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Government of India

## Ministry of Health and Family Welfare

# Minutes of the Drug Consultative Committee Meetings

(From XII to XVIII Meetings)

Central Drug Standard Control Organisation
Directorate General of Health services
New Delhi

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PART I



PART II

## MINUTES OF THE 14TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT PANAJI, GOA ON THE 8TH AND 9TH FEBRUARY, 1971

The Chairman welcomed the members and said that the Drugs Consultative Committee should meet at least once every six to eight months so as to ensure more intimate contacts among the Drug Control Authorities and intensive dialogue on drug control measures in the country. Listing the developments worthy of note in the Drug Control Organisation on an All India basis, he mentioned that the Drug Control Administrations of Maharashtra, Gujarat, Mysore, Andhra Pradesh and Delhi had further streamlined their organisations, Tamil Nadu had decided to have a complement of 50 Drugs Inspectors in their State. The State Government of Tamil Nadu have also made a plan provision for setting up their own testing laboratory. Rajasthan, for the first time, made arrangements for recruiting six inspectors including a senior inspector and that the State will be very soon having qualified and competent inspectors.

Based on information fed back by the Central Drug Control Officers in the various zones, the Chairman said that States such as Madhya Pradesh Punjab, Orissa, Rajasthan, U.P., Delhi and Tripura, had availed themselves fully of the facilities extended by the Zonal Officers and inspectorate of the Central Drugs Standard Control Organisation. Quality control consciousness about drugs was making its impress on drug manufacturers. The tone of control had improved particularly in States such as Andhra Pradesh, Madhya Pradesh and Rajasthan. He expressed the hope that continued joint efforts of the Central and State Drug Control Authorities would surely lead to further positive gains in this direction.

## Item - 55

Control over the manufacture and sale of Stains and Chemical Agents used as Diagnostic Agents under the Drugs and Cosmetics Act.

The question whether microscopic reagents, Stains and diagnostic agents should be controlled under the provisions of Drugs and Cosmetics Act was discussed. It was felt that while legally there may be no objection in controlling such substances under the Act, the question as to how best their standards could be regulated from the practical point of view needed examination.

The Chairman stated that the decision to control stains and diagnostic agents was taken mainly because complaints regarding their inadequate performance had been received. Besides, the reaction of the public if diagnostic reagents such as Benedix solution, teststrips for determining the content of sugar in urine do not give satisfactory results must not be ignored.

After discussion it was agreed that control for the present should be limited to very essential diagnostic reagents and stains which are commonly used by the hospital or the general public, sera etc. used for determination of blood groups, preparations for oral or internal use for diagnosis of the diseases etc. The Committee further decided that the Deputy Drugs Controller (India), Central Drugs Control Organisation (West Zone) should discuss the subject further with the Drug Control authorities in Maharashtra and Gujarat and draw up a list of reagents to be regulated and compile standards for them.

Side by side with the developments he also sounded a note of caution that State Drugs Controllers should be very vigilant about and stringent with the new firms that come up to ensure that they make quality products.

The Chairman brought to the notice of the members, two complaints about drug control measures made by the Public Accounts Committee of Lok Sabha. In one case tetracycline injection manufactured by M/s Cyanamid and purchased by Medical Store Depot, had become discoloured before the date of expiry was crossed. The other one related to sugarcoated ferrous sulphate tablets the coating of which had peeled off resulting in 'spotting' of tablets. The findings of the Public Accounts Committee give the impression that in the first case though Gujarat had not prosecuted the firm the Central Drug Control Administration could have taken up the prosecution.

In the second case it was difficult to convince the Public Accounts Committee of the therapeutic effectiveness notwithstanding the fact that they had developed spotting. Its view was that the firm had been licensed to manufacture the tablets in question when they did not have the technical competence to do. Another view of the Committee was the Central Drugs Laboratory, Calcutta had taken four months to send its test report. He asked the State Drug Controllers to be extra vigilant about such matters and to make sure that such small incidents are not allowed to develop into major developments and added that preventive steps in this connection could be taken only by organised and all coordinated efforts between the States and the Central Drugs Control Organisations. He further stressed that communications requiring personal attention of State Drugs Controllers and the Director Central Drugs Laboratory should be addressed through demi official letters, enquiries where deaths had occured should be pursued vigrously where there was something serious or urgent, an indication to this effect together with the background of the case against which the sample was sent for test could be given to the Government Analyst separately so as to enable him to accord priority for testing such samples.

Continuing the Chairman said that the manufacturing facilities and activities of firms which supply drugs to Civil Departments of the Govern-

ment, E.S.I.S., Railways, Armed Forces Medical Stores, Medical Store Depots and other State supplies should be kept under close survelliance. Such firms should not be allowed to supply drugs to Government and other major purchasing organisations if they do not have their own testing facilities. He informed the members of the Committee that D.G.S. & D had introduced a condition that no order should be placed with firms who have not been marketing their products quoted for by them at least for 2 years. He wished that as far as possible Drug Control Administrations should also advise other local purchasing organisation in the States to adopt a similar procedure while making purchases.

Stressing the need for quality control on drugs manufactured by small scale units, the Chairman informed the Committee that a Study Group which had been constituted by the Central Government under the Chairmanship of Shri Ramakrishnayya, Joint Secretary, Ministry of Petroleum and Chemicals and of which he was also a member, went into the measures to ensure satisfactory quality control measures over drugs produced by small scale sector of the pharmaceutical industry. One of the recommendations made by the Committee was that it was in the interests of such manufacturing units to have their own analytical and testing laboratory and that the Drugs Rules which at present allow manufacturing units to have their products tested by an outside laboratory should be suitably amended. A time-lag of three years has been suggested by the Committee for the revised rule to be brought into force. The Chairman stated that this recommendation should be brought to the notice of the Drug Manufacturers so that the latter could start from now onward to develop their own testing facilities. Reverting to firms which supply drugs to major Government purchasing agencies, the Chairman pleased that firms manufacturing sterile preparations should have their own testing facilities, especially arrangements to ensure that the processing operations where necessary are conducted under sterile conditions and that facilities for checking plate-counts etc. are available.

The Chairman informed the members that lack of accommodation at the Central Drugs Laboratory was the main factor which mainly limited the laboratory's capacity for testing samples and that it would take about two to three years to complete a new building of the Central Drugs Laboratory.

The Central Drugs Laboratory's work-load has become unmanageable and he requested the States to make use of the facilities available for testing of drugs with other laboratories e.g. Drug Testing Laboratory, Gujarat, Drug Testing Laboratory, Maharashtra, The Mysore State Drug Testing Laboratory and the Central Indian Pharmacopoeia Laboratory, Ghaziabad. The Chairman said that the Central Government would however be glad to arrange for the training of analysts from states at the Central Drugs Laboratory.

The Committee was also informed by the Chairman that the Central Government had recently decided to assume increased responsibility over the quality of drugs manufactured in the country, particularly over the drugs moving in inter-state commerce and that in pursuance of this decision the strength of the Central Drugs Inspectorate is also intended to be increased from 6 to 50, over the next two or three years. He assured the members that standing arrangements for the training of Drugs Inspectors from the states so as to bring their technical administrative and legal knowledge uptodate will be established. Referring to the Manual for the guidance of the Drug Inspectors, he complimented that the manuals which are being used in Maharashtra, Gujarat and Delhi are good and promised to make available a comprehensive 'All India Manual' for the guidance of Drugs Inspectors. Continuing, the Chairman regretted that it had not been possible for the various sub-committees which were appointed by the Drugs Consultative Committee during its last two meetings to complete the tasks entrusted to them. He promised to expedite their reports.

The subject of quality control over drugs including the drugs used by hospitals was discussed further. The concensus view on testing facilities available with manufacturing firms and drugs used by hospitals is given below :-

**Testing facilities available with manufacturing firms :**

(i) All manufacturers should be advised in their own interests to create in a period of two years, testing facilities of their own at least for testing of non-biological products. For tests involving expensive equipment, States may permit the use of the testing facilities available with them.

(ii) Manufacturers who do not maintain their own testing facilities particularly for Schedule C and C I products should **not** be allowed to manufacture sterile preparations and should not be recommended for purchase by Government hospitals.

**Drugs used by Hospitals :**

a. If drugs are manufactured for use of patients by Hospital in Hospital Pharmacies, the conditions of manufacture should be stringently controlled in the same manner as private manufacturers of similar items are controlled.

b. Facilities for sterilisation services in Hospitals should be frequently inspected by the Central and State Drugs Inspectors.

c. The manner in which drugs are ordered, stored and issued by the Hospitals should also be subjected to frequent checks so as to ensure that purchases are made in phased instalments to obviate financial loss to hospitals, that drugs which require special storage conditions are stored properly and that drugs which bear a date of expiry are issued or turned over by arrangement with manufacturers in such a manner that hospitals are not saddled with any time-expired stocks.

d. The responsibility for ensuring "good manufacturing practices" including sterilisation facilities in hospitals and management of hospitals stores should be fixed on specific members of the staff in hospitals who should also be made to maintain the necessary registers and records.

e. In view of the general reluctance exhibited by Hospital Superintendents to inspections of hospital stores and manufacturing facilities in hospitals by Drugs Inspectors, it would be helpful if Union Health Minister writes demi-officially to State Health Ministers requesting the latter to issue instructions to Superintendents of hospitals to extend all co-operation and provide facilities to Drugs Inspectors for inspecting Hospital Stores and Hospital Pharmacy. The fact that mutual co-operation between Drugs Control Authorities and Hospital authorities would ultimately contribute to improvement in hospital services in the country should be emphasised. A similar communication

should also be sent from Union Health Secretary to the Health Secretaries of States.

The Drugs Consultative Committee also recommended that in hospitals with 200 beds and above, a Chief Pharmacist who should be atleast a graduate in pharmacy should be appointed and given gazetted status with an appropriate salary scale. The Chief Pharmacist should have a thorough background, knowledge of drugs, their substitutes, storage conditions etc. and should be able to assist the hospital administration in maintaining the quality of drugs supplied to patients. The Committee also recommended that similar facilities should also be made available in smaller hospitals.

The annual reviews of the activities of the State Drugs Control Organisations received were thereafter circulated to the members. Similar reports from the Central Drugs Standard Control Organisations at the ports and the zonal offices were also circulated.

## AGENDA ITEM - 1

Conformation of the minutes of the last meeting of the Drugs Consultative Committee :

The minutes were confirmed.

## AGENDA ITEM - 2

Action taken on the recommendations made by the Drugs Consultative Committee at its last meeting.

The action taken on the minutes of the thirteenth meeting of the Drugs Consultative Committee was explained by the Chairman. It was agreed that Form 34 of the Drugs Rules should be amended in the manner recommended by the Government Analysts of Gujarat, Maharashtra and Central Drugs Laboratory, Calcutta. Shri R. Balasubramanian, Deputy Drugs Controller, West Zone, Bombay was requested to consult the head of the testing laboratory in Maharashtra and to forward the necessary amendment to Form 34.

The need for testing antibiotics on a planned basis with a view

to studying their life periods was stressed by the Chairman who suggested that the following plan for sampling of antibiotics could be adopted :-

1. Samples should be confined to preparations of Tetracycline and Penicillin.
2. Samples of drugs which are nearing the date of expiry as far as possible should be drawn.
3. All samples should be taken from the open market.
4. Samples should be drawn from areas representing different climatic conditions such as (i) humid areas (Assam, Cochin), (ii) Hot and humid areas (Bombay and Calcutta) (iii) Predominantly hot areas such as Nagpur Madras (iv) Veryhot and cold areas such as Chandigarh.
5. Samples should be drawn in triplicate to be tested at (i) Drugs Laboratory, Baroda (ii) Analytical Laboratory, Maharashtra and (iii) Central Drugs Laboratory, Calcutta or Central Indian Pharmacopoeia Laboratory, Ghaziabad.

Shri B.V. Patel suggested that samples to be tested should be of the same batch and kept at different places in the Country.

The Chairman agreed that Shri Balasubramanian should discuss with the Commmissioner Food and Drug Administration, Maharashtra the names of products, the name of manufacturers, the type of products, the areas from which samples should be drawn, the methods of analysis et. etc. so that the scheme of sampling of antibiotics preparations may be drawn up and executed.

The question as to what storage conditions should be insisted upon for vitamin products in the light of the storage conditions laid down for vitamins in USP XVIII was discussed. It was agreed that rather than prescribing storage conditions for vitamin preparations manufacturers of vitamins should by law be required to conduct stability studies on the preprations and assign life periods to them. The stability studies carried out on the particular formulation must take into account the conditions of temperature (not less than 40°C) and humidity obtaining in the country throughout the year. It was further

agreed that study of stability data by manufacturers of vitamin preparations should be made a pre-requisite condition to the grant of a manufacturing licence. Regarding the existing vitamin formulations manufacturers should be allowed sufficient time lag to carryout such stability studies.

Regarding sulphacetamide preparations, the Chairman said that The Drugs Laboratory, Baroda had planned to study the stability of Sulphacetamide Sodium Eye drops using a concentration of Sulphacetamide Sodium 30% under the following conditions :-

**Antioxidant to be employed :**

i. Sodium thiosulphate in different concentrations with and without EDTA.

ii. Sodium metabisulphite in different concentrations with and without EDTA.

**Temperature :**

iii. At room temperature

iv. At 37°C.

Same as above with nitrogen and without nitrogen.

Time : 0 hour to six months.

The Central Indian Pharmacopoeia Laboratory, Ghaziabad proposed to carryout parallel studies on the following lines :-

i. The stabilising effects of sodium metabisulhite in concentrations of 0.1 to 0.5 percent in ophthalmic solutions of sulphacetamide sodium (both 10% and 30% will be studied.)

ii. The efficacy of non-irritant alternative stabilisers, like ascorbic acid, sodium thiosulphate etc. will be examined.

iii. The effect of temperature and light upon the stability of stabilised solutions will be examined.

iv. As the hydrolysis of sulphacetamide Sodium will be quicker at higher pH, an attempt will be made to buffer the solutions to a lower pH.

v. The effect of chelating compounds when used in small quantities alongwith the stabilisers will be studied.

vi. The solutions will be sterilised both by autoclaving and by filtration and the effect of heat sterilisation, if any, on the stability of the solutions with regard to crystal formation and discolouration will be studied.

The Committee agreed that ISI standards for Cotton gauze absorbent, which had been prepared in consultation with various consumer interests, should be adopted in the Drugs and Cosmetics Rules and that a copy of ISI specifications should be circulated to State Drugs Controllers. Draft standard for absorbent cotton wool should also be circulated.

## AGENDA ITEM - 3(a)

Question whether pharmcopoeial preparations should be permitted to be marketed as patent and proprietory medicines with slightly different composition.

The Committee agreed after discussions that for pharmacopoeial preparations, the standards should be those prescribed in the Pharmacopoeia. Any variation from the pharmacopoeial standards should be specially approved by the Licensing Authority.

Side by side with the examination of the rationale and stability of the combination products the Committee felt that the most imortant point to be checked was the composition of the ingredients. It is necessary to ensure that the active ingredients in the combination are present in therapeutic and prophylactic quantities and that any variations from these norms are fully justified by manufacturers from the therapeutic point of view. The over-all policy should be to discourage multiplicity of patent and proprietary medicines.

Realising the fact that the Drugs Control Authorities in some states desire that action against combination products having constitutent ingredients in sub-therapeutic doses should be backed by appropriate rules, the Chairman drew attention to the fact that the standards specified in the Schedule to the Act permit the introduction of Rules for this purpose and that suitable draft rules covering this aspect will be circulated to the State Drugs Control Authorities.

Turning to the question of combination of drugs which had been withdrawn by the Federal Food and Drug Administration in the USA on the ground that they were therapeutically ineffective, the Chairman stated that the main attack by the U.S.A. Drugs Control Authorities was on combinations of different antibiotics or combinations of antibiotics with sulphas. He said that the question whether similar action should be taken in our country needed cautious examination and that hasty action on the lines followed by the F.D.A. might result in criticism from the medical profession.

After discussion it was agreed that the question whether the preparations which had not been permitted to be sold in the United States of America should also be prevented from being sold in this country should be examined from an All-India angle by the Central Drug Control Organisation. The Chairman agreed to place the matter before the Essential Drugs Committee which was being constituted by the Ministry of Health very soon and that pending a decision being taken by that Committee, no action need be taken to withdraw the preparations from the market, especially as the medical profession has not so far expressed any opinion in favour of such an action.

On the general question of licensing the manufacture of combination drugs by drug manufacturers, the Chairman drew the attention of the members to the decision taken on this subject at 12th meeting of the Drugs Consultative Committee held at Cochin whereby it was necessary to consider them as New Drugs and that till such time necessary rules for the approval of formulae of patent and proprietary medicines were introduced in the Drugs & Cosmetics Rules, the State Drugs Control authorities should screen the formula of patent and proprietary medicines at the time of grant and renewal of licences keeping in mind the following three guide lines :-

a. The ingredients in patent or proprietary medicines should be present in therapeutic/prophylactic quantities or in quantities which have scientifically been established to have synergistic effect.

b. The ingredients present shoud not be incompatible and the preparation should be stable;

c. The preparation as a whole should be harmless and safe.

Some of the members represented that manufacturers who market patent and proprietary medicines containing ingredients in strengths lower than the therapeutic or prophylactic doses justify the marketing of such preparations on the ground that they are meant for paediatric use. In many cases, the legend "For paediatric use only" had also been imprinted on the label of such preparations.

The Chairman stated that so long as the ingredients were present in quantities recommended for paediatric use (The Indian Pharmacopoeia or the National Formulary of India should be considered as guides for determining paediatric dosage), such preparations will have to be allowed on the distinct condition that they are labelled with the legend "For childrens' use only". The term "paediatric" will **not** be understood by any consumer.

## AGENDA ITEM - 3 (b)

Provision may be made for granting permission to manufacture additional items for repacking of drugs other than those in Schedule C and C I by regular licence holders in Form 25.

It was explained that in Form 25, under the name of the drug to be manufactured, which would include repacking also, each item will be required to be specified separately. As such even if a drug is to be repacked subsequent to the grant of the licence, the licensee will be required to obtain permission from the licensing authority. As such it would not be necessary to make any amendment in the Rules.

## AGENDA ITEM - 4

Consideration of the decision taken at the 4th meeting of the Drugs Controllers of Southern States to the effect that conditions for the grant of loan licences should be brought out and provision made in this regard.

The Committee reviewed the earlier decision and came to the conclusion that if quality control measures are to be maintained effectively, loan licences should be restricted and ultimately done away with, except with regard to certain special processing operations such as Strip-packing, Soft-gelatine encapsulation, radio-sterilization techniques etc. for which facilities in the country are limited in scope.

A rule should be framed banning the grant of loan licences. It was also agreed that to give effect to this decision suitable provision should be made in the Drugs Rules so as to strengthen the hands of the Drugs Control Authorities. Pending such an amendment of the Rules, loan licences should be restricted only to parties located within the State except for special processing operations. Where a loan licence is granted, it should be ensured that a competent person representing the loan licensee is present at the time of manufacture of their preparations.

## AGENDA ITEM - 5

Consideration of the strengths other than the usual strengths as mentioned in the pharmacopoeia.

This question had already been considered (under item 3(a) of the Agenda).

## AGENDA ITEM - 6

Central Drugs Control Organisation and its inspectorate - the question how best the Inspectors could assist the states in ensuring uniform and stringent enforcement of the provisions of the Drugs & Cosmetics Act and Rules thereunder :

The Chairman stated that the State Drugs Control authorities were anxious that the Central Drugs Standard Control Organisation should

play a more active role in assisting the organisation at the state level. In particular, it had been represented that follow-up action on drugs reported to be not of standard quality should be taken by the Central Drugs Standard Control Organisation to its logical conclusion and States should not be burdened with this task. After discussion the following lines of action were agreed upon :-

1. Adverse test reports on drugs moving in inter-state commerce will be investigated by the Central Drugs Standard Control Organisation to the maximum extent possible by inspection of firms independently as far as possible and jointly with the State Drugs Control Authorities when asked for. Priority will be given to reports of serious deficiencies and to cases of firms whose products have come to adverse notice repeatedly. The inspection reports will be forwarded to the State Drug Control Authorities in duplicate so as to enable them to take necessary action against the manufacturer for rectification of the deficiencies observed during the inspection and if necessary also warn them or suspend their manufacturing licences. If it was felt that the firm had not taken adequate action to rectify the deficiencies pointed out to them, more stringent action than in the first instance by way of suspension or cancellation of the manufacturing licence should be taken by the State Drug Control authority.

2. In regard to serious complaints from other states about the quality of products manufactured in a particular state, the Drugs Control authorities of the latter should take legal proceedings against the concerned firms in the matter. If the State's staff position does not permit it to conduct the prosecution the Central Drugs Standard Control Organisation will do so and the State should assist in the matter by placing their legal machinery and police personnel at the disposal of the Zonal Inspectorate.

3. Strict action against firms which deal in tinctures which are harmful or ineffective and barbiturates without proper accounts as to their purchase and disposal may be taken by the Zonal Officers. Similar action will be taken against preparations which contain ingredients in sub-therapeutic doses or which are positively harmful. Prosecutions in respect of spurious drugs or drugs which have been manufactured under conditions not conforming to good manufacturing practices and which should more appropriately be considered

as "adulterated drugs" should be launched by the State Drugs Control authorities without delay. The State Drugs Control authorities as well as State Governments will be approached about such cases.

Arising out of discussion on this subject, it was pointed out by Shri. Rangnekar that in quite a number of cases detailed and time consuming enquiries into the history of manufacture of Penicillin supplies have to be instituted on the basis of complaints received about the quality of Penicillin. In most of the cases the complaints originate on Pencillin sensitivity reaction incidence. It would be best for all concerned, particularly the manufacturers whose products become suspect and who in many cases have to withdraw supplies complained of from the market, if an on the spot enquiry could be conducted to elucidate whether the complaint is in relation to a single case of Penicillin sensitivity and whether the same batches of drugs have been used on other patients with no untoward results. The Committee agreed that the Director of Medical and Health Services of every state should be requested to constitute a committee of the physicians to enquire into cases of serious complaint **e.g.** to investigate the correct reason for reported sensitivity due to penicillin etc., to enquire whether the same batch was used elsewhere and the results thereof and then take necessary action.

## AGENDA ITEM - 7

Consideration of the proposal that the use of second hand battles in the manufacture of parenteral preparations should be banned.

Shri. Narasimhan raised the question whether second hand bottles randomly purchased from dealers in junk could be permitted to be used for the manufacture of transfusion solutions. While the Committee was not in favour of such a policy, it saw no objection to manufacturers of transfusion solutions being permitted to recall its bottles from hospitals etc. and re-using them after subjecting them to sterilisation procedures.

## AGENDA ITEM - 8

Consideration of the suggestion that the provisions of the Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 may be suitably

amended so as to prohibit publications of advertisements by indigenous medical practitioners who claim to cure or treat incurable diseases without referring to the names of drugs used or manufactured by them.

The Chairman explained that the amendment sought to be made in the Drugs and Magic Remedies (Objectionable Advertisements) Act would tentamount to controlling the medical profession and as such was beyond the scope of the Act which was aimed at regulating advertisements of drugs.

## AGENDA ITEM - 9

Consideration of the suggestion that the standards for patent and proprietary preparations as laid down in the Second Schedule to the Drugs and Cosmetics Act be suitably amended so as to provide for the tests such as disintegration time, weight variation, sterility etc.

The Chairman informed Shri. Narsimhan that an amendment on the lines proposed by him was already under consideration of the Central Government.

Shri. Patel said that combinations of antibiotics and other non pharmacopoeial combinations of drugs should also be subjected to test for toxicity, Antidepressor effect etc.

The Chairman said that this aspect would also be taken into account.

## AGENDA ITEM - 10

Consideration of the suggestion that effective measures should be taken to tighten up the control over the sale of Psychotropic drugs as the abuse of such drugs is increasing in the country.

The Chairman stated that the intention was to bring psychotropic drugs under stringent control under the Drugs and Cosmetics Rules and that a Sub-Committee of the Drugs Consultative Committee was seized of the subject.

## AGENDA ITEM - 11

Consideration of the question whether specific provision is necessary to be made in the Drugs Rules for publication of the names of manufacturers or dealers whose licences have been suspended or cancelled for information to Associations and other bodies as is done in the case of convictions by Courts under Section 35 of the Drugs and Cosmetics Act, 1940.

The Committee was of the view that where licences are suspended or cancelled, factual information should be circulated by the Licensing authority to the Associations of dealers as decided at the Cochin Conference held in September, 1968.

## AGENDA ITEM - 12

Consideration of the suggestion that provisions may be made to amend Form 16 of the Drugs Rule so as to include the seizure of incriminating articles in the said form.

The Committee noted that Form 16 does not enable seizure of incrimating articles which might constitute evidence for the offence and agreed that Form 16 should be amended suitably.

## AGENDA ITEM - 13

Consideration of the question whether consequent on the ban imposed on certain drug combinations of Antibiotics by F.D.A. (U.S.A), similar restrictions will apply in this country and if so the question of their uniform enforcement and the scope of items to which the restriction will apply :

The item was discussed alongwith agenda item 3(a). The Chairman said that the decision taken under item 3 (a) would apply in this case also.

## AGENDA ITEM - 14

a. Consideration of the question whether conditions pre-requisite to the grant of loan licences are being uniformaly implemented.

b. Consideration of the question whether combinations of antibiotics and special processes like capsulation can be allowed under loan licences.

This item was discussed alongwith agenda item 4. The Chairman said that the decision taken under item 4 will be applying in this case.

## AGENDA ITEM - 15

Consideration of the procedure that should be followed in licensing drugs for manufacture when manufacturers already licensed in one state shift to another state.

The Committee was of the view that no specific guide lines can be laid down in this regard which could be applied to all cases and that it was for the state licensing authority to satisfy himself about the adequacy of information on the drugs proposed to be manufactured by firms migrating from one state to another.

## AGENDA ITEM - 16

Consideration of the question of fixing time-limit for appeal to the State Government against the orders of cancellation or suspension of licence for selling homeopathic medicines (sub-rule 2 or Rule 67-H).

The Committee observed that the existing sub-rule of Rule 67-H does not provide any time-limit within which an appeal against cancellation or suspension of licence should be preferred. The Chairman said that this was an omission and that this would be looked into. It was further agreed that sub-rules (2) of Rule 67-H and sub-rule 2 of Rule 85-H of Drugs Rules would also require to be amended in this connection and that a time limit of 3 months may be provided for submission of appeals.

## AGENDA ITEM - 17

Consideration of the procedure that may be followed in withdrawing batches of transfusion fluids containing particulate matter.

Non-availability of rubber bung of suitable quality, it was represented by members, is mainly instrumental in development of particulate matter in transfusion fluids. A solution, it was urged, should be found whereby manufacturers who have taken all reasonable precautions on the quality of packing materials and on the processing lines are not penalized for no fault of theirs while suitable steps should simultaneously be taken to prevent the use of transfusion solutions which would clearly constitute a health hazard. After discussion it was agreed that manufacturers of transfusion solutions should be made to display a cautionary note on the labels of transfusion bottles reading 'NOT TO BE USED IF SUSPENDED MATTER IS PRESENT'.

The Chairman reiterated the decision taken at the earlier meeting of the Drugs Consultative Committee that if the presence of particulate matter in a particular batch is confirmed in another place, that batch of the drug should be withdrawn from the market notwithstanding the fact that many of the bottles in the batch might not have developed particulate matter. The committee unanimously agreed that manufacturing licences of firms which manufacture transfusion solutions should not be cancelled or suspended so long as Drugs Control authorities are satisfied that the manufacturing firms had taken all reasonable precautions to check on the quality of containers and closures and that the in-process checks and counterchecks exercised by the manufacturers were in confirmity with accepted "Good Manufacturing Practices". Cancellation or suspension of manufacturing licences in such cases might result in shortage of supplies of a vital product.

## AGENDA ITEM - 18

Consideration of the question whether tablets which are official in BP or BPC but are not official in IP should be exempted from complying with the specifications regarding uniformity of diameter of tablets.

It ws obseved that in BP 1968, the specifications for uniformity of tablets are mentioned in the imperial system while in BP addendum 1969 the same specifications have been given in the metric system. As a result of the change-over to the metric system of measurements the present sets

of dies and punches need not, it was decided, be replaced by new ones resulting in national waste.

The Chairman observed that as long as the quality of the tablets remained unaffected, the specifications according to BP 1968, may be permitted for the time being and the manufacturing firms allowed suitable time lag to fall in line with the revised specifications.

## AGENDA ITEM - 19

Consideration of the question whether Blood Transfusion Assembly (receiving set) disposal type should be considered as drugs within the meaning of section 3 (b) of the Drugs & Cosmetics Act, 1940.

Sterile desposable transfusion sets used for administering transfusion solutions to patients are made out of PVC or Polyethylene material. The Committee was of the view that it was desirable to safeguard the consumer against the toxic effects of such material and also to assure the consumer of the sterility of the contents. Keeping this in view, it was agreed that these transfusion sets should be deemed to be drugs and controlled accordingly in the same manner as clinical thermameters.

## AGENDA ITEM - 20

Consideration of the question whether Ferrous Sulphate tablets, thinly shellac coated should be considered as alternative to sugar coated Ferrous Sulphate tablets.

Shri. Rangnekar said that the I.P. required that Ferrous Sulphate tablets should be either plain or sugar coated. Thinly shellac coated tablets are neither plain nor sugar coated even though they are observed to disintegrate within one hour as required for sugar coated tablets.

After discussion, the Committee agreed that the use of non-toxic coating such as thin shellac coating may be allowed in the case of Ferrous Sulphate tablets.

## AGENDA ITEM - 21

Consideration of the question whether cosmetics containing antiseptic agents like hexachlorophene should be classified as drugs within the meaning of section 3 (b) of the Drugs & Cosmetics Act.

The Committee was of the view that when a cosmetic makes therapeutic claims, it should be considered as a drug. On the otherhand, if the labelling suggested that it contains an antiseptic it should be treated only as a cosmetic.

## AGENDA ITEM - 22

Consideration of the question whether manufacdture of combinations of Pencillin and Sulpha Drugs and Penicillin with Streptomycin should be banned in this country.

This had already been discussed under item 3 (a) of the agenda.

## AGENDA ITEM - 23

Consideration of the suggestion that some of the entries in the Schedule to the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 which do not set out the scope of the diseases covered by these entries should be recast or amended.

The Chairman said that if the Commissioner, Food and Drugs Administration, Maharashtra furnished a new list of the diseases or disorders for incorporation in the Schedule to the DMR (OA) Act, it would be examined in consultation with the Medical Council of India and the British code of Advertising.

## AGENDA ITEM - 24

**Veterinary Preparations**

a. Whether drugs manufactured for human use when used for veterinary purpose in the same packings need be subjected to labelling as per veterinary requirements.

It was decided that sale of drugs made for human use when required for veterinary purposes may be permitted without insisting on requirements of labelling as for veterinary use.

b. Whether veterinary feeds containing antibiotics should be considered as drugs within the meaning of section 3 (b) of the Drugs & Cosmetics Act, 1940.

The Chairman said that a reference in this regard had already been made to the Animal Husbandary Commissioner and that after his views on the subject have been received, the question would be examined by a sub-committee of the Drugs Technical Advisory Board.

c. Whether names and addresses of patients entered in the register as required under Rule 65 (3) (d) and Rule 65 (10) (b) of the Drugs & Cosmetics Rules 1945 should be replaced by the name and address of the owner of the animals for veterinary drugs.

The Committee agreed with Shri. Rangnekar's suggestion that the names and addresses of patients entered in the register as required under Rule 65 (3) (d) and Rule 65 (10) (b) of the Drugs Rules should be replaced by the name and address of the owner of the animals for veterinary drugs and that necessary provisions to this effect should be made in the Drugs and Cosmetics Rules.

d. Whether pharmacist should honour the prescription issued by stockmen for veterinary products, as these stockmen do not possess requisite qualifications as required under the relevant notification.

Considering that there was a paucity of Registered Medical Practitioners in Veterinary Hospitals particularly in the rural areas, the Committee agreed that the prescriptions issued by the stockmen should be allowed to be honoured by the Pharmacists/Chemists.

e. Whether additional provision on the lines of provisions of Rule 65 (12) should be made for storage of veterinary products.

The Chairman agreed with the Committee that since the dosage of veterinary drugs are high as compared to dosage applicable to humans, products intended for veterinary purpose should be stored separately and that necessary provision on the lines of Rule 65 (12) should be made in this regard.

## ADDITIONAL ITEMS WITH THE PERMISSION OF THE CHAIRMAN

### ITEM - 25

Deletion of Rule 67 and forms 22, 23 from Schedule 'A' of the Drugs & Cosmetics Rules.

Shri. Pany pointed out that arising out of the deleting of the warranty clause in section 19 (3) of the Drugs & Cosmetics Act, Rule 67 alongwith forms 22, 23 Schedule A of the Drugs Rules should also be deleted.

The Chairman informed Shri. Pany that a decision to delete the warranty clause and the forms had since been taken and that the necessary amendments are under issue.

### ITEM - 26

Training of Drugs Inspectors for manufacturing Ayurvedic and Unani Medicines.

The Chairman informed Shri. Pany that training of Drugs Inspectors for enforcement of control over Ayurvedic and Unani Drugs may have to be undertaken by the States themselves. The detailed syllabus for training of Drugs Inspectors had been sent to States. The Chairman said that states like Madras, Kerala and Maharashtra have made arrangements for such training.

### ITEM - 27

Question of safe limit for the use of paraphenylene diamine in hair dyes.

Shri. Seth (Delhi Drug Control Administration) stated that Paraphenylene Diamine is a hazardous substance and certain manufacturers were coming with a formulae for hair dye with a high concentrationof this ingredient. He desired that a safe limit for the contents of paraphenylene diamine in Hair dyes should be laid down.

Shri. Patel said that a reference to Sagarin's book on Cosmetics would indicate the safe limit for content of Paraphenylene Diamine. The Chairman said. that certain International references on this subject would also be consulted and that the Committee would be apprised of the results of the study. Pending the decision of the Committee, displaying of a cautionary note as provided in Rule 149 of the Drugs Rules, it was agreed, should be insisted upon.

ITEM - 28

**Use of colours in capsules to be regulated.**

Shri. Seth said that information regarding the colours which should be used in the manufacture of Empty Gelatine Capsules was not available.

The Committee ws unanimous in recommending that use of approved colours only should be permitted in the manufacture of empty gelatin capsules.

ITEM - 29

Consideration that drugs coming under the provisions of Dangerous Drugs Act, 1930 be declared as Schedule H drugs under the Drugs Rules.

Shri. Gopalkrishna Murthy stated that drugs such as Morphine, Apo-Morphine fall under the Dangerous Drugs Act but these drugs cannot be considered as Schedule H drugs since there is no 'Asterisk Mark' against them in Schedule E.

The Chairman explained that 'Morphine' is a narcotic drug and there is an asterisk before the word 'Morphine' in Schedule E as given in the latest edition of the pamphlet Drugs and Cosmetics Act and Rules. The asterisk had however been missing in the earlier edition of the pamphlet due to printing

mistake. Apomorphine is not a Narcotic drug and as such the asterisk is not given before the name of the drug in Schedule E.

**ITEM - 30**

Consideration of making a provision for suspension and cancellation of Drugs Licences of firms which contravene the provisions of the Drugs Prices (Control) Order, 1970.

The Chairman explained that licences to manufacture the drugs by firms have to be regulated under the provisions of the Drugs & Cosmetics Act and the Rules thereunder. Parties contravening the provisions of another legislation e.g. Drugs Prices (Control) Order, 1970 cannot be penalised under the provisions of the Drugs Act & Rules.

**ITEM - 31**

Consideration whether certain oils marketed by small scale units under 'Amla, Brahmi, Castor Oil' names may continue to be permitted.

Shri. B.V. Patel said that certain Hair Oils manufactured by Small manufacturers were being marketed under the name of Amla, Brahmi or Castor Oil. He said that these hair oils mostly do not contain the oils which are claimed to be present but contain only mineral oils or other vegetable oils. In some cases, only about 5% of the genuine ingredients was found to be present.

The Chairman agreed that a sub-committee consisting of the following members should examine the subject and make suitable recommendations on the subject :-

Shri M.K. Rangnekar
Shri B.V. Patel — Members
Shri R. Balasubramanyan - Member Convener

The sub-committee should also discuss the subject with big manufacturers of Hair Oils and take their views into consideration.

## ITEM - 32

Consideration of allowing more time than 3 months for renewal of licences where there is change in the constitution of a firm due to demise of a partner etc.

The Chairman said that this aspect was considered earlier, and the decision taken was that the prescribed time limit of 3 months for issue of manufacturing licence in case of change of partnership should not be altered and that the party concerned should be asked to apply for grant of a fresh manufacturing licence.

## ITEM - 33

Sale of Schedule H and L drugs without prescriptions. Consideration of provision requiring prescriptions to be retained by dealers.

Shri. Chandrasekharan Nair said that it was difficult to check the sales of Schedule H and L drugs if the covering prescriptions are not maintained by the licensee. He desired that a provision in the Drugs Rules should be made whereby prescriptions of Schedule H and L drugs should be made to be retained by the licensee for a period of one year.

The Chairman said that it was difficult to compel dealers to retain prescriptions as the latter, apart from the medicines prescribed by the doctor, contained essential information such as dose schedule, dietary instructions for the patient. The purchaser would not therefore be willing to part with the prescription.

## ITEM - 34

The term 'Hospital Pharmacy' may be defined and this may be brought under licensing control and the conditions for such licences may also be prescribed.

The Committee agreed that working of the Hospital Pharmacy should be subjected to greater surveilliance. The Chairman said that, as already decided, Union Health Minister would write to the Health Ministers of State

and a similar communication would be sent to the Union Health Secretary to the Health Secretaries of the States.

Referring to the storage conditions of drugs in Medical Store Depots, the Chairman said that the Zonal Officer, North Zone, Ghaziabad would visit Haryana to see the facilities available with them.

**ITEM - 35**

Consideration whether permission to manufacture Ayurvedic Injections be given to manufacturers.

Dr. K.V. Gupta from Jammu & Kashmir said that certain manufacturers are approaching them for permission to manufacture Ayurvedic Injections and desired to know whether permission for such injectibles could be granted.

The Chairman informed Dr. Gupta that the case of Ayurvedic Injections should be treated as distinctly different from Homoeopathic injections. He said in certain states such as Punjab, permission to manufacture Ayurvedic Injections had been refused. Whenever applications for the grant of manufacturing licence for Ayurvedic injections are made, they should be considered 'New Drugs'. Apart from the rationale of administering drugs in an injectable form, the therapeutic efficacy and sterility of the product, and the toxicity of the preparation as a whole should be examined.

Dr. Toshniwal from M.P. enquired whether Ayurvedic patent and proprietary medicines could be permitted to be manufactured. The Chairman said that the question was being examined by the Ayurvedic and Unani Drugs Technical Advisory Board.

**ITEM - 36**

Amendment to clauses of Schedule K requiring Registered Medical Practitioners to maintain records for all drugs dispensed, name and address of the patient etc.

Dr. Sekhon of Punjab stated that there were reports of death caused by medicines prescribed by the Ayurvedic Registered Medical Practitioners who had been recognised as "RMP's" in his State. He said that the exemption provided in clause 5 of Schedule K for drugs supplied by Registered Medical Practitioners should be suitably amended so as to require Registered Medical Practitioners to maintain a record of all the drugs supplied and the names and addresses of patients. The Chairman said that the best solution to the problem would be to de-recognise under the Drugs Rules those categories of medical practitioners whose registration as Registered Medical Practitioner is not desirable rather than impose additional restrictions on bonafide members of medical profession, Dr. Sekhon could take up the matter with the Punjab Government.

ITEM - 37

Labelling of containers of Cosmetics with manufacturing licence number.

Dr. Sekhon desired that both the inner and outer packages of cosmetics should be required to show the manufacturing licence number so that the public and the enforcement authorities could be assured of the bonafides of the manufacturing unit. The Chairman said that necessary steps to implement the suggestion are already being taken.

The following points, arising out of the discussions of the port and Zonal Officers of the Central Drugs Standard Control Organisation held on 6.2.1971 at Goa were brought forward for consideration of the Committee.

a. Provision for licensing of manufacture of parenteral and ophthalmic preparations only if the firm have facilities for carrying out sterility tests.

The Zonal Officers brought to the notice of the Committee that during inspections carried out during past 2 years it was noticed that certain manufacturers were engaged in the manufacture of sterile preparation including ophthalmic formulations without having adequate facilities for carrying out sterility tests. The Committee agreed that it

was necessary to ensure that sensitive preparations for ophthalmic use are manufactured under sterile conditions which should be kept under constant monitoring and subjected to plate count check etc. Only such manufacturers who have adequate facilities for carrying out sterility tests should be licensed to manufacture the preparations in question. The Chairman impressed upon the members to ask the manufacturers who do not have adequate facilities for ensuring sterile conditions to equip themselves suitably and that a time-lag of one year should be allowed for this purpose.

b. Marketing of patent and proprietary medicines in plastic containers of 5 litre capacity.

The Zonal Officers observed that some products such as cough syrup, antibiotic paedriatic drops etc. were found to be marketed in many States in plastic containers of 4 to 5 litre capacity without having being marked with the words "For Hospital use only". Such a practice attracted the provisions of Rule 105 of the Drugs & Cosmetics Rules. The possibility of the stability of the preparations being affected by plastic containers cannot be ruled out.

The Committee was of the view that while marketing patent and proprietory medicines in containers other than those intended for retail sale, the containers of such preparations should be distinctly marked with the words, "FOR HOSPITAL USE". The manufacturers of such products, it was further decided, should be asked to carryout stability studies on the products when packed in plastic containers.

Winding up the proceedings, Shri. Rangnekar on behalf of the members of the Committee thanked Dr. Frias, Drugs Controller, Goa and his officers and other members of his staff for making excellent arrangements for the meeting of the Drugs Consultative Committee and for the comforts of the members. Endorsing the observations of Shri. Rangnekar the Chairman stated that the meetings would not have been a success but for the efforts put in by Dr. Frias and his colleagues.

It was tentatively fixed that the next meeting of the Committee should be held at Bhubaneswar in August, 1971 and that Shri. Pany, Joint Drugs

Controller, Orissa might consult his State Government in the matter and let the Chairman know the decision.

The meeting then terminated with a vote of thanks to the Chairman.