizes under Rule 105 of the Drugs and Cosmetics Rules.

The members pointed out certain anomalies in the proposed recommendations. Dr. Dhawan desired to know why two different dosage forms namely 1 ml. and 2 ml. have been mentioned for Morphine and Pethidine injections.

Dr. Siddiqui pointed out that activated charcoal powder should be replaced by charcoal tablets in suitable pack sizes.

Likewise, Shri Ramanbhai Patel desired that pack sizes in respect of eye/ear preparations need reconsideration as these are being marketed under different sizes (2 ml, 5 ml, 10 ml etc.).

The members were of the opinion that the proposed draft amendment needs rationalizing before it is finalized.

The member secretary explained that the Board should approve, in principle, the action to be taken for amendment of Drugs and Cosmetics Rules to lay down standard pack size of drugs once the draft notification is published. The comments received will be taken into consideration before the amendment is finalized.

ITEM NO. 6

Consideration of the report of the Drugs Technical Advisory Board subcommittee under the Chairmanship of Dr. S.N. Saxena, Director (R), Kasauli at the last meeting of DTAB to propose revision of Schedule 'F'.

The Member Secretary explained that a subcommittee of Drugs Technical Advisory Board had been constituted to propose revision of schedule 'F' of Drugs and Cosmetics Rules, which lays down additional standards for biological and special products. The subcommittee has given the report and have suggested a draft amendment to delete certain parts and sections of schedule 'F' since these standards have already been included in Indian Pharmacopoeia.

The Board agreed to the proposed draft amendment.

ITEM NO. 7

Consideration of the proposal for the amendment to Schedule V to the Drugs and Cosmetics Rules relating to the problem of disintegration time of non- pharmacopoeial patent and proprietary preparations in the form of tablets/soft gelatine capsules.

The Member Secretary explained that Schedule V of the Drugs and Cosmetics Rules relates to standards for patent and proprietary medicines. It lays down test for disintegration time of patent and proprietary medicines in the form of tablets and capsules.

It has been pointed out that there is a variation in the disintegration time for enteric coated tablets given in IP and Schedule V. Likewise, it has been brought to the notice of the Drugs Controller, India that disintegration time for certain patent and proprietary medicines marked in soft gelatine capsules do not disintegrate in 60 minutes as prescribed in Schedule V.

A suggestion was made by the industry that requirement for patent and proprietary preparations in soft gelatine capsules should either be deleted from Schedule V or it should be enhanced.

Dr. Nadkarni explained that proviso 1 to 2 of Schedule 'V' are in conflict with each other. He stated that he would send a note regarding suggestions in this regard.

Other members also gave their views and after discussion it was decided that this item needs further examination and may be looked into by Drugs Controller (India) after receiving suggestions from Dr. Nadkarni and other members.

ITEM NO. 8

Consideration of the reports of the subcommittee appointed by the DTAB to suggest suitable amendments to various sections of the Drugs and Magic Remedies (Objectionable Advertisement) Act to prevent advertisements given by medical practitioners for treatment of diseases and disorders.

The Member Secretary explained that the Board at its last meeting had appointed 2 subcommittees, one under the Chairmanship of Dr. H.H. Siddiqui to suggest a revised list of

diseases mentioned in the Schedule to the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954. The second committee was appointed under the Chairmanship of Dr. J.L. Kaul to suggest suitable amendments to the various sections of the Act to control even such advertisements where name of the drug is not mentioned.

The reports submitted by the 2 subcommittees were examined by the Board and it was felt that it needs further examination to recommend amendment of the said Act.

Member Secretary requested the members to go through the report and send their comments within a period of one month from the receipt of the minutes.

ITEM NO. 9

Consideration of the proposal to amend Rule 69-A of the Drugs and Cosmetics Rules, 1945 for changing the fee from Rs. 100/- to Rs. 200/-.

The Board agreed with the suggestions to amend proviso to Rule 69-A of Drugs and Cosmetics Rules.

ITEM NO. 10

Consideration of the proposal for the amendment to Schedule M of the Drugs and Cosmetics Rules.

The Board agreed to the suggestion that separate provision for Internal use and External use preparations may be incorporated in Schedule M of the Drugs and Cosmetics Rules, 1945.

ITEM NO. 11

Consideration of the inclusion of new provisions in the Drugs and Cosmetics Rules relating to manufacture and sale of 7 Benzodiazopines and Phenobarbitone, based on the recommendations made by the DTAB at its last meeting on 22/4/1988.

The Members Secretary informed that DTAB at its last meeting held in April 1988 had considered the report of the subcommittee of DTAB appointed for examining the provisions of Schedule X of the Drugs and Cosmetics Rules, 1945.

The Board had decided that 7 Benzodiazopines viz. Diazepam, Lorazepam, Furazepam, Nitrazepam, Chlordiazepoxide, Oxazepam and Alprazolam should continue to remain in Schedule H in Drugs and Cosmetics Rules as at present.

The Board had 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.

The Member Secretary informed that the State Drugs Controllers consulted in this connection had also agreed that Phenobarbitone should be removed from Schedule X and be added in Schedule H of the Drugs and Cosmetics Rules.

The Board agreed to the proposal that Phenobarbitone should be removed from Schedule X and added in Schedule H.

ITEM NO. 12

Consideration of the recommendations of the Drugs Consultative Committee regarding weeding out harmful/irrational/ineffective fixed dose combinations.

The DTAB concurred with the recommendations of DCC (DCC had given its recommendations at a meeting held on the 13/9/1989) to weed out the following fixed dose combinations for the reasons given below:-

(i) Ethambutol is synthetic compound that is less active than isoniazid, rifampicin and streptomycin and should be used only in combination. However, while examining FDC of Ethambutol with INH, the experts had opined that all FDC of ethambutol and INH, other than the following, do not meet the recommended dosage per day of the drugs and hence should be withdrawn.

The recommendation was agreed to by the DTAB:

INH	Ethambutol
200 mg.	600 mg.
300 mg.	800 mg.

(ii) All fixed dose combinations containing more than one antihistamine as addition of more than one antihistamine in a pharmaceutical preparation is not rational. Formulations containing more than one antihistamine do not have edge over the single one.

(iii) Fixed dose combinations of anthelmintic with cathartic purgative, except for piperazine anthelmintic, which has a short lasting effect and may require cathartic to expel the worms provided such a combination is approved by Drugs Controller (India).

(iv) Fixed dose combination of Salbutamol or any other bronchodilators with centrally acting anti-tussive and/or antihistamine as addition of anti-tussive and/or an antihistamine in no way complements the therapeutic effects of bronchodilators in clinical situation, where bronchodilators are prescribed.

(v) Fixed dose combinations of laxatives and/or antispasmodic drugs in enzyme preparations as enzyme preparations are essentially for helping digestion and as such there is no role of laxative and/or antispasmodic in such preparations.

(vi) Experts had opined that fixed dose combination of metoclopramide promoted for varied indications of GI disorders are not rational and prolonged use of such formulations containing metoclopramide may lead to extra-pyramidal side effects. Accordingly, they had recommended withdrawl of fixed dose combinations of metoclopramide.

DTAB while concurring with the recommendation had opined that fixed dose combination of Metoclopramide with other drugs should be withdrawn except for preparations containing metoclopramide and aspirin/Paracetamol which are used for short-course symptomatic relief of migraine headaches. Such short-course exposure is not reported to be associated with extra-pyramidal side-effects.

There is a rationale of fixed dose combination of metoclopramide with aspirin/Paracetamol as metoclopramide patients and helps absorption of aspirin/Paracetamol but also relieves premonitory symptoms of nausea and vomiting. The combination is marketed abroad.

(vii) The fixed dose combination of centrally acting anti-tussive with antihistamine having high atropine like activity in expectorants as this group of drugs would cause pharmacological antagonism and adversely affect the therapeutic effect of expectorants. (This item also covered under Item no. 18).

(viii) The preparations claiming to combat cough associated with asthma, containing centrally acting anti-russive and/or an antihistamine, as these drugs have no role to play in combating cough associated with bronchialasthma (This item also covered under Item no. 18).

(ix) Liquid oral tonic preparations containing glycerophophates and/or other phosphates and/or CNS stimulants and such preparations containing alcohol more than 20° proof.

ITEM NO. 13

Consideration of the proposal to ban the use of Chloral Hydrate as drug.

The DTAB had concurred with the recommendations of the DCC to ban the use of Chloral Hydrate which has become an obsolete drug and on the ground that it causes adverse effects such as gastric irritation, ataxia, night mares, confusion, etc.

It may be pertinent to mention here that Government had in the meantime prohibited manufacture and sale of formulations containing Sodium Bromide/Chloral Hydrate vide entry No. 7 of the Notification No. GSR 578 (E) dated 23/7/1983.

ITEM NO. 14

Consideration of amendment of entry 16 of the notification No. GSR No. 578 (E) dated 23/7/1983 prohibiting the manufacture and sale of fixed dose combination of ergot with other drugs.

The DTAB had streamlined the entry No. 16 of the Notification No. GSR 578 (E) dated 23/7/1983 by virtue of which the manufacture and sale of fixed dose combination of crude ergot with other drugs is prohibited for the reasons that the preparations containing crude ergot were being indiscriminately used for termination of pregnancy resulting to serious bleeding to the pregnant women together with other side effects. However, the intention of the entry was not to prohibit manufacture and sale of rational combinations of ergot alkaloids such as ergotamine with other drugs permitted for the treatment of migraine headaches.

As per the advice of the DTAB, the entry No. 16 of the above said notification will now read as follows:-

“Fixed dose combinations of Crude Ergot preparations except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine headaches”.

ITEM NO. 14(a)

Consideration of the proposal for amendment of Schedule 'H'.

A suggestion was placed before DTAB that a new drug which was approved with the condition that such a drug will be sold against the prescription of Registered Medical Practitioner would automatically be a part of Schedule 'H' after the expiry of the period mentioned in Rule 122 (E) (ii).

The DTAB had agreed and advised that a new proviso be added to Rule 122 (E) to give effect to the above suggestion.

ITEM NO. 14 (b)

Deletion of Pirantel Pamoate from Schedule 'H'.

Since Pirantel Pamoate is a drug of choice for mixed worm infestantions such as round worm (Ascariasis), thread worm (Enterobias) and also hook worm and is given as a single oral dose and the drug has been in the market for many years, the DTAB had agreed to a representation received by the Directorate that the drug may be removed from Schedule 'H' and be Over The Counter (OTC) drug for the convenience of the consumers.

Whenever similar representations are received regarding broad spectrum anthelmintics like Mebendazole backed with epidemiological data, this can be examined in consultation with DTAB for deletion of such broad-spectrum anthelmintics from Schedule 'H'.

ITEM NO. 14 (c)

Promotion of Ibuprofen 200 mg tablet as non-prescription (OTC) drug.

The DTAB had examined the representations received by the Directorate for permitting Ibuprofen tablet containing 200 mg to be sold without prescription.

The Board did not agree to the proposal as it felt that Ibuprofen, being a scheduled drug, exception to a particular dosage form/strength of drug cannot be granted under the existing provision of Drugs & Cosmetics Act.

ITEM NO. 15

Consideration of the proposal to declare Homoeopathic Laboratory, Ghaziabad as laboratory under Rule 3-A of Drugs & Cosmetics Rules.

The Member Secretary informed the members that at present no laboratory has been notified in Rule 3-A of Drugs and Cosmetics Rules to test Homoeopathic drugs.

Ministry of Health and Family Welfare has suggested that Homoeopathic Pharmacopoeial Laboratory, Ghaziabad should be notified for the purpose. It is proposed to amend Rule 3-A of Drugs and Cosmetics Rules to state that the functions of Central Drugs Laboratory in respect of Homoeopathic drugs shall be carried out by HPL Ghaziabad.

The Board agreed to the proposed amendment.

ITEM NO. 16

Consideration of the report of the subcommittee constituted by the DTAB to prepare necessary standards and to suggest the mode of exercising control over the quality of Intraocular lens.

The Member Secretary explained that DTAB in its last meeting had constituted a Committee under the Chairmanship of Advisor (Ophthalomology) to prepare standards and suggest the mode of exercising control over the quality of Intraocular lens. The report of the subcommittee was examined by the members and it was felt that standards for in-process controls and other relevant tests as well as guidelines on GMPs required for manufacture of intraocular lens have to be laid down before these can be notified as 'Drug' under Drugs and Cosmetics Act.

It was decided that the subcommittee consisting of Dr. Madan Mohan as Chairman and Dr. Kannan, DDC(I) may consult some other persons in this regards and prepare detailed guidelines for the purpose, after which further action to notify intra ocular lens as 'Drug' will be taken.

ITEM NO. 17

Consideration of the proposal for amending Rule 49 of the Drugs and Cosmetics Rules, 1945 concerning qualifications of inspectors consequent to notification of qualification for licensing authority and controlling authority under rules 49-A and 50-A of the Drugs and Cosmetics Act and the Rules thereunder.

The Member Secretary explained that consequent to the incorporation of Rule 49-A and 50-A, laying down qualifications of Licensing and Controlling Authorities, the Govt. of Maharashtra has suggested as follows:

i) Provisions of Rule 49 may be got amended so as to make it at par with the qualifications prescribed under Rule 49-A.
ii) Provisions of Rule 50-A may be got amended so as to incorporate IAS as another qualification for the Controlling authority.

The matter was discussed in detail and as regards i) above, the members agreed, in principle, that the existing Rule 49 laying down qualifications for Drugs Inspectors would need amendment so as to bring it at per with the qualifications now laid down under Rule 49-A.

It was decided that the members should send their suggestions regarding amendment of Rule 49 so that these can be examined for the purpose of amendment.

As regards ii) above, the Board members did not agree to incorporate IAS as another qualification for controlling authority in the recently amended Rule 50-A.

Dr. Nadkarni however, stressed that IAS should be included in the qualifications.

ITEM NO. 18

Consideration of the proposal for streamlining cough formulations.

The DTAB had felt the necessity of rationalizing cough formulations moving in the market. It had agreed to the broad classification of cough formulations made by the subcommittee of experts viz. (i) preparations for dry cough, (ii) preparations for productive cough and (iii) preparations for cough associated with bronchial asthma.

It has also agreed to the recommendations made by the subcommittee in connection with rationalization of each type of cough preparations mentioned above.

These recommendations were annexed with the agenda.

ITEM NO. 19

Consideration of the question of showing the name and address of the manufacturer where the drug has been manufactured on the label of the drug by loan licence.

The Member Secretary brought to the notice of members the recently published Draft Notification on the question of showing on the lable of the drug:-

a) The name and address of the premises of the manufacturer where the drug has been manufactured and
b) Substituting the word 'manufacture' for the word 'Business' in the proviso.

He informed that a number of comments have been received from the industry raising a query whether the above rule would also apply to loan licensees.

Member Secretary pointed out that the intention of the amendment was to make sure that the name of the manufacturer and address of the premises where drugs are actually manufactured should appear on the label and not the place of principal 'Business' which in many cases is not the place of manufacture. He further stated that this should not pertain to the loan licensees where the place of manufacture is different than the place of loan licensee.

He asked for the views of the members.

The Board agreed with the views of the Member Secretary and suggested that clarification in this regard may be issued stating that this amendment does not apply to loan licensees.

ITEM NO. 20

Consideration of use of Pectin and Kaolin in anti-diarrhoeal preparation.

The DTAB had greed to ban formulations containing Pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed which have rationale for use in diarrhoeal conditions.

ITEM NO. 21

Consideration of the proposal for the amendment of Schedule P of the Drugs and Cosmetics Rules in relation to enhancement of expiry date for whole human blood.

The Member Secretary explained that as per the present entry of Whole Human Blood in Schedule P, an expiry date of 21 days has been mentioned. This was done when ACD solution was being used. It was informed that now many blood banks are using CPD-A instead of ACD and for CPD-A, expiry period of 35 days is recommended.

The Member Secretary further informed that Drugs Consultative Committee in its meeting held in September 1989 discussed and suggested that schedule P may be suitably amended to enhance the life period of Whole Human Blood to 35 days, if collected in CPD-A.

The Board agreed to the said proposal.

ITEM NO. 22-23

Consideration of the proposal to amend the Notification No. 443 (E) dated 12/4/1989 regarding inclusion of Govt. Analyst in the proviso to the qualification of licensing and controlling authority under Rule 49-A and 50-A of the Drugs and Cosmetics Rules, 1945.

Member Secretary explained that this item is a resolution sent by Dr. Nadkarni, a Member of the Board to be discussed in the meeting. He also said that a similar letter has been received from Dr. Janki Reddy, another Member of the Board.

The matter pertains to the draft amendment GSR 443 (E) dated 12/4/1989 regarding qualifications of licensing and controlling authorities under Rule 49-A and 50-A of the Drugs and Cosmetics Rules, 1945. In the said amendment, a proviso has been added which states that the academic qualification will not apply to Inspectors appointed under this Act and who are in position on the date of announcement of this amendment.

Dr. Nadkarni and Dr. Janki Reddy desired that similar exemption for qualification should also be given to Govt. Analyst as has been given to the Inspectors.

The Members discussed the matter in-depth and agreed that proviso already given under Rule 49-A and 50-A should be suitable amended to include Govt. Analysts also alongwith Drugs Inspectors for exemption to the academic qualifications who are in position on 12/4/1989, the date of issue of final notification.