MINUTES OF THE 27th MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 31st & 1st FEBRUARY 1991

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MINUTES OF THE 27TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON THE 31ST & 1ST FEBRUARY 1991

Dr. Prem K. Gupta, Drugs Controller (India) welcomed the members and wished them all a happy new year. He stated that the last meeting of Drugs Consultative Committee was held in September 1989 and the meeting scheduled to be held in November 1990 has to be postponed due to unavoidable reasons. He said he was happy to see good attendance from the States, although there was no representative from Uttar Pradesh, Bihar, Andhra Pradesh and Himachal Pradesh.

Dr. Gupta introduced Shri R. L. Mishra, Secretary (Health) to the members of DCC and thanked him for having agreed to address the members. All present then introduced themselves.

Secretary (Health) said that he was happy to meet Drugs Controllers of various States and Union Territories. He was of the view that such meetings are always useful to exchange ideas and discuss problems faced in the enforcement of Drug Laws. Secretary (Health) expressed surprise that many States still do not have a qualified full-time Drugs Controller, adequate number of Drugs Inspectors and a fully equipped testing laboratory.

Secretary (Health) emphasized the need to have stron Drug Control Organisation at the Centre and at State level to exercise effective control on the quality of drugs manufactured and sold in the country. He expressed concern that drug manufacturers in some States do not conform to all the requirements under the Law and do not observe Good Manufacturing Practices as laid down. He stressed the need to have more vigilance and better monitoring of the quality of drugs moving in inter-State commerce. Secretary observed that there are only 700 Drugs Inspectors in the country as against the requirement of about 2700 recommended by the Task Force. He emphasized that the Central and State Governments should take steps to augment Drug Inspectorate Staff.

Secretary (Health) further mentioned that at present only 4 States have a fully equipped testing laboratory and many States have no testing facilities at all. He was of the view that this situation needs to be improved immediately. He informed the members about the Central Government's proposals to provide financial assistance to States for setting up or strengthening of testing facilities and also augmenting the Drug Inspectorate staff in the 8th Five Year Plan. He, however, cautioned that providing more Drugs Inspectors and testing laboratories alone will not serve any good purpose unless there is a will to enforce the provisions in order to achieve results. He suggested that the matter regarding strengthening of Drug Control Organisations should be taken up in the meetings of States Chief Ministers / Chief Secretaries.

Secretary (Health) desired that stringent action should be taken against manufacturers of spurious and sub-standard drugs. He further suggested that Stated should set up legal-cum-intelligence cells to unearth spurious drug rackets. He expressed concern that the enforcement of Drugs & Cosmetics Act and Rules thereunder is not upto the level required in States like Uttar Pradesh, Bihar, Rajasthan, Punjab and Haryana.

Secretary (Health) brought to the notice of members the problem faced by the Ministry of Health in getting information from States in respect of Parliament Questions. He desired that State Drug Controllers should furnish prompt replies in such matters. The members then apprised the Secretary (Health) the various issues and problems involved in the enforcement of Act and the Rules. The following points emerged during discussion :-

i) More training programmes for Drugs Inspectors.

ii) Cases of spurious and adulterated drugs to be publicised in the press. Case of sub-standard drugs to be investigated and action initiated.

iii) Guidelines to be framed for better inter-State co-ordination.

iv) More stringent mechanism for approval of testing laboratories and better intelligence of their activities.

v) Regular inspection of manufacturing premises.

vi) Guidelines to be issued for better hospital practices especially for administration / mixing of drugs in I.V.fluids.

vii) To examine whether number of drugs to be permitted for manufacture can be limited.

viii) Facilities for testing vaccines and other biological products.

Shri M. S. Dayal, Addl. Secretary (Health) emphasized that the State Drugs Controllers should initiate immediate action whenever there is a report of death or adverse reaction due to administration of drugs. He suggested that in cases of suspension / cancellation of licence, the body of the licence should be endorsed with the words, "Suspended for ..... Or cancelled" as the case may be.

Dr. S.D. Sharma, Addl. Director General cautioned the members about the growing number of manufacturers and large number of formulations in the market. He advised that the State Drugs Controllers should be more vigilant at the time of issuing licences and should not hesitate in taking stringent action whenever necessary.

Shri Balbir Singh, Joint Secretary informed the members about the two proposed Centrally sponsored schemes for giving assistance to States – one to set up / strengthen testing laboratories and the other for augmentation of drug inspectorate staff. He

observed that the six States / Uts which do not have any testing laboratory were asked to give proposals for utilizing the assistance but except Goa and Tripura no response has been received from others. The States were asked to give their proposals for Central Assistance to set up / strengthen their testing laboratories so that the same can be considered during the next financial year.

Regarding assistance for Drugs Inspectors Shri Singh informed that the Central Govt. will give money to appoint Drugs Inspectors to the States provided the State Govt. share the cost on 50:50 basis. The Central Govt. will fund the appointment of Drugs Inspectors if the State Government sanctions an equal number of posts in their budget. He requested the State Drug Controllers to sent their budget. He requested the State Drug Controllers to sent their requests supported by the State Govt. commitment so that further action can be taken to consider their proposals.

Shri J. Vasudevan, Joint Secretary Ministry of Health gave details of Central Govt. schemes to develop and modernize Blood Banking and Transfusion Services in the country. He informed the members about the report submitted by M/s. Fergusan wherein it is mentioned that there are 1018 blood banks in the country and the majority are unlicensed. He observed that a blood donor screening programme has been successfully started in four metropolitan cities where 28 zonal blood testing centres are now functioning. He further informed that 37 additional centres have been identified in 16 States which will be operationalised in a time-bound manner. 21 of these centres have become functional.

Shri Vasudevan reminded State Drug Controllers about the letter issued to them by Drugs Controller (India) for carrying out inspection of all blood banks in the States under a time-bound programme. He requested them all to send their reports expeditiously to enable us to know the exact position on the total number of blood banks licensed as well as unlicensed.

The technical session started after lunch. The Chairman observed that a lot has happened since the last meeting. He highlighted some of the achievements as follows :-

a) Some additional posts have been sanctioned for CDSCO at the headquarters.
b) A new Central Drug Testing Laboratory is being set up at Bombay.
c) Offices of ADC(I) at Nhava Seva port and Air Cargo Complex at Delhi have started functioning.
d) Two sub-zonal offices, one each at Patna and Lucknow ill start functioning in 1991.
e) Three final amendments and 12 draft amendments to Drugs & Cosmetics Rules have been issued.
f) Notifications to ban 14 categories of drugs are in the press.
g) Addendum –I to I.P. 1985 was released in 1989 and Addendum-II is in press.

Dr. Gupta observed that there have been many press reports on the quality of I.V. fluids. He reminded the State Drug Controllers about the letter issued to them for

thorough inspection of I.V. fluids manufacturers and the reports on action taken to be sent. He informed that the detailed information on the number of units inspected and the acion taken against those manufacturers who do not conform to Good Manufacturing Practices (GMPs) and other requirements has not been received from many States. He requested that the same should be expedited.

Dr. Gupta also drew the attention of the members to the letter issued to them for carrying out inspection of blood banks in a time-bound programme. He appealed that the detailed information on the total number of blood banks operating in each State (Government & Private), number licensed and those unlicensed along with the reasons for not licensing them should be furnished immediately as the Ministry of Health requires this information. It was also urged that such blood banks which do not conform to the minimum requirements should not be permitted to operate since the quality and safety of blood is of utmost importance.

The Chairman told the members that replies to many Parliament Questions depends on the information received from the States and in many cases replies are not received from all States for a long time with the result that it becomes difficult to fulfil the assurances. He also commented about the delay in receiving routine statistical information on the activities of States Drug Control Organisations from many States. He requested that the information in respect of licenses granted, suspended or cancelled, samples tested, samples found not of standard quality and action taken on these reports spurious drugs detected, prosecutions launched and the cases decided with results should be furnished to this Directorate every year for record.

Dr. Gupta expressed the need to improve the information systems. He stated that all States should have computer facility for proper storing and retrieval of primary data. He proposed that a computer comparible proforma can be designed and distributed to all State Drug Controllers. This proforma should be circulated to all licensees requesting them to submit the information in the said proforma at the time of grant or renewal of licenses. By doing so, complete information in respect of all licenses granted or renewed in the country will be available in a span of 2 calender years. This information will be stored in a centralized computer and will be updated every year for easy retrieval and dissemination. The Chairman mentioned about the growing concern expressed at various consumer fora that the action taken on the sub-standard reports is not always prompt and adequate. He observed that as licensing authorities, it is our responsibility to see that adequate action is taken against such manufacturers which do not conform to all requirements under the Law and do not follow GMPs and also whose products are found not of standard quality.

The Chairman also desired that the functions of Drugs Inspectors should be planned by the licensing authority and clear instructions should be given for the number of inspections of manufacturing units to be carried out, surveillance and inspection of retail shops to be done and the number and categories of drugs to be drawn by Drugs Inspectors. He advised the members that the initial inspection prior to grant of licence

should be tightened and licences should be granted only if all the manufacturing and testing facilities as per requirements and also the GMPs are complied with.

After this the agenda items were taken up for discussion.

1. **Confirmation of the minutes of the last meeting of Drugs Consultative Committee held on 14th and 15th Sept., 1989 :**

The minutes of the 26th meeting of Drugs Consultative Committee were confirmed.

2. **Statement of action taken on the recommendation made by the last Drugs Consultative Committee held on 14th and 15th Sept., 1989 :**

The action taken on various points arising out of the last Drugs Consultative Committee meeting as given in Annexure-A was noted.

3. **Consideration of the following reports of sub-committee constituted in the last Drugs Consultative Committee meeting :**

a) **Reports of the sub-committee to frame rules consequent to the amended provision of section 26 and 32 of the Drugs and Cosmetics Act :**

The report of the sub-committee to suggest rules to give effect to provisions of section 26 and 32 of the Drugs and Cosmetics Act was discussed. The members observed that the provisio of the suggested rule gives same procedure for drawal of sampole by consumers as stipulated for Drugs Inspectors. It was felt that it may not be possible for the consumer to follow the same procedure. After discussion, the Chairman agreed with the members that the matter needs clarification with regard to the exact purpose of this provisio. Since Dr. M.A.Patel, Chairman of the sub-committee was not present, the member from Gujarat was asked to clarify and submit the revised report within three months.

b) **Report of the sub-committee on the amendments suggested to Drugs and Cosmetics Act and Rules at the 25th Drugs Consultative Committee meetings :**

The report of the sub-committee to suggest various amendments required under Drugs and Cosmetics Act was taken up for discussion.

The Chairman appreciated the excellent work done by the sub-committee to produce a valuable report on various aspects of amendments of the Act and Rules.

As some members wanted more time to go through the report, Chairman agreed that the members should go through and send their comments within a period of three months.

c) **Report of sub-committee on use of colours and flavours in patent & proprietary medicines :**

The report of the sub-committee on the question of restriction to manufacture Patent & Proprietary medicines in different colours & flavours was accepted.

Item No. 4 : Consideration of adoption of IS 4707 : 1988 (Part 1) as cosmetic colours under Drugs & Cosmetics Act in place of Schedule "Q" :

The Chairman explained that there are about 73 colours included in Schedule "Q" of Drugs and Cosmetics Rules. Bureau of Indian Standards (BIS) has prepared a list of 84 colours which are approved internationally. Some of these are manufactured indigenously and are being used in cosmetics. It was stated that BIS has classified various types of colours to be used in different cosmetics preparations.

After discussion it was agree that a small sub-committee may study the BIS Report and give recommendation for adoption of BIS document for replacing Schedule "Q" of Drugs and Cosmetics Rules.

The sub-committee consists of the following members.

Chairman :Commissioner Food & Drugs Administration,
Maharashtra State.

Member : Director, Drugs Control Administration, West Bengal.

Member : Drugs Controller, Karnataka State.

Member : Drugs Controller, Kerala State.

Convenor : Dy. Drugs Controller (India), C.D.S.C.O. (South Zone), Madras.

The sub-committee shall submit its report within 3 months.

Item No. 5 : Consideration of the proposal to amend Rule 74(l) & 78(m) in the event of taking samples out of the "Reference sample" maintained by the licensee :

The Chairman stated that in case of complaints, samples are required to be drawn from the control sample of the manufacturer when regular samples are not available. He informed the members about a court case reported to have been lost in Tamil Nadu on the ground that the sample drawn from the control sample cannot be considered intended for sale. Drugs Controller, Tamil Nadu however, could not give details of the case.

After discussion members were of the opinion that there is no need to amend the existing rules. It was the consensus view that the control sample is a representative part of the batch and it should be treated as sample intended for sale. The Chairman requested Drugs Controller, Tamil Nadu to send the copy of the Judgement of the said case to all the members for their information and record.

Item No. 6 : Consideration of the number of reference samples to be kept for Large Volume Parenterals :

Chairman complained that a representation has been received from the Pharmaceutical Manufacturers Association Tamil Nadu for amending Rule 78 (m) of Drugs & Cosmetics Rules. It is suggested that in order to satisfy the existing rule a large number of I.V. fluid bottles are to be stored as control sample which occupy large area.

After discussion the members did not agree to the request made by the Association for amending Rule 78(m).

Item No. 7 : Consideration of amendment to rule 65(15) (c) (ii) of Drugs and Cosmetics rule to substitute "Registered Pharmacist" in the place of "qualified Person" :

The Chairman explained that under the provisions of Rules 65 (1), 65 (2) and 65 (15) (c) (ii) of the Drugs and Cosmetics Rules, compounding or supply of Drugs on the prescription of a Registered Medical Practitioner shall be effected under the supervision of a "Qualified Person" where as Pharmacy Act requires that only a "Registered Pharmacist" can perform these activities.

The sub-committee constituted in the last D.C.C. meeting in its report has suggested that the definition of "Qualified Person" under rules 65 (15) (c) (ii), 65 (1) and 65 (2) of Drugs & Cosmetic Rule needs to be changed to coincide with Section 42 (1) of Pharmacy Act.

After discussion members agreed with the suggestion of the sub-committee report for amending the provisions of rule 65 of Drugs & Cosmetics Rules.

Item No. 8 : Consideration of whether a drug dealer should also know constitutions of the manufacturer :

The Chairman informed that Indian Drug Manufacturers Association has brought to the notice of the Directorate an Administrative order issued by the Directorate of Medical & Health Services, Rajasthan stating that a dealer selling Drugs of particular manufacturer should also know about the constitution of the manufacturer / supplier to take necessary legal action in the event of a drug declared not of standard quality.

After discussion the members felt that such orders do not have a legal standing.

Item No. 9 : Consideration of shifting of Phenobarbitone from Schedule "X" to "H" of Drugs & Cosmetics Rules.

The Chairman informed that based on the earlier decision of D.C.C. the matter was placed before DTAB in March, 1990. The Board had agreed to the proposal of shifting Phenobarbitone from Schedule "X" to "H" and suggested that some condition may be stipulated. The Chairman asked the members whether any special conditions can be laid down for Phenobarbitone alone after shifting to Schedule "H".

The members agreed that Phenobarbitone should be shifted from Schedule "X" to Schedule "H" of Drugs and Cosmetics Rules and no special conditions are necessary as this drug is seldom misused.

Item No. 10 : (Central Item No. 1 of supplementary agenda)

Consideration of amendment to Schedule "M" of the Drugs & Cosmetics Rules 1945 in regard to manufacture of Large Volume Parenterals :

The Chairman explained that consequent to the complaint filed by Director common cause against Drugs Controller (I) and State Drugs Controllers regarding alleged adverse reaction / death due to administration of contaminated intravenous fluids, the national consumer dispute redressal commission desired that a committee of experts should be set up to review the provision of existing legislation. As desired the expert committee recommended that Schedule "M" of Drugs & Cosmetics Rules, should be amended to incorporate a separate section on Large

Volume Parenterals. Accordingly, the proposed amendment is given at Annexure-IV.

The Chairman asked the members to go through and send comments on the proposed amendment within three months.

Item No. 11 : (Central items No.2 of supplementary agenda)

Consideration of inclusion of the colour Iron Oxide Black to be used in Drugs under Rule 127 of Drugs & Cosmetics Rule :

The Chairman explained that a representation has been received to consider inclusion of Iron Oxide Black in the part of colours permitted under rule 127. This colour is an approved one by F.A.O/W.B.O. Red Oxide and Yellow Oxide of Iron are already permitted under rule 127 of Drugs & Cosmetics Rules.

Item No. 12 : (Central item No.3 of supplementary Agenda)

Action taken by the Central Government under section 26A of Drugs & Cosmetics Act should be made unquestionable by any body in a Court of Law :

The question whether the provisions of section 26A of the Drugs & Cosmetics Act should be amended so that it is not challengeable in a Court of Law was discussed.

The members felt that the Law Ministry may be consulted in the matter.

Item No. 13 : (Central Item No. 4 of the Supplementary Agenda)

Provision to be made in the Drugs and Cosmetics Rules to empower Licensing Authority to direct manufacturer to stop manufacture and also to empower to destroy the Drugs Unit for use where no legal action are contemplated :

Chairman explained that at present there appears to be no provision in the Act and Rules for the licensing authority to order on the spon stopping of manufacture without giving show cause memo whenever there is cause to do so. It was decided that this item may be referred to the sub-committee constituted under Item No.1 to examine and report.

Item No. 14 : (Central Item No. 5 of Supplementary Agenda)

Adoption of BIS Standards on toilet soaps, liquid toilet soap and baby toilet soap.

Chairman informed that BIS has formulated standards for Toilet Saop (IS 2888:1983 second revision), liquid Toilet soap (IS 4199:1974) and for Baby Toilet soap (IS 10523:1983). The standards were considered by the members and were approved.

Item No. 15 : (Central Item No. 6 of Supplementary Agenda)

Consideration of inclusion of standards for medical devices in draft Notification GSR 1003 (E) dated 9.11.1989 on the basis of recommendation of the sub-committee report on medical devices.

Chairman said that the sub-committee constituted by 26th DCC under the Chairmanship of Shri M. A. Patel has submitted detailed guidelines / GMP to be adopted by such units. The same was circulated to all members by the Directorate vide letter No. X.19013/3/90-D, dated 18.7.90. The sub-committee also proposed necessary qualification for the expert staff for the manufacture of medical devices and the standards to be incorporated in the Drugs and Cosmetics Act and Rules thereunder.

The members approved the recommendation of the sub-committee.

Item No. 16 : (Central Item No. 7 of the Supplementary Agenda)

Consideration exempting Toilet soap preparations from the purview of Drugs and Cosmetics Act & Rules.

Chairman informed that Indian Soap & Toiletries makers Association, Bombay have been representing to exempt toilet soaps from the purview of Drugs & Cosmetics Act and Rules.

The members felt that there is no need to exclude Toilet soaps from the definition of 'cosmetic' at this stage.

Thereafter the items suggested by the States were taken up for discussion.

Item No. 17 : (Item No.7 to No.9 of the agenda proposed by State of Andhra Pradesh)

These items were not discussed as Drugs Controller, Andhra Pradesh was not present.

GUJARAT

Item No. 18 : Question of drug considered as a new Drug if variation are there in the quantity of ingredients.

Chairman explained that State Licensing Authorities should not give licence for any new combination of a drug. They should direct the licencee to apply to Drugs Controller (India). It was explained that any change in the existing formulation would make it a new drug under the new definition.

Item No. 19 : Definition of New Drug.

Chairman clarified that a new drug continues to be a new drug for four years from the date of first introduction and approved by Drugs Controller (India) or when it is included in the Indian Pharmacopoeia, whichever is earlier.

KARNATAKA

Item No. 20 : Cost of the sample drawn by Drugs Inspector for Test to be borne by the manufacturers / dealers.

The members did not agree to this suggestion.

Item No. 21 : Provision of sale licence for cosmetics, Ayurvedic, Unani & Siddha Drugs under the provision of Drugs & Cosmetics Act.

Chairman explained that the matter was discussed in the last DCC meeting. The members felt that it is premature to consider sales licences for cosmetics and Ayurvedic drug due to paucity of inspectorate staff.

Item No. 22 : Provisions for maintenance of purchase invoice for the raw materials.

It was explained that maintenance of purchase invoice for raw materials is covered in Schedule U of Drugs & Cosmetics Rules.

Item No. 23 : Testing of HIV antibodies of Blood and labeling the same.

Chairman informed that in the proposed amendment of Drugs & Cosmetics Rules on Blood Bank, the wording has been changed to read that HIV can be tested either in the blood bank laboratory or at Survillance centre.

Item No. 24 : Standards for Boric Acid Revision required.

Chairman asked Drugs Controller, Karnataka to refer the matter to I.P. Committee.

Item No. 25 : Provision for rejection of the application other than Form 27 & 27B.

Chairman informed that this item has been considered in the sub-committee report at **Annexure II** of the Agenda.

KERELA

Item No. 26 : Need for provision in the Drugs and Cosmetics Rules to check disposal of drugs by licencees at the time of business.

The members felt that it is not necessary to amend the rule.

Item No. 27 : Combination of Ayurvedic / Allopathic drug to be banned.

Chairman observed that combination of Ayurvedic and Allopathic drugs should not be allowed.

Item No. 28 : Amendment of Rule 153, 153-A & Rule 154 of Drugs & Cosmetics Rules.

It was agreed to examine and if found necessary the Rules may be amended.

MAHARASHTRA

Item No. 29 : Reviewing the existing guidelines in respect of samples found to be not of standard quality.

Chairman observed that the earlier guidelilnes on action to be taken on sub-standard reports and inter state coordination needs reviewing. It was agreed that the sub-committee constituted under Item No. 1 may review the whole matter afresh and submit report on the guidelines to be followed for :

i) acton on sub-standard reports.
ii) Launching of prosecution.
iii) Inter-state co-ordination on matters referred to the State Drugs Controllers.

ORISSA

Item No. 30 : Consideration of making provisions in the Sch. T of Drugs and Cosmetics Rules for the manufacturers of sterile Ayurvedic product.

The Ayurvedic Adviser explained that there is no injection formulation under the definition of 'Ayurvedic drugs'.

Item No. 31 : Cosidering the enlargement of the present list of Drugs in Sch. X in view of the Narcotic Drugs and Psychotropic substances Act, 1985.

It was decided that there is no need to enlarge the list of drugs in Sch. X.

Item No. 32 : Consideration of amendment in Schedule "S" of Drugs & Cosmetics Rules for cosmetics by replacing the name of ISI with BIS.

It was agreed that there is a need to change ISI to BIS in Drugs & Cosmetics Rules. Chairman suggested that Drugs Controller, Orissa should write to BIS for working out standards for Dantaghasa Gudaku as the same is a cosmetic preparation and at present there are no standards.

Item No. 33 : Consideration of same patent name for Drugs having different pharmacological action to avoid prescription error.

Chairman suggested that whenever cases of drugs having the same patent and proprietary names are noticed the concerned Stae Drugs Controller should initiate necessary action to see that the manufacturer who registered later withdraws his product from the market.

RAJASTHAN

Item No.34 : Consideration of separate Form of Licence for Drugs to be stored in godowns of licencees.

The matter was discussed by the members, Commissioner, Food & Drugs Administration, Maharashtra told that the present Form 20B & 21B etc. holds good for the purpose. Members felt that there is no need to have separate Forms for licensing the godowns.

Item No. 35 : Specification of inspection belt :

Chairman explained that as per GMP, inspection belt was necessary for sorting out the defective tablets and it is for the licensing authority to use its discretion for allowing any alternative equipment if it serves the purpose equally well.

TAMIL NADU

Item No. 36 : Continuation of Loan Licensing System up to 31.12.1991.

Chairman explained that as per decision taken by Cabinet Committee on Economic Affairs the Loan Licensing System will stand discontinued on 31.12.1991. A notification to amend Drugs & Cosmetics Rules is in

progress. Chairman also informed that Loan Licence for Gamma radiation has been recommended to be continued.

Item No. 37 : Qualification of technical staff incharge of testing in the manufacturing concerns.

Chairman stated that it is for the licensing authority to ensure that the person is competent to test pharmaceutical preparation even though chemistry may not be his main subject. Members felt that there is no need to amend the Rules for this purpose.

Item No. 38 : Duties of Inspectors.

Drugs Controller, Tamil Nadu informed that the State Pubilc Service Commission had considered two different types of duties given in Rules 51 & 52 and treated Science & Pharmacy graduates separately for the purpose of recruitment.

He wanted the two Rules to be merged into one. The members felt that there is no need to amend the Rules. DC Tamilnadu was asked to explain the PSC the need to treat all applicants at par since the Drug Inspector appointed under the Act can be asked to do all the duties given in Rules 51 & 52.

Item No. 39 : Qualification of Inspectors.

Chairman explained that consequent to the amendment of Drugs & Cosmetics Rules regarding qualification of licensing and controlling authorities, DTAB in its last meeting had agreed that there is a need to amend the relevant rules for the qualification of Drugs Inspectors also and to bring those in line with the qualification of licensing / controlling authorities. It was agreed that the sub-committee constituted under Item No.1 may examine and propose a draft for the said amendment.

Item No. 40 : Testing of raw material before commencement of the manufacturing.

Chairman observed that the present provisions require every raw material to be tested and it implies that the testing should be done before manufacturing a product. It was agreed that there is no need for amendment.

Item No. 41 : Maintenance of manufacturing records in a bound register.

The members dis not agree to this suggestion.

Item No. 42 : Discrepancies in Form 18.

Chairman agreed to examine and make amendment if found necessary .

Item No. 43 : Motor vehicle licence for distribution of Homoeopathic Drugs.

Adviser Homoeopathy felt that there is no need to introduce a separate licence for distribution of Homoeopathic drugs in motor vehicle.

Item No. 44 : Inclusion of Kajal in Sch "S".

Chairman explained that before including any cosmetics in Schedule S, it is necessary that its standards are laid down by BIS.

Item No. 45 : Consideration amendment of Rule 65 (18) of Drugs & Cosmetics rule to include of Rule 96 (1) (IX) (which deals with the physician samples) instead of Rule 96 (i) (VIII).

Chairman agreed that there is an error in printing and necessary amendment will be carried out.

Item No. 46 : Inclusion of Batch Number in cash bills.

Members did not agree for this amendment.

TRIPURA

Item No. 47 : Standards for powdered crude drugs.

Chairman stated that IPC is not a book of standard under Drugs & Cosmetics Act.

Item No. 48 : Sale of Sch "C&G" Drugs against prescription of RMP only.

The members felt that there is no need for the amendment.

WEST BENGAL

Item No. 49 : Consideration regarding whether "Bleaching Powder" should be trated as drug or not.

Chairman informed that Bleaching Powder is considered a drug as it has disinfectant properties and disinfectants are covered under the notification.

Item No. 50 : Life period of Ayurvedic & Homoeopathic medicines.

Chairman said that combination of Ayurvedic with Homoeopathic medicines are not allowed. Regarding life period, chairman said in the absence of any guidelines 5 years from the date of Mfg. can be taken as expiry date pending fixation of expiry date by Homoeopathic Pharmacopoeia, Dy. Adviser said it is not possible to give any expiry date for Ayurvedic preparations.

Item No. 51 : Combination of Ayurvedic and allopathic drugs in formulations.

Already discussed under Item 27.

Item No. 52 : Competent Technical staff-approval need for uniformity.

It was agreed that all States should have a uniform policy for approval of competent technical staff. The sub-committee may examine and give its recommendation.

Item No. 53 : Requirement of machinery, equipments & records to be incorporated in Sch "T" for Ayurveda, Siddha & Unani drug units.

Dy. Adviser (Ayurveda) said that revision of Sch "T" is under consideration.

Item No. 54 : Institutional packing.

Chairman explained that the proposed amendment to Schedule P is for retail packs.

Item No. 55 : Competent Technical staff for manufacture of Homoeopathic medicines.

Chairman stated that Homoeopathic sub-committee will be asked to suggest the qualifications for the technical staff to manufacture Homoeopathic medicines.

Item No. 56 : Licensing authority may be given power under Rule 65 of Drugs & Cosmetics Rules to take action against licencee violating price control order.

It was agreed that it is not possible to bring any amendment in Drugs & Cosmetics Rules for any action to be taken under Drugs Price Control Order.

Item No. 57 : Revision of clause in From 25C as related to Rule 85D.

It was decided that the matter may be referred to Homoeopathic sub-committee.

WEST BENGAL

Item No. 58 : Change of constitution.

Drugs Controller, Goa informed that vide letter No. 15-45-82-DC dated 24.8.72 Drugs Controller (India) had classified different types of action to be taken by the licensing authority during change of constitution. A copy of the letter issued by the Directorate is at Annexure-A.

Item No. 59 : Consideration of list of items falling under disposable perfusion sets.

It was agreed that the sub-committee constituted under Item No.1 should examine this aspect and give recommendation.

Item No. 60 : Adding of small quantity of alcohol in Ayurvedic prickly heat powder : as an ingredient.

Dy. Adviser Ayurveda informed that there is no Ayurveda prickly heat powder in the Text books. So there is no question of adding alcohol.

Item No. 61 : Definition of New Drug.

The Chairman asked Drugs Controller, West Bengal to refer the particular case to this Directorate for examination.

Item No. 62 : Consideration of amendment of Rule 65 (17) of Drugs and Cosmetics Rule for the drugs banned under Sec.26A of Drugs & Cosmetics Act.

Chairman observed that there is no need to amend Rule 65 (17) of Drugs & Cosmetics Rules as Sec.26A takes care of the sale as well.

GOA

Item No. 63 : Whether drugs which are repacked can be labeled with proprietary name in addition to the generic pharmacopoeial name.

The members felt that there should be no objection for repacking drugs under patent & proprietary name.

Item No. 64 : Whether pharmacopoeial products manufactured below the strength of usual strength mentioned in IP can be considered as not of standard.

Chairman explained that the usual strength of preparation as given in IP is not a standard and preparation below the usual strength, if licensed, should not be declared as not of standard quality but should be brought to the notice of licensing authority by the Govt. Analysts. He further stated that Aspirin tablets for Paediatric use are not permitted to be marketed.

Item No. 65 : Consideration of sending a copy of test report to the State Drugs Controller in respect of HIV positive on blood samples by the surveillance Centre.

Chairman observed that the Surveillance Centres are aware of eh procedure to be adopted when a blood unit is found HIV positive.

Item No. 66 : Testing & releasing of Human Blood without carrying out HIV test in extreme emergency case.

The members felt that the provisions need not be changed.

Item No. 67 : Consideration to incorporate the word "Name of the drug" after the serial No.2 in Form 26 & 26 C.

It was agreed to examine and amend the Forms, if necessary.

Item No. 68 : Whether permission can be granted by the State Drugs Controller in Form 29 for the purpose of examination of a new drug.

Chairman informed that the permission to manufacture 'new drug' under Form 29 should be given only after clearance by Drugs Controller (India).

Item No. 69 : Whether further new drug permission is required for a manufacturer to manufacture in different dosage form where a tablet dosage form was already cleared by Drugs Controller (India).

Chairman explained that under Sch.Y it is necessary to apply to Drugs Controller (India) for a different dosage form of the new drug.

Item No. 70 : Consideration of the need to allow the Blood Bank to release blood after performing the Elisa test in their own laboratory.

Chairman said the proposed amendment will provide for Blood Bank to test HIV antibodies either at Surveillance Centre or in their own laboratory.

Item No. 71 : **Consideration of the need to extend penalty clause in Drugs and Cosmetics Act to approved testing laboratories.**

It was agreed that the sub-committee constituted under Item No.1 should examine and give recommendation on this.

HARYANA

Item No. 72 : **(Supplementary agenda item No.1)**

Consideration of the question for showing name and address of the manufacturer on the label of the Drug by the Loan Licensee where the Drug has been manufactured.

Chairman clarified that the loan licence must have its own address in the State where the licence is granted and that should be given on the label.

Item No. 73 : **(Supplementary agenda Item No.2)**

Controlling authority or Ayurvedic and Unani Drugs.

It was explained that the authority which exercise the power for grant and renewal of licence for Ayurvedic and Unani drugs is the licensing and controlling authority for the purpose.

DELHI

Item No. 74 : **(Supplementary agenda item No.3)**

Powers of licensing authority / controlling authority under Sec. 25(4) of Drugs & Cosmetics Act.

Chairman felt that Sec.25(4) of the Act gives powers to the Licensing Authority to request the court to send the retained sample to Central Drugs Laboratory, Calcutta.

Item No. 75 : **(Supplementary agenda item No.4)**

Amendment of Rule 62-A of Drugs and Cosmetics Rule 1945 in respect of issuing restricted licenses.

Chairman said that this item has been clarified in the sub-committee report enclosed at Annexure II of the Agenda.

Item No. 76 : **(Supplementary agenda item No.5)**

Standards for the raw materials used in the manufacture of cosmetics.

Chairman informed that BIS is supposed to be making a list of raw materials which should not be used in cosmetics.

Item No. 77 : (Supplementary agenda of Item No.6)

Relaxation of qualification of competent persons for the manufacture of cosmetics.

Chairman said this item was earlier discussed in 24th DCC meeting where a decision was taken not to dilute the qualification for the technical staff in the manufacture of cosmetics.

Item No. 78 : (Supplementary Agenda item No.7)

Condition of licence in Form 25G at par with other licence forms.

Chairman agreed that the matter will be examined and if found necessary the amendment will be carried out.

Item No. 79 : (Supplementary agenda item No.8)

Incorporation of condition in Form 25-C.

Chairman requested Adviser Homoeopathy to look into this matter and suggest necessary amendment if required.

Item No. 80 : (Supplementary agenda item No.9)

Consideration for amendment of Rule 67-G of Drugs & Cosmetics Rules to include Batch Number in the Cash / Credit Memo.

It was not considered necessary.

Item No. 81 : (Supplementary agenda item No.10)

Amendment of Rule 2(g) of he Drugs and Cosmetics Act & Rules.

The members agreed that there is no need to amend Rule 2 (g) of Drugs & Cosmetics Rules.

JAMMU & KASHMIR STATE

Item No.82 : (Supplementary agenda item No.11)

Person in charge of quality control to be whole time employee.

It was agreed that as per GMP the role of quality control is essential and it implied that a full time technical person be employed for quality control.

Item No. 83 : (Supplementary Agenda item No.12)

Whether drug samples need to be referred to Govt. Analyst in case of visible defect.

Chairman explained that under the existing provision the Govt. Analyst report is necessary for taking legal action against the manufacturer.

Item No. 84 : (Supplementary Agenda item No.13)

Labelling Provisions.

Chairman stated that while the problem exists there does not seem to be any solution at present.

Item No. 85 : (Supplementary agenda item No.14)

Drugs Price Control Order.

Chairman suggested that Drugs Controller J&K may write about this problem to Ministry of Petroleium and Chemical.

Item No. 86 : (Supplementary agenda item No.15)

Consideration of definition of RMP under Rule 2 (ee) of the Drugs and Cosmetics Rule 1945.

Chairman suggested that this matter may be examined by the sub-committee.

Item No. 87 : (Supplementary agenda item No.16)

Uniformity of packages.

It was informed that standardization of packages is under consideration for being incorporated in the Drugs and Cosmetics Rule.

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

Annexure – I
(Item no. 2 of the 27th meeting)

Statement showing the action taken on the decisions taken at the 26th Meeting of the Drugs Consultative Committee held in New Delhi on the 14th & 15th September 1989.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
1.	Gazette Notification G.S.R. 365 (E) dated 17.3.1989 notifying Sterile Hypodermic Syringes, Sterile Hypodermic needles and IV sets as 'drugs' – Steps to publish the draft Rules.	The Chairman informed that the three devices (Hypodermic needles, syringes and I.V. sets) have been notified as 'drugs' and the manufacturers of these devices should be licensed immediately. Dr. M.A.Patel, Chairman of the sub-committee on medical devices was asked to prepare guidelines / GMPs to be adopted by such units, in consultation with other members of the sub-committee, so that the same are circulated to all State Drugs Controllers for uniform enforcement. Dr. Gupta suggested that representative of 'Isomed' may also be consulted in the matter and this work should be completed in 2 months time.	The subcommittee has already submitted its report together with guidelines: which has been circulated to all State Drugs Controllers vide Dte. letter no. X 19013/3/90-D dated 18/7/90.
2.	Need to frame Rules consequent to the amended provisions of Section 26 and 32 of the Drugs & Cosmetics	It was decided to refer the matter to a subcommittee under the chairmanship of Sh. M.A. Patel, Commissioner FDA, Gujarat and submit report.	The subcommittee has submitted its report.

	Act.		
3.	Amendment to the Drugs & Cosmetics Act and the Rules suggested by the State Drugs Controllers in the last meeting of the Drugs Consultative Committee.	It was decided to refer the matter to a subcommittee under the chairmanship of The Commissioner, FDA, Maharashtra.	The subcommittee has submitted its report and is at Anexure-II.
4.	Recommendation of the Sub-Committee for weeding out harmful / irrational formulations.		The recommendations accepted by the DCC and were placed before DTAB.
5.	Amendment to part XII-B of the Drugs & Cosmetics Rules and monograph of Whole Human Blood in B.P. with regard to date of expiry, when CPDA solution is used as anti-coagulant.	It was decided to carry out amendments/corrigendum in the Drugs & Cosmetics Act and Rules/I.P.	Necessary amendments are being carried out in the Drugs & Cosmetics Act and Rules.
6.	Amendment to Section 27A(i) of the Drugs & Cosmetics Act, 1940.	Suitable correction may be made in the Act as 17 D instead of 17 C to Section 27 A (i).	Necessary amendments are being carried out in the Drugs & Cosmetics Act and Rules.
7.	Amendment of Section 18 of the Drugs & Cosmetics Act 1940.	While considering the question of amending Section 18 of the Act, the Drugs Controllers Delhi, Madhya Pradesh and Commissioner, F.D.A. Maharashtra suggested that Section should be	The subcommittee has submitted its report.

		amended. During discussion it was proposed that 'comma' should be added after the word 'Stock'. Chairman stated that the original Gazette notification will be checked and if a 'comma' is already not there, as suggested in the item, necessary amendment will be carried out.	
8.	Amendment to Section 22(2A) of the Drugs & Cosmetics Act 1940 read with Rules 55A of the Drugs & Cosmetics Rules, 1945.	Commissioner, F.D.A., Maharashtra suggested to enhance the period of return of the documents seized by the inspector from twenty days to forty five days. The Chairman stated that the matter will be examined. The Drugs Controller (Tamil Nadu) was, however, requested to furnish a copy of the relevant judgement which has been delivered concerning the matter.	The subcommittee has submitted its report.
9.	Restriction to manufacture Patent and Propreitary medicines of the same strength under the same trade name under different colours and flavours.	It was decided to refer the matter to a subcommittee under the chairmanship of The Commissioner, FDA, Maharashtra as chairman and submit report.	The subcommittee has submitted its report.
10.	Need to check correctness of setting time of plaster of Paris Bandages B.P. '88.	The Committee decided that necessary clarification would be sought from B.P. Commission.	The Director, CIPL, Ghaziabad has been asked to take up the matter with B.P. Commission vide letter No. X19013/1/90-D.
11.	Restrictions for grant of retail /	It was decided to refer the matter	The subcommittee has submitted its report.

	wholesale licences.	appointed to the sub-committee under Item No. 14 and submit the report.	
12.	Need for amending rules 69-A of the Drugs and Cosmetics Rules 1945.	It has been decided to carry out the amendmenting Rule 69-A for changing fee from Rs. 100/- to 200/-.	Necessary action has already been taken to amend the Rule 69-A.
13.	Compounding of offences.	It was decided to refer the matter to the subcommittee formed under Item No. 14.	The subcommittee has submitted its report.
14.	Veterinary drugs are omitted from Schedule 'V', especially in case of standards for patent or proprietary medicines, containing vitamins : Schedule 'V' is required to be amended for this purpose.	It was decided that the matter concerning these items will be considered by the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.
15.	Suggestion to amend entry No.2 of Schedule V, viz. standards for patent or proprietary medicines containing vitamins to include veterinary use.	It was decided that the matter concerning these items will be considered by the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.
16.	Suggestion to amend rule 65(5) (1) of the Drugs & Cosmetics Rules in pursuance of the amendment to Rule 64(2) which required premises holding licences in form 20B	It was decided that the matter concerning these items will be considered by the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.

	and 21B are required to be in charge of a 'competent person'.		
17.	Suggestion to amend Schedule 'M'.	It was decided that Schedule 'M' should be suitably amended to incorporate separate requirements for 'internal use' and 'external use' preparations.	Necessary action to amend Schedule 'M' has already been taken.
18.	Amendment of Section 3(b) of the Drugs and Cosmetics Act, 1940 regarding patent or proprietary medicines.	It was agreed by the committee to refer the matter to Ayurvedic Drugs Consultative Committee for consideration.	The matter has been taken up with the Advisor, ISM for necessary action.
19.	Suggestion to amend Form 34 for Analysis of Cosmetics.	It was stated by the Chairman that the matter is under consideration of a group of Govt. Analysts already constituted for the purpose.	It was recommended by the Group of Govt. analysts to amend Form 34 intentional to Form 13.
20.	Suggestion for provision of existing Schedule of fees under the Drugs and Cosmetics Rules, 1945.	Individual State Government, they so desire, may consider to amend the relevant Rules under powers vested with them.	The matter was however discussed by the subcommittee and submitted its report.
21.	Mushroom Growth of Pharmacies.	It was decided to refer the matter to the sub-committee appointed under Item No. 14.	The subcommittee already submitted their report.
22.	Amendment concerning Drugs and Magic Remedies (O.A.) Act and Drugs & Cosmetics	The matter concerning updating of Schedule J is already under consideration of the sub-committee appointed by	The subcommittee submitted their report.

	Act.	DTAB.	
23.	Drugs bearing hospital markings.	It was decided to refer the matter to the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.
24.	Competent Technical Staff.	It was decided to refer the matter to the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.
25.	Sampling procedures.	It was decided to refer the matter to the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.
26.	Protection under Sec.19(3) of Drugs and Cosmetics Act.	It was decided to refer the matter to the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.
27.	N.F.I. Drugs.	It was decided to refer the matter to the sub-committee appointed under Item No. 14.	The subcommittee has submitted its report.
28.	Clause under Rule 64(2) of the Drugs and Cosmetics Rules 1945 should be incorporated similar to clauses available under 'Pre-conditions for grant of all types of Drugs Manufacturing Licences'.	The matter was referred to the subcommittee appointed under item No. 14.	The subcommittee has submitted its report.

29.	A point was raised that the word 'approved' in 'entry 2' of the licence in Form 25 before the words 'expert staff' should be added as in the case in Form-28 for the reason that an anomaly might result in names of even unapproved staff being entered on licence in Form 25. Therefore a suitable amendment was sought to be made.	The matter was referred to the subcommittee appointed under item No. 14.	The subcommittee has submitted its report.