MINUTES OF THE 28th MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON THE 16th & 17th JULY 1992

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MINUTES OF THE 28TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON THE 16TH & 17TH JULY 1992

Dr. Prem K. Gupta, Drugs Controller (India) welcomed the members. He stated that the 27th meeting was held in February, 1991 and the 28th meeting has been delayed due to several reasons including preoccupation of all officers during Parliament Sessions. He informed the members that Secretary (Health) and Shri Vinod Vaish, Joint Secretary, Department of Chemicals & Petro-Chemicals have agreed to address the members on the second day. He stated that Central Drugs Standard Control Organisation is planning to have a computerized Central Registry which would have all the relevant information about the licences granted and the drugs permitted for manufacture. He informed that he has requested Mr. Bose, Director, National Informatics Centre to discuss the matter and give a demonstration in the afternoon.

The Chairman observed that many things have happened since the last DCC meeting. He informed that the Addendum II to 3rd edition of Indian Pharmacopoeia was released in the month of January and the work on 4th edition of I.P. to be published in the year 1995 has been initiated. The Indian Pharmacopoeia Committee was reconstituted in 1991 and several sub-committees have also been constituted. He further stated that 11 final amendments and 11 draft amendments to Drugs and Cosmetics Rules have been published. He requested the members that whenever draft amendments are published they should send their comments so that these can be considered before finalizing the amendment. He also stated about the training programmes of State Drugs Inspectors on the art of inspection of Blood Banks which were arranged by the zonal officers of Central Drugs Standard Control Organisation.

He informed that Central Drugs Laboratory at Bombay is expected to start functioning by the end of this year and three regional laboratories at Guwahati (Assam), Hyderabad (Andhra Pradesh) and Chandigarh have been planned to be set up by the Central Govt. during he 8th Five Year Plan.

Dr. Gupta stated that Central assistance has been given to some States for setting up or for augmenting the testing facilities during 1991 and it is hoped that more States will be given the assistance in future. Ther other Centrally sponsored scheme to provide Drugs Ispectors to the States is also expected in the 8th Five Year Plan allocations.

The Chairman reminded the members that replies to Parliament Question depends on the information received from the States and unless the same is received promptly, it becomes difficult to manage. He observed that some States do not send the desired information in time and hence this Directorate finds it very difficult to fulfil the assurances given to Parliament. He observed that States like U.P., West Bengal, Madhya Pradesh, Pondicherry and Jammu & Kashmir have not sent even the annual reports of their organizations for several years. He requested the members from these States to send

their Annual reports as early as possible. He also expressed that many States have not forwarded information regarding Blood Banks in their States. He reminded the members to send complete information regarding number of blood banks licensed / unlicensed in their State and whether these are in private or public sector, etc. Dr. Gupta expressed that it is shocking to know that some private blood baks in some States are operating without licence. He emphasized that there is no justification in permitting private blood banks to function without licence and told the State Licensing Authorities to take immediate steps to close down such private blood banks which do not have the storage and testing facilities as required under the Drugs and Cosmetics Rules. He told them to strictly enforce the provisions in respect of Blood Banks as it is very important to ensure safe blood to the consumers. He said that even the Government Blood Banks should be licensed and efforts should be made to see that they provide all testing and storage facilities.

Dr. Gupta also reminded the members about the information required in respect of I.V.Fluids manufacturers in each State. He stated that it was necessary to exercise strict vigil on the quality of I.V. Fluid marketed in the country. He requested the members to complete the inspection process and furnish the desired information regarding I.V. Fluids manufacturers immediately.

He also requested the members to send upto date information on the number of substandard / spurious drugs found and action taken by them, the number of prosecutions launched and the results thereof.

He requested the members to tighten enforcement of Drugs & Cosmetics Act and Rules at all levels in the States. He emphasized that the Good Manufacturing Practices should be enforced strictly an dthe manufacturing firms should have their own testing laboratories to test majority of their products.

He told the members that incidents like Sura tragedy ruins the reputation of whole Drug Control machinery in the country. He emphasized the need to exercise stricter control over the manufacture and quality control of all drugs including Ayurveda, Siddha, Unani and Homoeopathic systems and also cosmetics. He also desired that the activities of the approved laboratories should be closely monitored.

Dr. Gupta stated that the Zonal Offices make certain observations after carrying out inspection of manufacturing units, and requested that the States should take necessary action on the recommendations made by the Zonal Offices. He informed that two sub-zonal offices at Ptna and Lucknow have been set up and two more sub-zones, one in West and another in South will be set up shortly. He requested the members to cooperate with the zonal and sub-zonal offices in order to achieve uniformity in enforcement. He also emphasized that State Drug Controllers should give importance to the complaints received from the consumers regarding the quality of drugs etc. He observed that some States are publishing the cases of sub-standard drugs in the press and desired that other States may also do the same.

The Chairman drew attention of the members of the complaints received regarding availability of scheduled drugs without prescription. He advised the members that rules regarding the aspect should be enforced adequately so that sale without prescription leading to self-medication by the consumers is discouraged. The Chairman observed that many of the diagnostic reagents are manufactured without valid drug licence. He emphasized that all the diagnostic reagents fall under the definition of 'drugs' and should be licensed for manufacture. He advised the State Drugs Controllers that the new drugs which have not been cleared by the Centre should not be licensed by them even for export. He explained that there is a definite procedure followed by the Ministry of Commerce to recommend manufacture of unapproved drugs for export and hence it should be left for Drugs Controller (India) to take such decisions.

Dr. Gupta informed the members that a computer proforma has been devised by this Directorate in consultation with National Informatics Centre (NIC). This proforma is required to be filled by the licensee at the time of application fro grant / renewal of licence. The proforma received from the States will be fed in the computer to maintain a centralized registry. He requested the members to cooperate in this regard so that complete picture about the number of manufacturers, formulations permitted etc. in the country will be available centrally. He advised the State Drugs Controllers also to install computers in their Department for easy transmission of information.

On 17.7.92, Dr. Gupta, Drugs Controller (India) welcomed the Secretary (Health) and Addl. Secretary (Health) and after introducing, requested Secretary (Health) to address the members of DCC.

Secretary (Health) said that he was happy to share his views with the State Licensing Authorities. He expressed that such meetings should be held more often to enable frank discussion amongst the members. He said it is hardly necessary for him to emphasise the importance of quality control in drugs in this country. He observed that the task of quality control of drugs is rather complex because of several factors; one of them is the prevalence of several systems of medicines, viz. modern system, Ayurveda, Unain and Siddha system and the standardization for many of the drugs has not been worked out. He therefore emphasized that the Drugs Control Organisation in Centre and States should be strengthened not only in terms of manpower but also in terms of status of the people, qualifications and experience. He emphasized that there should be an independent Drugs Control Organisation in each State headed by a full time Drugs Controller who has necessary qualification as per law. He also emphasized that he Drugs Control Organisation should be totally dedicated to the task of enforcement and should have well qualified personnel who have knowledge, expertise and training in the drug manufacturing and in testing areas.

Secretary (Health) stated that States should also have proper field force to monitor and inspect the manufacturing units periodically to see whether rthe units are following the Good Manufacturing Practices (GMPs) and whether the firms have competent qualified technical staff as prescribed unde the law. He said, in order to detect spurious / sub-standard drugs the States should have adequate laboratory facilities with well trained

staff so that prompt action can be taken against those who are guilty of manufacturing sub-standard / spurious drugs. He regretted that inspite of our repeated requests many States do not have proper machinery to enforce Drugs & Cosmetices Act and Rules. He further observed that some States have excellent organization while other need to strengthen the enforcement. He emphasized the need to strengthen the organization on priority basis wherever the States are lagging behind in the enforcement. Secretary informed that in April 1991 he had written a letter to the Chief Secretaries of all States requesting them to pay special attention on enforcement and he was happy that some States Health Secretaries responded favourably while other responded in general. He also mentioned about the meeting that the Health Minister, Govt. of India had with the State Health Ministers in the month of January, 1992 where the attention was focused on the drugs enforcement laws. The Union Minister for Health and Family Welfare emphasized the paramount need for strengthening the Drug Control Organisation in the States.

Secretary drew the attention of the members to the fact that the country is passing through a very difficult fiscal period and the Centre may not be able to help all the States. He was however hopeful that some funds will be available in the 8th Plan allocations for Central assistance to States.

He further informed that Central Drug Control Organisation is being strengtehened since Drugs Controller (India) has been loaded with various responsibilities and is functioning with skeleton staff. He said he was happy to inform that the proposals to strengthen central organization have finally got through and will be implemented shortly. Secretary (Health) opined that the drugs control is not a State subject only but is in the concurrent list and the Centre has the major responsibility for quality control of drugs. He observed that the drugs manufactured in one State are consumed in other States and the welfare of the people in other Staets is the concern of Central Govt. He therefore felt that the Central Drugs Control Organisation has to play a monitoring role to check sub-standard / spurious drugs manufactured in one State and sold in other parts of the country.

Secretary (Health) stated that the Central Government have identified certain items like blood and blood products, I.V. Fluids and sera / vaccines where Drugs Controller (India) would play a more active role even at the licensing stage. He was of the opinion that one has to be extremely cautious in licensing the manufacture of blood and blood products, I.V. fluids and sera / vaccines and that is why the Centre is taking over little more responsibility in the area. He also said that the I.V. fluids, if not manufactured under hygienic conditions, can be extremely dangerous. He therefore emphasized that the manufacture of I.V. fluids is an area which require strict quality control and only those having GMPs and testing facilities should be allowed to manufacture.

Secretary (Health) expressed that even after a drug is found sub-standard, the action taken by the State authorities is not always prompt and stringent. He observed that the licence is suspended / cancelled in respect of that particular drug only and the

manufacturer is permitted to manufacture the remaining items, and this does not make any difference to the erring manufacturer. He also realized that with delayed procedure of judiciary, prosecution is also not a favourable remedy. He was of the opinion that a strong executive action is the only remedy in such cases.

Secretary (Health) stated that there appears to be a fairly large scale production and distribution of sub-standard drugs in the country and it is the responsibility of all to stop this activity.

ON 17.7.92, Mr. Vinod Vaish, Jt. Secretary, Department of Chemicals and Petro-Chemicals addressed the members of the Drugs Consultative Committee. He emphasized the need to have closer liaison and cooperation of the State Drugs Controllers in enforcing the provisions of DPCO. He observed that some States are sending them monthly reports in the shortage of drugs and requested others also to do the same so that they can monitor the availability of essential drugs. He pointed out that brand shortage is not the real shortage and the report should indicate whether or not the drug in generic name is available.

The members raised several querries which were clarified by Mr. Vaish. Some members pointed out that under the present provisions for any minor violation of DPCO (e.g. overcharging of a few paise) the only action provided is prosecution. They suggested that if the DPCO can be amended to include departmental action like suspension / cancellation of drug licence, if there is contravention of the provisions, the state licensing authorities will be able to enforce this order in a better way.

Dr. Gupta thanked Mr. Vaish and his officers for sparing time to exchange their views with the members of the Drugs Consultative Committee and also for circulating all the relevant notifications and circulars.

The agenda items were taken up for discussion.

Item No. 1 : Confirmation of the minutes of the 27th Drugs Consultative Committee Meeting held on 31st January and 1st February, 1991.

The minutes of the 27th meeting of the Drugs Consultative Committee were confirmed.

Item No. 2 : Statement of action taken on the minutes of the 27th Drugs Consultative Committee meeting held on 31st January & 1st February, 1991. (Annexure – I)

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

Item No. 3 : Consideration of the report of the Sub-Committee constituted in the last meeting of D.C.C. on various amendments suggested to the Drugs and Cosmetics Act and Rules.

The report of the sub-committee was discussed in detail by the members after which it was accepted with the following modifications.

Review of the existing guidelines in respect of samples found to be not of standard quality :-

(i) Addition of non-permissible colour should be added in liquid oral as category A defect on page No.8.

(ii) Addition of the following at Sr.No.5 under the Principles for institution of prosecution at page 11.

"Where a drug is found grossly sub-standard repeatedly".

Consideration of list of items following under disposable transfusion sets :-

The Chairman informed that the draft notification is being publisehed regarding the standards, manufacturing facilities, GMPs and testing facilities for medical devices which have been notified as drugs. He also informed the members that BIS has constituted a Committee for revision of standards relating to transfusion / infusion equipments.

Curtailing the number of licenses required for stocking distribution or sale of drugs :-

The Chairman told the members that it would be advisable if the same committee goes through the various aspects on the amendments proposed in the report and furnish the required draft amendments to Drugs Controller (India) for further action.

Expert Standing Sub-Committee :-

A suggestions had been made in the Sub-Committee report that there should be a mechanism by which matters requiring uniform guidelines can be examined on a continued basis by an Expert Standing Committee of D.C.C. The recommendations of this Sub-Committee can be put before regular meeting of the D.C.C. It was also suggested that the Expert Committee may be constituted with one State Drugs Controller from each Zone on rotational basis.

The Chairman agreed with the suggestion to constitute an Expert Standing Committee as follows :-

Commissioner, Food & Drugs Administration, Maharashtra.	-	Chairman
Director, Drugs Control, West Bengal.	-	Member
Drugs Controller, Delhi.	-	Member
Drugs Controller, Karnataka.	-	Member

Chairman requested Commissioner, Food & Drugs Administration, Maharashtra to convene the meeting whenever required.

Item No. 4 : Suggestions received from the State Drugs Controllers on the report of the Sub-Committee on the amendments suggested on Drugs & Cosmetics Act and Rules at the 25th Drugs Consultative Committee meeting.

These were discussed by the members and after discussion it was agreed that the suggestions made in the sub-committee may be accepted.

However, with regard to amendment of Section 22(a) (iii) of the Drugs & Cosmetics Act to extend the period of freezing order to 60 days it was felt that in all such cases Govt. Analyst may be requested to furnish the report within the stipulated time.

As regards the amendment to make the offence as cognizable for manufacture of spurious cosmetics, Commissioner, Food and Drugs Administration, Maharashtra was requested to re-examine whether such amendment is necessary.

Item No. 5 : Classification of formulations containing protein, Hydrolysates, Vitamins, Carbohydrates, Minerals etc.

The Chairman explained that the Protein Manufacturers Association and other have represented to this Directorate from time to time regarding the status of the preparations whether these items should be considered as drugs or food supplement. The matter was taken up with experts like Director, Central Food Testing Research Institute (CFTRI), Mysore,

National Institute of Nutrition, Hyderabad, Head of the Endocrinology Deptt., A.I.I.M.S., New Delhi. Director, CFTRI said protein formulations are considered as drug whereas AIIMS and National Institute of Nutrition considered these formulations food supplement and Nutrient supplements.

Smt. Debi Mukherji, Assistant Director General of Health Services (PFA) said that many formulations containing Protein Hydrolysates, Vitamins, Carbohydrates, and Minerals are manufactured and sold by Pharmaceutical firms in the form of liquids, capsules, powder and the label indicates 1 or 2 tea-spoon a day as dose. She also clarified these formulations are nothing but vitamin tonic preparations and under no circumstances these are considered to be food items. She also pointed out that CFTRI, Mysore which is one of the internationally recognized institution has commented that such preparations should be marketed as drug. Therefore, she laso suggested that such products should be covered under Drugs and Cosmetics Act and Rules thereunder.

After discussion, the members agreed that these formulations should be considered as drugs and not as food supplements.

Item No. 6 : Recommendations of National Society for prevention of blindness, India, New Delhi.

The Chairman explained that the National Society for the Prevention of Blindness, New Delhi has forwarded certain recommendations pertaining to the quality of Eye drops manufactured in the country. The Society suggested different colour coding on the label to distinguish different categories of Eye drops as per their side effects. The Society also suggested usage of plastic vials with single unit having nozzle system instead of glass container which are in use at present. The Society also recommended that ophthalmic preparations should be used within two weeks after opening eh container instead of 30 days as laid down if Schedule FF of Drugs & Cosmetics Rules.

The members discussed these issues in depth and agreed on the following points :-

(a) The suggested colour code may be accepted to distinguish various categories of ophthalmic preparations.

(b) The suggestion to print symbol of Eye on the label was accepted.

(c) The suggestion to have a squeeze type plastic vial for eye drop was accepted.

(d) It was agreed to constitute a sub-committee to examine the other suggestion like failure in sterility test, variations in pH and drop size of ophthalmic drops etc.

A Sub-committee was constituted as follows :-

Commissioner, Food & Drugs Administration, Maharashtra.	-	Chairman
Drugs Controller, Karnataka.	-	Member
Commissioner, Food & Drugs Administration, Gujarat.	-	Member
Director, Central Drugs Laboratory, Calcutta.	-	Convenor

The Sub-committee may conduct a survey on various ophthalmic preparations marketed in the country and submit its report within 3 months.

Item No. 7 : Test regarding net volume / content in respect of P&P formulations.

Chariman explained that many of the oral liquid P&P formulations were declared not of standard quality by the Govt. Analysts in respect of volume. At present Schedule V prescribes that volume of liquid oral dosate form in the container shall not be less than the labeled volume.

Chairman also observed that some Manufacturers Associations have represented their problems on this issue.

The matter was discussed and the Committee agreed to constitute a Sub-Committee as follows :-

Commissioner, Food & Drugs Administration, Gujarat.	Member
Govt. Analyst, Food & Drugs Administration, Maharashtra.	Member

Shri A. K. Ogale, Convenor
Assistant Drugs Controller (India).
Bombay-Port.

This committee will go through all aspects and suggest the required amendments to Schedule-V of the Drugs and Cosmetics Rules in respect of volume / content.

Item No. 8 : Competent Technical Staff for the manufacture of Homoeopathic medicines.

The members agreed with the proposal to amend Rule 85(E) of the Drugs and Cosmetics Rules.

Item No.9 : Amendment to Schedule M of Drugs and Cosmetics Rules.

The Chairman stated that the Indian Pharmaceutical Association, Bombay has suggested certain changes in the existing Schedule M to Drugs & Cosmetics Rules and have forwarded a copy of the draft amendment to Schedule M of the Drugs and Cosmetics Rules. The Chairman observed that there are certain variation in the draft suggested by the above Association from the existing GMP. After deliberation, it was decided that a sub-committee should be constituted to examine the proposed draft amendment and submit report within three months.

The following sub-committee was constituted :-

Commissioner, Food & Drugs Administration, Maharashtra.	-	Chairman
Drugs Controller Tamilnadu.	-	Member
Drugs Controller, Karnataka.	-	Member
Drugs Controller, West Bengal.	-	Member
Dy.Drugs Controller (India) (South zone) Madras.	-	Convenor

Item No.9A : Labelling of cosmetics with composition of ingredients and date of expiry – amendment of Rule 148 of the Drugs and Cosmetics Rules.

The Committee agreed with the proposal to amend rule 148 of the Drugs & Cosmetics Rules.

Item No.9B : Continued marketing of "Dover's Powder".

The Chairman explained that the Drugs Consultative Committee for weeding out harmful / irrational / ineffective formulations in its meeting held on 9th July, 1992 have observed that the active ingredients of Devers Powder are Ipecacuanha, opium and lactose. There is no therapeutic role of ipecacuanha as analgesic / antipyretic / couth expectorant and there is no scientific literature to establish that addition of inpecacuanha with opium synergises the analgesic properties of opium. It was stated that the drug is no longer used in medical practice and has become obsolete. In view of the above the experts recommended withdrawal of the preparation from the market. The Commissioner, Food & Drugs Administration, Gujarat and Maharashtra informed that the drug is mostly misused in the country and welcomed the ban on its sale. The members unanimously agreed that the manufacture and sale of Dovers Powder should be banned under Section 26-A of the Drugs and Cosmetics Act.

ASSAM

Item No. 10 : Classification on Schedule K of the Drugs and Cosmetics Rules.

The Drugs Consultative Committee did not agree with the proposal.

Item No. 11 : Rule 64 - condition to be satisfied before a licence in form 20 & 21 is granted.

The Chairman suggested that the matter be examined by the Expert Standing Sub-Committee. (Item No. 3)

Item No. 12 : Rule 67 F –Condition to be satified before a licence in form 20-C or 20-D is granted.

The Drugs Consultative Committee did not agree with the proposal.

Item No. 13 : Control over sale of ayurvedic drugs.

The members of the Drgus Consultative Committee felt that it is impossible to enforce sale licence for ayurvedic drugs a present due to paucity of staff. However, it was considered that restricted items like Aristam and Asavas require sale licence as thes items are likely to be misused. The Chairman told the members that the above suggestion will be placed before the Ayurvedic Drugs Consultative Committee for further necessary action.

BIHAR

Item No. 14 : Deletion of licences in forms 20 and 21A.

The Drugs Consultative Committee did not agree for deletion of licences in Form 20 & 20A.

Item No. 15 : Amendment to parts VII to X, XIV, XV of the Drugs & Cosmetics Rules.

The Chairman told the members that the matter would require further examination by this Directorate.

Item No. 16 : Sale licence for Ayurvedic drugs and cosmetics.

Already discussed under Item No.13.

CHANDIGARH ADMINISTRATION

Item No. 17 : Labelling of the base used in shampoos.

The Chairman explained that there are two different standards prescribed by BIS for shampoos viz. soap based and synthetic detergent based.

It is therefore necessary that the label of shampoos should clearly indicate whether it is soap based or synthetic detergent based, to enable the analyst to carry out tests accordingly.

Item No. 18 : Standard for orthopaedic padding.

The Chairman requested the Drugs Controller, Chandigarh Administration to ascertain the use of this padding from the PGI, Chandigarh and furnish the same to this Directorate for further necessary action.

Item No. 19 : Clarifications on setting up of laboratory by manufacturing firms.

The Chairman explained that as per rules every manufacturer must provide testing facilities of his own. As regards the list of instruments and equipments to be used in these laboratories the Chairman requested the Drugs Controller, Chandigarh to obtain the same from the Dy. Drugs Controller (India), Central Drugs Standard Control Organisation, North Zone, Ghaziabad.

DELHI

Item No. 20 : Maintenance of records of Homoeopathic medicines containing alcohol.

The Chairman explained that the matter would be placed before the Homoeopathic Sub-Committee of Drugs Technical Advisory Board for opinion.

Item No. 21 : Manufacture of one drug formulations under more than one brand name.

After prolonged discussion the members agreed that normally a drug formulation should not be permitted to be manufactured under more than one brand name by the same manufacturer. It was however, felt that the permission may be given for more than one brand name in case it is meant for export.

Item No. 22 : Sale of retail packs of drugs without tempering.

The members discussed the matter and it was felt that the subject is covered under Rule 105 of the Drugs and Cosmetics Rules.

GUJARAT

Item No. 23 : Active ingredients added in small quantities and estimation by quantitively.

The Chairman observed that it is the responsibility of the manufacturer to furnish methods of analysis for all the ingredients added by him in the formulation. The licensing authority should examine this aspect before permitting the manufacture.

Item No. 24 : Action on sub-standard drugs.

The item has already been discussed vide item No.3 of the agenda.

Item No. 25 : Inclusion of details of label in the report of Govt. Analysts.

The Committee agreed to the suggestion. It was decided that the licensing authorities should take up the matter with their Govt. Analysts.

Item No. 26 : Challenging the report of Govt. Analyst by the manufacturer.

The Chairman stated that Sec.25(4) is very clear and the manufacturer can seek the help of the court to send the sample to the appealate laboratory as per provision.

Item No. 27 : To mention the name of the colour on the label of the cosmetics.

Already discussed vide item No.9A of the Agenda.

Item No. 28 : Issue of reference standard by C.D.L.

The Director, Central Drug Laboratory, Calcutta told the members that as far as possible the reference standards are supplied by them when called for by the Govt. Analysts. However, in some cases the Central Drug Laboratory has not been able to procure the reference standards. As such they are not in a position to supply those reference standards.

Item No. 29 : Provision to export banned drugs under Sec.26A.

The Chairman informed that export of banned drugs is not allowed by Drugs Controller (India) unless the exporter produces a letter from the Health Authorities of the importing country stating that they are aware of the ban and would still like to import the said drug as the same is permitted in their country.

Item No. 30 : Schedule M – Provision for powder preparations for internal / external use separately.

The Chairman stated that the matter may be examined by the Expert Standing Committee (Item No. 3).

GOA

Item NO. 31 : Whether Hanky perfumes' are to be considered as cosmetics.

The Chairman observed that it would be difficult to distinguish between Hanky perfumes and other perfumes as the usage can be similar in both cases.

Item No. 32 : Control over the sale of ACD / CPD bottles which are used in the collection of blood.

The Chairman told the members that it may not be necessary to amend the Drugs & Cosmetics Rules for this purpose. He suggested that the licensing authority should ask the manufacturer of such bottles to mark on their label 'TO BE SOLD TO LICENSED BLOOD BANKS ONLY'.

Item No. 33 : Clarification as to whether buld drugs can be manufactured and marketed under a trade name.

The members were of the view that manufacture of bulk drugs under trade names should not be allowed.

Item No. 34 : Question as to whether new drugs already cleared by the Drugs Controller (India) should carry on the label of such drugs the symbol Rx.

The Chairman stated that the licensing authorities may ask the manufacturers to do the same before granting manufacturing licences.

Item No. 35 : Clarification as to whether 'soaps' manufactured for Five Star Hotels under their logo required a Drug Licence.

The Chairman observed that if the weight of the soap is more than 10 gms. then it should comply with the requirements under Drugs & Cosmetics Rules.

Item No. 36 : Consideration of the question as to whether 'Toilet Soaps' marketed with less than 60% TFM content and claimed as such on the label be considered as not of standard quality.

The Chairman stated that the soap manufacturers may be asked to strictly follow the BIS Standards and no 'Toilet Soap' containing less than 60% TFM should be allowed to be marketed.

Item No. 37 : Use of Kaolin as suspending agent (2% to 4%) with a drug which is systematically absorbed from GI tract ....

The Chairman explained that the combination of Kaolin with any other drug which is systematically absorbed from GI tract is banned as it was considered irrational. However, if Kaolin is used in the formulation as a suspending agent purely as a pharmaceutical necessity and not as a therapeutic agent, the licensing authority may permit after satisfying itself.

Item No. 38 : Whether permission can be granted to manufacture same drug formulation under two different trade names.

Already discussed vide Item No.21 of the agenda.

JAMMU AND KASHMIR

Item No. 39 : Blood Donation Camps.

The Chairman explained that only these voluntary agencies which are linked with licensed blood banks should be allowed to organize Blood Donation Camps and they must provide proper storage facilities during collection at the camp. He has asked the members that recognized blood banks only should be allowed to conduct such blood donation camps.

Item No. 40 : Standards for bandages and Gauze cloth.

The Chairman told that the bandages and gauze should conform to the standards laid down in IP and by BIS and we should not think of giving any relaxation.

Item No. 41 : Labelling of blister packs.

The Chairman agreed that there seems to be problem and the manufacturer should be asked to find better printing methods to make the print legible.

Item No. 42 : Schedule for cosmetics standards.

The Chairman stated that BIS is required to lay down standards for same raw materials used in the cosmetics.

KARNATAKA

Item No. 43 : Loan licensing policy.

The Chairman stated that the Central Govt. has already decided to abolish the loan licence system. Central Govt. has moved in the Supreme Court fo common hearing of all writ petitions filed in various High Courts and the matter is at present sub-judice.

Item No. 44 : Food supplements in capsule form.

The point has already been discussed under item No.5 of the agenda.

Item No. 45 : Licensing of Blood Banks attached to Govt. Hospital Pharmacy Unit.

The Chairman told that the licensing authorities should take up the matter with their concerned State authorities to ensure that the blood banks provide basic requirements as given in the Rules for collection, storage and testing of blood after which all these blood banks should be licensed.

Item No. 46 : Diagnostic reagents.

The Chairman told the members that diagnostic reagents are covered in the definition of drug as given in the Drugs and Cosmetics Act. The

manufacturer should be asked to furnish standards of such reagents and should tests the quality in their laboratory. If the licensing authority is satisfied about the quality, the licence may be issued.

Item No. 47 : Revision of fees under Schedule B of the Drugs & Cosmetics Rules.

The Chairman agreed that the matter needs examination. A Sub-committee was constituted with the following members :-

Director, Central Drugs Laboratory, Calcutta.	-	Chairman
Drugs Controller, Karnataka.	-	Member
Commissioner, Food & Drugs Administration, Gujarat.	-	Member

The Committee was requested to submit its report in 3 months time.

KERALA

Item No. 48 : Inclusion of Buprenorphine and Pentazocine in Schedule X.

The Chairman asked the members to generate more data of the misuse of these drugs. The information may be forwarded to this Directorate for examination and further action.

Item No. 49 : Labelling of physician's sample.

The Chairman stated that the licensing authorities should insist for proper labeling of physician's samples as per provision in Drugs & Cosmetics Rules.

Item No. 50 : Hospital stocking drugs without valid drug licences.

The matter was already been discussed in the Sub-committee report vide item 3 of the agenda.

MAHARASHTRA

Item No. 51 : Amendment in Forms 20 and 21.

The Chairman told the members that the licensing authorities should use their discretion with regard to the are of the premises.

Item No. 52 : Experience for grant of licences in Form 20B and 21 B.

The Chairman suggested that the matter may be examined by the Expert Standing Committee (Item No.3).

Item No. 53 : Amendment to rule 65 of the D&C Rules.

The item was discussed the last D.C.C. meeting.

Item No. 54 : Provision to recall ayurvedic drugs found not of standard quality.

The Committee agreed to the proposal.

Item No. 55 : Format of Analytical reports.

Already discussed under Item No.25.

Item No. 56 : Show cause notice to manufacturers in one State by Drugs Controller of other States in case of sub-standard drugs.

The matter was discussed at length. The members felt that it is not correct for the Drugs Controller of one State to issue such notices to manufacture in other States.

ORISSA

Item No. 57 : Permitting Pharmaceutical Tinctures for marketing inpacking of 60 ml. and 100 ml.

The Chairman told that State Drugs Controller should send the list of tincture / preparations which have become obsolete and are not in the Hospitals in their State.

Item Not. 58 : Action to be taken by the licensing authority on test reports issued by Govt. Analyst where test for all the vital ingredients have not been carried out.

Already discussed.

Item No. 59 : Provision of Central assistance to the State Drugs Testing Laboratory, Bhubaneswar for purchase of Pharmacopoeial / Reference books and Scientific Journals.

The Chairman stated that there is no provision of such assistance under the centrally sponsored scheme.

Item No. 60 : Action on products declared not of standard quality.

Already discussed under item No.3 of the agenda.

Item No. 61 : Uniform action to be taken on large volume parenterals and other parenteral preparations containing particulate matter.

The Chairman told the members that if the product is not of standard quality the licensing authority should take action against the manufacturer. However, the proposal of laying down standards for 'particle size' for large volume parenterals, is under consideration of the I.P.Committee.

PUNJAB

Item No. 62 : Amendment of definition of competent person under second proviso of rule 64 (2) (ii).

The Committee did not agree to the proposal.

TAMIL NADU

Item No. 63 : To amend section 23 of Drugs & Cosmetics Act to enable the Drugs Inspector to draw samples against credit bills.

The Chairman told the members that necessary amendment will be considered if there is any court judgement on this matter.

UTTAR PRADESH

Item No. 64 : Power, function, duties of controlling authority.

The Chairman told the members that there is no need to amend the Drugs & Cosmetics rules for this purpose. The Govt. should issue administrative orders for this purpose.

Item No. 65 : Delegation of powers.

The Chairman stated that the powers of the licensing authority for manufacturing licence should remain with him and not be delegated.

Item No. 66 : Prohibition on alcoholic drugs.

Already discussed under Item No. 57.

RAJASTHAN

Item No. 67 : Change of nomenclature of Drugs Inspectors.

The members were told by the Chairman to obtain the views of the Drug Inspectors Association of their States together with detailed reasons for such a change and forward the proposals to this Directorate.

Item No. 68 : Ceiling on formulations specially vitamins, cough expectorants etc.

The Chairman told the members that the licensing authority should examine the matter and use discretion before granting licence.

Item No. 69 : Non supply of constitution and other particulars by State Drug Controller to their counter parts in case of sub-standard drugs.

Already discussed under Item No.3 of the agenda.

Before winding up, the Director, Drugs Control, Andhra Pradesh requested the Chairman to clarify the points suggested by him which he has circulated only during the meeting. The Chairman agreed to his request and the points raised by him were clarified.

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

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Annexure – I
(Item no. 2 of the 28th meeting)

Statement showing the action taken on the decisions taken at the 27th Meeting of the Drugs Consultative Committee held in New Delhi on the 31st January & 1st February 1991.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
1.	Need to frame rules consequent to the amended provision of section 26 and 32 of the Drugs and Cosmetics Act :	The committee decided to refer the matter to the subcommittee appointed by the 27th Drugs Consultative Committee and submit report.	The report of the subcommittee has already been circulated to the members vide letter No. X 19013/2/92-D, dated 21/4/92 as part of the agenda for the next meeting.
2.	Consideration of the	The Chairman requested the members to	The comments received from some State

	amendments suggested to Drugs and Cosmetics Act and Rules at the 25th Drugs Consultative Committee meetings :	go through and send their comments within a period of three months.	Drugs Controllers are at (Agenda Item No. 4)
3.	Consideration of adoption of IS 4707 : 1988 (Part 1) as cosmetic colours in place of Schedule "Q" under Drugs & Cosmetics Act and Rules.	It was decided to refer the matter to the subcommittee with Commissioner, FDA, Maharashtra as the Chairman.	The subcommittee has submitted its report which has already been circulated vide Dte. Letter No. X 19013/2/92-D dated 21/4/92.
4.	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 committee agreed for amending the provisions of Rule 65 of the Drugs & Cosmetics Rules.	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.
5.	Consideration of shifting of Phenobarbitone from Schedule "X" to "H" of Drugs & Cosmetics Rules.	The committee agreed that Phenobarbitone should be shifted from Schedule "X" to Schedule "H".	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.
6.	Consideration of amendment to Schedule "M" of the Drugs & Cosmetics Rules 1945 in regard to manufacture of Large Volume Parenterals.	The Chairman asked the members to go through and send comments on the proposed amendment within three months.	No comments have been received so far. Further action will be taken to carry out the amendment as proposed.
7.	Consideration of inclusion of	The committee agreed to the proposed for	Necessary amendment is being carried out

	the colour Iron Oxide Black to be used in Drugs under Rule 127 of Drugs & Cosmetics Rule :	including the same in the Drugs & Cosmetics Rules.	in the Drugs & Cosmetics Rules.
8.	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 committee decided to consult the Ministry of Law in the matter.	The Law Ministry has opined that Judicial review is a basic feature of our constitution and can not be completely shut out. The views of Law Ministry have already been circulated to all the members vide Dte. letter No. X 19013/9/91-D dated 13/8/91.
9.	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	It was decided to refer the matter to the subcommittee constituted under the Chairmanship Commissioner, FDA, Maharashtra.	The report of the subcommittee has already been circulated to all members vide Dte. Letter No. X11013/2/92-D dated 21/4/92 as part of the agenda for the next DCC meeting.
10.	Adoption of BIS Standards on toilet soaps, liquid toilet soap and baby toilet soap.	The standards were considered by the committee and were approved.	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.
11.	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	The members approved the recommendation of the subcommittee.	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.

	medical devices.		
12.	Revision for Standards for Boric Acid.	Chairman asked Drugs Controller, Karnataka to refer the matter to I.P. Committee.	The DC, Karnataka was requested to refer the matter to I.P. Committee vide Dte. letter no. X 19013/5/91-D dated 3/6/91.
13.	Provision for rejection of the application other than Form 27 & 27B.	Chairman informed to the members that the item has been considered in the sub-committee report of the Agenda.	The item was considered by the subcommittee constituted by the 26th DCC and its report was circulated to all members during 27th DCC. But no comments have been received by this Directorate so far.
14.	Amendment of Rule 153, 153-A & Rule 154 of Drugs & Cosmetics Rules.	It was agreed to examine the issue and if found necessary the rules may be amended.	The matter is under consideration of Ayurvedic DCC and ADTAB.
15.	Reviewing the existing guidelines in respect of samples found to be not of standard quality.	It was decided to refer the matter to the subcommittee constituted under the Chairmanship of Commissioner, FDA, Maharashtra.	The report of the Subcommittee has already been circulated to all members vide Dte. letter No. X 19013/2/92-D dated 21/4/92.
16.	Qualification of Inspectors	It was decided to refer the matter to the subcommittee constituted under the Chairmanship Commissioner, FDA, Maharashtra to propose a draft for the said amendment.	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.
17.	Discrepancies in Form 18.	Chairman agreed to examine and make amendment if found necessary.	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.

18.	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.	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.
19.	Competent Technical staff-approval need for uniformity.	It was agreed that the sub-committee may examine and give its recommendation.	The report of the subcommittee has already been circulated to all members vide Dte. letter No. X19013/2/92-D dated 21/4/92 as part of the agenda for the next DCC.
20.	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.	The matter is under consideration by the ASUDCC.
21.	Competent Technical staff for manufacture of Homoeopathic medicines.	Chairman stated that Homoeopathic sub-committee of DTAB will be asked to suggest the qualifications for the technical staff to manufacture Homoeopathic medicines.	The Homoeopathic subcommittee of DTAB recommended in the meeting held in 1988 following qualifications and experience for technical staff for manufacture of Homoeopathic medicine: 1. He shall be holding qualifications included in 2nd 3rd schedule to MCCH 1973 with 18 months of experience in manufacture of Homoeopathic medicines. or, 2. a graduate in science with chemistry as one of the subjects with three years experience in manufcture of

			Homoeopathy medicines. or, 3. a graduate in pharmacy with 18 months of experience in the manufacture of Homoeopathic medicine. The Homoeopathic subcommittee of the DTAB held on 10/5/91 suggested that this should be discussed again in the DCC meeting. (Agenda Item No. 8)
22.	Revision of clause in From 25C as related to Rule 85D	It was decided that the matter may be referred to Homoeopathic sub-committee.	The Homoeopathic adviser is of the opinion that this need not be changed.
23.	Consideration of list of items falling under disposable perfusion sets.	It was decided to refer the matter to the subcommittee to examine the aspect and give recommendation.	The report of the subcommittee has already been circulated to all members vide Dte. letter No. X19013/2/92-D dated 21/4/92 aspect of the agenda for the next DCC.
24.	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.	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.
25.	Consideration of the need to extend penalty clause in Drugs and Cosmetics Act to approved testing laboratories.	It was agreed that the subcommittee should examine and give recommendation.	The report of the subcommittee has already been circulated to all members vide Dte. letter No. X19013/2/92-D dated 21/4/92.
26.	Condition of licence in Form 25G at par with other licence	Chairman agreed that the matter will be examined and if found necessary the	Necessary amendment is being carried out in the Drugs & Cosmetics Rules.

	forms.	amendment will be carried out.	
27.	Incorporation of condition in Form 25-C.	Chairman requested Adviser Homoeopathy to look into this matter and suggest necessary amendment if required.	The Adviser Homoeopathy is of the opinion that since a retail licence under Form 20 C is a precondition for issue of Form 25 C, there is no necessity to introduce a sub clause under Rule 85 D in this respect.
28.	Consideration of definition of RMP under Rule 2 (ee) of the Drugs and Cosmetics Rule 1945.	The matter was referred to the subcommittee.	The report of the subcommittee has already been circulated vide Dte. letter No. X19013/2/92-D dated 21/4/92.
29.	Uniformity of packages.	The Chairman informed that standardization of packages is under consideration for being incorporated in the Drugs and Cosmetics Rule.	Final amendment is being carried out in Drugs & Cosmetics Rules.