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# MINUTES OF THE 29TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON 6TH & 7TH JANUARY, 1994

The Chairman, Dr. P. Das Gupta, while welcoming the members requested them to self introduce themselves to Hon'ble Dy. Minister of Health, who had kindly spared his valuable time and agreed to address the members of the D.C.C. He also had asked them to feel free to point out any constraint which comes on the way of implementing various provisions of the Drugs & Cosmetics Rules.

**Shri Pawan Singh Ghatowar, Hon'ble Dy. Minister for Health and Family**

The 29th Drugs Consultative Meeting was inaugurated by Shri Pawan Singh Ghatowar, Hon'ble Dy. Minister for Health and Family in the morning of 6th January, 1994.

The **Hon'ble Minister** while inaugurating the 29th DCC and wishing the greetings of the New Year desired that they should channelise their energy with greater momentum towards ensuring quality of drugs and pharmaceuticals to the public at large. He stated that the Drugs Controllers of both State and Centre are well aware of the public health and social welfare measures enforced by them by ensuring compliance of various provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder.

He stated that this is a golden opportunity, once in a year, for interaction with various authorities of Central Drug Control Organisation and State Drugs Controllers. He also emphasized that the expectations of consumers has undergone a sea-change with regard to medical practices and pharmaceutical manufacturers who supply strong weapons in the form of medicines to fight diseases and their prevention.

The Minister further stated that it is necessary that the provisions given under the Act are strictly adhered to. It is reported that the drugs declared not of standard quality by Government Analyst of one State, when referred to concerned State Drug Controller where the unit is located, takes undue time for transmitting this information to the manufacturer and sometimes when the manufacturer comes to know about the test reports the drug has already reached its date of expiry leaving no scope for further investigation. Therefore, he urged all the Drugs Controllers of States to have better coordination which can easily be done within the constraints of the existing framework.

In the end, the Hon'ble Dy. Minister also mentioned about the Central Licence Approving Authority (CLAA) for notified drugs like blood and blood products, sera and vaccines and intravenous fluids. The Drug Controller (India) has already taken a special meeting to explain the operative part of the such licensing and expected the cooperation in the matter of all the State Drug Controllers. He also mentioned the necessity of harmonious cooperation between different sectors of pharmaceutical industry which can only be perceived when a minimum standard of quality is maintained.

In conclusion, the Hon'ble Minister stated that amendments of Drugs & Cosmetics Rules cannot answer all the problems. What is required is the enthusiasm with which the implementing authorities like to act in order to attain the objectives.

He also informed that the Central Govt. have initiated steps to help in augmenting the Drugs Testing facilities and Drugs Inspectorate staff of the States and it is for the State Drugs Controllers to ensure that the money allocated to them is properly utilized in this direction.

Lastly, Hon'ble Dy. Minister wished that during these two days the deliberations amongst Drugs Controllers (India) and the State Drugs Controllers will come out with

definite recommendations which will plug many of the weaker areas and will help in proper enforcement for which we are answerable to the public.

**Item No. 1 : Confirmation of the minutes of 28th Drugs Consultative Committee Meeting held on 16th & 17th July, 1992.**

The minutes of the 28th Meeting of the Drugs Consultative Committee were confirmed by the members.

**Item No. 2 : Statement of Action Taken on the minutes of 28th D.C.C. Meeting held on 16th & 17th July, 1992.**

The Chairman explained the members about action taken by the Directorate arising out of the minutes of the last D.C.C. Meeting.

Members agreed with the statement of action. However, on certain items the following decisions were taken :

**2 (a) Consideration of the proposal concerning curtailing number of licences for drugs specified under Schedule C and C(1) and other than Schedule C and C(1) – Report of sub-committee constituted under item No.(3) of 28th D.C.C.**

The Chairman informed the members that the Sub-Committee constituted under item (3) of the 28th DCC has submitted its report and it is with the members for their perusal.

Since the report was received by the members on the day of discussion, they requested the Chairman to give them some more time to study and give comments on the report.

The Chairman requested the members to send their comments within 2 months to decide further course of action.

**Item No. 3 : Consideration of the proposal to fix limits concerning net volume / content in respect of P&P preparations under Schedule 'V' of Drugs & Cosmetics Rules, 1945.**

The report of the Sub-Committee constituted under 28th DCC under item No. (7) regarding net volume / content with regard to P&P formulations was discussed.

FDA, Gujarat, after highlighting the salient features of the findings of the report, proposed the Chairman that no lower limits need be permitted under Schedule 'V' and the present provision in the said Schedule

concerning the net content havng "not less than the labeled claim" be retained.

So far as checking of net content / volume in dry syrup is concerned, the test should be applied by the Govt. Analyst after reconstitution as is recommended by the manufacturer.

Chairman and members of the DCC, while accepting the findings of the report, agreed to refer to IP Committee the anamoly of not prescribing the test on net content / volume in liquid oral preparations and to take suitable decision to mention the same in the forthcoming new edition.

Item No. 4 : **Consideration of the report of the Expert Standing Committee constituted under 28th DCC regarding :**

(A) **Minimum area with regard to retail sale of drugs under Rule 64.**

(B) **Provisions for having separate area for powder prepartions meant for external and internal use under Schedule 'M'.**

(C) **Inserting additional qualifications under Rule 64 (2) for competent person in respect of sale of drugs by way of wholesale.**

The Chairman explained to the members that opinion on the recommendation made by the Expert Standing Committee may be discussed.

4 (A) After discussion, the members made the following suggestions for amending Rule 64 in respect of retail sale, etc. :

(i) An area not less than 15 sq.m., wherever licences in respect of both wholesale and retail are granted in the same premises, should be specified under Rule 64 in addition to the area already specified in the said rule in accordance with the Schedule 'N'.

(ii) For retail licences in Forms 20 and 21, the area should be not less than 10 sq. m.

A proviso should also be added to give protection to those premises which were already there and was available presently under provisions of drugs being sold by way of wholesale.

The Chairman agreed with the suggestions made by the members for carrying out necessary amendment under the Drugs and Cosmetics Rule, 1945.

4 (B) FDA, Gujarat explained to the members that provisions of Part II of Schedule M for requirement of equipments and area was specific with regard to formulations only. These provisions were based on the nature and processes involved in the manufacture of drugs and not based on their use whether for external or internal use.

It was for consideration of the members whether practices should be adopted that external preparations and preparations used internally should not be permitted in the same section. However, such provisions were not available for having separate sections for such products under the Drugs and Cosmetics Rules, 1945.

After discussion, DCC recommended that suitable changes in the form of 'proviso' or as a 'Note' at the end of Schedule 'M' may be inserted in this regard.

4 (C) The Chairman sought opinion of the members if the qualifications with regard to competent person for wholesale of drugs under Rule 64 (2) required any enlargement to the existing qualifications and experience of the said person.

DC, Tamilnadu stated that provisions under the said Rule prescribed no legal obligation on the part of the competent person but was only for endorsing the name of the person on the licences.

The Chairman informed the members that the legislation was being made for holding him liable if any contravention was observed.

Commissioner, FDA, desired that the experience of the person should be reduced.

DC(J&K) proposed that the qualification of the person should be Graduate in Science rather than Graduate in any faculty.

The Chairman, however pointed out that presently the qualification did not include any discipline of studies.

After discussion, the Chairman agreed with the views of the members that the definition of 'Competent Person' should be enlarged to include 'Person with degree in any faculty but should have one year experience in dealing with drugs'.

**Item No. 5 : Consideration of the report of Sub-Committee constituted to examine proposal made by IPA to amend the GMP in the existing Schedule 'M' of Drugs & Cosmetics Rules.**

The Chairman requested DDC(I), South Zone to explain to the members the findings of the report of the Sub-Committee on the suggestions made by IPA regarding amendment to various provisions of Schedule 'M' to the Drugs & Cosmetics Rules, 1945.

DDC(I), South Zone explained to the members that perhaps the technical wing of IPA have attempted to redefine the GMPs documents and based on their observations, the Sub-Committee rationalized the various provisions in addition to the guidelines stated by the WHO (Report Series 823).

The recommendations of the Sub-Committee are at Annexure II of the report which may be considered by the members.

While initiating discussion on the report, Commissioner FDA, Maharashtra stated that Standard Operative Procedures (SOP), as laid down in Schedule M of the Rules, are to be developed by the manufacturers. He propsed that the procedures being laid by the licensee viz. procedure of destruction of drugs should be with the consent of the State Licensing Authority (SLA) and not to be left upon the licensee.

DC(Orissa) supported FDA in this regard.

Drugs Controller, Delhi proposed that at least the staff responsible for rejection / destruction of batch of a drug should be stated in the document.

FDCA, Gujarat stated that GMPs is a concept and SOPs drawn by the licensee should be scrutinized and approved by SLAs.

After discussion, it was agreed that the document prepared by the Sub-Committee could remain as guidelines. The Chairman appreciated inclusion of concept of 'Self-Inspection' in the report for implementation by the licensees.

**Item No. 6 : Consideration of the report of Sub-Committee constituted by 28th DCC, vide Item No.47, for revision of fees under Schedule 'B' of the Drugs & Cosmetics Rules.**

The Chairman requested Director (CDL), Calcutta to apprise them regarding the revision of fees for testing of various categories of formulations stated under Schedule 'B' of the Drugs & Cosmetics Rules.

Director (CDL) requested members to permit them to raise the fees structure concerning testing of various categories of samples tested by them.

The members objected to the revision of fees for the reason that this would unnecessarily put financial constraints on the States on the samples which are being sent to the Central Drugs Laboratory for testing.

The Chairman intervened and informed the members that the revision of fees with respect to different categories of formulation is overdue and would also benefit the State Govt. as they are also the analyst for their State.

The members agreed with the revision of fees under Schedule B as they accepted that the revision of fees under said Schedule has been made proportionate to the salary structure as well as the cost of equipments, chemicals, etc.

The Chairman, however, requested Director (CDL) to send a detailed noted to DC (I) covering the aspects and reasons for enhancing the fees structures of various categories of drugs before carrying out the exercise of substituting Schedule B with revised rate as proposed by the Sub-Committee.

**Item No. 7 : Consideration to include human insulin and anti-rabies vaccine with enhanced shelf-life period under Schedule 'P' of the Drugs & Cosmetics Rules'45.**

The Chairman informed the members that Pure Insulin (e.g. Human Insulin) and Anti-rabies vaccine based on Tissue Culture Techniques have been permitted and approved by the Drugs Controller (India) for marketing in the country. These new innovations have greater shelf-life period than what is stated under the Schedule 'P' of the Drugs & Cosmetics Rules.

The members agreed that these categories of drugs could be included in the said Schedule with enhanced shelf-life.

However, Director, Drugs Control Admn., West Bengal proposed that while inserting them, necessary care with regard to the temperature gradient, as stated in their stability data, may also be taken into consideration.

**Item No. 8 : Consideration to amend Rule 49 concerning qualifications of Drug Inspectors.**

The Chairman informed the members that Central Government have amended Rule 49, vide GSR 658 (E) dated 19.10.93, to bring at par with the qualifications under Rules 49A & 50A with respect to licensing and controlling authority.

Presently, one of the requirements to be eligible as Inspector is that the person should have Degree in Medicine with 'specialisation in Clinical Pharmacology'.

'Clinical Pharmacology' is 'a Postgraduate Qualification' whereas other disciplines stated in the Rule correspond to Graduation only.

It was also for consideration of the members to discuss whether any 'protection' was to be given to those inspectors, who are already in service, and are discharging statutory functions.

The members after discussions, agreed that the words 'Clinical Pharmacology' occurring in the said Rule should be deleted and while amending Rule 49 necessary protection should also be given to those Drugs Inspectors who are already discharging duties under the Drugs & Cosmetics Act, 1940 and Rules thereunder from the date of commencement of the above referred to notification.

**Item No. 9 : Consideration of the proposal to amend Schedule 'J' of the Drugs and Cosmetics Rules, 1945 prescribing list of diseases for which a drug may not purport to prevent or cure.**

The Chairman explained to the members that Ministry of Health & F.W. is in the process of incorporating Schedule to the DMR(OA) Act prescribing list of diseases for which a drug may not purport to prevent or cure.

Since, it will take some time to prepare comprehensively Bill to be enacted by the Parliament, it was proposed to adopt the list of the diseases for the said purpose under the Drugs & Cosmetics Rules, 1945.

The Chairman also furnished a list of diseases, which was earlier cleared by the DTAB, for the perusal of the members.

After scrutinizing the list of diseases, the members felt that some more diseases could be added to make it comprehensive. Under the circumstances, the list to be included was revised.

DCC agreed to adopt the list for the purpose of substituting it with the existing Schedule 'J' under the Drugs and Cosmetics Rules, 1945.

**Item No. 10 : Amendment to Rule 85 of the Drugs and Cosmetics Rules, 1945 empowering licensing authorities to direct manufacturers to stop manufacturing and to destroy drugs considered unfit for use.**

The Chairman informed the members that 43rd Meeting of DTAB on the recommendations of Drugs Consutlative Committee considered the proposal to include a provision empowering regulatory authorities to direct manufacturers to stop manufacturing and destroy drugs considered unfit for use especially in those cases where legal action is not contemplated. Further, there seems to be an 'omission' under the said rule where a licensee, whose licence has been cancelled / suspended, may also prefer an appeal to the State / Central Govt. for redressal of his grievances.

The members, after discussion, agreed that both the regulatory authorities may be empowered under the respective Sub-rule (1) and (2) concerning stopping of manufacture and destruction of drugs considered unfit for human consumption.

The members also recommended that necessary provision should be made in respect of preferring an appeal to the State / Central Govts., as the case may be, i.e. a mechanism for natural justice for the offended licensee. This is considered necessary because such a mechanism is available in respect of Blood Banks, Cosmetics, Homoeopathic, Ayurvedic as well as under sales licences and seems to have been omitted under the recently substituted rule 85.

**Item No. 11 : Consideration of the proposal to check misuse of "Phensedyl Cough Linctus" in certain States.**

The Chairman explained to the members that Phensedyl, containing Codeine as one of the ingredients, is reportedly being misused in the North – Eastern States as many people were consuming it as an 'alcoholic' and 'narcotic drug'.

The Chairman also informed the members that the Expert Committee at its meeting held on 20th & 21st July, 1993 as well as on 1st and 2nd Nov. 1993 examined the matter.

It was, however, for the consideration of the Committee to further examine whether the existing composition of the said drug falls within the guidelilnes or not.

The Chairman asked the members to give their opinion regarding the extent of abuse in their States of the said preparation.

Drugs Controller, Orissa, was of the opinion that it was for consideration whether the said preparation could be banned under Section 26-A as the preparation is irrational and harmful.

The Chairman clarified that it was not a question of irrationality but a question of misuse and abuse.

Drugs Controller, West Bengal informed that the preparation was being extensively misused in North Eastern States like Manipur, Meghalaya and Assam. The State of West Bengal had already banned the sale of the said preparation but the manufacturer has changed the nomenclature from 'linctus' to 'expectorant'.

Drugs Controller, Karnataka while proposing solution to the problem stated that the wholesale distributors in his State were directed that the medicines should be supplied to their distributors against a cheque to curb further misuse of the medicine.

Meanwhile, the Chairman requested Drugs Controller, Karnataka to give a detailed note for circulation among members so that similar strategy could be formulated by them also to curb misuse of the drug.

After discussion, the members unanimously agreed that the matter should be referred to a sub-committee. The sub-committee shall consist of the following members :

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| Commissioner, FDA, Maharashtra | Chairman |
| DCs of Karnataka, Gujarat, West Bengal, Tripura | Members |
| DDC(I), CDSCO, South Zone, Madras | Member-Convenor |

The sub-committee shall give its report with in 6 months.

**Item No. 12 : Consideration of the proposal to amend the Rule 96 for enlarging the labeling requirements in matters concerning mentioning adverse reactions.**

FDCA, Gujarat, on the request of the Chairman, explained to the members that Consumer Association of Gujarat felt that besides the statutory provisions of labeling of drugs, details like nausea, headache, vomiting, etc. should also be recorded on the label specially in vernacular language to make them more self explanatory. However, Gujarat State Drugs Advisory Board, of which the manufacturers are also the members, felt that the labels, particularly of drugs packed in aluminium foils and blister packs, have labeling details in a already over-crowded and microsized words.

The members felt that the drugs sold under prescription need not contain all details regarding adverse reactions in vernacular language as it is the physician who would be guiding the patients while prescribing drugs to them.

Hence DCC did not agree to the proposal.

**Item No. 13 : Consideration to include bathing bars under Schedule 'S' of the Drugs & Cosmetics Rules, 1945.**

The Chairman asked the members to examine whether bathing bars which are being marketed can be considered to be included in the existing Schedule 'S' to the rules in view of the specifications published by the BIS. The members may keep in view that the "Bars" do not contain TFM as is necessary for the toilet soaps.

The Chairman also informed the members that various queries concerning the matter would be answered by the representatives of the BIS.

BIS clarified that their specifications in respect of bathing bars do not emphasise the inclusion of TFM as an important component but includes synthetic ingredients which provided equal lather value of the said preparations. Thus the bars are more of performance wise and are dermatologically safe. Further BIS also clarified that 'safety test' are prescribed in the specifications.

BIS further clarified with reference to the enquiries of the members that nomenclature "bars" was devised by the industry itself and such nomenclature is also prevalent in the developed countries.

Commissioner, FDA, Maharashtra proposed that the preparations should mention on their labels that they are synthetic in nature. He proposed to BIS that the industry may be persuaded to incorporate ingredients having minimum TFM in them as is necessary for the toilet soaps.

Other members agreed with the proposal given by the FDA.

In view of the discussions, Chairman requested BIS to have a dialogue with the industry on the matter and based on the discussion, they may consider incorporating suitable provision in their specification with regard to minimum TFM as well as stating on the label that the bars are synthetic based.

Meanwhile, DCC recommended the bathing bars may be included in Schedule 'S' on the basis of the standards already specified for their publication IS:13498:1992.

**Item No. 14 : Consideration of the proposal for prohibition to market certain anti-diarrhoeal preparations under Section 26-A of the Drugs & Cosmetics Act, 1940.**

The Chairman informed the members that the Expert Committee on weeding out of irrational / sub-therapeutic / harmful drugs recommended prohibition of anti-diarrhoeal preparations. The recommendation had been made on the basis of "WHO Technical Report on the Rational Use of Drugs in the Management of Acute Diarrhoea in Children".

Before recommending the prohibition the experts in the committee had carefully heard the representatives of the manufacturers, manufacturers' associations.

The Chairman requested the members to give their opinion as to whether the anti-diarrhoeal containing different sets of combination as illustrated in the agenda from (a) to (f), could be banned under Section 26-A of the said Act.

Commissioner, FDA, Maharashtra felt that 50 per cent of the anti-diarrhoeal preparations available in the market at present would get banned which would result in non-availability of anti-diarrhoeal for the management of diarrhoea. The Chairman should keep this in view while banning the anti-diarrhoeal combinations which are presently available in the market.

Drugs Controller, West Bengal proposed that the word "Paediatric" wherever occurring may be replaced with the words "liquid oral diarrhoeal".

The Chairman informed that these anti-diarrhoeals are ineffective or harmful for children and the shortage of thes anti-diarrhoeal due to ban cannot be the reason for continuation.

After discussion, the committee recommended that the combinations proposed from (a) to (f) of the agenda may be banned under Section 26-A of the Act keeping in view the proposal made by Drugs Controller, West Bengal.

**Item No. 15 : Consideration of the proposal of streamlining of patent & proprietary oral rehydration salts (ORS).**

The Chairman explained to the members that large number of firms of Patent and Proprietary preparations are available in the market. The products of ORS marketed are found to vary in their formulation in

sodium ion content from 30 to 90 millimoles and Dextrose Sodium ratio from 1 : 1 to 1 :3 and total osmolarity upto 740 millimoles. Since most of them are either not efficacious or suspected harmful in diarrhoea management.

The Chairman further informed the members that the Expert Committee recommended prohibition on marketing of P&P ORS except those conforming to the parameters stated under (a) to (c) of the agenda.

The Chairman requested the members to discuss and give their recommendations.

Drugs Controller, J&K, requested the Chairman that the quantification of the ratio should be in "grams" and not in "millimoles" so that the figures stated in the notification become self-explanatory and ultimately would be in the benefit of the manufacturer.

After discussion, DCC agreed and recommended the proposal of the Chairman in view of the recommendations made by the Expert Committee.

The Chairman also agreed to send circulars on conversion procedure of millimoles to grams to all the members as a guideline.

**Item No. 16 : Consideration of the proposal to make amendments in the notification No. GSR-69(E) dated 11.2.91 regarding fixed dose combinations (FDC) of anti-helmintic with cathartic / purgative.**

The Chairman, for the sake of recapitulation, informed the members that on the basis of the recommendations of the DCC and DTAB, FDC of anthelmintic with Cathertic / purgative except Piperazine Citrate were banned under the said notification. One of the affected manufacturer of anthelmintic containing Santonin with purgative pleaded before the Expert Committee that purgative was required to expel the worms that are stunted by Santonin.

After deliberations, the Experts felt that there was rationality in FDC of Santonin with Purgatives.

DDC(I), South Zone, felt that the combination may be banned on the basis of category.

After discussions, the members recommended that the following clause may be inserted :

'FDC of anthelmintic with cathartic / purgative except Piperazine and Santonin or any drug acting identically:.

**Item No. 17 : Amendment to Notificaiton No. GSR 49(E) dated 31.1.84 banning fixed dose combination of Tetracycline with Vitamin C.**

The Chairman explained, in detail, the background of the item. He stated that the pharmacological action of Oxytetracycline and Tetracycline are same. Therefore, there is a logic in banning the fixed dose combination of Tetracycline with Vitamin C and other drugs of the Tetracycline as well. Hence the members may opine on the same.

There was a unanimous opinion of the members that fixed dose combination of any of the Tetracycline group with Vitamin C should be banned.

**Item No. 18 : Reconsideration of the question of adoption of standards for ophthalmic preparations laid down under Schedule FF for Homoeopathic ophthalmic preparations. (Rule 126A)**

The Chairman explained to the members that Ministry of Health & Family Welfare published draft notification inserting Rule 126 B in respect of Homoeopathic ophthalmic preparations under the said Rule of the Drugs & Cosmetics Rules, 1945. However, Ministry of Health felt that there seems to be no justification for inserting new Rule but the said category of preparations under the Homoeopathic System can be accommodated in the existing rule 126 A.

The members agreed that there seems to be no need to provide a new Rule but appropriate insertions may be made in Rule 126A itself which already exist for allopathic system of medicines.

**Item No. 19 : Consideration to enlarge list of cosmetics under Schedule 'S' to the Drugs & Cosmetics Rules.**

The Chairman informed the members that BIS have published specifications in respect of other cosmetic items which include Lipsalve, Powder Hair dye, Bindi (liquid), Kum-Kum powder and Henna powders for enlarging the list of Schedule 'S'. The members were requested to adopt these cosmetics under said Schedule so that their quality could be ensured to the interest of the consumers.

BIS informed that the standards in respect of said cosmetics were devised because of their fast marketability (hair dyes), export obligations (henna powder) as well as keeping in view the consumer interest (lipsalve). It was observed by BIS that specification in respect of these cosmetics are

urgently required because standards elsewhere were not available and therefore checks on the quality of these cosmetics may not be ensured.

Drugs Controller, Karnataka desired to know whether standards of Kum-Kum excludes red / yellow colours in view of the judgement pronounced. BIS clarified that the word Kum-Kum has been explicitly defined in the "foreword" of the specification laid for them. However, the specifications do not include "composition" but lay stress on parameter relating to quality aspects. In hair dyes, caution has been included in the form of "patch test" keeping in view the sensivity aspect of hair dye to an individual.

The members unanimously agreed to include the listed items for inclusion in Schedule 'S' to the Drugs & Cosmetics rules as per the specifications formulated by the BIS.

**Item No. 20 : Consideration to adopt BIS as statutory marking for cosmetics.**

The Chairman exhorted the members to examine whether Scheme of Cosmetics Testing Laboratories as available under BIS can be utilized to examine testing of cosmetics as the facilities available under drugs control administration is inadequate and requires strengthening. The Chairman emphasized that this has become all the more necessary because concern has been expressed in different fora like consumer associations, parliament and lay press that the quality of cosmetics should be ensured.

BIS informed that their certification scheme is voluntary in nature. Further sampling, inspection, etc. are rigidly carried out by the BIS so as to ensure that the products once certified under BIS meet up the specifications laid down by them and quality cosmetics are available to the consumers.

After finding that the members have divergent views on the matter, Chairman accepted the proposal of FDA, Maharashtra that it may be left to the individual stakeholders if they would like to adopt the scheme subject to the consent of the industry.

**Item Nos. 21 to 25 : Items Nos. 21 to 25 proposed by Chandigarh administration could not be discussed as the concerned member was not present.**

**Item No. 26 : Consideration of the question of permitting to manufacture under cosmetics licence toilet soaps labeled as bathing bars with less than 60% TFM specifications of which were given by BIS (IS 13498 of 1992).**

The matter has already been discussed Item No. 13.

**Item No. 27 : Consideration of the question whether tablets containing same active ingredients but having different colours can be permitted to be manufactured and packed in one single container by assigning one batch number.**

The Drugs Controller, Goa informed that he has received a test report issued by the Govt. Analyst, Maharashtra under a batch containing tablets having different colours, but same ingredients, was declared to be of standard quality.

It is for the consideration of the members to discuss whether such practice of manufacturing tablets having same ingredients but different colours would be marketed under a single batch.

After discussion, the Chairman requested DC, Goa to furnish a copy of the said test report to Commissioner, FDA, Maharashtra for further examining the matter.

The Chairman also requested FDCA, Gujarat to give a write-up regarding marketing of formulations containing different colours but same ingredients. However, Chairman told the members that the same batch of finished products should not be marketed in different colours.

**Item No. 28 : Consideration of the question whether liquid oral preparations with sugar syrup can also contain saccharine as an additional sweetening agent.**

Drugs Controller, Tamil Nadu informed the committee members that patent and proprietary preparations containing saccharine should not be permitted in paediatric syrups as was decided in the earlier DCC. However, Drugs Controller Andhra Pradesh felt that no artificial sweetening agent should be permitted.

**Item No. 29 : Consideration of the question whether pastes containing tobacco labeled as 'Creamy Snuff' can be considered as cosmetic under the provisions of Drugs & Cosmetics Act, 1940.**

Drugs Controller, Goa informed the members that number of *defacto* tooth pastes containing tobacco and labeled as 'Creamy Snuff' were being marketed in the country. Further, he felt that the said preparation containing tobacco was actually circumventing the notification dated 30.4.92 under which tooth pastes containing tobacco have been banned and as such creamy snuff should have come within the purview of this notification.

After discussion, the Chairman agreed with the members that 'creamy snuff' being marketed should not be treated as 'drug' or 'cosmetics'.

**Item No. 30 : Consideration of the question as to whether drugs can be permitted to be repacked in the pack sizes other than those specified by Drugs Controller (India) (vide Circular No. 19013/4/80-D dated 12.3.82)**

The Chairman agreed with the members that the list of drugs permitted to be repacked and circulated by Drugs Controller (India) needs revision so far as inclusion of pack sizes of various drugs is concerned.

The Chairman clarified to Drugs Controller, Andhra Pradesh that pack-sizes specified other than those under the list can be permitted in case such pack-sizes were to be supplied against tenders to the Govt. institutions as 'Hospital packs' only.

In such cases the member should rather use his discretion and may give permission keeping in view the end-use of various categories of drugs.

The Chairman agreed with the members that in order to update the list, a Sub-Committee may be constituted with the following composition :

| | | |
|---|---|---|
| Drugs Controller, Orissa | - | Chairman |
| Drugs Controller, Delhi | - | Member |
| Drugs Controller, Punjab | - | Member |
| Drugs Controller, Karnataka | - | Member |
| Drugs Controller, Bihar | - | Member |
| Drugs Controller, Rajasthan | - | Member |

The Chairman requested Drugs Controller, Orissa to finalise the recommendations of the Committee within 3 months.

**Item No. 31 : Consideration of the proposal to amend Rule 96 to include assignment of date of expiry (DOE) to bulk drugs under Scheduel 'P' of the Drugs & Cosmetics Rules, 1945.**

Drugs Controller, Goa explained to the members that Rule 96, as well as Schedule 'P', was silent regarding assigning of expiry date on bulk drugs. Such an anamoly resulted in the availability of large number of bulk drugs which do not bear any DOE. Consequently, the preparation being formulated from these bulk drugs were being assigned DOE as 5 years from date of manufacture rather it should have been from the date of manufacture of bulk drugs.

Drugs Controller, Delhi concurred with the views of Drugs Controller, Goa that at present large number of bulk drugs were available in the market without stating the DOE on them.

It was proposed that clause (vii) of Rule 96 may be suitably amended so that the bulk drugs not included in Schedule 'P' can also be assigned the specific expiry date.

The Chairman requested the members to opine whether Rule 96 required any changes to ensure effective mechanism of stating DOE on bulk drugs.

The Commissioner, FDA, Maharashtra proposed that clause (vii) of Sub-Rule (1) to the principal Rule 96 may be suitably amended to incorporate the words "Drugs & their preparations" in the said sub-rule.

After discussion, the members agreed that the proposal given by the Commissioner, FDA, Maharashtra for making suitable changes under Rule 96 of D&C Rules.

While discussing the matter, the Drugs Controller, AP proposed that Chairman may also consider revising Schedule 'P' also.

He also requested the Chairman to intimate to the State Licensing Authorities (SLAs) the details of shelf-life data submitted by the manufacturer of 'New Drug' as the same was invariably not found appended at the time of receipt of approved drugs.

The Chairman agreed to send the same.

**Item No. 32 : Consideration of the question whether colour and sweetening agents can be permitted to be used in the preparation of oral rehyderation salts (ORS) bicarbonate / citrate which are official in IP Addendum – II.**

The Drugs Controller, Goa informed the members that presently the colours and sweetening agents in ORS are not mentioned in IP but such preparations containing these two agents were available in the market.

After discussion, the Chairman clarified that the matter shall be referred to I.P. Committee for further examination.

**Item No. 33 : Consideration of the question whether the cough preparations can be permitted to be manufactured with the parameters other than those which had been recommended under Item NO.14-A(XIV) in the 26$^{th}$ DCC Meeting.**

After discussion, the Chairman clarified that the SLAs shall be reminded that the recommendations and the decisions taken under the said item of 26th DCC should be adhered to for the sake of uniformity in the implementation of the decision taken in the said meeting.

The Chairman told the members not to licence cough preparations other than those recommended by the 26th DCC. He requested Drugs Controller, Goa to send details of such cough preparations to the SLAs and to this Directorate for necessary action.

**Item No. 34 : Consideration of the question whether shampoo preparations claiming to cure dandruff could be permitted to be manufactured as drugs.**

The Drugs Controller, Goa informed the members that presently number of companies were marketing shampoo preparations claiming on their labels that they cure dandruff.

The Chairman clarified that "tall claims" being made by the companies that shampoos could cure dandruff cannot stand to scrutiny.

The members were advised that the shampoos should be considered as "Cosmetics".

**Item No. 35 : Clarification sought whether cosmetics products can be permitted to claim on the label the net contents of the preparation in the container stating the legend "when packed".**

Drugs Controller, Goa explained to the members that samples of various cosmetics (creams, soaps, etc.) were being declared to be not of standard quality by the Govt. Analyst as they did not conform to "Net Contents".

The manufacturers agrued that "when they pack" these products, were very much conforming to the parameters of stating net contents. However, due to environmental factors, or other conditions, the products were likely to undergo significant variation in respect of Net Contents. Further, Rule 148 makes it incumbent upon the licensees to declare the net contents which should be expressed in terms of weight for solid, semi-solid and fluid measures for liquids.

The Chairman sought opinion of the members on the points raised by Drugs Controller, Goa. Drugs Controller, A.P. and Orissa stated that there was no such provision to declare "Net Contents" as "when packed". They felt that the exact amount of net contents must be stated on the label instead of the legendry words "when packed".

Drugs Controller, Delhi objected that the test reports (TRs) on cosmetics should rather not declare the product as a whole not of standard quality but failure of net contents should be given as a 'Note' in the test reports.

Commissioner, FDA, Maharashtra supported the contention that 'net contents' had to be stated even though there may be less weight due to moisture, evaporation, etc.

The Chairman agreed with the opinion of the members that it was the responsibility of the manufacturer to ensure the quality and quantity of the product manufactured and sold by him.

**Item No. 36 : Consideration of the question as to whether "EAU DE PERFUME" containing alcohol content less than the labeled claim could be declared as sub standard.**

The members disagreed with the Drugs Controller, Goa that the licensee whose cosmetics product was found to contain less percentage of alcohol did not come within the ambit of the provisions of Drugs & Cosmetics Rule, 1945.

The Chairman agreed with the suggestion of Drugs Controller, Karnataka that the licensee attracted the provisions of misbranded cosmetics in addition to contravention of provisions of Drugs & Cosmetics Rule, 1945 once the cosmetic had been found to be not complying with the percentage of alcohol.

**Item No. 37 : Consideration of laying down guidelines for plant and machinery required for manufacturing diagnostic reagents together with their labeling requirements.**

Drugs Controller, Goa explained to the members that in lieu of any guidelines for requirements of premises, plant and equipments required for the manufacture of diagnostic reagents, SLAs had to accept the specificications furnished by the manufacturer on the products intended to be produced.

Further, in absence of such specifications, the quality of these products could also not be ensured through sampling.

After discussion, the Chairman agreed with the members to constitute a sub-committee having the following composition :

Commissioner, FDA, Maharashtra - Chairman

D.C.Goa, Gujarat, West Bengal,

| | | |
|---|---|---|
| Delhi, Andhra Pradesh | - | Members |
| DDC(I), Headquarters | - | Member Convenor |

The Chairman proposed that the sub-committee should examine various aspects of diagnostic kits and reagents which may also include their definitions, classifications, state of art in their manufacture together with their specifications, various aspects to control them, nodal testing agency, etc.

The Sub-Committee may also co-opt BIS as they were already carrying out an exercise in this regard. The Chairman requested FDA, Maharashtra to submit report within 6 months.

**Item No. 38 : Consideration of the question whether drugs reported to be not of standard quality due to serious defects need to be published in the leading newspapers.**

FDCA, Gujarat informed the members that on instructions from the State Govt., those drugs which were manufactured by other States and reported sub-standard with a serious defects were prohibited from further sale in this State and publicised with a view that the concerned State Drugs Controller, manufacturer as well as the lay consumer comes to know of it.

FDCA, Gujarat sought opinion of other members whether they were also taking the same steps.

Commissioner, FDA, Maharashtra informed that they were also publishing the information as per the specific recommendations made by Lentin Commission. The copies of the listed drugs were also being sent to the hospitals, chemists and druggists association, etc. for the sake of effective recall of the stock of batches if any lying with them and to put stay from further use of drug.

DC, Orissa also confirmed that they were also following the same practice.

DC, Rajasthan and Himachal Pradesh informed that they were sending the test reports to the concerned member States.

DC, Karnataka proposed that information instead of being published, could be sent telegraphically.

DC, A.P. felt that no useful purpose would be served by publishing and proposed it would be sufficient in case concerned member State was informed about the nature of the defect, distribution pattern, etc.

The Chairman appreciated the mode of action taken by way of publication the quality of drugs in the media for the sake of interest of the consumers. However, he cautioned that too much publicity, might create an apprehension in the lay public mind. Further, unnecessary queries might also be raised.

After discussion, DCC decided that *status quo* may be maintained in the matter.

**Item No. 39 : Consideration of the question to furnish protocols of tests applied by Govt. Analyst (GA) on patent and proprietary (P&P) medicines.**

After discussion, the members agreed with Director (CDL) that in case the method of analysis on the sampled drug was not available with the GA, the concerned inspector, who has drawn and sent the sample, should be requested to ask the manufacturers to furnish the analytical methods concerning the P&P medicinies. In case such details were not forthcoming, the sample may be tested as per the method available with them and report sent.

The members requested DC(I) to write to all the GAs not to take up the matter as far as possible directly with the manufacturer whose sample was being tested by the GA and the GA may ask the method of analysis through concerned SLA.

**Item No. 40 : Consideration of the question regarding action to be taken for serious cases of drugs reported to be sub-standard.**

The Chairman requested FDCA, Gujarat to furnish the details of the copy of the judgement together with the copies of the complaint and counter affidavit filed in the case for further perusal of DC(I).

**Item No. 41 : Consideration of the question to adopt norms for allocation and misuse of the allocated narcotic drugs.**

The Chairman informed the members that one of the norms adopted for allocation of narcotic drugs and psychotropic substances was on the basis of earlier consumption certification by the member State.

After discussion, the members proposed that a sub-committee may be constituted to lay down the norms for allocation and misuse of narcotic drugs.

The Chairman agreed with the proposal and constituted a sub-committee having the composition as per Item No.(11).

Further, the Chairman requested that the material furnished by FDA in this regard to the Task Force constituted in his State may be sent to the Chairman of the sub-committee for their information and necessary action.

Likewise, DC, Kerala was also requested to pass on the write-up on the abuse potential of narcotics to the Chairman for his perusal.

The Chairman requested that sub-committee should send their recommendations within 6 months.

**Item No. 42 : Consideration for laying down norms concerning advertisements on T.V. over-emphasising results of Ayurvedic & OTC drugs.**

FDCA, Gujarat sought opinion of the members whether Code of Ethics can be laid down in respect of Advertisements which were being telecast in Mass-Media creating a wrong impression in the minds of the viewers of better and quick results of certain drugs.

As for instance, telecasting of 'VICKS' was cited where an impression was being created by way of advertisement as if it was no more a drug but a 'Candy' for consumption of children. Likewise 'Swad' was being offered to the family as a "grab" after dinner.

The Chairamn agreed with the concern expressed by the members that given in respect of advertisement being shown by the multinational firms need be regulated through code of ethics.

It was agreed that DC(I) will take up the matter with the concerned association and Ministry.

**Item No. 43 : Consideration of the question whether samples of drugs showing visible defects need be referred to Govt. Analyst (GA).**

The Commissioner, FDA, Maharashtra and Drugs Controller, Karnataka opined that in such cases samples may be sent to G.A. and on the basis of the observations reported by him on the sampled drugs, further action could be initiated.

Director CDL informed that since samples fail to comply with the parameters under "Description", Test reports declaring the samples to be sub-standard with visible defects was being issued.

Drugs Controller, Orissa shared the opinion with the members that seizure of the impunged drug be made; submission made to the court and a

complaint filed against the defaulter. Such contention was being accepted in the court of law.

The members agreed with the views expressed by the Drugs Controller, Orissa.

**Item No. 44 : Drugs Price Control Order.**

Chairman requested **Sri B. Balgopal Dy. Secretary, Department of Chemicals and Petrochemicals** to explain the various provisions of Drugs Price Control Order as well as drug policy.

Mr. Balgopal explained that under the present Drugs Price Control Order, Small Scale Industries are exempted from obtaining price approval under DPCO. He also explained that a new Drugs Price Control Order will soon be published and the number of items will also be reduced from the purview of new Drugs Price Control Order. Further, he explained that under the existing Drugs Price Control Order, non-scheduled drugs are not covered for fixation of price and it is not possible to scrutinize the prices of non-scheduled formulations.

Mr. Balgopal also clarified that various notifications have been issued on fixing of the maximum price for bulk drugs. If any stockist sells the bulk drugs more than a price fixed by the Government, action can be initiated by the respective State Government.

**Item No. 45 : Consideration of the question to bring Ayurvedic, Unani, Siddha drugs under the purview of sales licences.**

Drugs Controller, Jammu & Kashmir informed the members that large number of sales-outlets dealing in ISM had come up. However, they were also stocking drugs under Modern system. Since inspectors for ISM were different from the Modern system of medicine, it becomes irregular for such inspectors to draw samples of drugs under the ISM. This gave an apprehension that drugs of doubtful quality were being passed off to the unwary patients.

Adviser Ayurveda clarified the member that Aswas, Aristam & Sura preparations shall be notified under sales licence.

After discussions, members agreed to form a sub-committee to go into various aspects of Ayurveda medicine including sales licence and herbal medicines standards.

The sub-committee shall consist of – Drugs Controller, Gujarat, Drugs Controller, Delhi, Drugs Controller, Kerala, Drugs Controller, Bihar,

Director, PLIM, Ghaziabad, K.C.Sharma, ADC(I) Headquarters, Dr. P.D.Sethi, Director, CDTL, Bombay – Convenor.

**Item No. 46 : Consideration of the proposal to take action on irrational and harmful drugs prohibited from sale under Section 26-A by one State but were being manufactured and marketed by another State.**

The Chairman clarified to the members that the prohibition of the drug was based on its composition and not on the brand name which an individual firm perhaps built up after much stranuous efforts. Under the circumstances, it was likely that the composition and contents of the products might have been streamlined as per the notification but brand names continue to remain the same.

Further, courts might have given stay orders in a particular case. Drugs Controller, Jammu & Kashmir stated that it was observed that some States did allow scuh combinations with the result that manufacturers located in his State were at disadvantage to market the same.

The Chairman requested members to take up the matter with such States giving details of the matters to them under intimation to DC(I) for the sake of follow-up action.

The members cited the cases of Sol Pharmaceuticals and Lark Laboratories for examining their combinations by DC(I). Further, the members were of consensus view that whenever one State finds the irrational combination being sold in their State, such case should be referred to the State under, whose jurisdiction the manufacturer is located, for the purpose of examining its rationality.

The Chairman advised the members that the combination permitted by one State should not be blindly followed by the other State. It was further proposed that such irrational combination, if any, moving in their State could be got examined by the State Advisory Committee which included Pharmacologist, as an Expert Member, and their views may be intimated to DC(I).

The members impressed upon the Chairman to constitute a Standing Expert Committee to examine the whole issue of permitting and marketing in the interState commerce movement of irrational combination of drugs.

The Chairman agreed to constitute a Expert Standing Committee for the purpose to examine irrational drugs, banned combinations containing drugs of doubtful efficacy, which continued to be sold in the market etc. The Chairman constituted the Committee having the following composition :

| | |
|---|---|
| Commissioner, FDA, Maharashtra | Chairman |
| D.C. Bihar, West Bengal, Karnataka, Gujarat, Tripura | Members |
| DDC(I), CDSCO, South Zone | Member Convenor |

The Chairman requested the members to send the list of combination which were irrational and were moving in the market; combinations considered to be irrational etc. to the Member Convenor.

The Chairman further clarified that the said committee would act as a 'Follow-Up Committee' and would facilitate easy phasing out of irrational combinations under the monitorship of Member Convenor.

**Item No. 47 : Consideration regarding implementation of notification of marketing of Mrtisanjivani Sura and Mahadrakhyasaba preparations in packing of 30 ml. and 120 ml. only.**

The Chairman clarified to D.C., Orissa that Govt. have already published notification controlling the said preparations thereby restricting their pack sizes to 30 ml. and 120 ml. so as to stay put to their misuse. However, High Courts of Calcutta and Patna have, in recent W.Ps filed by different manufacturers, had stayed the operation of the implementation of this notification. The Central Govt. has filed counter affidavits to get the stay vacated.

During discussion, DC, Orissa desired that necessary steps may also be taken to insert the words "Ayurveda" under rule 157 (ii) (d) which the Chairman agreed to refer to DTAB (Ayurvedic) for their further consideration, etc.

**Item No. 48 : Consideration of the proposal for conducting regular training programmes for inspectors in blood banking and quality control of blood products.**

The Chairman, on the request of the members, agreed to organize under CDSCO regular training programme of Inspectors in matters concerning with blood banking and related blood products in view of the recent changes made under the provisions of Drugs & Cosmetics Rules, 1945.

He further informed the members that it was intended to work out such programmes of training periodically under the aegis of zonal officers so that sufficient number of inspectors could be trained exclusively for the said notified category of drugs.

The Chairman further requested the members to write to the concerned zonal officer for finding out the Schedule of carrying out such programmes for their Drugs Inspectors.

During discussion, the members also requested Chairman to devise a similar type of programme to a set of Inspectors regarding WHO certification scheme so that the trained Drugs Inspectors could also be exclusively deputed by the State Govt. for the said purpose.

The Chairman informed the members that zonal officers would be also requested to organize such programme for training inspectors with regard to grant of WHO certificates.

**Item No. 49 : Prices of bulk drugs under DPCO, 1987.**

Already discussed vide Item No.44.

**Item No. 50 : Consideration of framing uniform policy pending abolition of loan licensing system with regard to manufacture of drugs in units other than the parent firm.**

DC, Orissa requested members to devise ways and means to curb the practice by which these manufacturers, who did not have their own facilities but were still getting certain items manufactured from the companies who have adequate facilities to produce those drugs. Thus the parent manufacturer was mentioning on their label as if they were marketing the product manufactured on behalf of other units.

The members joined with DC, Orissa in expressing the concern that this was another way of circumventing loan licensing system. Commissioner, FDA, Maharashtra informed that they were granting loan licenses as per the court directions. The fresh licences or renewal of licences were being granted subject to the clearance of court case or decision taken by Supreme Court or amendment, if any, made with regard to notification whichever was earlier.

The Chairman felt that no retrogrative steps should be taken for this matter specially with regard to grant of laon licences for LVPs and bulk drugs in view of the earlier decision reached by the DCC.

Further DC(AP) and FDCA, Gujarat informed the Chairman that loan licences relating to bulk drugs had been stayed by the Courts in their States.

After discussion, the Chairman requested Commissioner, Food and Drugs Administration, Maharashtra to give a write-up on the manner of grant or renewal of loan licences in his State so that the same could be circulated for information and necessary perusal by the other members.

**Item No. 51 : Consideration of the question of action on statutory samples of drugs which got expired following delayed reference or during the tenure of investigation.**

Drugs Controller, Orissa desired to know the mode of action that should be initiated on cases where no opportunity could be given to the principal manufacturer for eliciting its comments on its quality or where the sealed portion of sample could not be got tested by him as it crossed its life period.

The Chairman informed the members that such samples, which are suspected to be spurious or grossly sub-standard or adulterated, shall be taken up with the concerned Govt. Testing Laboratory for speedy analysis and the investigations shall be carried out immediately so as to avoid delay.

**Item No. 52 : Allocation of funds to State Govt. for strengthening testing facilities, etc.**

The Chairman explained, in detail, to the members the various steps being taken by Central Govt. to provide or augment the testing facilities in different States.

While concluding the discussion, the Chairman requested the members to intimate the utilisaion of the funds already allocated to different States for the said purpose for information of Central Govt.

Chairman also informed the members that under centrally sponsored scheme about Rs.2.35 crores have been distributed to most of the States since 1991. Under 8$^{th}$ Five Years Plan, Rs.7 crores have been allocated for testing facilities to the States.

He hoped that by end of 8$^{th}$ Five Plan all the States will get their due share for modernising their testing facilities.

**Item No. 53 : Consideration of the question to make offences cognizable and non-bailable under the provisions of Drugs & Cosmetics Act, 1940.**

After discussion, the members felt that the provisions already given under the Act are adequate for the purpose.

The Chairman asked the individual member to approach their Government in case they desired to include special provision under the Drugs and Cosmetics Act as was being done by State of U.P. and West Bengal.

**Item No. 54 : Testing facilities for blood products and diagnostic reagents, etc.**

Chairman informed the members that imported Blood Products are tested for freedom from HIV Antibodies in the notified laboratories before release. Further, an institute is being set up by Central Govt. by the name 'National Institute of Biologicals' for quality control of diagnostic reagents.

**Item No. 55 : Charging fees for issue of GMP Certificate / WHO GMP Performance Certificate.**

After discussion, the members felt that there seemed to be no worthwhile purpose to prescribe fees as issue of said certificates by the authorities was not under the provisions of Drugs and Cosmetics Rules, 1945.

**Item No. 56 : Consideration of the question to amending Rule 96 (1) (vii) for fixing an expiry date.**

This has already been discussued under Item No. 31.

**Item No. 57 : Consideration of stating minimal and maximal limit of assays to Amplicillin under Indian Pharmacopoeia.**

The Chairman clarified to the members that such steps were already taken in the Addendum issued under Indian Pharmacopoea.

**Item No. 58 : Consideration to restrict to express content of liquid oral preparations in terms of 5 ml. under Rule 96 of Drugs and Cosmetics Rules, 1945.**

Drugs Controller, Rajasthan explained to the members that presently certain dosage forms especially the liquid oral preparations contained active ingredients in terms of one or two table spoon full (i.e. 15 – 30 ml.) where as it is more convenient to express formulations containing active ingredients in terms of 5 ml.

The members proposed amendment in the rules which otherwise defeated very purpose of Schedule 'V' under which the minimum and maximum limit in respect of Vitamains preparations were mentioned.

The members desired that necessary amendment to entry (a) to clause (iii) of subrule (1) to Rule 96 may be carried out so that the words "or multiple

thereof" where deleted. This omission would only allow liquid oral preparations in terms of 5 ml. only.

The Chairman agreed with the proposal made by the members in this regard.

**Item No. 59 : Uniform guidelines in making accused for contravention of the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.**

Drugs Controller, Rajasthan desired the views of the members for uniform implementation of the provisions relating to launching prosecustion against the defaulters for contravening provisions of Act and Rules thereunder. He further desired to know whether the licensee, together with the technical persons incharge, could also be made as accused as they were also responsible for the manufacture and testing of drugs.

The members felt that exact action against the individual involved only be taken on the basis of investigations made in the specific case. Drugs Controller (Delhi Administration) felt that the technical personnel might not come within the ambit of the law because of Master/Servant/ liability relationship.

After discussion, the Chairman requested Drugs Controller, Delhi and FDCA, Gujarat to give a write-up on the matter for further examining the matter.

**Item No. 60 : Consideration of the proposal to ban fixed dose combinations of Codeine Phos with Phenothiazine derivaties in cough linctus.**

Already discussed under Item No.11.

**Item No. 61 : Consideration of criteria for herbal cosmetics.**

The Chairman informed the members that some of the State Drugs Controllers were receiving applications for grant of permission to manufacture herbal cosmetics and as such Drugs Controller (India) has been asked to lay down criteria for naming a cosmetic a herbal cosmetics.

The DC(I) informed the State Drugs Controllers that various parameters should be kept in mind before permitting a herbal cosmetic.

On being requested by the Chairman, BIS clarified that herbal cosmetics are being so named because the manufacturers are including in their preparations certain herbs in them as additional components.

The specifications formulated by BIS do not make any therapeutic claim but includes standards for chemicals incorporated in the said herbal cosmetics. They informed that herbs added to these cosmetics can not be controlled through any specific standards. The Chairman requested BIS to give a write-up on the matter to further examine it.

BIS agreed to send the write-up on the matter.

**Item No. 62 : Specifying date of expiry for bulk drugs under Schedule 'P' of the Drugs & Cosmetics Rules, 1945.**

Already discussed under Item No.31.

**Item No. 63 : Uniform implementation of the guidelines framed by sub-committee of DCC relating to drugs declared to be not of standard quality.**

The Chairman again requested the members to keep in view the guidelines framed by the Sub-Committee and accepted by DCC concerning drugs declared to be not of standard quality.

**Item No. 64 : Consideration of the question of proposal to extend testing facilities available with the approved institutions for the samples being sent by Govt. and traders.**

Drugs Controller, Delhi stated that the testing facilities available with the approved institutions could only be availed by the licensed manufacturers of drugs and cosmetics and not by the Govt. institutions, traders, etc. Drugs Controller, Delhi proposed that Rules may suitably be amended in this regard.

After discussion, the members felt that there seemed to be no need to bring out any change in the Rules on the samples submitted for tests other than the licensed manufacturers of drugs and cosmetics.

**Item No. 65 : Consideration of the question of omitting provision relating to setting up of testing laboratories by the cosmetic manufacturers under Schedule M-II under Drugs and Cosmetics Rules, 1945.**

Drugs Controller, Delhi Administration explained to the members that in view of the notification published on 11.8.92 concerning GMPs to Cosmetics, the provisions had been made in the Schedule itself that it was mandatory for a cosmetic unit to set up a testing laboratory in his own premises whereas Rule 139 of the said rules stipulates that the applicant firm shall 'either provide a testing laboratory of its own or shall make arrangements with an approved institutions for testing of raw materials and finished cosmetics'. It was, therefore, felt that both the provisions

made under Schedule M-II may be omitted and arrangements of testing facilities be made discretionary for the applicant firm as stipulated under Rule 139. This had become necessary because of the fact that large number of cosmetic manufacturers were in the cottage industries.

The members discussed the matter and felt that cosmetics manufacturer should continue to be insisted upon to provide a testing laboratory in their own premises. However, the provisions made under the Schedule M-II may be omitted and sub-rule (5) to Rule 139 havnig clauses (i) and (ii) should be substituted appropriately so that each licencee has testing facility in its own premises. However, cosmetics requiring testing by sophisticated instrumentation techniques may be permitted to opt their testing at the approved institutions as is available under Rule 74 and 78 of the Drugs & Cosmetics Rules, 1945.

**Item No. 66 : Consideration of licensing of in-vitro diagnostic products.**

The matter will be further examined by this Directorate.

With the permission of the Chair, the following agenda were also taken :

## KERALA

**SUPPLEMENTARY AGENDA ITEM NO. 1 :**

**(i) Consideration of revision of licence fees in respect of different categories of drugs.**

DC, Kerala informed the members that in order to meet up the meager revenue resources and stringent economic measures, it was porposed that the existing licence fees in respect of different forms needed to be enhanced. The revision was considered necessary because the fees were prescribed long time back.

The Chairman pointed out to the members that case was already pending with the High Court at Patna which had taken strong objection to the enhancement of fees in respect of particular category of drug. Under the circumstances it would not be appropriate to go for revision of fees under the D & C Rules, 1945.

**(ii) Prescribing fees for WHO / GMP Certification system.**

Already discussed under Item No.55.

(iii) **Consideration of amending Sub-Section (1) (a) of the D&C Act empowering States to prescribe own fee for grant / renewal of drug licences.**

The Chairman after seeking views from Commissioner, FDA, Maharashtra requested him to send circular or procedure in respect of the said matter for information and perusal of the DC, Kerala under intimation to DC(I).

**SUPPLEMENTARY AGENDA NO. (2) :**

**Consideration to include provisions under Section 33 EEC to prescribe standards of quality in respect of Ayurvedic / Unani and Siddha drugs as well as licence fees for Ayurvedic drug sales premises.**

The Chairman informed the members that the matter concerning ISM shall be brought to the notice of DTAB (Ayurveda) for their consideration and necessary action.

**SUPPLEMENTARY AGENDA NO. (3) :**

**Consideration to reduce period of experience in cases of Graduates and Post-Graduates of Pharmacy under Rule 44.**

The Chairman informed the members that the matter concerning amendment to Rule 44 in the form of draft notification was being processed by the Ministry of Health & F.W. The members were requested to give their comments as and when the draft notification is published and sent to them for further consideration of DC(I).

**SUPPLEMENTARY AGENDA ITEM NO. (4) :**

**Consideration of exemption under Entry 5 of Schedule K of the D&C Rules, 1945.**

The Chairman informed the members that the matter concerning amendment of entry 5 of Schedule K of the D & C Rules, 1945 in the form of draft notification was being processed by the Ministry of Health & F.W. The members were requested to give their comments as and when the draft notification is published and sent to them for further consideration of DC(I).

**SUPPLEMENTARY AGENDA ITEM NO. (5) :**

**Consideration for laying down criteria for grant of fresh retail licences under 64(2) of the D & C Rules, 1945 with regard to restricting grant of licences on the basis of population etc.**

The Chairman informed the members that the said matter was considered in the earlier DCC meeting.

**SUPPLEMENTARY AGNEDA ITEM NO. (6) :**

**Consideration of the question to state address of the cosmetic manufacturing unit under Rule 148 of the D & C Rules, 1945.**

DC, Kerala sought opinion of other members whether similar provisions as available under Rule 96(i) (iv) also should be available in respect of cosmetics under Rule 148.

After discussion, the members agreed that necessary provisions were required to be made by amending appropriately Rule 148 of the D & C Rules, 1945.

**SUPPLEMENTARY AGENDA ITEM NO. (7) :**

**Consideration of the proposal to depute expert in the grant or renewal of licences for the manufacture of LVPs.**

DC, Kerala informed that presently DC(I), as Central Licence Approving Authority (CLAA), was asking the SLAs to seek expert advice of a pharmacologist attached to the medical hospital, as an expert, at the time of grant or renewal of licences in respect of LVPs. DC, Kerala, proposed that an expert from the pharmaceutical field or from the pharmaceutical institution could be also be opted as an expert for the said purpose.

The DC, Tamil Nadu, Andhra Pradesh, Gujarat concurred with the views of DC, Kerala.

After discussion, the Chairman clarified that the adoption of expert in the said field was done with the concurrence of decision taken by the Ministry of Health & FW at the time of purchase of LVPs for the Govt. institutions from those firms which were adopting BFS technology in the manufacture and supply of I.V.fluids in plastic containers.

The Chairman accepted the advice of members that experts may be chosen from the pharmaceutical institution, in addition to the present practice of selecting an expert as a pharmacologist form the medical hospital, located in the concerned States.

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

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**Annexure – I**
**(Item no. 2 of the 29th meeting)**

**Statement showing the action taken on the decisions taken at the 28th Meeting of the Drugs Consultative Committee held in New Delhi on the 16th & 17th July 1992.**

| NO. | SUBJECT DISCUSSED | DECISION TAKEN | ACTION TAKEN |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| 1. | 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 was accepted with the following modifications. | The guidelines were issued to all the members vide Dte. letter No. X 19013/6/92-D dated 13/5/93 for information and necessary compliance. |
| | (i) Review of the existing guidelines in respect of samples found to be not of standard quality | The Chairman informed that the draft notification is being published regarding the standards, manufacturing facilities, GMPs and testing facilities for medical devices. | The final notification is under process. |
| | (ii) List of items following under disposable transfusion sets | | |
| | (iii)Curtailing the number of licenses required for stocking distribution or sale of drugs | The Chairman advised that the same committee goes through the various aspects on the amendments proposed | The report of the subcommittee is still awaited. |
| | (iv)Expert Standing Sub- | | |

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| | Committee | in the report and furnish the required draft amendments to Drugs Controller (India) for further action.<br><br>The Chairman agreed with the suggestion to constitute an Expert Standing Committee as follows :-<br><br>Commissioner,<br>Chairman<br>Food & Drugs Administration,<br>Maharashtra.<br><br>Director,<br>Member<br>Drugs Control,<br>West Bengal.<br><br>Drugs Controller,<br>Member<br>Delhi.<br><br>Drugs Controller,<br>Member<br>Karnataka. | Expert committee constituted and their report on the items referred by 28th DCC is placed for consideration. |
| 2. | Suggestions received from the State Drugs Controllers to various amendments to Drugs & Cosmetics Act and Rules (Report of the subcommittee | The suggestions made by the subcommittee may be accepted. | DTAB did not agree to the proposal. |

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| | constituted by 25th Drugs Consultative Committee meeting). | | |
| | a) Amendment to Sec 19 (3) of the Drugs & Cosmetics Act. | | DTAB did not agree to the proposal. |
| | b) Amendment to Sec 22 (2A) of the Drugs & Cosmetics Act. | | DTAB did not agree to the proposal. |
| | c) Amendment to Sec 23 (4) of the Drugs & Cosmetics Act- procedure of sampling. | | DTAB did not agree to the proposal. |
| | d) Amendment to Sec 33- Revision of licence fees. | | DTAB did not agree to the proposal. |
| | e) Deletion of the word 'NFI' from Rule 96(1)(c). | | DTAB did not agree to the proposal. |
| | f) Consideration to amend Rule 65 prescription register specially maintained. | | DTAB did not agree to the proposal. |
| | g) Deletions of provisions to Rule 66 (1) | | DTAB did not agree to the proposal. |
| | h) Display of Board at prominent place- amendment to Rules 65, 67, 67-G, 74, 74-A, 74-B, 78-A, 88-H, 142, 142-B and 150-T | | DTAB did not agree to the proposal. |

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| 3. | Recommendations of National Society for prevention of blindness, India, New Delhi. | A subcommittee was constituted to examine the other suggestion like failure in sterility test, variations in pH and drop size of ophthalmic drops etc. | DTAB did not agree with regard to colour code, symbol of eye on the label and squeeze type plastic vial. However with regard survey of various ophthalmic preparations Director, CDL, Calcutta who conducted the survey have opined that all the samo;es passed the test "antimicrobial preservative effectiveness". |
| 4. | Test regarding net volume / content in respect of P&P formulations. | The matter is referred to a subcommittee. | The subcommittee has submitted its report. |
| 5. | Competent Technical Staff for the manufacture of Homoeopathic medicines. | The Committee agreed to amend Rule 85(E) of the Drugs and Cosmetics Rules. | DTAB at its 43rd meeting held on 29/3/93 discussed the issue and approved amendment to Rule 85 (E). |
| 6. | Amendment to Schedule M of Drugs and Cosmetics Rules. | The matter was referred to a subcommittee under the Chairmanship of Commissioner, FDA, Maharashtra | The subcommittee has submitted its report. |
| 7. | 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. | The matter was placed before 43rd DTAB meeting held in March 93. They wanted further examination of the matter by BIS. |
| 8. | Continued marketing of "Dover's Powder". | The committee agreed that the manufacture and sale of Dovers Powder should be banned under Section 26-A of the Drugs and Cosmetics Act. | DTAB have approved the amendment and the case is being processed. |

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| 9. | Rule 64 - condition to be satisfied before a licence in form 20 & 21 is granted. | The matter was referred to Expert Standing Sub-Committee. | The subcommittee has submitted its report. |
| 10. | Control over sale of ayurvedic drugs. | The Chairman told the members that the above suggestion will be placed before the Ayurvedic Drugs Consultative Committee. | The matter has been referred to Advisor (Ayurveda) for necessary action. |
| 11. | Amendment to parts VII to X, XIV, XV of the Drugs & Cosmetics Rules. | The matter requires further examination. | |
| 12. | Maintenance of records of Homoeopathic medicines containing alcohol. | It was decided to place the matter before the Homoeopathic subcommittee of the DTAB. | DTAB homoeopathic subcommittee is under constitution and the point will be placed at the first meeting of the reconstituted Homoeopathic DTAB subcommittee. |
| 13. | Schedule M – Provision for powder preparations for internal / external use separately. | It was decided to refer the matter to Expert Standing Committee. | The subcommittee has submitted its report. |
| 14. | Revision of fees under Schedule B of the Drugs & Cosmetics Rules. | The matter was referred to a subcommittee under the Chairmanship of Director, CDL, Calcutta. | The subcommittee has submitted its report. |
| 15. | Experience for grant of licences in Form 20B and 21 | It was decided to refer the matter to Expert Standing Committee. | The subcommittee has submitted its report. |

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| | B. | | |
| 16. | Change of nomenclature of Drugs Inspectors | The Chairman told the members to forward the views of the Drug Inspectors Association of their States together with detailed reasons for such a change | No proposal has been received by this Directorate so far. |