MINUTES OF THE FORTYFIFTH DRUGS TECHNICAL ADVISORY BOARD MEETING ON FEBRUARY 1, 1996 AT NEW DELHI

The Member Secretary, Dr. P. Das Gupta, Drugs Controller General (India), introduced the members of the reconstituted Board. Dr. Das Gupta requested the Chairman, Dr. A.K. Mukherjee, who presided over the meeting, to welcome the members and start the proceedings.

Dr. A.K. Mukherjee, Director General of Health Services, welcomed the members and informed the Board about the setting up of the National Drugs Authority as well as upgradation of the post of Drugs Controller (India) to the rank of Addl. Director General. Dr. Mukherjee stressed that the responsibility of the Drugs Control Organizations and of Drugs Technical Advisory Board (DTAB) shall increase especially in the field of Blood Banking System owing to the recent pronouncement of judgement by the Hon'ble Supreme Court. Dr. Mukherjee informed the Board that because of his preoccupation with other urgent meeting may propose the name of Prof. B.N. Dhawan to chair the meeting during his absence. The Chairman, with the consensus of the members of the reconstituted Board, requested Dr. Das Gupta to continue to work as the Member Secretary and to explain to the members on the action taken/initiated on various items which were taken up during the last meeting as well as the Agenda items placed for the consideration and discussion by the Board.

Before taking up the agenda proper, the Member Secretary informed the new members that DTAB, being a highest Technical and Statutory Body, is governed by Section 5 of the Act and mainly concerned is rendering advise to the Govt. on all technical matters. The member Secretary explained in detail the salient features of Section 5 as well as the regulation of procedure and conduct of business for the information of the new members of the Board.

The Member Secretary, with the permission of the chair, also circulated the Supplementary Agenda items for consideration and discussion by the Board.

ITEM NO. 1

(a) Confirmation of the minutes of the last meeting of DTAB held on 10/1/1994.

The minutes were confirmed.

(b) Action taken on various agenda items of the last DTAB meeting held on 10/1/1994.

The Chairman, Dr. A.K. Mukherjee, DGHS, asked Member Secretary to explain the various important agenda items on which the actions have been initiated or completed by the Govt. or pending for action of the Board.

The Member Secretary invited attention of the members regarding items under which different reports were to be submitted by the Chairman of the subcommittee for consideration of the members of the 45th DTAB meeting:-

(a) S.No. (3) of Annexure I on laying down minimum standard of Vitamins for animal use.

It was explained to the members that the last DTAB meeting had requested Director IVRI to examine whether Patent or Proprietary Medicines containing Vitamins meant for Vet. formulation require any minimum and maximum limit of individual vitamins which could be incorporated in them.

The committee, after consulting various Experts, could formulate dose regimen of individual vitamin for prophylactic and therapeutic use with regard to different sets of animals including poultry.

The Chairman asked Member Secretary to circulate the copies of the draft as the Director, IVRI was not present for consideration and discussion by the members.

The members studied the draft and approved that the same may be laid down under Schedule V to the Drugs and Cosmetics Rules, 1945.

(b) S. No. (6) of Annexure-I concerning status paper on revision of the Part X of the Drugs and Cosmetics Rules, 1945.

The Member Secretary explained that consequent upon circulation of status paper prepared concerning amendment to Rules 115, 121 and 121-A to the members of the Board, Director, Central Drugs Laboratory, Calcutta has written that no useful comments were received in this regard from Director, CDRI, Lucknow, Dr. B.E. Rao, Prof. C.K. Kokate, Dr. P.D. Pilankar, Dr. (Mrs.) J. Sokhey and Sh. A.G. Shah. Further, Director, CDL, Calcutta has expressed his inability in the work as he has limited practical experience on Sera & Vaccines which are dealt under Part X.

In view of the above, the Board decided to involve Shri K.C. Sharma, Dy. Drugs Controller (India), CDSCO, South Zone to give a status paper on rules which require amendments under the said part. Shri Sharma may also co-opt members from the Central Testing Laboratory (CIPL)/I.P. Committee, Legal experts (Asstt. Drugs Controller (I), H.Q., some State Drugs Control Authorities) so that the status paper is submitted within 8-12 weeks.

(c) S.No. (4) of Annexure I regarding Report by Subcommittee concerning amendment of Schedule 'M' with regard to Large Volume Parenterals (LVPs) through different technologies.

The Member Secretary informed the Board that DTAB in its last meeting constituted a subcommittee under the Chairmanship of Dr. B.E. Rao, Managing Director, IDPL assisted by Sh. A.G. Shah, Commissioner, Gujarat and Dr. P.D. Pilankar, Govt. Analyst, DTL, Maharashtra to propose specific provisions under Schedule 'M' of the Drugs and Cosmetics Rules, 1945 to ensure stringent control over premises, quality and manufacture of LVPs in technologies involving glass, plastic containers (By BFS) and plastic pouches (together with the classification of plastics; raw materials specifications; sterilization techniques employed; Biological tests, compatibility of plastic materials employed vis-à-vis formulations to be manufactured/stored etc.).

The Member Secretary pointed out that the subcommittee was requested to submit the report within a period of 4-6 months. However, the report was not submitted till date and it is since understood that the subcommittee had held some meetings of different Associations in this regard.

Dr. Mukherjee took a serious note of it and asked Member Secretary to request Dr. Rao to complete and in case he found difficult to continue to complete the task, the Board may request Sh. A.G. Shah to carry forward the work and complete it.

ITEM NO. 2

Consideration of the proposal to amend Rule 3A(5) of the Drugs and Cosmetics Rules, 1945 to entrust upon specific functions of the laboratory in respect of intra uterine devices and falope rings to Director, Central Drugs Testing Laboratory, Thane in place of Director, Dept. of Bio Medical Engineering of IIT, New Delhi.

The Member Secretary explained that Union Govt. has established a new laboratory as Central Drugs Testing Laboratory, Thane to share the existing load of testing of samples of drugs. The said laboratory has been strengthened with modern equipments to carry out testing of drugs requiring sophisticated analytical technology.

In view of the above, the Union Govt. desires to entrust the specific function in respect of Intra uterine devices and falope rings to the said in place of Director, Dept. of Bio- Medical Engineering of IIT, New Delhi as per provisions of Rule 3 A (5) of the Drugs and Cosmetics Rules, 1945.

After discussion, the members agreed to entrust specific functions to CDTL, Thane in place of IIT, New Delhi under the said rule. Simultaneously, Chairman advised to identify CIPL, Ghaziabad and other approved Labs. which can test the devices.

ITEM NO. 3

Consideration of the proposal to amend Schedule 'M' to prohibit use of second-hand containers and closures for pharmaceutical preparations.

The Member Secretary pointed out that the use of second-hand bottles constituted a potential source of contamination and as such affects the quality of medicines in them. Hence, it is for consideration of the Board to decide whether the use of such containers and closures could be prohibited under the codified Schedule 'M' for GMPs.

The members desired to know the mechanism to find out whether the containers are fresh or second-hand. The members felt that it would not be practicable to put a blanket ban on re-use of containers meant for pharmaceutical formulations because of the cost factors and likelihood of shortage of glass bottles and hence making a legislation would only remain theoretical in nature.

After discussion, it was decided to form a working group to examine the whole issue of reuse of second-hand containers. The group shall give specific recommendations as to how the reuse of containers could be minimized and would also identify those therapeutical formulations where use of second-hand containers could be very harmful and in the

categories where only fresh containers need to be used and also the categories of formulations where re-use could be permitted.

The working group would comprise of Shri Sami Khatib and other co-opted members.

ITEM NO. 4

Consideration of the proposal to include British Pharmacopoeia (Veterinary) under Rule 124-A of the Drugs and Cosmetics Rules, 1945.

The members agreed that necessary amendment under Rule 124-A may be made for the words "British Veterinary Codex" with the words "British Pharmacopoiea (Veterinary)".

ITEM NO. 5

Consideration of the proposal to change the expiry date of Erythromycin Estolate Tablets under Schedule 'P' of Rule 96 of the Drugs and Cosmetics Rules, 1945.

The Member Secretary explained to the members that Schedule 'P' to the Drugs and Cosmetics Rules, 1945, lays down life period of bulk drugs as well as various categories of formulations based on stability studies.

Prof. Dhawan, who acted as Chairman of the DTAB, pointed out that the main question is whether bulk drug shall have larger period of shelf-life that the comparative lower period of the pharmaceutical formulation manufactured out of it. Prof. Dhawan pointed out many other bulk drugs which appear in the said schedule are having larger life period than their formulations.

In view of the above, the members agreed with Prof. Dhawan that there seems to be not much justification for bringing any change in the said entry and hence status-quo shall be maintained.

ITEM NO. 6

Consideration of the proposal to amend and include human insulin and anti-rabies vaccines under Schedule 'P' to the Drugs and Cosmetics Rules, 1945.

The Member Secretary explained that the newer products like Human Insulin and Anti-Rabies Vaccines which are based on tissue culture techniques (Vero Cell-Human Diploid Cell) are now being marketed in the country. In order to have uniform shelf-life of the said products, it was proposed to be included in Schedule 'P' of the Drugs and Cosmetics Rules, 1945.

After discussion, the Board agreed that Human Insulin are newer Insulins, they can be assigned the life period of 30 months while the shelf life of Anti-Rabies Vaccines should be prescribed as 24 months.

ITEM NO. 7

Consideration of the proposal under Rule 105 (5) (ii) to insert Pack-Sizes of "50 ml" for liquid oral preparations as well as provision for approval of specific pack-sizes by the Licensing Authority under Rule 21.

The Member Secretary explained that Rule 105 relating to "packing of drugs" was amended in 1992 in pursuance to the "New Drug Policy" to rationalize and streamline the consumers' pack sizes of different types of dosage forms meant for retail sale. Pharmaceutical industry has since been representing for the inclusions of '50 ml pack' for liquid oral preparations in addition to the other pack-sizes available under Rule 105 (2) (ii).

As per Medical literature, dose for co-trimoxazole syrup is stated to be 5 ml twice for 5 days or 10 days. Some members expressed the view that since '60 ml' pack has already been stipulated under the said Rule, it might not be expedient to include '50 ml' also.

After discussion, it was decided to constitute a subcommittee to examine the issue of including/excluding '50 ml pack size' for liquid oral preparations as well as to include a proviso under the said rule for the approval of specific pack sizes of certain formulations/dosage forms by the Licensing Authority under Rule 21 with specific justification and concurrence of the State Licensing Authority.

The subcommittee constituted compromising of Sh. M. Venkateshwarlu, Dy. Drugs Controller (I), CDSCO (WZ) (Convenor), Jt. Commissioner, FDA, Maharashtra, Sh. B.R. Wadhawan, Asstt. Drugs Controller (I), DGHS and if required, a member from BICP.

The Committee would submit its report within 6 months.

ITEM NO. 8

Consideration of the proposal of omitting provisions relating to setting up of testing laboratories in their own premises by cosmetics manufacturers under Schedule M-II/Rule 139 (5) of the Drugs and Cosmetics Rules, 1945 – Finalization/Re-publication of the clubbed draft notification GSR 94 (E) dated 24/2/1995.

The Member Secretary explained that diversified and non-supportive comments were received from Drugs Controllers (Rajasthan & Delhi) as well as small drugs manufacturers organizations of India to dispense with an option of requiring the cosmetics manufacturers to provide and maintain adequate staff, premises and lab. equipments in their won premises.

After discussion, the members recommended that the existing provisions may continue in view of the difficulties expressed by the industry. Hence, status-quo may be maintained.

ITEM NO. 9

Consideration of the proposal to amend rule 74 (c), 74 (b), 74 (f) and 78 (c) (ii) of the Drugs and Cosmetics Rules, 1945 relating to setting up compulsorily testing laboratory in the licensee's own premises for analysising each and every batch of drug

manufactured-finalization/republication of the draft notification GSR 730 (E) dated 30/9/1994.

The Member Secretary explained that diversified and non-supportive comments were received from small manufacturers associations of India urging the usefulness of 3rd party independent testing undertaken by the private testing institutions approved and licensed by the State Licensing Authority under Part XV (A) of the said rules in preference to the idea of having in-house testing labs by the manufacturing companies.

After discussion, the members recommended that the existing provisions may continue in view of the difficulties expressed by the Industry. Hence status-quo may be maintained.

ITEM NO. 10

Consideration of the proposal to amend Rule 148 so as to state on the label the address of the premises of the manufacturer where the cosmetics has been manufactured.

The Member Secretary explained that the existing provisions of Rule 148 requires to mention the name of the manufacturer together with Principle place of business of the cosmetics manufacturer but not the exact address of the manufacturer as is stipulated under Rule 96 (iv) with regard to drugs. It was further pointed out that the said distinction on the labeling requirement was made as perhaps the rigid adherence to the provision would detract the sale value and export potentialities of the branded cosmetic products and cluttering up too many details on their label.

The members after discussion agreed that the inner label of the cosmetic shall give the address of the licensed premises where the manufacture has been carried out. Appropriate amendment under Rule 148 shall be inserted for the purpose.

ITEM NO. 11

Consideration of the proposal for inclusion of Hyderabad Airport as entry point under Rule 43 A of the Drugs and Cosmetics Rules, 1945 in Respect of Drugs Imported by AIR.

The Member Secretary explained that in view of the request sent by Deptt. of Revenue, Ministry of Finance, the Board may consider of inclusion of Hyderabad Airport under Rule 43 A as one of the places for permitting Drugs to be imported by air into India. Further, the Govt. has already set up a sub-zonal office in the State of Andhra Pradesh at Hyderabad which is being looked after by the Asstt. Drugs Controller (I).

The members gave their approval for carrying out necessary amendment under Rule 43A to include the port of Hyderabad as one of the entry points under the said rule.

ITEM NO. 12

Consideration of the proposal to lay down modalities of procedure under the Drugs and Cosmetics Rules, 1945 for effective recall of not of standard quality, adulterated or spurious drugs within the shortest time frame by the manufacturers as well as sales licensees.

The Member Secretary explained the background of the proposal of laying down procedures under Drugs and Cosmetics Rules, 1945 for effective recall of drugs by the manufacturers as well as sale licensees for uniform approach through out the country. It was proposed to set up time frame viz. 48 hours for effective recall in case of grossly sub-standard or adulterated or spurious drugs. It was also explained that concern had been expressed in various fora that there should be fool-proof mechanism to freeze the sale and manufacture of impugned drugs, within the shortest period of time, from further availability to the consumers.

During the course of discussion, the members felt that there would be practical problems both at the industry level as well as effective and uniform enforcement by the State Drugs Control Authorities in case the provisions giving a specific time-frame are incorporated in the Drugs and Cosmetics Rules, 1945.

The members felt that the time is not yet ripe for incorporating a statutory provision relating to time bound recall of the drugs. However, the Drugs Controller General (India) may issue guidelines to the State Drugs Control Authorities on the ways and means that should be devised and the procedures to be followed for effective recall of the drugs.

ITEM NO. 13

Consideration of the proposal to amend sub clause (i) of Section 27-A of the Drugs and Cosmetics Act, 1940 to substitute the word '17C' to '17D'.

The Member Secretary explained that under clause (i) of Section 27-A of the Drugs and Cosmetics Act, 1940, reference has been made of Section 17 C pertaining to Spurious Cosmetics. While spurious cosmetics have been defined under Section 17 D of the said Act. It was, therefore, proposed to substitute the word and figures '17C' to '17D' in the above said clause.

The Board unanimously agreed for making necessary amendment under the Drugs and Cosmetics Act, 1940.

ITEM NO. 14

Consideration of the proposal to amend Section 2 of the Drugs and Cosmetics Act, 1940 to substitute with the words "The Narcotic Drugs and Psychotropic Substances Act, 1985" in place of "The Dangerous Drugs Act, 1930".

The Member Secretary explained that the Dangerous Drugs Act, 1930 have since been repealed and a new legislation called "Narcotics and Psychotropic Substances Act, 1985" is now in force at its place. Section 2 of the Drugs and Cosmetics Act, 1940 still refers to the Dangerous Drugs Act, 1930. It is proposed to amend the said Section accordingly.

The Board unanimously agreed for carrying out necessary changes in Section 2 of the said Act.

ITEM NO. 15

Amendment to Rule 49 of the Drugs and Cosmetics Rules, 1945 to omit the words "with specialization in clinical pharmacology or microbiology" and to insert proviso at the end of the Rule to give protection to those persons which are already serving as Inspectors-finalization/republication of the draft notification GSR (E) dated 9/8/1994.

The Member Secretary explained that on the recommendation of the 44th DTAB, the Government of India published draft rules for amending the qualification of 'Inspector' under Rule 49 of the Drugs and Cosmetics Rules, vide GSR 616 (E) dated 9/8/1994. It was proposed to delete the words 'Medicine with specialization in Clinical Pharmacology or Microbiology' with the words 'Bachelor degree in medicine with post-graduation in Pharmacology or Microbiology'. Large number of comments were received from the various Associations of Pharmacy graduates, individuals, State Drugs Controllers and Pharmaceutical industry opposing the amendment.

Board discussed the pros & cons of the provisions of Rule 49 and felt that it would be desirable to maintain the status-quo and the proposed amendment to qualification may be withdrawn. However, there was no objection to the proviso for giving protection to the in-service Inspectors as published in the draft rules/notification.

ITEM NO. 16

Consideration of the proposal to amend Rule 65 (18) of Drugs and Cosmetics Rules for inserting a proviso for stocking of physician's samples/free samples in depots and C&F premises.

The Member Secretary explained that the Drug Manufacturers Associations have represented that their authorized stockists, C&F agents or Depots may be permitted to store Physician's samples to be redistributed to the Medical representatives because of logistic problems in sending samples directly to them which are spread out in various parts of the country.

The Board was informed that under Rule 65 (18) of the Drugs and Cosmetics Rules, authorized chemists are permitted to store drugs marked for ESIS, CGHS and other specified Govt. Institutions. These stamped drugs are required to be stored & separate records are to be maintained for their receipt and distribution.

The members felt that the problem of forwarding samples to the remote areas through the normal channel is realistic one. The Board, therefore, agreed that the Rule 65 may be amended appropriately so that the Depots, C&F agents and stockists authorized by manufacturer, in writing, shall be permitted to store physician's samples for distribution subject to the condition that the samples shall be stored separately from the trade stocks and separate records shall be maintained of the stocks received and distributed by them.

ITEM NO. 17

Consideration of the proposal to include "Guidelines for clinical practices" under Schedule 'Y' of the Drugs and Cosmetics Rules.

The Member Secretary explained that it has been proposed to prepare guidelines on 'Good Clinical Practices (GCPs)' for trials on pharmaceutical products to be performed in India. The document would provide standards for biomedical and clinical research of pharmaceutical products on human beings. Similar guidelines are in vogue in many developed countries and their introduction in the country would integrate clinical research activities and harmonize evaluation of pharmaceutical products in human beings in India.

The Board agreed, in principle, for the introduction of such guidelines under the Drugs and Cosmetics Rules, 1945 for trials of pharmaceutical products in India.

SUPPLEMENTARY AGENDA

Supplementary ITEM NO. 1

Consideration of the proposal to exercise control over the manufacture and quality of intraocular lenses under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

The Member Secretary informed the Board that BIS has prepared the specifications for intraocular lenses (IOL). It has been proposed to include the IOL in the Drugs and Cosmetics Rules, 1945 and for this purpose it would be necessary to examine the following points:-

(1) Whether IOL are covered within the definition of drug under Section 3 (b) or a separate notification would be required to be issued.
(2) Whether IOL could be deemed to be covered under entry (16) of Schedule 'C' as 'Sterile Disposable Devices for single use'.
(3) Whether GMPs covered under Schedule M-III would cover the requirements of manufacture of IOL or separate provisions are required to be incorporated for IOL.
(4) Qualification and experience of the supervisory staff under Rule 76.
(5) Whether the specifications formulated by BIS are pragmatic and can be incorporated under Schedule R-1 of the Drugs and Cosmetics Rules. If not, the changes required to be made in the specifications.
(6) To identify the nodal testing laboratories for testing the samples of IOL.

After considering the matter, the Board decided that a subcommittee may be constituted to study the whole question of laying down requirements of areas, environmental controls; viability of specifications formulated by BIS etc.

(1)	Dr. S.S. Badrinath, Medical Director, Medical Research Foundation, 18, College Road, Madras-600006 or His representative	Chairman
(2)	Dr. S.K. Talwar, Director,	Member

CIPL, Ghaziabad

(3)	Mr. R.W. Gudal, Jt. Commissioner, FDA, Maharashtra	Member
(4)	Mr. B.R. Wadhawan, Asstt. Drugs Controller (I), DGHS, New Delhi	Member
(5)	Sh. K.C. Sharma, Dy. Drugs Controller (I), CDSCO (SZ), Madras	Member

The report shall be submitted within 6 months.

Supplementary ITEM NO. 2

Consideration of the proposal of classification of diagnostic kits and reagents and laying down requirements for plant, machinery, equipments etc.

Member Secretary explained to the members that the question of inclusion of the said items were considered in the last meeting and based on the approval accorded by the Board, Union Ministry of Health and Family Welfare published draft notification for including them under Schedule C and C (1) of the Drugs and Cosmetics Rules, 1945. However, the same could not be finalized as the whole question of control over them came up for discussion in the 29th DCC meeting for laying down guidelines for plant and machinery required for their manufacture; their definition; classification; state of art in their manufacture; their standards; quality control parameters; identification of nodal testing labs.

A copy of the report submitted by the subcommittee of the DCC is with the members for their perusal and consideration.

In view of the above, DTAB considered and discussed the following:-

(a) Diagnostic Kits and Reagents were covered under the definition of Section 3 (b) (i) of the Act. However, the following definition shall be incorporated under the Drugs and Cosmetics Rules, 1945:-

"Diagnostic Kits and Diagnostic Reagents means in-vitro Diagnostic products mean those reagents and system intended for use in the diagnosis of diseases or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent diseases or its sequelae in human or animals. Such products are intended for use in the collection, preparations and examination of specimens taken from the human or animal body."

(b) Requirements of factory's premises for manufacture of Dia. Kits and Reagents shall be incorporated in a separate Schedule rather than Schedule M as recommended by the subcommittee.

The requirements shall include:

(i) General requirements (ii) Requirements of manufacture of Diagnostic Kits and Reagents which shall include the process of manufacture comprising of different operations; equipments and space needed for basic manufacture or on the basis of their mode of manufacture (which may include Chemical reagents, Enzymatic reagents, Immune reagents, Nucleic Acid Probes based Kits, biosensors of different categories of Diagnostic kits and reagents together with their bio-environmental control; raw-materials; storage area; washing, cleaning and drying areas; sterilization; testing facilities; labeling section etc.

A note should be included for exercising discretionary powers to the licensing authority to examine the adequacy or otherwise of factory's premises, space, plant and machinery and other requirements and requisites with regard to the nature and extent of the manufacturing operations.

(c) Qualification of competent technical staff in respect of manufacture and testing may be inserted or incorporated separately under rule 71 and 76, as the case may be. In this regard persons with degree in Medicines or Science from a recognized University who for the purpose has studied Microbiology as a principal subject with 18 months practical experience in the manufacture of Diagnostic Kits and Reagents. Further, a Post-Graduate in Bio-Chemistry with at least 6 months practical experience in their manufacture after P.G. shall be incorporated.

(d) Assignment of batch No. and DOM for these items shall be inserted as recommended by the Subcommittee.

(e) (1) Standards shall be included under Rule 124 whereas standards for P&P items shall be included under Schedule V subject to the conditions that such standards/specifications shall be approved by the licensing authority under Rule 21.

(2) Second Schedule of the Act shall be amended by inserting entries 5 (c) & 5 (d) relating to standards to be compiled with respect to imported drugs/drugs manufactured for sale.

(f) Part I of Schedule U shall be amended by inserting a new sub-clause concerning records as recommended by the subcommittee.

(g) The Govt. shall take steps to identify nodal testing labs. as recommended by the subcommittee. However, the Central Govt. shall elicit views and concurrence of their nodal administrative authority before declaring them as the nodal testing labs.

(h) Categorization:

Diagnostic Kits and Reagents shall be categorized under the related Schedules to Drugs and Cosmetics Rules depending on their nature, claim, use, mode of manufacturer. As recommended by the subcommittee, the items shall be categorized as under:

(1) Non-sterile Chemical Reagents/Kits.
(2) Diagnostic Kits/Reagents in the form of Enzymatic Powders/Tablets.
(3) Sterile Immuno Diagnostic Reagents and manufacture of Diagnostic Kits/Reagents from them.
(4) Nucleic Acid probes based Kits.
(5) Biosensores

After hearing the views of the Member Secretary, the members requested the Chairman that the Board may give them some time to offer their comments on the matter.

The Chairman accepted, in principle, the report of the subcommittee and requested the members to go through the entire issue and offer comments within 4 weeks time.

Supplementary ITEM NO. 3

Consideration of the proposal for introduction of regulatory requirements for herbal medicines.

The Member Secretary explained that in order to exercise control in respect of safety, efficacy and quality of herbal medicines [excluding those covered under Indian System of Medicines (ISM)], regulatory measures are proposed to be introduced in the Drugs and Cosmetics Rules, 1945.

The members agreed, in principle, that some mechanism should be introduced for regulating the quality of herbal medicines. It was proposed to constitute a subcommittee to examine to incorporate the definition of Herbal Medicine; framing guidelines for evaluating the safety and efficacy of the Herbal Medicines; parameters to be laid down for approval by the Licensing Authority under Rule 21 prior to their manufacture; GMPs; qualifications and experience of expert technical staff; requirement of factory's premises, plant, equipments etc. and to explore possibilities of inserting a separate Schedule for the purpose; conditions of licences and separate forms (if any) required under the relevant rules.

The Chairman agreed to constitute a subcommittee comprising of the following persons:-

1. Dr. C.L. Kaul	Chairman
2. Prof. C.K. Kokate	Member
3. Director, CDRI	Member
4. Traditional Drugs Physician	Member
5. Sh. Ashwini Kumar	Member Secretary (Convenor)

The committee shall furnish report within 6 months. Further, the report should also be placed/sent to the DCC/State Licensing Authorities for their perusal and comments.

The Chairman also requested members of the Board to examine the documents and send their comments to Member Secretary as well as to Dr. Kaul.

Supplementary ITEM NO. 4

Consideration of the proposal to amend rule 67 F (1) of the Drugs and Cosmetics Rules, 1945 in respect of Homoeopathic Medicines for permitting the sale of homoeopathic medicines in manufacturer's packings through allopathic sales outlets.

The Member Secretary explained that Homoeopathy Advisory Committee have recommended that finished homoeopathic formulations in the original retail packing of the manufacturer which could be sold across the counter, should be permitted to be stocked and sold through the allopathic retail outlets. For the sale of such packed drugs, the professional attention of a competent homoeopathic pharmacist is not required. If the board agrees to the proposal, Rule 67 F could be amended to leave it at the discretion of the Licensing Authority to judge the competency of the person in-charge for grant of licence in Form 20 C.

The Board, however, felt that it would not be desirable to mix up the two systems of medicines. Moreover, the allopathic retailers may not be in a position to own the responsibility of the quality of homoeopathic medicines in case the drug is sampled and declared as not of standard quality and also interpret correctly instructions for use.

In view of the above, Board did not agree to the proposal.

Supplementary ITEM NO. 5

Consideration of the proposal to amend Drugs and Cosmetics Rules so as to change the nomenclature of "Surveillance centres on AIDS" to "Zonal blood testing centres" in pursuance of the provisions of Part XII-B of Schedule 'F' relating to Blood Banks.

The Member Secretary explained that the nomenclature of "Surveillance Centres on AIDS" occurring in Para H of Part XII-B of Schedule 'F' gave a connotation as of the reference centres identified under notifications, GSR 710 (E) dated 25/7/1989 and GSR 877 (E) dated 17/11/1992, were epidemiological in nature.

The members after discussion agreed to make appropriate amendments under the Drugs and Cosmetics Rules, 1945 in place of "Surveillance centres on AIDS" to "Zonal blood testing centres" as adopted by National AIDS Control Organization.

Supplementary ITEM NO. 6

Consideration of the proposal to amend entry 17 of the gazette notification GSR 578 (E) dated 23/7/1983 relating to "Fixed dose combinations of vitamins with anti-T.B. Drugs except combinations of isoniazid with Vit. B_6 issued under Section 26-A of the Drugs and Cosmetics Act, 1940.

The members after discussion approved the proposal to make appropriate insertions/deletions under entry (17) to the Gazette Notification GSR 578 (E) dated 23/7/1983 so as to prohibit under Section 26 A of the Drugs and Cosmetics Act, 1940. Fixed dose combinations of Vitamins with any other Anti-Tubularculosis Drugs except combination of Isoniazid with Vitamin B_6.

Supplementary ITEM NO. 7

Consideration of Proposal of enacting a separate legislation for regulating the collection, processing, storage, distribution and transportation of blood and operation of the blood banks in the country.

The Member Secretary explained that the main intention was to apprise and place before the Board the directions given by the Hon'ble Supreme Court for improving the Blood Banking System in the country by contemplating to formulate a comprehensive law on regulating the collection, processing, storage, distribution, transportation of blood. It was further pointed out that the modalities of the enactment of the legislation as a separate law or as a separate chapter under the existing Drugs and Cosmetics Act, 1940 and rules thereunder or under the National Drugs Authority Bill were being worked out.

The Board took cognizance of the judgement delivered and directions issued by the Hon'ble Supreme Court in connection with enacting a comprehensive legislation to improve and regulate the system of Blood Banking System in the country.

The Chairman asked Dy. Drugs Controller (I), CDSCO (WZ) and State Drugs Controller (A.P.) to submit to the Board a draft bill on Blood Banking System in pursuance of the directions given by the Hon'ble Supreme Court. They may also coordinate in this regard with Dr. Salunke and Jt. Commissioner, FDA, Maharashtra. The draft bill together with the objectives and reasons shall be submitted within 3 months so that the same could be circulated to the members of the Board for their perusal and comments.

Supplementary ITEM NO. 8

Consideration of the proposal to amend clause (a) of Rule 122 (E) concerning definition of new drug.

The Member Secretary explained that the existing meanings and definition laid down under Clause (a) of Rule 122 (E) was not comprehensive and hence needed to be revised so as to make it at par with the parameters stated under Section 3 (b) of the Drugs and Cosmetics Act, 1940.

In view of the above, the members after discussion felt that clause (a) of Rule 122 (E) needed to be substituted with other words so that it could cover devices and delivery systems, any other substance (other than food) which may affect the structure or any function of the human body and the substances intended to be used as components of a drug get equated with the components of the definition of the 'drug' laid down under Section 3 (b) of the Act.

The Board approved the proposal for substituting appropriately Clause (a) of Rule 122 (E) under Drugs and Cosmetics Rules, 1945 to cover the above said products also.

Supplementary ITEM NO. 9

Consideration of the proposal to delete "Methaqualone" from Schedule 'X' to the Drugs and Cosmetics Rules.

The Member Secretary explained that even though the manufacture and sale of the drug Methaqualone was banned in 1984, the drug still appears in Schedule 'X' of the Drugs and Cosmetics Rules. It was proposed to delete the entry from the Schedule 'X'.

The Board unanimously gave its consent to delete the entry Methaqualone from Schedule 'X' of the Drugs and Cosmetics Rules, 1945.

Supplementary ITEM NO. 10

Continued marketing of fixed dose combination of streptomycin with penicillin.

The Member Secretary explained the background under which the withdrawal of the Fixed Dose Combination (FDC) of Streptomycin with Penicillin has been considered. The Hon'ble Supreme Court of India in the matter of WPC No. 696/93 "Drugs Action Forum v/s U.O.I." to obtain a report in regard to the continuation banning of FDC of streptomycin and penicillin from the Committee of Experts under the Chairmanship of Dr. J.S. Bajaj, Member, Planning Commission.

The Committee of Experts in, its meeting held on 8/1/1996 recommended that the above said FDC 'For human use' should be withdrawn from the market by 1/1/1997.

It was also pointed out that even through the case is still being heard by the Supreme Court, the decisions/recommendations of the Committee of Experts have been placed before the Board for its consideration.

The members after discussion agreed, in principle, to prohibit the use of the FDC of streptomycin and penicillin under Section 26 A of the Drugs and Cosmetics Act, 1940 from the date as directed by the Hon'ble Supreme Court of India.

The Chairman, however, requested Member Secretary to circulate the salient features of the judgement as and when the case is decided by the Hon'ble Supreme Court.

ANY OTHER MATTER WITH THE PERMISSION OF CHAIR.

Sh. Sami Khatib, with the permission of the Chair, raised the issue of manufacture and marketing of formulations containing animal blood for Iron deficiency, anaemia, pregnancy, and other dimorphic anaemias.

Sh. Khatib requested the Chairman that he may be permitted to give a 'write up' on the matter for consideration of the Board.

The Chairman agreed to the proposal and asked Sh. Khatib to submit his 'write up' to the Member Secretary for examination.