MINUTES OF THE THIRTYNINTH DRUGS TECHNICAL ADVISORY BOARD MEETING HELD ON DECEMBER 19, 1984 AT NEW DELHI

ITEM NO. 1

Confirmation of the minutes of Thirty Eighth meeting held at New Delhi on 24th December, 1982.

Member Secretary, Dr. S.S. Gothoskar, Drugs Controller (India), informed the members that some comments were received on the minutes of the last meeting and these related to the draft amendment that was proposed to be published for public comments laying down the qualifications of the 'Licensing Authority' and 'Controlling Authority', in pursuance of the provisions of the Drugs and Cosmetics (Amendment) Act, 1982. However, these comments were in the nature of observations of the members on the proposed qualification and it was not necessary to change the minutes as such.

The minutes of the last meeting of the Board were, therefore, confirmed without any change.

ITEM NO. 2

Consideration of the questions arising out of the Minutes of the Thirtyeighth Meeting.

Member Secretary informed the members that a "Statement of the action taken on the various decisions arrived at the last meeting of the Drugs Technical Advisory Board" 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

Proposal for inclusion of Riboflavine as a Colouring Agent in Rule 127 of the Drugs and Cosmetics Rules, 1945.

The proposal to include Riboflavine as a colouring agent for drugs in rule 127 was agreed to.

Member Secretary clarified that when Riboflavine is used as a colour, in terms of the provisions of rule 127 it will be necessary to mention the name of Riboflavine as a colouring agent, and no therapeutic claims can be made by the manufacturer for the Riboflavine that has been added.

ITEM NO. 4

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

Member Secretary explained the proposal which has been received from the Food and Drug Administration, Maharashtra.

The provisions of the Drugs and Magic Remedies (Objectionable Advertisements) Act are applicable only when any claim is made in respect of any Drug or Magic Remedy in relation to the 54 diseases and conditions given to the Schedule to this Act and also the provisions of this Act. In case there is any advertisement by any medical practitioner offering any treatment for any disease specified in this Act or there is any invitation for treatment in general terms, the provisions of this Act cannot be invoked. The views of the Ministry of Law confirming this position were obtained earlier and the proposal of the Food and Drugs Administration, Maharashtra State, if accepted by the Board will require the amendment of the Drugs and Magic Remedies (Objectionable Advertisements) Act before such activities could be brought within the ambit of this statute. The suggestions made by the Food and Drugs Administration, Maharashtra in the two proposed clauses are of a sweeping nature and the Ministry of Law would have to be consulted on the feasibility of including them in the Act.

The members, while endorsing the views of the Member Secretary, stated that generally persons claiming to be practitioners in the Indigenous System of Medicines give objectionable advertisements in the lay press inviting persons for treatment, especially on sexual matters. It is difficult to curb such activities and it would be a welcome step if the provisions of the Drugs and Magic Remedies (Objectionable Advertisements) Act could be extended to curb such anti-social activities.

ITEM NO. 5

Proposal for establishment of the Indian Pharmacopoeia Commission.

It was explained that at the last meeting of the Board, a recommendation was made that Prof. Harkishan Singh, the then member of the Board, will make a working paper for establishment of Indian Pharmacopoeia Commission. The paper now to be considered by the Board has been made on the basis of this recommendation.

Member Secretary clarified that the setting up a Commission would require the approval of the Cabinet and he felt that this purpose would be served if the Indian Pharmacopoeia Committee is made an autonomous organization so that it would function more efficiently. For this purpose under the 7th Five Year Plan, necessary provision has been made and the Plan Scheme is now under consideration of the Planning Commission.

The Chairman, Dr. D.B. Disht, stated that the Indian Pharmacopoeia Committee should be a separate body, but the funds that may be allocated to this body should be accountable.

Enquiries were made about the progress of printing of the 3rd Edition of the Indian Pharmacopoeia and the members were informed that the printing work is being done in a private press and the work is proceeding smoothly.

Dr. Parvinder Singh stated that there should be a continuity in the functioning of the Indian Pharmacopoeia Committee and for this purpose only about 1/3rd of the members should retire every five years.

It was agreed that this suggestion will be borne in mind when the Indian Pharmacopoeia Committee is next reconstituted.

ITEM NO. 6

Proposal to amend schedule D of the Drugs and Cosmetics Rules so as to exempt Sterile bulk drugs which are imported by holders of licence in Form 28.

The proposal for amendment of Schedule D was agreed to by the Board.

ITEM NO. 7

Proposal for amendment of rule 44 (qualification of Govt. Analyst) and rule 49 qualification of Drugs Inspectors) of the Drugs and Cosmetics Rules.

The Board agreed to the views of the Ministry of Law that the terminology adopted under the prevention of Food Adulteration Rules, namely, "holds a degree in ……. from University established in India by law or has an equivalent qualification recognized and notified by the Central Govt. for such purposes" may be adopted in the Drugs and Cosmetics Rules, whenever such qualifications are laid down.

ITEM NO. 8

Consideration of a proposal for exemption of sale of Band Aid Medicated Dressings and Medicated Plasters from sale licence under the Drugs and Cosmetics Act and Rules thereunder.

The Board considered the proposal and was of the view that since there is a demand for Medicated Dressings in rural and some urban areas which may not be having adequate retail outlets for drugs, it would be reasonable to exempt the sale of Medicated Dressings from the requirement of a sale licence so long as the product has been manufactured under a drug manufacturing licence.

So far as "Medicated Plasters" are concerned, Dr. Garg was of the view that these plasters have little therapeutic justification and exempting their sale from the requirement of a licence would only be encouraging their use.

Dr. Qadry, however, felt that Medicated Plasters could be exempted alongwith medicated dressings.

After discussion, it was agreed that medicated dressings may be exempted but so far as "Medicated Plasters" are concerned further medical opinion should be obtained.

ITEM NO. 9

Proposal for amendment of rules 142 and 148 of the Drugs and Cosmetics Rules to include certain provisions relating to 'Toilet Soap'.

Member Secretary explained the genuine difficulties which are being faced by the manufacturers of toilet soaps, consequent on toilet soaps being brought within the definition of the term 'cosmetic' under the Drugs and Cosmetics Act by the Amendment Act, of 1982.

The Board agreed to the proposed changes to rules 142 and 148 of the Drugs and Cosmetics Rules.

In regard to the list of colours which have been suggested for use in toilet soaps by this Association, it was explained that the suggestions made by the Associations are incomplete and further action can be taken only when the list of colours with full chemical names, colour index number are furnished.

ITEM NO. 10

Consideration of the Report of the subcommittee on Good Manufacturing Practices of the Drugs Technical Advisory Board.

The Board was informed that the subcommittee appointed by it earlier has drawn up the new provisions of Good Manufacturing Practices. Shri V.C. Sane was the Chairman of this subcommittee and it had met three times to finalise its report.

In case the members have any comments on the report, these could be considered.

Dr. Parvinder Singh stated that when the new provisions for Good Manufacturing Practices are laid down in the Drugs and Cosmetics Rules, the drug industry will require a time of about 2 to 3 years to comply with the new requirements.

It was explained that initially the new provisions will be published as draft amendments to the Drugs and Cosmetics Rules and those will be finalized on the basis of comments that are received from the public. This will give adequate time to the Industry to make preparations for complying with the new provisions.

Dr. Parvinder Singh further stated that the terms 'competent person' and 'expert staff' have been used in various parts of the new provisions and only one terminology should be adopted. Again, the words 'building' and 'premises' have also been used and it would be necessary to adopt only one terminology.

The Board agreed to the suggestions.

He also said that there are some other suggestions which he has to make. He was requested to send a letter to the Member Secretary enumerating the changes he has to suggest, so that necessary action could be taken.

Subject to the above, the Board accepted the report of the subcommittee for Good Manufacturing Practices.

ITEM NO. 11

Consideration of a proposal for exemption of sale of Mosquito Repellent Creams like Odomos for sale licence under the Drugs and Cosmetics Act and Rules thereunder – consequent on the enforcement of the Drugs and Cosmetics (Amendment) Act of 1982 on 1/2/1983.

The Board agreed to the proposal for giving exemption to Mosquito Repellent Creams from being covered by the sale licence.

ITEM NO. 12

Consideration of a proposal to omit item (2)-A.P.C. tablets and powders from entry 13 of the Schedule K to the Drugs and Cosmetics Rules.

The Board agreed to the proposal to omit the entry '(2)-A.P.C. tablets and powders' from entry 13 of Schedule K to the Drugs and Cosmetics Rules.

In its place, however, Tablets of Paracetamol should be included.

ITEM NO. 13

Consideration of comments received on the draft amendment to rule 96 (1) (iv) of the Drugs and Cosmetics Rules so that the address of the manufacturing premises is only given on the lable of the drug.

Member Secretary explained that after the draft amendment to sub-rule (1), clause (iv) of rule 96 to the Drugs and Cosmetics Rules was published by which it was necessary that the name and address of the manufacturer where the drug has been manufactured, has to be shown on the lable of the drug. A large number of comments have been received from the manufacturers explaining the difficulties that will arise where the manufacturer has more than one manufacturing place in two different States and also in the cases of loan licensees.

The Board may, therefore, consider the comments which have been received and give its recommendations.

Dr. M.A. Patel stated that in case a manufacturer has a manufacturing premises and a registered office in two different states, it is necessary that both the addresses should be given on the lable so that investigations, on the basis of complaint received on the quality of drug, can start without any delay. This is especially necessary in cases of serious complaints about the quality of a drug.

Dr. Parvinder Singh stated that whereas the points mentioned by Dr. Patel are valid, it is difficult for a drug manufacturer which has manufacturing establishments in different places to carry on inventory of various sets of lable. He felt that the object of the amendment could be achieved if the manufacturing licence number could be so devised so as to indicate the state where the product is manufactured.

It was pointed out by the Member Secretary that for cosmetics which are exported, a code number has been given to each state and this could be used before the licence number.

After some discussion, it was decided that the State Drug Controllers should, while giving the licence number, prefix the number with the code of the State as given by the Drugs Controller (India). This can be done when the firms come up for renewal of their manufacturing licence.

No amendment to the present rule is necessary.

ITEM NO. 14

Proposal for inclusion of standards for Sterilized Umbilical Polyester Tape and Umbilical Cotton Tape under the Drugs and Cosmetics Rules.

The Board agreed to the proposed standards for Sterilized Umbilical Polyester Tapes and Umbilical Cotton Tape for inclusion in the Drugs and Cosmetics Rules.

Dr. Parvinder Singh, however, pointed out that the Tensile Strength given in the standards may be in terms of a unit of area like Sq. cm. or so.

The Board, requested that this point may be examined before the standards are finalized.

ITEM NO. 15

Consideration of the recommendations of the Drugs Consultative Committee for introducing a new Schedule M-1 in the Drugs and Cosmetics Rules specifying the minimum equipments, space etc. required for the manufacture of Homoeopathic Drugs.

The Board agreed to the draft Schedule M-1 which lays down the requirements of the Factory premises for manufacture of Homoeopathic preparations.

ITEM NO. 16

Consideration of the report of the subcommittee of the Drugs Consultative Committee for suggesting revision of Schedule F to the Drugs and Cosmetics Rules regarding Blood Banks.

It was explained that the provisions laying down the requirements of a Blood Bank in Schedule F to the Drugs and Cosmetics Rules are quite old and a need was felt to revise these provisions, especially as Blood Banks run by hospitals, which distribute blood to their own Patients, have now been brought under the control of the Drugs and Cosmetics Act. Further, activities like Blood Fractionation have also to be controlled. Accordingly, a subcommittee of the Drugs Consultative Committee has drafted the new provisions, which lay down the requirements for 'Blood Banks' and also for fractionation of whole human blood and human blood components. New licence forms have been provided and it has been laid down that these licences shall be renewed after one year, as compared to a period of two years for an ordinary drug manufacturing licence, so that a better compliance of the requirements of periodic inspection can be ensured in respect of these Blood Banks.

The Board, after some discussion, desired that if possible a definition of the term 'Blood Bank' may be included in these provisions.

Some minor changes were made in the provisions, namely, that in page 91, instead of-

"PART X

Requirements for the Collection, Processing of Whole Human Blood and Human Blood Components", the words

"Requirements for the Collection, Storage, Processing and Distribution of Whole Human Blood and Human Blood Components" will be substituted.

The above change shall also be made in the draft standards, wherever the above terms occur. Subject to this, the draft requirements were agreed to by the Board.

ITEM NO. 17

Consideration of the recommendations made by the Drugs Consultative Committee that entry 5 (c) of Form 39 to the Drugs and Cosmetics Rules should be amended to read as 'Batch size' as represented by sample.

The Board agreed to the proposed change in Form 39.

ITEM NO. 18

Consideration of the question whether retail dealer in drugs can sell drugs to hospitals.

The Board agreed to the proposed amendment permitting a retail dealer to sell drugs to a hospital, dispensary, medical institutions etc.

ITEM NO. 19

Consideration of the proposal for amendment of Form 20 B and 21 B of the Drugs and Cosmetics Rules for showing the names of the competent person in these Forms in the light of the recommendations of the Drugs Consultative Committee.

The Board agreed to the proposed change.

ITEM NO. 20

Consideration of the proposal to amend rule 64 of the Drugs and Cosmetics Rules to incorporate the word 'renewal' after the word 'granted'.

The Board agreed to the proposed change.

ITEM NO. 21

Consideration of the recommendations of the Drugs Consultative Committee to include standards for patent or proprietary preparations in the Drugs and Cosmetics Rules.

The Board agreed to the proposal for inclusion of standards for patent or proprietary preparations in Schedule V as recommended at the Fifth Govt. Analysts Conference. However, certain minor changes were suggested in the text of the draft standards which were taken note of.

ITEM NO. 22

Consideration of the question of banning the marketing of combinations of anabolic steroids with other drugs in the country.

The Board considered the reasons which had weighed with the Government in banning the marketing of combinations of anabolic steroids with other drugs. Dr. Garg was of the view that there was no therapeutic justification whatsoever for the marketing of anabolic steroids with other drugs. He felt that Anabolic steroids should be marketed singly and not in combination with any other drug.

This view was also supported by others.

The Board, therefore, unanimously agreed to the banning of marketing of combinations of anabolic steroids.

ITEM NO. 23

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

The Board agreed to the constitution of the Homoeopathic subcommittee with the members as has been proposed. It, however, recommended that another member of the Board, namely, Shri C. Gopalakrishna Murthy, Director, Drug Control Administration, Andhra Pradesh may be included as a member of the subcommittee.

ITEM NO. 24

Consideration of a proposal to amend Schedule X to the Drugs and Cosmetics Rules.

While introducing this proposal before the Board, Member Secretary explained that 17 Psychotropic drugs which are included in the Convention on Psychotropic Substances 1971 and which are approved for marketing in the country were earlier included in a new Schedule X to the Drugs and Cosmetics Rules so that a more rigid control over import, manufacture and sale of these drugs could be exercised. However, after these rules were brought into force, the Chemists and Druggists in many parts of the country had protested against the imposition of the new restrictions and had not applied for licences to sell Schedule X drugs with the result that these drugs were not easily available. This has caused inconvenience to the public particularly in case of Phenobarbitone preparations which are used by epileptic patients. Now if more items are to be included in Schedule X, these would also not be easily available to the public.

After some discussion, it was decided that a small group may look into the new rules and Schedule X which have been introduced with a view to ascertain as to what difficulties are

being faced by the Chemists and Druggists, patients and doctors in complying with the new requirements. It would be helpful if this group could have a dialogue with the Chemists for this purpose. This group could also examine whether the 5 benzodiazepines could be included in Schedule X.

The Board, therefore, recommended that the following subcommittee may be constituted to go into this question:-

1. Dr. M.G. Garg	-	Chairman
2. Dr. M.A. Patel	-	Member
3. Sh. C. Gopalakrishna Murthy	-	Member
4. Dr. S.S. Gothoskar	-	Member Secretary

ITEM NO. 25

Proposal for inclusion of names of some drugs and also amendment of the names of drugs now included in Schedule H to the Drugs and Cosmetics Rules.

The Board agreed to the inclusion of the drugs in Schedule H as proposed. However, in accordance with the practice followed, anti-cancer drugs and anti-diabetic drugs should be included in Schedule G to the Drugs and Cosmetics Rules.

It was recommended that necessary action to amend Schedules G and H may be taken accordingly.

ITEM NO. 26

Any other item with the permission of the Chair.

i) Proposal for amendment of rule 96 (1) (viii) of the Drugs and Cosmetics Rules, 1945 regarding giving of expiry date on the labels of drugs included in Schedule C (1).

The Board agreed to the amendment to the first proviso in Schedule P.

ii) Revision of Schedule F to the Drugs and Cosmetics Rules.

Some members of the Board stated that the provisions of Schedule F to the Drugs and Cosmetics Rules which lay down the additional standards for biological and special products included in Schedule C and C (1) are outdated and require revision.

The Board agreed that a subcommittee with the following members may be constituted to revise Schedule F to the Drugs and Cosmetics Rules:-

1) Dr. S.N. Saxena	-	Chairman
2) Dr. M.A. Patel	-	Member
3) Sh. V.C. Sane	-	Member
4) Sh. A.D. Nadkarni	-	Convener

iii) Order of the Bombay High Court for considering the submissions of M/s. Godrej Soaps Ltd., for permitting the use of Hexachlorophene in their toilet preparations.

Dr. Gothoskar informed the members that the Bombay High Court had on 11/9/1984 passed an order on the writ petition of 1982 filed by M/s. Godrej Soaps Ltd., Bombay praying that they may be permitted to use Hexachlorophene in the manufacture of their toilet soaps (Cinthol soap) and toilet powder (Cinthol Powder) atleast to the extent of 1% and 0.5% respectively.

He gave the background of this court case and thereafter read out the Order of the Bombay High Court which inter alia has directed that the petitioners (M/s. Godrej Soap Ltd) should file material before the Drugs Technical Advisory Board so that the Board could consider the reports in support of the claim of the petitioners justifying the use of Hexachlorophene and the Chairman of the Board issue a Speaking Order on the prayer of M/s. Godrej Soap Ltd.

Dr. Gothoskar stated that in pursuance of the High Court order M/s. Godrej Soaps Ltd., have on 23/10/1984 written to the Chairman Drugs Technical Advisory Board forwarding their submissions which include printed material to establish the beneficial effects of Hexachlorophene to justify its use in Cinthol Powder and Cinthol Soap. M/s. Godrej Soaps Ltd. have requested that this material may be placed before the Drugs Technical Advisory Board. M/s. Godrej Soaps Ltd. have been requested to send 30 copies of this letter with enclosures so that the same could be circulated to the members of the Board.

He stated that it would be necessary to call a special meeting of the Board to consider this matter and the date of the meeting will be fixed with the approval of the Chairman and the members will be informed in due course.

A preliminary discussion on this matter was held and the Board recommended that in order to enable it to discuss this subject it would be useful if:-

1) the 110 Medical colleges in the country are addressed to let us know whether the use of cinthol powder and cinthol soap had given rise to any adverse effects to the users, which might have come to the knowledge of these Medical colleges/hospitals with full details.
2) the Consumers Associations of India may also be addressed similarly to let us have their experience whether there has been any adverse reactions on the users of Cinthol powder and Cinthol soap.
3) the status of Hexachlorophene i.e. whether it is permitted to be used in cosmetics and soaps in foreign countries, alongwith the relevant rules laying down restriction/permission may be obtained.
4) the World Health Organisation may also be addressed to give relevant information on the Hexachlorophene in cosmetics and soaps and whether their use has been banned or restricted in other countries.
5) the Chief Librarian, National Medical Library of Health Ministry may be requested to forward any published papers on the toxicity of hexachlorophene.

The Chairman stated that since the Board will be considering the submissions of M/s. Godrej Soaps Ltd., which are on the basis of the order of the Bombay High Court, and legal questions are involved, it would be appropriate if a Representative of Ministry of Law is also requested to attend this meeting of the Board, so that it could benefit from his advice, if any legal issues are raised or have to be discussed.

The meeting terminated with a vote of thanks to the chair.