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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 II

MINUTES OF THE 12TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT COCHIN ON THE 19TH AND 20TH SEPTEMBER, 1968.

The Chairman made a reference to Shri S.K. Borkar's contribution to the development of Drug Standard Control in the country and in particular to the Drugs Consultative Committee. At his suggestion, the Committee placed on record its sincere appreciation of the services rendered by Shri Borkar to Drugs Standard Control and to the Committee.

The Chairman pointed out that the Central Government, in pursuance of the provisions contained in the Drugs and Cosmetics Act, had decided that the Central Drugs Control Organisation should participate actively and assist the States in the enforcement of Drugs Standard Control. The Central Organisation had accordingly embarked on a new phase of activity in collaboration with the States through the four regional officers and their Inspectors. He appreciated the assistance extended to the Central Organisation by the State Drugs Control Authorities. The Central Organisation, the Chairman continued, cannot do much unless it received the full support of the States.

The Chairman pointed out that the Committee on Drug Control had highlighted the deficiencies obtaining in Drug Control Administrations in various States and it had also given the staffing pattern that should be followed by each State. Most of the States had not been able to rectify the deficiencies in their organisations and augment their organisation to the desired extent. The Chairman requested the members to write to him about the present staffing pattern and also the steps taken to augment their organisation. The difficulties that are encounted in expanding the Drug Control Departments to the level recommended in the report of the Committee on Drug Control may also be mentioned in this letter. The Central Organisation, he said, would seek the assistance of the Government of India, Ministry of Health, Family Planning and Urban Development to take up the matter with the State Governments.

Continuing, the Chairman stated that for effective implementation of Drug Standard Control, adequate testing facilities are essential. The Central Drugs

Laboratory's work load is fairly heavy and it may not be possible for the Central Drugs Laboratory to undertake any additional load. The Drugs Testing Laboratory, Gujarat and Drug Testing Laboratory recently set up by Maharashtra have spare testing facilities and suggested that such of those State Drug Control Authorities as wished to avail themselves of their facilities might approach the Government of Gujarat and Maharashtra through their respective State Governments.

The Chairman expressed his concern over spurious drugs that have been reported to be moving in the market and in particular, to faked preparations purporting to be "Durabolin", "Chloromycetin". He informed the Committee that the Central Intelligence Department had already been alerted and it would be as well if the State Drug Control authorities exercise vigilance in this regard. The Police, in case it is felt necessary, would contact the State Drug Control authorities at the highest level in the course of their investigations.

The Chairman also dwelt on the need for correcting data supplied in the Indian Pharmacopoeia 1966 edition. He requested members, particularly the Drug Control authorities of Maharashtra, Gujarat and West Bengal where the industry was concentrated, to get in touch with the drug manufacturers located in their respective States and to ascertain the corrections that need to be made in the I.P. 1966.

Agenda Item - 1

Confirmation 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. (Refer Annexure I)

The action taken on the minutes of the eleventh meeting of the Drugs Consultative Committee was explained by the Chairman. Regarding the action taken on Item 1(v)

about the use of time-expired drugs, the members stated that it would be more appropriate if the Government of India, Ministry of Health, F.P. and U.D. wrote to the States on this subject. The recommendation made by the Drugs Consultative Committee on this issue could be forwarded to the States for the guidance of their Administrative Medical Officers.

Shri B.V. Patel, Director, Drugs Control Administration, Gujarat, stated that Governemnt Analysts had declared batches of Cholera Vaccine as not of standard quality because the vaccine did not contain 8000 million micro-organism per ml. This test in his view had a significance only in regard to freshly-made vaccines especially as there was bound to be lysis of the organisms subsequently, and if all the manufacturing units in the country are able to attain the standards recommended by the Central Research Institute, the test involving the count of micro-organism would become superfluous. The Chairman agreed that the test could not be considered as an index of the efficacy of the vaccine and that the Central Research Institute, Kasauli had recently succeeded in raising the organism count in cholera vaccine to 16,000 million.

Agenda Item - 3 (a)

Suggestion made by the Director, Drugs Control, West Bengal that if medicinal Glucose is controlled under the Drugs and Cosmetics Act, Medicinal Lactose should also be treated on the same footing and that both could be brought under control if the word 'Lactose' is removed from the exemption clause.

The Committee considered the question whether "Lactose" should be removed from the entry 10(ii) of Schedule 'K' wherein it has been described as an article of food as well as drug, on the same anology as "Glucose". Since Glucose for which no therapeutic claims are made is not considered as drug, the Committee recommended that 'Lactose' under identical conditions, should also not be considered as a drug. It was agreed that entry 10(ii) of Schedule 'K' should be amended suitably.

The Chairman said that following the decision taken, a rise in the prices of Glucose and Lactose could be expected. He however said that since Glucose was taken as a food supplement by invalids, it was necessary to make sure that the article

sold in the market was of standard quality. Standards for glucose had been laid down under the P.F.A. Act and these standards would be circulated to the State Drugs authorities who, in turn, could draw the attention of the authorities responsible for enforcing the quality of food items to those standards.

Agenda Item - 3 (b)

Suggestion made by the Drug Control Authority, Madras to lay down guidelines for screening the composition of Patent or Proprietary medicines by the Drugs Control authorities of the States.

Shri Narasimhan, Assistant Drugs Controller, Madras stated that there is no rationale or therapeutic justification for some of the patent or proprietary medicines which are now marketed. When firms manufacturing such preparations were asked to furnish justification for their being marketed, the manufacturers had questioned the authority of the State Drug Controller to screen the formula of patent or proprietary medicines under the provisions of the Drugs and Cosmetics Rules. He felt that some guidance from the Committee was necessary so that a uniform policy could be followed in all the States. Shri. Rangnekar stated that in Maharashtra the formulae of patent or proprietary medicines were screened at the time of renewal of licences for manufacture. They also screen patent or proprietary medicines before granting permission for their manufacture.

The Chairman stated that it had been brought to his notice that patent or proprietary medicines containing antibiotics and sulphas and also A.P.C. tablets are being marketed with ingredients in sub-minimal doses. The formulae of such preparations should be checked in particular before grant/renewal of licences. He informed the Committee that in pursuance of a recommendation made by the Mukhopadhya Committee, which has been endorsed by the Drugs Technical Advisory Board, it is proposed to lay down a new rule in the Drugs and Cosmetics Rules according to which the formulae of all patent or proprietary medicines will have to be approved by the Central Drugs Control Organisation. The guidelines for approval of such formulations will be that :-

(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 should not be incompatible and the preparation should be stable;

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

Before introducing this rule, Government will have to consider the setting up of a machinery for approval of formulae of patent or proprietary medicines especially as there are about 1,600 manufacturers who market patent or proprietary medicines and it would be a stupendious task to undertake approval of all the formulations moving in the market and also those which would be marketed in future.

The Committee recommended that till such time as the necessary rules for the approval of formulae of patent or proprietary medicines were introduced in the Drugs and Cosmetics Rules, the State Drug Control authorities should screen the formulae of patent or proprietary medicines at the time of grant and renewal of licences keeping in mind the three guide-lines mentioned above.

Agenda Item - 3 (c)

Consideration of the suggestion made by Dr D. Ghosh, Director, Central Drugs Laboratory, Calcutta on the recommendations of the Drugs Consultative Committee regarding provision to be made under the Drugs and Cosmetics Act and Rules for the Government Analyst to give his opinion regarding the labelling of drugs and declare them to be misbranded whenever necessary.

The Chairman, explaining the background against which the Director, Central Drugs Laboratory had requested for making a provision in the Drugs and Cosmetic Rules to enable a Government Analyst to give his opinion regarding the labelling of drugs and if necessary to declare the drug misbranded, stated that at the last meeting of the Government Analysts held at Calcutta in March 1967, it was decided that the Government Analysts report should confine itself to the quality aspect of the drug and that any information regarding non-compliance with the labelling provisions should be forwarded to the Drug Control authority in a separate forwarding note. The Director Central Drugs Laboratory felt that unless the labelling deficiencies

and other gross defects such as the incorporation of an unauthorised colour in a preparation or the overall-shortage in contents are actually mentioned in the analytical report itself, it may be difficult for the enforcement authorities to take action against the manufacturer. At the same time, the members of the Committee were of the view that the observations made in the analytical report should not be such as to embarrass the authorities to force them to take legal action where such action was **not** warranted.

The Committee, after discussion, recommended that :-

(a) the test report of the Government analyst should essentially comment on the fact whether the drug is of standard quality or not;

(b) and that actual comments on other aspects of the drug (such as labelling, net content, packing/container etc.) might be shown below as an "observation" or a "Note" or "N.B." in such a manner as to leave it to the State enforcement authorities to draw their own conclusion from the facts set out as to whether the drug is "misbranded" or not.

Agenda Item - 3 (d)

Suggestion made by West Bengal that the question of a suitable definition of the term 'Batch' in respect of medicinal gases may also be considered in the light of general manufacturing practices.

The Committee considered the points raised by the Director, Drugs Control, West Bengal. Shri Rangnekar and Dr Sarkar stated that the manufacture of medicinal gases being a continuous operation, it would be difficult to consider a day's outturn as a batch. The manufacturers have taken the responsibility for the quality of the medicinal gases manufactured and marketed by them. They had also given an undertaking that the tank containing the medicinal gas would be emptied every week. No sample of medicinal gases had failed on test so far. The Committee agreed that the production of medicinal gases in a week from one tank load should be considered as a "Batch" provided the tank was emptied every week. In case, however, the manufacture was a continuous process in which the tank was not unloaded after a week, a day's production might be considered as constituting a "Batch". The Director, Drugs

Control Administration, Maharashtra stated that he had drawn up a list of tests that might be carried out on the medicinal gases and these might be helpful to other State Drugs Control authorities. The Chairman requested Shri. Rangnekar to forward the information to the Central organisation so that it could be circulated to all the State Drug Control authorities.

Agenda Item - 3 (e)

Consideration of the report of the Sub-committee of the Drugs Consultative Committee on the following subjects (vide Item No.10 of the minutes of the 11th meeting of the D.C.C.

(1) The manner of labelling of ampoules taking into account the current pattern of trade practices in regard to the sale of ampoules to consumers and also representations made by a representative of the OPPI at the Tenth Drugs Conference held in Calcutta on 14th & 15th March, 1967 and suggestions made by OPPI regarding amendments to rules 96 to 109 of the Drugs & Cosmetics Rules.

(ii) The manner in which the date of expiry should be shown taking into account the present practice followed by some manufacturers of showing only the month and the year which leaves the trade in doubt whether the drugs are expected to retain their potency till the end of the month or till the beginning of the month.

(iii) The procedure that could be followed by manufacturers for indicating on the label that the drugs conform to the National Formulary Standards.

(iv) The question of defining the term "compounding" and "Dispensing" as Suggested at the Tenth Drugs Conference and the question whether experience of sale across the counter could be deemed to be adequate to consider a person as a "qualified person" under the Drugs and Cosmetics Rules.

The Committee considered the report of the sub-committee. The recommendations made by the sub-committee regarding the amendments to rules 96 to 109 were agreed to subject to the following changes being made in the draft amendments to the Rules :

1. In Rule 96 (I) (i) (c) for the words "word (N.F.I)" substitute the words "letters (N.F.I.)".

2. In Rule 96 (I) (iii) (a) for the words "dose being indicated in millilitres" the following words may be substituted "dose being indicated in 5 millilitres or multiple thereof. Provided where the dose is below 5 millilitres, the actual quantity of the dose may be expressed in millilitres".

3. In Rule 97 (I) (e) under the heading "warning" the words "by a retailer" may be substituted by the words "by retail".

The recommendation made by the sub-committee that in view of the fact that the term 'dispensing' included 'compounding' it was not considered necessary to define the terms 'dispensing' and 'compounding' separately was accepted by the Committee.

The recommendation made by the sub-committee that a new category of persons possessing the minimum academic qualifications of S.S.C. or an equivalent examination and with an adequate knowledge of preparation of drugs, their action, stability, dosage, storage conditions and the different Schedules under which the drugs are classified etc. should be permitted to sell prescription drugs, other than habit-forming drugs, in original packings or in loose form was discussed by the Committee.

Shri Narasimhan, stated that at present the salary scale of a Registered pharmacist in Madras was of the order of Rs.100-150. If a new category of persons was introduced into the profession, the future prospects of Registered Pharmacists would be affected adversely. Such a step would, apart from hitting hard those who chose profession of pharmacy, retrograde and nullify all the endeavours that have been made and are being made during the last two decades for raising the status of the practising pharmacists. The number of persons available for employment as "qualified persons would be so large that they would be at the mercy of the employers.

The Chairman explained to the Committee that apart from the recommendation made by the Sub-Committee and the opposing view put forward by Shri. Narasimhan, there was a third aspect which had also to be taken into consideration by the Committee namely, that the Pharmacy Council of India and the Drugs Technical

Advisory Board had recommended that clause (c) under "Explanation" to rule 65(15)(c) under which persons having not less than four years practical experience of dispensing are approved as "qualified persons" should be deleted and that protection should be given to such persons as have already been approved as "qualified persons" under section 42 of the Pharmacy Act.

Dr. Sarker stated that there was a shortage of Registered Pharmacists in West Bengal. Dr. Sarker said that before agreeing to the recommendation of the Sub-committee it should be ensured that the new category of persons proposed to be approved have adequate background knowledge of the duties they would have to perform. If the proposal were agreed to, the Diploma Course in Pharmacy would ultimately have to close down. Dr. Rishi and Shri. Pany agreed to the proposal. Shri. Chandrasekharan Nair stated that the proposal if implemented would provide jobs to matriculates. However, it would at the same time reduce the scope for employment of Registered Pharmacists. Shri. Barbora stated that the proposal was in conflict with the amendment suggested in the Pharmacy Act. Shri. Gopalakrishna Murthy stated that Diploma holders in Pharmacy were not getting jobs in Andhra as persons with lower qualifications were being employed by the drug stores. The diploma holders in pharmacy were now pleading for being absorbed as competent persons for supervising the manufacture of drugs. Shri. Patel suggested that as a via media it could be provided that sales establishments in cities might be manned by Registered Pharmacists while the chemists' shops in villages might be in-charge of persons of the proposed category. The Chairman pointed out that such a distinction cannot be made between cities and villages and that in any case the proposal would run counter to the changes suggested in the Pharmacy Act and rule 65 (15) (c) of the Drugs and Cosmetics Rules.

The recommendation of the sub-committee was finally accepted by a majority vote, seven members voting in its favour and six against it.

Agenda Item No. - 4

Consideration of the question of laying down guidelines for the enforcement of rule 62 (B) (2) and 54 (2) of the Drugs and Cosmetics Rules, 1945 so as to enable the Licensing authorities to use their discretionary powers properly.

The Chairman enquired from the members about the procedure that was followed in their States in exercise of discretionary powers contained in Rules 64 (2) and 62 (B) (2).

Shri. Patel explained that in Gujarat parties applying for sale licences were discouraged unless they intended to set up a full-fledged chemist and druggist shops. Such a procedure was however did not have the backing of the rules.

The Chairman said that the existing rules 64 and 62 (B) are not comprehensive and do not lay down proper guidelines granting sale licence keeping in mind the limitations set out in them. He stated that the regulations followed in France, Goa, and Portugal for grant of sale licences of drugs on the basis of the population would be studied and a note circulated to the members.

Agenda Item No.5

Question whether the Drugs & Cosmetics Rules should be amended so as to require Chemists and Druggists to retain the original prescription of a registered medical practitioner for habit-forming drugs such as barbiturates, Amphetamines and Tranquillisers for a specified period of time.

Shri B.V. Patel, stated that prescription for habit-forming drugs are required to be retained by the chemists after supply of the drugs under the Dangerous Drugs Act and the rules there under. The retention of prescription under the Drugs Rules for these drugs will therefore not be difficult. The Chairman explained that the Drugs Technical Advisory Board had also considered earlier a proposal for amendment of rule 65 of the Drugs and Cosmetics Rules which **inter alia** required that prescriptions for drugs included in Schedules H & L should be retained by the dispensing chemists after the sale of the drugs. It was considered that the prescription is the property of the patient and at times the prescriptions contained not only the name of the drugs included in Schedule H & L but other drugs. Directions on diet and other instructions of the physician were also often recorded on the prescription of doctors. Since in the past, the reaction from the public was not favourable to prescription being retained by the dispensing chemists the Chairman felt that it was very doubtful whether the present suggestion would be acceptable.

Shri. Rangnekar suggested that the existing Schedules G, H & L of the Drugs and Cosmetics Rules should be amended as has been recommended by the Committee on Drugs Control and a new Schedule containing the names of drugs such as barbiturates and amphetamines and tranquillisers and other drugs which are habit-forming and are liable to be misused should be classified as a new Schedule. Rules for exercising control over the manufacture, sale and distribution of these drugs as recommended by the Committee on Drugs Control should also be introduced. In particular he stated that it should be provided that Pharmacies should be manned by Pharmacy Graduates as recommended in the report.

The Drugs Controller, Punjab and the Assistant Drugs Controller, Orissa pointed out that Pharmacy Graduates are not available in adequate number and hence the recommendation that pharmacies should be manned by Graduates would not be a practical proposition.

The Committee appointed a sub-committee with the following members to revise the existing Schedules E, G, H & L and to draw a new Schedule and a new set of rules as recommended in the report of the Committee on Drug Control :-

Dr. B.B. Sarker Director, Drugs Control, West Bengal	Member
Shri B.V. Patel Director, Drug Control Administration, Gujarat	Member
Shri M.K. Rangnekar Director, Drug Control Administration, Maharashtra	Member
Dr. S.S. Gothoskar Deputy Drugs Controller (India)	Convener

Agenda Item - 6

Question regarding the addition of Stomach Extract/Intrinsic factor to Oral Liver Extracts.

The Committee considered the replies received from the medical specialists and the institutions about adding stomach extract/intrinsic factor in oral liver extracts preparations. The mere fact that analysts cannot test the presence of stomach extract/ intrinsic factor in oral liver extracts would not constitute sufficient justification

to ban these such preparations. The Chairman summed up the discussions saying that from the summary of the replies received from the medical specialists it was evident that the use of preparations containing stomach extracts would not cause any harm to the user. The question whether liver extracts for oral use with stomach extracts or with intrinsic factor are essential or not is a matter for the Government of India's Essential Drugs Committee to consider. So far as the standards of such preparations are concerned, the manufacturers sholud be asked to test the stomach extract powder before it is added to the preparation. The standards of the ingredients and also of the finished preparation should be given by the manufacturers to the Drug Control authority of the State where the manufacture is located. The preparations need not be banned.

Agenda Item - 7

Consideration of the question whether supplies in original containers of Schedule C, E or L drugs against the prescription of a Registered Medical Practitioner are required to be recorded at the time of supply in the prescription Register.

The Committee observed that the supply of any drug on the prescription of a Registered Medical Practitioner is required to be effected only by or under personal supervision of a "qualified person". This covers the supply of Schedule L drugs which are to be sold in retail only against prescriptions.

The Committee further noted that in Rule 65 (2) the words "and of any drug" had been omitted after the words "any preparation containing any such drug". This printing mistake should be rectified and a circular letter may be issued to all concerned.

Agenda Item - 8

Consideration of the question of laying down a proviso for the destruction of date-expired drugs by a licence in the presence of a Drug Inspector or otherwise, if manufacturers refuse to withdraw them or reimburse their value.

The Committee was of the view that the responsibility for the disposal and destruction of date-expired drugs lay with the dealer and that he should be held

responsible for any contravention of the law.

Agenda Item - 9

Consideration of the question of inclusion of a proviso to rules 69A, 71, 71A, 76, 81, 82, 85E, 139 and 75A on the lines of rule 64 (3) providing for an appeal against the order of the licensing authority passed on the applicants for the respective manufacturing licences.

The Chairman read out the note conveying the views of the Ministry of Health on the suggestion made earlier by the Drugs Consultative Committee that a provision be made in the rules so that in those cases where a show cause notice should be issued by the licensing authority to the applicant whenever it proposed to refuse to grant or renew a licence. The Government of India's view was that the existing provisions for the grant or renewal of the licence in the Drugs Rules were adequate and that the proposed amendment may give rise to complications and might lead to whittling down the powers of the licensing authority. As such, the Government of India did not consider any amendment necessary. In the light of these views, the Committee decided not to suggest any amendment to rule 64. Shri. M.K. Rangnekar, recorded his vote of dissent.

Agenda Item - 10

Consideration of the question of laying down a suitable definition for the term "Registered Medical Practitioner" in respect of persons practising the Homoeopathic, Ayurvedic and Unani Systems of medicines in the same manner as in the case of those practising the modern system of medicine.

The item was not discussed as the Drugs Controller, Pondicherry who had sponsored it was not present to explain the proposal.

Agenda Item - 11

Uniformity of policy in regard to the manufacture of pharmacopoeial formulations in different strengths.

The Committee decided that manufacturers of drugs should be permitted to market pharmacopoeial drugs in the following strengths :

1. In case the pharmacopoeia lays down the "usual dose" the tablets should be in the strength of the usual dose. The tablets may be marked so that they could easily be divided so as to facilitate administration to children who may need reduced dosage.

2. In case the pharmcopoeia prescribed under dosage a range of the strength of the tablets without mentioning the usual dosage, the tablets should be in strength which shall not be lower than the lowest dose given in the pharmacopoeia.

Agenda Item - 12

Uniform policy should be laid down in regard to labelling with standards of certain glandular drugs contained in patent medicines.

The Committee considered the manner of labelling of glandular preparations such as extracts of heart, stomach etc. and agreed that the label of preparations containing such drugs should show the content of the glandular ingredients in such a manner as to be intelligible to the Government Analyst and the medical profession. The extracts from such glands should indicate the concentration in terms of the number of parts of the gland in specific parts of water or other solvent. The source of the extract of the glandulr product i.e. from sheep, cattle etc. need not be mentioned on the label unless it is required to be given as per the monograph in a pharmacopoeia (viz. in case of insulins).

Agenda Item - 13

Consideration of the question of licensing the manufacture and sale of Diagnostic agents and laying down standards for them.

The Committee decided that diagnostic agents should be considered as "drugs". The manufacturers should be asked to furnish the standards of diagnostic agents maintained by them. A licence for manufacture of diagnostic agents should be insisted upon.

It would be useful if the standards for diagnostic agents including stains and enzyme strips for diagnosis as might have been laid down by the Food and Drug Administration of U.S.A. and Canada are obtained and circulated to the State Drugs Control Authorities for their information. The Chairman stated that he shall write to the F.D.A. and the Canadian authorities for this purpose.

Agenda Item - 14

Consideration of the question whether manufacture of articles like perfumery compounds, aromatic chemicals which are used as raw materials in other industries besides the cosmetics industry should be required to be licensed under the Drugs and Cosmetics Act and Rules, treating them as components of cosmetics.

The Director, Drug Control Administration, Maharashtra explained that in his State the practice had been that if an item was used in the manufacture of cosmetics as well as in other industries, no licence for its manufacture under Drugs Act was insisted upon. The Committee, recommended that the same procedure might be adopted by other States subject to the conditions that the item was not labelled as of "Cosmetic grade".

Agenda Item - 15

Question whether the exemption granted under Schedule K to biological and patent or proprietary veterinary drugs from provisions of Chapter IV of the Act and Rules made there under should be omitted.

The Chairman explained that the relevant entries 3 and 4 in Schedule K to the Drugs and Cosmetics Rules in respect of veterinary biological and other special products and also veterinary patent or proprietary medicines are being deleted in the finalised rules relating to the control of veterinary drugs.

Agenda Item - 16 (a)

Question of amending Section 22 (a) of the Drugs and Cosmetics Act to make specific provision empowering an Inspector to inspect any premises where drugs are sold, stocked or exhibited for sale or distributed, similar to the one relating to manufacture which already exists.

Shri. Patel explained that under Section 22 of the Drugs Act, 1940, there was no specific provision empowering the Inspector to inspect premises where drugs are sold or stocked or exhibited for sale or distribution similr to the one relating to manufacturing firms. When the Act did not vest the Inspector with specific powers rule 51 cannot go beyond the scope of the provision of the Act. It was, therefore, necessary to amend Section 22 of the Act vesting the Inspector with the said powers. The Chairman stated that the view of the Law Ministry would be obtained as to whether rule 51 is in consonance with the parent provision in the Act.

Agenda Item - 16 (b)

To make specific provision in Rules authorizing an Inspector to inspect the plant process of manufacture and means employed for standardisirg and testing drugs other than those included in Schedule C and C (I) of the Drugs and Cosmetics Rules, 1945.

The Chairman explained that a consolidated list of amencments to rules 74, 78 etc. of the Drugs and Cosmetics Rules was now under publication in the final form and they covered the specific points raised.

Agenda Item - 17

Suggestion to include Soda Bicarb, Sodium Chloride, Liquid Glucose, Menthol, Saccharine, Citric Acid, etc. under item 10 of Schedule 'K' to the Drugs and Cosmetics Rules, 1945.

Shri. Patel stated that if items like Soda Bicarb, Sodium Chloride, Saccharine, etc. were labelled with the words "Not for medicinal use" an impression was created that the substances in question are not acceptable for use in any other field. The Chairman said that by altering the words "Not for medicinal use" the purpose in view may not be achieved. The Committee decided that the status quo might continue.

Agenda Item - 18

Consideration of the question as to what standards may be adopted in regard to metal particles found in eye ointments.

The Committee discussed the question and recommended that manufacturers of metal tubes in the country should be requested to follow the British Standards Institutions specification for metal particles in eye ointment tubes. The Indian Standards Institution, it was agreed, should also be requested to draw up similar standards for use in this country. The Zonal Officers of the Central Drugs Standard Cntrol Organisation should be asked to ascertain the names of manufacturers of Metal Tubes in the country and the standards followed by them for this.

Agenda Item - 19

Suggestion to change the packing of Absorbent Cotton Wool.

The Chairman explained to the Committee that recently the Defence Ministry had sent a communication stating that the manufacturers of surgical dressings were unable to attain the Indian Standards Institution specifications, even though the I.S.I. specifications were drawn up keeping in view the performance potentialities of the handloom sector. The points raised by the Defence Ministry, it was mentioned, had been forwarded to the I.S.I. for its comments.

The Committee recommended that if polythene packing for absorbent cotton wool was found to maintain the sterility of the packs it could be suggested for adoption by manufacturers for packing 4 oz. and bigger packs of Absorbent Cotton Wool. It was decided that the Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad should be requested to carry out study on the suitability of polythene packs and give his opinion. The Drugs Laboratory, Baroda may also be requested to collaborate with the Central Indian Pharmacopoeia Laboratory in this study. The Director, C.I.P.L., it ws agreed, should get in touch with the Director, Drugs Control Administration, Maharashtra and Gujarat and draw up a plan of study.

Pending report on the suitability of polythene pack, manufacturers should be asked to comply with the present labelling provisions for absorbent cotton wool. It was further decided that manufacturers should be advised to maintain conditions which would prevent contamination during manufacture. Those manufacturers who sterlize Absorbent Cotton Wool should be asked to continue displaying the labelling legend "sterilized when made to be sterlized before use". Other manufacturers may

display the legend "To be sterilised before use". The Committee agreed that no action should be taken against manufacturers of absorbent cotton wool on the basis of an analytical report declaring the product to have failed to pass the sterility test.

Agenda Item - 20

Manufacture of Aspirin tablets I.P. in chewable form for children.

The Committee considered the points raised by the Director, Drug Control Administration, Gujarat and also examined the packing of 'Mejoral' and "Minalgets" containing Aspirin, which are now being marketed. The Committee recommended that aspirin tablets in chewable form for children should be permitted to be marketed in dosage of 75 mg. of a aspirin per tablet and each packing should contain not more than 10 tablets. No special warning legend was considered necessary.

Agenda Item - 21

Provision should be made to restrict the wholesale licences for a particular category of drugs only e.g. as licences for house hold remedies only or Schedule C (I) drugs only.

Shri. Shanbhogue, explained that in Mysore there were dealers who had taken out wholesale and restricted retail licences and that they sold drugs included in Schedule 'H' without appointing "qualified persons". To check such malpractices, he desired that the scheme of licensing should be altered as proposed by him.

The Chairman stated that introduction of additional categories of licences in the Drugs and Cosmetics Rules would run counter to the recommendation of the Committee on Drug Control, which suggested only two categories of licences, one covering wholesale dealing and another retail dealing. The Committee agreed that no change should be made in the Drugs Rules. However, sale by retail of drugs included in Schedules H & L should be effected only under the supervision of a qualified person against a regular licence for retail sale.

Agenda Item - 22

Consideration of the question as to what minimum 'provings' should be accepted for the manufacture of Homoeopathic patent and proprietary medicines.

The Chairman stated that Homoeopathic patent or proprietary medicines may be permitted to be manufactured and sold on condition that they contained known Homoeopathic ingredients or ingredients of proven efficacy. Particulars of other preparations may be sent to the Drug Control Organization at the Centre for obtaining the views of the Adviser in Homoeopathy to the Government of India.

Agenda Item - 23

Consideration of the question of prescribing standards for Homoeopathic, Ayurvedic and Unani medicines.

The Chairman informed Dr. Chopra, that sulphur, menthol, thymol, arsenic etc. are used in Ayurvedic drugs. Should there be any doubts about the classification of any product, samples of such drugs along with their full formula and other particulars may be sent to the Central Drug Control Organization so that the views of the Adviser in the Indigenous Systems of Medicines could be obtained.

Agenda Item - 24

Arrangements to be made for testing of finished Homoeopathic medicines.

The Chairman explained that while mother tinctures could be subjected to assay, no methods of testing of Homeopthic potency preparations have been developed so far and that in the absence of methods of test, it would not be possible to test Homoeopathic potency preparations. He however, said that M/s. Bhandari & Sons who are one of the leading manufacturers of Homoeopathic drugs would be asked to obtain any information on the subject which their principals in Germany may have with them.

Agenda Item - 25

Provision mahy be made to levy penalty in the case of loan licensees who fail

to apply for renewal of licences before expiry.

The Chairman stated that certain provisions were now being made in the rules and forms for loan licences. The suggestions made for the introduction of a provision for levy of penalty in the case of loan licensees who failed to apply for renewal of loan licence before expiry would be taken into account while processing the amendments.

Agenda Item - 26

Consideration of the question of laying down provisions in the rules for licensing of approved testing laboratories.

The Committee considered the question of exercising control over private laboratories which undertake the testing of drugs sent by manufacturers who do not have their facilities for such test. It was recommended that the testing laboratories should be licensed under the Drugs and Cosmetics Rules and that the terms and conditions under such licences should be examined, by a Sub-Committee consisting of the following members :

1.	Shri M.K. Rangnekar, Director, Drugs Control Administration, Maharashtra	Member
2.	Dr. B.B. Sarker, Director, Drugs Control, West Bengal	Member
3.	Dr. R.L. Chopra, Drugs Controller, Haryana	Member
4.	Shri R. Balasubramanyam, Deputy Drugs Controller (India), West Zone	Convener

The Sub-committee will also recommend the amendements in the Drugs and Cosmetics Rules that will have to be made in this connection.

Agenda Item - 27

Consideration of the question of the various provisions of the Act and their enforcement with regard to liability of Managing Director, Production Manager and other Supervisory Officers in cases where products are reported to be not of standard quality or adulterated or misbranded.

The Chairman explained that the question raised had also been examined at the Drugs Conference held earlier on the 16th and 17th of September, 1968 at Cochin. The Committee agreed that according to Section 34 of the Drugs and Cosmetics Act every person, who at the time the offence was committed, was in charge and was responsible to the Company for control of the business of the company was liable for action. Besides, while the proviso to the said section afforded an opportunity to the accused to put forward plea, it did not protect such a person from being prosecuted. The person concerned will have to stand prosecution even though prima-facie he may not be liable.

Agenda Item - 28

Consideration of the difficulties faced by the Drug Control Administration in exercising control over Cosmetics.

(i) Facilities for testing of raw materials.

The Chairman stated that the Indian Standard Institution has published specifications for quite a number of raw materials used in the manufacture of cosmetics and that draft standards for any other raw materials used in the cosmetics industry were also under finalization. The manufacturers of cosmetics in the country might be advised to adopt the I.S.I. standards, wherever these have been laid down for raw materials to be used in cosmetics. The Committee further recommended that wherever standards for raw materials for cosmetics had not been laid down by the I.S.I. specifications for such raw materials as laid down by the Toilet Goods Association of U.S.A. (T.G.A. standards) and by the Toilet Preparations Federation of the U.K. (T.P.F. Standards) might be suggested for adoption by manufacturers.

(ii) Payment of fees.

The Committee recommended that the existing rule 138 of the Drugs and Cosmetics Rules should be applied only to small-scale manufacturers and not to firms manufacturing item other than cosmetics.

(iii) Classification of certain items as cosmetics.

The Committee recommended that normally such items as hair oils, tooth powder, etc. which are used as cosmetics should be considered as "Cosmetics" for the purpose of the Drugs & Cosmetics Act. However, if therapeutic claims were made for these items, they should be considered as drugs. Rules for the control of Ayurvedic and Unani medicines under the Drugs and Cosmetics Rules have already been laid down. In case these items are claimed to be Ayurvedic or Unani medicines their manufacture should be regulated under a licence for manufacture of such medicines.

(iv) Minimum conditions for manufacture of nail lacquers.

Shri. Rangnekar explained the hazards that may arise in the manufacture of nail lacquers and informed the Committee that the Drug Contorl Administration, Maharashtra had drawn up a note giving the safety measures that should be adopted by manufacturers of nail lacquers. The Committee recommended that this note might be circulated to the members for information and guidance.

(v) Use of Boric Acid in Baby Powders.

The Chairman explained that the I.S.I. which had drawn up specifications for baby powders was now considering the question whether boric acid and borax may be permitted to be used in baby powders or not. It would be worthwhile awaiting the recommendation of the I.S.I.

(vi) Licensing of Nylon Hair manufacturers.

The Committee recommended that Nylon Hair need not be considered as cosmetic.

Agenda Item - 29

Consideration of the question whether ADRENALINE INJECTION should be packed in amber coloured or colourless glass ampoules.

The Committee considered whether Adrenaline Injection should be packed in amber coloured or colourless glass ampoules. It was decided that adrenaline

Injection, for which a life period of twelve months has been laid down and which is required to be sold in single dose containers should be packed in colourless glass ampoules so that any change in colour or physical appearance of the contents could be detected. The glass container should be packed in cartons.

Agenda Item - 30

Consideration of the Principles to be followed for institution of prosecutions under the Drugs and Cosmetic Act.

The Committee considered the subject matter suggested by the Kerala Drugs Controller. The Chairman pointed out that the Committee had already examined a similar issue at its earlier meeting in Calcutta, when the Director, Drug Control Administration, Maharashtra desired to have guidelines setting forth the types of offences for which prosecutions should be launched and the offences for which other penal measures should be imposed.

The Committee, after detailed discussions, reiterated the stand taken by it at its eleventh meeting. It also felt that its view-point had been sufficiently spelt out in the "Instruction Manual" supplied to the Drugs Inspectors at the time when the training programme for Drugs Inspectors was held in Maharashtra and Gujarat in 1962. The relevant extract from the Inspectors' Manual is enclosed as Annexure-II.

The Committee recommended that its views expressed at the Calcutta meeting, supplemented by the advice given in Annexure II of these minutes could be followed as a guide line by the State Drug Control Administrations in deciding upon the action to be taken against offences under the Drugs and Cosmetics Act.

Agenda Item - 31

Suggestions that Loan Licences in Forms 25A and 28A should be subject to suitable conditions in addition to those stated in the licence forms.

The Chairman explained that conditions of licences in forms 25A and 28A for manufacture of drugs under a loan licence were now being laid down in the Drugs and Cosmetics Rules and that a consolidated list of amendments for this purpose was under publication.

Agenda Item - 32

Suggestion that further conditions should be incorporated in Rules 74 and 78 to ensure good manufacturing practices and processing of drugs.

The Committee accepted in principle the suggestion made by the Director, Drugs Control, West Bengal for laying down provisions in rules 74 and 78 to the Drugs and Cosmetics Rules to ensure good manufacturing practices. The Chairman stated that a consolidated list of draft amendments which **inter-alia** specified the nature of records of manufacture and testing of drugs by the manufacturers was now under publication in final form. The World Health Organisation had prepared a draft code of Good manufacturing Practices. Since the suggestions made by the Director, Drug Control, West Bengal would require detailed examination the Committee recommended that the Sub-committee constituted under item 26 of the Agenda might also consider the proposal.

Agenda Item - 33

Suggestions that the additional provisions should be included in Schedule 'M'.

The Committee agreed that the suggestion for including additional provisions in Schedule 'M' might be considered by the Sub-committee appointed under item 26 of the Agenda.

Agenda Item - 34

Any other item with the approval of the Chair.

(1) Fees for duplicate copy of the renewal certificate in Form 21-C, and Loan Licences etc.

The Chairman stated that an overall check will be made of the provisions relating to grant or renewal licences and for grant of duplicate copies of licences and necessary action taken to set right any deficiencies.

(2) Maintenance of Inspection Book for licence holders in form 25(B) :-

It was explained that a new form setting forth the manner in which an Inspection Book is to be maintained by the licencees was now under publication in final form.

(3) Addition of the Word Schedule 'H' after the word "Schedule L" and the deletion of the word "or" from clause (f) of sub-rule (3) of rule 65.

The Chairman informed the Committee that sub-rule (3) of rule 65 was now being amended in consultation with the Drugs Technical Advisory Board, and necessary change will be made in this rule in case the same is not already made in this amendment.

(4) Duties of Government Analyst to test samples of cosmetics.

The Committee recommended that rule 45 of the Drugs and Cosmetics Rules may be amended to add the words "and cosmetics" after the words 'drug.'

(5) Labelling requirements for cosmetics showing of the manufacturing licence number.

The Chairman stated that the proposal was considered at the Drugs Conference held in Calcutta in 1967 and the opinion that prevailed was that the manufacturing licence number need not be shown on the label of cosmetics. The members of the Committee felt that the statutory requirements that dealers should buy cosmetics from a licensed manufacturers cannot be fulfilled unless the manufacturing licence is shown on the label. This aspect, the Committee felt, should be brought to the notice of Government.

(6) Clarification regarding Entry 1 to Schedule 'K' of the Drugs and Cosmetics Rules in respect of items like Petroleum Jelly, Soda Bicarb, Glycerine etc., which are labelled as "Not for medicinal use".

Shri. Rangnekar, stated that manufacturers of drugs used raw materials such as Petroleum Jelly, Soda Bicarb, Glycerine, etc. which were labelled. 'Not for Medicinal use' after testing them and making sure that they are of pharmacopoiel quality. The Chairman said that the question had also been discussed at the Drugs Conference held on the 16th and 17th September, 1988 at Cochin. The Committee

agreed that the list of items which the manufacturers' organisation promised to supply should be examined and that Glycerine, Dextrose, Boric Acid, Kaolin, Soda Bicarb, Talc, Liquid Glucose, and such other items re may come to the notice of the State Drug Control authorities may be permitted to be used by the manufacturers of drugs after being tested and found to be of quality even though they are labelled 'Not for medicinal use'.

(7) Consideration of the question of giving the expiry dates on Antibiotics formulation.

The Chairman stated that a circular letter had already been issued to the State Drugs Control authorities recommending that the date of expiry of finished preparations of antibiotics should not be fixed beyond the date of expiry of the antibiotic in bulk from which the finished products are processed. The Committee endorsed the policy.

(8) Consideration of the question of giving date of expiry to Vitamin 'K' in bulk.

The Committee considered the suggestion that there should be a date of expiry for vitamin K in bulk. It was, however, observed that Schedule P to the Drugs and Cosmetics Rules, which lays down the maximum period upto which the manufacturers are permitted to show the date of expiry of drugs, did not include vitamins. In the absence of specific entries for vitamins, it would not be possible to insist on the date of expiry to be shown on the labels of these vitamins.

(9) Consideration of the question of laying down standards for raw materials to be used in the manufacture of Petroleum Jelly of Pharmacopoeial quality.

The Chairman said that the range of specifications for Petroleum Jelly in the Indian Pharmacopoaia was wide enough to permit manufacturers of the item to manipulate a product which would just satisfy the minimum requirements laid down in the pharmacopoeia. The Jelly is, in many cases, made by blending cheap quality pale oil and microcrystalline wax. Complaints had been received from drug manufacturers making ointments, particularly eye ointments, that their products

made with such Petroleum Jelly had deteriorated due to separation of the constituent ingredients in the Jelly.

Shri. Rangnekar also explained the results of a survey made by them of the Petroleum Jelly industry in Maharashtra.

The Committee recommended that strict control should be exercised over the manufacture of Petroleum Jelly and the quality of raw materials like micro-crystalline wax and pale oil used for manufacture of Petroleum Jelly. The specifications of Petroleum Jelly compiled by the Director Drug Control Administration, Maharashtra (Annexure III), it was agreed, should be adopted by the Drug Control authorities of the States.

In regard to the suggestion made for deleting the standards for Yellow Petroleum Jelly (Yellow Soft Paraffin) in the Indian Pharmacopoeia 1966, the Chairman stated that this item is used in large quantity by the manufacturers. It will be necessary to make an enquiry from the manufacturers who use yellow petroleum jelly as to whether the monograph for this drug should be retained or deleted form the I.P. 1966. The suggestions received from manufacturers would be passed on to the Indian Pharmacopoeia Committee for necessary action.

It was also brought to the notice of the Committee that Petroleum Jelly of inferior quality had been supplied to drug manufacturers in the Punjab and Haryana. It was decided that samples of petroleum jelly suspected to be of inferior quality should be sent for test and if the samples were reported to be not of standard quality, the suppliers should be prosecuted.

Shri. Narasimhan mentioned that bees wax supplied to the drug manufacturers from Mysore was not of standard quality. It was agreed that the question should be taken up with the Drug Control Administration, Mysore under advice to the Central Drug Control Administration.

(10) Consideration of the question of laying down minimum conditions for manufacture of Ophthalmic Ointment.

Shri. Rangnekar stated that the Drugs Control Administration, Maharashtra had circulated to manufacturers the conditions under which the manufacture of Ophthalmic Ointments should be carried out. The Committee agreed that the recommendations made by the Drug Control Administration, Maharashtra (Annexure IV) might be adopted by other States.

(11) Consideration of the question of laying down upper limits for Antibiotic formulations.

The Committee recommended that no overages of antibiotic in formulations should be permitted except to the extent prescribed in the individual monograph of the Pharmacopoeias. For anti-fungal antibiotics, however, the Food and Drug Administration of the U.S.A. had laid down certain limits for overages which could be adopted.

(12) Consideration of the question of laying down sampling by repackers of repacked drugs.

The Committee considered the scale of sampling of repacked drugs. in the light of the scale of sampling that has been adopted by the Drugs Control Administration, Maharashtra. It was agreed that if the drug to be repacked is purchased in 5 containers and if all the containers bear the same batch number then samples from two containers should be drawn and without mixing them the same should be sent for test and analysis. If reports on both the samples are found to be of standard quality the drug contained in the 5 containers bearing the same batch number should be deemed to be of standard quality and permitted to be repacked. In case the purchase is from 5 to 10 containers of the same batch, 4 samples should be drawn and sent for test and analysis and the drug reported to be of standard quality, if all the samples pass the tests. In case the purchase is from 10 to 15 containers, 5 samples should be sent and the drug would be reported of standard quality if all the 5 samples pass the tests. If the purchase is from 15 to 20 containers, six samples should be sent for test and analysis and if are reported to be of standard quality, the same should be permitted to be used. In case the containers bear different batch numbers, the same procedure shall be followed in case of containers with the same batch number.

(13) Consideration of the question of action to be taken in respect of parenteral preparations containing suspended matter.

The Committee discussed the question of laying down a uniform policy of action in cases where suspended matter in parenteral preparations was reported by the Government Analysts. It was felt that this was a matter for the Government Analyst to consider and that no guide lines could be suggested by the Committee.

(14) Action to be taken in respect of Rubber Contraceptives reported to be "not of standard quality".

The Chairman stated that the question of testing condoms which are imported or manufactured in the country had been discussed with the manufacturers and that the decisions taken had been communicated to the State Drug Control authorities. The Family Planning Department was keen on ensuring that only condoms of standard quality are permitted to be marketed. It was therefore necessary to exercise strict control over condoms which are imported and manufactured and that no relaxation from the existing provisions should be permitted. The scale of sampling of condoms from the premises of dealers or manufacturers is yet to be decided on a statistical basis and Chairman requested Shri. Patel and Shri. Rangnekar to expedite their discussions with the statistical authorities.

(15) Consideration of the question of colouring of coated tablets.

The Committee examined the question whether colours should be permitted to be added to pharmacopoeial preparations even though in the monographs of the Indian Pharmacopoeia the addition of colours was not specifically permitted. A recent letter received from the British Pharmacopoeia Commission on the subject was read out by the Chairman. The Committee decided that no colour need be permitted to be added to pharmacopoeial preparations unless the use of a colour was specifically permitted in the respective pharmacopoeia.

(16) Consideration of difficulties experienced by the Government Analyst in reporting on Form No.34 of the Drugs and Cosmetics Rules.

The Committee considered the difficulties experienced by Government Analysts in issuing reports on cosmetics in Form 34 which was inadequate for the purpose. It was agreed that the Director, Drugs Control Administration, Maharashtra and Gujarat should consult their Government Analysts and suggest the specific changes that should be made in the form.

(17) Suggestion that retail dealers may be permitted to maintain two sets of cash memos for meeting the requirements of Rules 65(3) and 65(4) of the Drugs and Cosmetics Rules instead of present practice of three separate sets of cash memo.

The Committee examined the provisions of the rules for maintenance of records for sale of drugs and felt that the question as to whether two or three sets of Cash Memos should be maintained by the dealers is a matter which should be left to the administrative convenience of the State Drug Control authorities. No amendment to the rules was considered necessary.

(18) Provision to maintain records by Licensees in Form 25.

and

(19) Testing of raw materials and finished products and maintenance of records thereof.

The Chairman stated that a consolidated list of finalised amendments including a new Schedule to the Drugs and Cosmetics Rules was under publication and that the schedule in question covered aspects relating to the maintenance of the necessary records by licensees in Form 25 and also for maintenance of records of tests of raw materials and finished products by manufacturers.

(20) Qualification of Analysts

The committee considered the proposal for laying down qualifications for persons who could be considered as suitable for supervising the testing department in a manufacturing establishment. It was felt that the provisions of rules 71 and 76 were adequate and elastic enough to permit the State Licensing Authorities to approve of

persons who would supervise the testing operations, keeping in mind the nature of drugs to be tested.

(21) Provision to compound offences

The proposal that provision should be made for compounding of offences was considered by the Committee and it was felt that the existing penal provisions of the Drugs and Cosmetics Act were sufficiently deterrent and that there was no need to amend the Act for this purpose.

(22) Appeal on the decisions of the Licensing Authority.

The Chairman stated that the Government of India, on the basis of a communication received from the Parliament Secretariat, had already initiated action for providing for appeals against the licensing authority for cancellation or suspension of licence to be made to the State Government in all the cases.

(23) Patent and Proprietary Medicines under the Ayurvedic (including Sidha or Unani) drugs.

The recommendation made under item 23 of the Agenda, it was agreed, would apply in this case also.

(24) Modification of Forms 15 and 16 of the Drugs and Cosmetics Rules.

The Committee was of the view that it was not necessary to amend Forms 15 and 16 of the Drugs and Cosmetics Rules.

(25) Drug Licence Fees ;

The Committee was of the view that if the licence fees for sale of drugs were to be increased there would be protests from the dealers. The proposal was not agreed to :

(26) Provision for realisation of fees for duplicate copy of certificate of renewal of licences.

The Committee recommended that necessary provision for issue of duplicate copies of certificates of renewal of licences and fees therefore should be provided in all cases in the Drugs and Cosmetics Rules.

(27) Licence forms may be amended so that Licensee cannot sell drugs from the premises in any other name and style than mentioned in the Licence.

The Drugs Controller, Kerala stated that his suggestion was a sequal to a judgement of the Kerala High Court. The Chairman desired that a copy of the judgement might be sent to him so that the proposal could be examined further.

(28) Suggestion to amend the rules to levy **pro-rata** fees for renewal of licence after the expiry of licence.

The Chairman explained to the Committee that the Committee's recommendation for the levy of a **pro rata** fee for renewal of a licence after its expiry was supported by the Drugs Technical Advisory Board. The Government of India, however, did not accept the recommendation as it felt that to permit sale of drugs after the expiry of licence would be tantamount to encouraging sale without a licence. Moreover, with the introduction of a system whereby renewal of licence had been made effective from the 1st of January of a calendar year, the chances of licensees not renewing their licences would be few and far between.

The Committee, however, felt that the present procedure resulted in certain anomalies in that while a party which applied for renewal after one month of expiry of the licence was required to pay a late fee for renewal, parties which applied for renewal after one month, need not pay any renewal fee at all. Besides, prosecution of firms which carried on their manufacturing or sale activities without renewing their licences which is the only penal action possible in such cases, presented considerable difficulty to the State Drug Control authorities especially in the collection of evidence etc. The Committee decided that its earlier recommendation should be taken up again with the Government in the light of the above facts.

(29) Relabelling (Re-dressing) of Drugs and Cosmetics.

Kerala Drugs Controller desired to know whether the practice followed by certain firms to send unlabelled stocks to their own storage depots in different states and to send separately the labels for being affixed on them should be permitted. The Committee was of the view that no stocks of drugs should be allowed to go out of manufacturing premises without being labelled properly and if any firm was found not to conform to this requirement, particulars of the firm should be furnished by the Drug Control Authority of the State in which such cases were detected to the authorities of the State where the manufacturing firm is located.

(30) Addition of words 'or Pharmacy' after the words 'graduate in medicine or science' in the 1st proviso to rule 44 to enable pharmacy graduates to become Government Analysts for Schedule C drugs.

The Chairman stated that rule 44 had been revised and that the revised rule had taken into account the point raised.

(31) Amendment to Section 7A of the Drugs and Cosmetics Act.

The Chairman stated that consequent on the publication of the rules for the control of Ayurvedic and Unani medicines the States have to appoint Licensing authorities for regulating the manufacture of Ayurvedic and Unani drugs. The proposal to amend Section 7A of the Act is linked with the enforcement of Ayurvedic and Unani Rules and no action at this stage appeared necessary.

(32) Permission for availing of testing facilities of drug testing laboratories by manufacturers who do not have their own facilities of testing.

In the absence of a representative from the Delhi Drugs Control Administration the Chairman stated that the provision in the Drugs Rules permitting firms to get their products tested at another approved laboratory had been reported to be abused. Reports that manufacturing firms get samples from a few batches tested from another laboratory and continued the manufacturing activities under the same batch numbers had been received. In his opinion, manufacturing firms whose turn over was sufficiently large should be given a time limit and allowed to build up their own testing facilities.

If necessary, the rules should be suitably amended.

The Committee recommended that the Sub-committee appointed under item 26 should consider this aspect also.

(33) Filling of gelatin capsules by hand.

The Chairman explained that in some States like Delhi, manufacturers did not have semi-automatic machines for filling capsules and that the capsules were being filled with the drug mechanically by workers. The Committee recommended that the filling of capsules should be done with at least semi-automatic filling machines.

(34) Standards for Surgical dressings

The Chairman stated that the Ministry of Defence had informed him that manufacturers of surgical dressings were unable to comply with the I.S.I. specifications even though the I.S.I. had originally drawn the specifications keeping in view the standards that could be attained by the handloom sector of the textiles industry. The I.S.I. has already been requested to forward its comments on the points raised by the Defence Ministry. The State Drug Control authorities will be apprised of the views of the I.S.I. If considered necessary, the I.S.I. would reconsider its standards for surgical dressing after which those standards could be adopted in the Drugs and Cosmetics Rules. Meanwhile, the Committee agreed that the I.S.I. standards should be followed for the purposes of Drug Control.

(35) Proposal for approval of formula of patent or proprietary medicines before these are permitted to be marketed - amendment to the Second Schedule to the Drugs and Cosmetics act.

The subject had already been discussed under item 3 (b) of the Agenda.

(36) Standards for cosmetics should be laid down.

and

(37) Testing of raw materials and finished cosmetics.

The two points raised by the Delhi Drugs Control Administration, namely (i) the standards that should be adopted for finished cosmetics and raw materials used in the manufacture of cosmetics, and (ii) the manner in which Form 34 have to be amplified had already been discussed under Item Nos. 28(i) and 34 (16) of the agenda.

(38) There are drugs and cosmetics which have not been manufactured by manufacturers whose names are given on the label. The Act may be amended so that samples of such drugs and cosmetics can be sent to the manufacturer whose name is given on the label.

The Committee was of the view that it would not be necessary to amend the Drugs and Cosmetics Act so as to provide for samples of drugs and cosmetics alleged to be misbranded to be sent to the manufacturer whose name is given on the label for verification of the bonafides of the drug. The genuine manufacturer, in such cases, should be called upon to give evidence before the Court.

(39) Consideration of the interpretation of the term 'New Drug' as defined in the Drugs and Cosmetics Rules, 1945.

The points raised by the Delhi Drugs Control Administration were that (a) will a New drug continue to be a New drug in case it is not made bfficial in any prescribed pharmacopoeia, (ii) will it be necessary to specify a period after which the New drug will cease to be a New drug and (iii) if one firm has been given permission to manufacture a New drug, will it be necessary for the other firms also to have permission to manufacture the same New drug. The Committee discussed these issues and agreed that a 'New drug' eventhough approved for a particular firm would continue to be a New drug for other parties also until it is absorbed in a prescribed pharmacopoeia. It is necessary that all firms which want to import or manufacture such 'New drug' should be made to obtain the approval from the Central Drugs Control Administration as standards in many cases for these New drugs vary

(i) Standards for Clinical Thermometers.

Shri. Rangnekar stated that in terms of entry 18 to Schedule K to the Drugs and Cosmetics Rules manufacturers of Clinical Thermometers were exempted from the requirement of taking out manufacturing licence and complying with the conditions of manufacture, if the thermometers manufactured conformed to the I.S.I. standards. He enquired of the nature of control that should be exercised over a manufacturer of clinical thermometers who did not like to join the I.S.I. Certification Scheme. The Chairman informed the Committee that the I.S.I. was now fully equipped to undertake the testing of clinical thermometers and operate the Certificate Scheme.

The Committee agreed that the manufacturers should be persuaded to take out I.S.I. Certification Licence. It was further recommended that a note on the facilities provided by the I.S.I. for the testing of clinical thermometers under the I.S.I. Scheme and also the list of manufacturers of clinical thermometers in the country as supplied by the I.S.I. should be circulated to the members.

(ii) Ban on Penicillin Ointment

Shri. Rangnekar pointed out that preparations like pencillin ointment which result in sensitisation and constitute health hazards should be banned. The Committee observed that there was no specific provision to ban the marketing of such items. It was recommended that an omnibus provision should be introduced in the Drugs and Cosmetics Act enabling Government to prevent the marketing of drugs which constitute a positive health hazard to human beings.

(iii) Amendment of Form 21.

Shri. Patel pointed out that in licence Form 21, the words "and to operate a pharmacy on the premises situated at subject to the condition specified below and to the provision of the Drugs and Cosmetics, Act, 1940 and the rules thereunder" are not laid down though the form 20 provides for the operation of a pharmacy. The Committee agreed that suitable change should be made in Form 21.

The Chairman, suggested that the State Drugs Control authorities should publish a list of licensed dealers of, drugs in their States and send copies of it to Associations of Chemists and Druggists and others who may be interested so that the dealers

could comply with the condition that drugs should be purchased by them from only licensed dealers. Amendments to this list may also be made every month and circulated to the Associations.

Before concluding, the Chairman thanked Shri Chandrasekhran Nair, Drugs Controller, Kerala and the members of his Inspectorate and other staff for the excellent arrangements made by them for the meeting of the Drugs Consultative Committee and the Drugs Conference and for the co-operation extended by them. The Committee also placed on record its grateful thanks to the Government of Kerala for the help extended by them.

It was decided that the next meeting of the Drugs Consultative Committee should be held at an early date at Indore or Jaipur.

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

PART II

ANNEXURES TO THE MEETINGS

ANNEXURE I

STATEMENT SHOWING THE ACTION TAKEN ON THE MINUTES OF THE ELEVENTH MEETING OF THE DRUGS CONSULTATIVE HELD AT CALCUTTA ON 16TH & 17TH MARCH, 1967.

Item No.2 of the 12th D.C.C. Meeting

Item no of Agenda (1)	Recommendations of the Drugs Consultative Committee (2)	Action taken (3)
1(i) Question whether the side effects of Streptomycin have been noticed by the T.B. Hospitals and other Institution in other States similar to Gujarath.	Dr. B.V. Patel stated that some of the patients who were treated with Streptomycin in Gujarat had exhibited vertigo. The question whether it is due to Streptomycin or other inherent factors in the patients was still under examination. The Chairman suggested that the question whether the patients were treated previously with Streptomycin or whether they were new cases might also be taken into consideration. A suggestion was made to the members of the Committee that they might, if possible make enquiries whether similar side- effects had been noticed by the T.B. Hospitals and other institutions in their States.	An enquiry was made of the Drugs Control authorities of other States whether similar side-effects (vertigo) as exhibited by patients in Gujarat State who were treated with streptomycin, had been noticed by T.B. hospitals and other institutions in their States. Most of the States have informed that similar side effects of streptomycin have been reported by T.B. hospitals and institutions in their States. The question was therefore taken up with the Industan Antibiotics Ltd. to examine the matter and to initiate necessary comparative studies on the toxicity of streptomycin manufactured by them and other well-established manufacturers in India and other countries. M/s Hindustan Antibiotics have informed this Directorate that they had carried out a detailed analysis of the toxicity of streptomycin sulphate manufactured by them and compared it with samples of imported streptomycin from reputed manufacturers abroad. The results of investigations so far carried out including LD/50 studies and chromatographic investigations did not indicate any particular defect in the quality of Streptomycin Sulphate manufactured by M/s. Hindustan Antibiotics. However, further investigations are continued to be carried out by them in this regard.

(1)	(2)	(3)
(v) Question regarding use of time-expired drugs could be permitted.	On a question raised by the Drug Controller, Punjab whether the use of time-expired drugs could be permitted, the Chairman stated that the matter had to be considered against the background in which a drug which is time-expired is required for use. If it was a question of life or death of a patient it was for the attending doctor to decide whether he could take the risk of using a time-expired drug in the larger interests of saving the patient. Institutions, however, should **not** use time-expired drugs, even with increased dosage. Once the date of expiry is crossed it was **not** easy to say whether the integrity of the active ingredients of a product could be vouched for and whether, because of deterioration, certain breakdown products and also products resulting from reaction between the original ingredients and the degradation productions would not be present vitiating their therapeutic officacy. The hospitals and other institutions should be advised to plan carefully their purchase of drugs which are liable to deteriorate on storage to ensure that they are stored under ideal conditions and are issued or tried over before their dates of expiry are crossed. Periodic inpection of Hospital Stores by Drugs Inspectors would go a long way towards improving matters in this regard.	The State Drugs Control authorities have been advised to inform the Institutions, Hospitals and Drugs Inspectors in their respective States to comply with the decision of the Drugs Consultative Committee.
(vii) Exhibition of film on the Pharmaceutical and Hospital equipment.	Shri. B.V. Patel stated that the production of a film on the pharmaceutical industry in Gujarat State was under consideration. Shri Shanbhogue informed the Committee that a film on pharmaceutical and hospital equipment manufactured in India produced by the Films Division of the Government of India was being screened in foreign countries as part of the export promotion programme. The Chairman was of the view that the film should also be exhibited within the country so that the medical profession and the general public could be made to acquire greater confidence in the quality of products manufactured in the country. The Films Division, he said, would be approached to consider such a proposal.	The film entitled "Hospital Equipment from India" has since been approved by the Film Advisory Board, Ministry of Information and Broadcasting, for general release. The said film will be released shortly in all the Cinemas in the country.

(1)	(2)	(3)
Agenda Item 2	Action taken on the recommendations made by the Drugs Consultative Committee.	
	Action taken on the minutes of the tenth meeting was explained by the Chairman.	
	In regard to the grant of "Loan Licences" the Chairman said that the views of the Ministry/Department concerned with the drug industry at the Centre were not in consonance with the views expressed by the Drugs Consultative Committee. The Union Ministry of Health had therefore decided that, for the present, the status-quo in regard to the grant of loan licences should be maintained and that the question could be reviewed later on, if necessary. This meant that statutorily the grant of loan licences has to be continued though State Drug Control authorities might apprise the applicants applying for loan licences that there is every possibility of such licences being discontinued at a future date and that it would be in their interests if they maintain their own arrangements for manufacture or processing of drugs.	The members have been requested to maintain the status-quo in regard to the grant of loan licences. They have also been informed vide this Directorate letter No.11-3/65-DC/D dated 5.10.1967 that as there is at present no provision in the Drugs and Cosmetics Rules under which loan licences can be granted for manufacture of Cosmetics and necessary rules, forms for application and forms for grant of loan licences for cosmetics are now being made. Till such time these rules and forms are included in the Drugs and Cosmetics Rules, they have been requested to grant loan licences for the manufacture of cosmetics in Form 32 and enforce the same conditions of manufacture as laid down for drugs manufactured under similar circumstances in respect of cosmetics manufactured against loan licences.
	As regards the status of loan licences for purposes of import of raw materials under the Import Trade Control Regulations, it was agreed that the comsumption of raw materials of such firms should be worked out on the basis of consumption during three earlier years and that a suitable allowance (not exceeding 15%) might be allowed for expansion of business. In regard to new firms the Licensing Authority has to use its discretion. The Chairman added that while recommending imports of raw materials for manufacturers the overall turnover of the firms, their financial outlay, etc. should also be kept in view, and that the value of licence recommended for such firms should have a reasonable relation to these factors.	

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Manufacture of empty hard geletin capsules' and colours used in their manufacture should be regulated under the Rules.	As regards the question of bringing hard gelatin capsules within the purview of the definition of the term "drug" in the Act, the Chairman stated that this had to wait till the Act is amended next time. In the meantime it was agreed that State Drug Control Administrations of Maharashtra and Gujarat, where the manufacturers of empty gelatin capsules are now located might persuade the manufacturers to use only these colours which are approved as food colours by the U.S.A. authorities. Gelatin being highly susceptible to the growth of microorganisms it was essential the manufacturers of gelatin capsules should be apprised of the need to take steps in the manufacture to prevent the growth of microorganisms in gelatin capsules. The Chairman agreed to supply the members with a complete list of colours approved by the Food Drugs Administration and other countries.	The question of bringing the hard gelatin capsules within the purview of the definition of the term 'Drugs' will be taken up at the time of next amendment to the Drugs & Cosmetics Act. As regards supply of complete list of colours approved by the Food and Drug Administration, U.S.A. to the members, a copy of the 'Compilation of Regulations for Colour Certification' received from the Administration, U.S.A. and containing lists of colours for use in Food, Drugs and Cosmetics as approved by the Administration had been circulated to the members under this Directorate letter No.53-21/67-D dated the 26th October, 1967. Action has also been initiated to obtain the lists of colours approved by other important countries namely U.K., U.S.S.R. and Canada and the lists will be supplied when received.
Amendment of rules for controlling veterinary drugs.	Regarding the amendments to the Drugs Act and the Rules which would be necessary for controlling veterinary drugs, the Committee was of the view that the draft amendments should be published at an early date for eliciting comments of the public. Till such time as the rules are amended, it was agreed that manufacturers who process the same formulations for human as well as veterinary use should be asked to take suitable precautions to ensure that there is no mix-up of the two categories of drugs on the processing line at any stage.	The finalised rules have been sent by the Ministry of Health & F.P. to the Ministry of Law for vetting.

to take suitable precautions to ensure that there is no mix-up of the two categories of drugs on the processing line at any stage.

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Agenda No.3(i) Screening of therapeutically inactive formulations and formulations not covered by N.F.I.	It was represented that unless there is legal backing in the Drugs Act and the Rules it would not be possible to prevent the circulation of therapeutically ineffective formulations. Nor would it would be possible to make sure that only formulations covered by the National Formulary of India are marketed by firms. The Chairman stated that the difficulties represented are genuine and that in order to meet them it is proposed to lay down additional standards in the body of the rules providing that patent or proprietary medicines, apart from displaying the formulae on the label as required by entry at (I) in the Second Schedule to the Act, should also contain the active ingredients in therapeutic or prophylactic quantities. Wherever the content of the ingredients fall below the therapeutic or prophylactic manner, it should be made incumbent on manufacturers to adduce sufficient evidence in support of the therapeutic efficacy of the product. When these amendments are carried out, the hands of the States Drug authorities would be strenthened. Till such time as the amendments are made, the Committee agreed that when manufacturers, approach the State licensing authorities for renewal of their manufacturing licences they might be informed of those formulations which, in the opinion of the Licensing Authority, are therapeutically ineffective and advised to stop their manufacture or alter their composition in a suitable manner.	A recommendation to the effect that multiplicity of formulations should be checked and prevented by requiring prior approval of the formula, was considered by the Drugs Technical Advisory Board at its meeting held on 14th July, 1967. The Board agreed to the recommendation in principle. It was however felt that unless there was a statutory provision to register patent and proprietary medicines from the angle of therapeutic efficacy, stability etc., it would **not** be possible to implement the recommendation. The Board recommended that the possibility of setting up a Central agency within the ambit of Drugs and Cosmetics Act for registration of Patent and Porprietary medicines should be examined. Further action to implement the decision of the D.T.A.B. is under consideration of this Directorate.
Agenda Item 3(ii) Clearance of Pharmaceutical preparations under the provisions of rule 69B(i) and 75B(i).	The point represented was that unless the definition of the term "New Drug" is amended so as to bring within its scope the "efficacy" aspect, it might be legally difficult to refuse clearance under Rule 69B(i) and 75B(i) of preparations which are not efficacious. The Chairman said that the Drugs Technical Advisory Board had also suggested that the definition of the term "New Drug" should be revised in such a manner as to make it possible for the efficacy of formulations to be controlled. An amendment covering this aspect is already under examination.	The action is under way for amending the definition of the term "New Drug" under the Drugs & Cosmetics Rules. The following draft amendment to Drug and Cosmetics Rules has been suggested to the Ministry of Health & Family Planning for eliciting comments from the public, namely :-

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		"The 'Explanation' to rule 30-A of the Drugs and Cosmetics Rules, 1945 shall be substituted by the following namely :- 'Explanation' - For the purposes of this rule, "New Drug" means a drug the composition of which is such that the drug is not generally recognised among experts as efficacious and safe for use under the condition recommended or suggested on the label thereof and also includes any drug the composition of which is such that the drug as a result of investigations for determining its efficacy and safety for use under such conditions, is so recognised, but which has not, otherwise than during the course of such investigations, been used to any appreciable length of time under the said condition".
Agenda item - 4 Consideration of the following Reports of the Sub-Committee of the Drugs Consultative Committee.	(i) Consideration of the question of Enforcement of the conditions of storage of drugs as notified by the State Licensing Authorities and the difficulties that may arise in enforcing these provisions. (ii) Consideration of question of suggesting a suitable definition of the term 'Batch' in the light of the General Manufacturing practices.	(i) It has been ascertained from the Indian Metrological Department, New Delhi that the necessary data regarding the maximum temperature reached in shade in different parts of the country is available in 'Climatological Tables of Observatories in India (1953), the revised edition of which is in press and will be available in a few months time. The question will be examined after the information is received.

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	(iii) Consideration of the proposal as to how the scheme of licensing manufacturers of drugs under the Drugs and Cosmetics Rules could be amplified to regulate the quantitative production of drugs. The Committee considered the three reports of the Sub-Committees and approved of the recommendations made in them. The Committee also placed on record its appreciation of the services rendered by the members of the Sub-Committee. Regarding the question of enforcement of the conditions of storage of drugs, the Committee agreed that until further work was done in the manner suggested in the Sub-Committee's reort, the "cool storage" conditions for vitamins need **not** be enforced. The Committee further decided that a definition of the term "Batch" should be introduced in the Drugs Rules on the lines recommended in the Sub-Committee's report. Third recommendation was made by the Committee that the Drugs Rules should be amended to provide for regulation of quantitative production of drugs as recommended by the Sub-Committee.	The necessary data regarding conditions of storage for Vitamin preparations is being collected from the States. Further examination will be done after the information is received from the States. (ii) Necessary amendment to the Drugs and Cosmetics Rules to provide for an explanation of the term 'Batch' with reference to various categories of drugs, such as parenteral products, tablets, liquids, powders, ointments etc. has been referred by the Ministry of Health and Family Planning to the Drugs Technical Advisory Board for its consideration. However the State Drugs Control Authority, West Bengal has pointed out that although the Sub-committee considered it possible to give the definition of the term 'Batch'in respect of various categories of drugs incldiuing medicinal gas, it did not give any specific opinion as to how a batch of medicinal gas should be defined. Though medicinal gases would be covered by drugs manufactured by a continuous process in respect of which the Committee has recommended that the quantity produced in a single shift may constitute a batch, the State Drugs Control authority is of the opinion that a week's out-turn should be taken as a batch in the case of medicinal oxygen and the quantity produced in a shift in the case of other gases. This aspect will therefore be

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		discussed at the forth coming meeting of the D.C.C. (iii) The proposal has been referred by the Ministry of Health & F.P. to the Drugs Technical Advisory Board for its consideration.
Agenda Item - 5 The question raised at the Ninth Drug Conference regarding the manner in which the prescription Register specified in rule 65(3) should be maintained.	The Committee considered at length the difficulties pointed out by the drug trade in this regard and agreed that in respect of drugs which are **not** compounded and which are supplied from original containers against prescriptions of Registered Medical Practitioners it should be adequate if all the required particulars are entered in a separate Cash Memo in the manner specified in Rule 65(3). The Committee felt that the Cash Memo books in which particulars are maintained should be maintained under the custody of the qualified person who is in-charge of the premises.	The Ministry of Health & F.P. have referred to D.T.A.B. for its consideration the draft amendment of (a) Sub-rule (2) of rule 65 to require the supply of Schedule C or Schedule L drugs also to be effected only by or under the supervision of a qualified person and (b) sub-rule (3) of ruir 65 to the effect that the records should be maintained by the Chemists and Druggists in the prescription register for drugs which are made up i.e. compounded at the premises and supplied against doctors' precriptions and that records in respect of drugs which are not compounded at the premises but supplied from or in the original containers of the manufacturers may be maintained on the Cash Memos instead of the prescription register if the licensee so opts.
Agenda Item - 6 Difficulties encountered in marketing tablets and capsules in strip packing and uniform	The Committee examined the pros and cons of compelling manufacturers to market patent or proprietary tablets and capsules in strip packing, including the price aspect to the consumer. It was agreed that the provisions of Rule 105 should be enforced in the interests of the quality of drugs supplied by dealers to consumers. The Committee noted that more and more manufacturers were taking recourse to strip packing in their own interests and that the difficulties	The decision taken with regard to strip packing may be borne in mind by the enforcing authorities.

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Policy in regard to enforcement in this regard.	which were previously experienced in obtaining machinery, metal foil for strip packing etc. are getting themselves resolved progressively. Those manufacturers who are desirious of marketing their products in strip-pcked form should be encouraged to do so. Otherwise it should be ensured at the manufacturing level that patent and proprietary medicines are marketed only in containers which should be sold intact.	
	Continuing the discussions further, the Committee felt that a rule should be introduced making it mandatory on the part of dealers that whenever they effect sales of drugs in containers other than the one in which the manufacturer has marketed the drug, such drugs should be enclosed in any envelope or other suitable wrapper containing the following particulars on the label :- a) Name of the drug b) the quantity and c) the name and address of the dealer.	This proposal has been referred by the Ministry of Health and F.P. to the Drugs Technical Advisory Board for its consideration.
Agenda Item - 9 Question to be considered in regard to the transfer of administration of the Dangerous Drugs Act 1930 from the State Excise Authorities to the State Drugs Control Department.	The Chairman stated that it was obvious from the review of Drug Standard Control activities in the States as recounted by the State Drug Control authorities at the beginning of the meeting that some State Drug Control Administrations had already taken over the administration of the Dangerous Drugs Act. He however drew the attention of the members of the note circulated with the agenda wherein the points which have to be borne in mind by the State Drug Control. Administration in taking over the work connected with the Dangerous Drugs Act have been set out. Copies of the draft rules received from the Excise Department werecirculated at the meeting to the members who were requested to convey their views in writing to the Chairman.	As per the decision taken at the meeting the members were approached in the matter and requested to give their views after careful study of the implications of the transfer of administration of the Dangerous Drugs Act to the Drugs Control Departments. Replies have been received from some members who are of the view that the Administration of the Dangerous Drugs Act 1930 can be taken over by the Drugs Control Department only on the condition that additional staff for that work is provided. The views of these members

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		have been communicated to the Govt. of India, Ministry of Finance. The members who have not yet conveyed their views are being reminded in the matter.
Agenda Item - 10 The question of evolving uniform policy to be adopted towards the labelling ampoules containing injectable products with date of expiry under Rule 109(1) of the Drugs and Cosmetics Rules.	The Chairman stated that though the question arose over the labelling requirements of a specific injectable product containing Vitamin 'C', the Committee will have to examine what labelling requirements should be insisted upon on an ampoule label. Guidelines as to the categories of drugs where such requirements should be insisted upon may also have to be laid down so as to secure uniformity of enforcement of the provision. In the specific case of Vitamin C ampoule (Redoxas of Roche), the Committee agreed that since the date of expiry was shown on the carton label, the manufacturer would disclaim responsibility for loss of potency of the preparation after the expiry date was crossed. In view of Clause (d) of Sub-Rule (1) of Rule 109, the date of expiry of the preparation it was agreed must be shown on the ampoule label. Arising out of these discussions, Shri. Patel stated that the normal trade practice of sale of ampoules in loose form from original containers should be borne in mind while deciding what labelling requirements have to be insisted upon in the case of ampoule label. The Chairman felt that the entire subject matter needed further examination and it would be advisable to appoint a Sub-Committee. A Sub-Committee consisting of the following members was constituted to go into the question. Shri. B.V. Patel — Convener Shri. M.K. Rangnekar Dr. B.B. Sarkar Shri K.N. Shanbhogue	The matter has been referred to the Sub-Committee of the Drugs Consultative Committee for examination. The minutes of the meeting of the Sub-Committee held on the 20th September, 1967 at Baroda will be placed before the next meeting of the Drugs Consultative Committee for their approval.

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	The terms of reference of the Committee will be 1. to recommend the particulars that should be shown on ampoule label, taking into account the current pattern of trade practices in regard to the sale of ampoules to consumers and also representations made by a representative of the O.P.P.I. at the Tenth Drugs Conference held in Calcutta on the 14th and 15th. 2. to recommend the manner in which the date of expiry should be shown taking into account the present practice followed by some manufacturers of showing only the month and the year which leaves the trade in doubt whether the drugs are expected to retain their potency till the end of the month or till the beginning of the month. 3. to recommend what procedure could be followed by manufacturers for indicating on the label that drugs conform to the National Formulary Standards (There was a representation made at the Tenth Drugs Conference that the Drugs Control Administration in certain States did **not** allow the abbreviation N.F.I. to be displayed immediately after the proper name.	
	(d) Labelling of Cosmetics	
Agenda Item - 14 Review of the enforcement of the provisions relating to Cosmetics.	The question as to whether the Batch number, the name of the manufacturer and his principle place of business and the manufacturing licence number should be shown on the label of Cosmetics was considered. In the light of representations made from cosmetics manufacturers that rigid adherence to the provisions will detract from the sale value and export potentialities of the products. After discussion it was agreed that the control measures over cosmetics should be enforced in a manner as not to hamper the cosmetic industry and that interpretation of the rules and regulations in this regard should be lenient and as far as possible to the advantage of the Cosmetics manufacturers. The name of the manufacturers could be permitted to be shown in	The decision taken may be born in mind by the enforcing authorities. As regards compilation of All-India list of licensed Cosmetic Manufacturers, the action has already been initiated and the particulars of these manufacturers are being included in the list that are received by this Directorate from time to time from the State Drugs Control authorities. It may also be added that the title 'The All India List of Licensed

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	a brief manner without the principle place of business and the most important particulars that should be insisted upon are the net contents and the batch number.	
	Regarding the display of the manufacturing licence number on the label, the Chairman said that the representation made by manufacturers of cosmetics that cosmetics being sophisticated products their aesthetic value will be considerably affected if their labels are cluttered up with far too many details, seemed to have weight. He suggested that in the initial stages, the enforcement authorities need not be neticulous about cosmetics showing the manufacturing licence number. The Central Drug Control Organisation will be glad to compile and All-India list of licenced cosmetics manufacturer if the State Government would supply requisite data. This compilation could be circulated for guidance to the State Drug Control authorities and to the Associations connected with the drug trade.	Drug Manaufacturers' has also been changed to read as "The All India List of Licensed Drug and Cosmetic Manufacturers' in which the particulars of the drug manufacturers and the Cosmetic manufacturers are shown separately.
Agenda Item - 15 Provision to be made under the Drugs and Cosmetics Act and rules for the Government Analyst to give his opinion regarding the labelling of drugs and declare them to be misbranded whenever necessary.	The Chairman stated that the forms in which the analytical reports are to be issued do not provide for any observations to be made by the Analyst on matters other than the standards. However there could be instances where because of difficiencies in labelling or omission of important details the Analyst might be inclined to suspect the bonafides of the drug. In such cases the Analysts observations on aspects other than the standards of the drug would be helpful to the enforcement authorities. After discussions, the members were of the view that the report should contain only the observations of the Analyst on the standards of the drug and that any extraneous observations which the Analyst might wish to make could be done in separate covering letter. It was however, agreed that the question should be discussed at the Analysts's Conference which was scheduled to be held on the following day.	The question was considered at the Analysts Conference held at Calcutta on 18th March, 1967. The following minutes of the Conference in this regard were communicated to all the members of the Drugs Consultative Committee vide this Directorate letter No.53-20/67-D, dated 9.10.1967. The question whether Analysts should declare samples of drugs "misbranded" on the ground that the labelling requirements of the Drugs & Cosmetics Act are not complied with was raised by the Chairman who stated that the Drugs Consultative Committee which met on the 16-17 March, 1967 was unanimously of the view that the Analyst should comment in the report

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		only on the quality of the drug and that in case he wanted to bring to the notice of the Drug Control authorities the fact that the labelling requirements had not been complied with, it could be done in a separate forwarding letter. The State Drug Control authorities felt that a report stating that the drug is of standard quality but is misbranded all the same because of labelling deficiencies would put the authorities in an embarrassing situation. The Dirctor, Central Drugs Laboratory and the Government Analyst from Bihar were of the view that information regarding non-compliance with the labelling provisions could be useful to Drug Control authorities. After discussion, it was agreed that the Analyst's report should confine itself to the quality aspect of the drug and that any information regarding non-compliance with the labelling provisions may be forwarded to the respective. Drug Control authorites in a separate forwarding note." Dr. D. Ghosh, Director, Central Drugs Laboratory, Calcutta has since informed this Directorate that the decision taken at the Analysts Conference is not adequate to cover the view point of the Drug Control authority, Delhi who raised question at the meeting. In view of the observations of Dr. Ghosh and certain comments since received from other

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		Analysts in this Directorate, the questions will be further discussed at the next meeting of the Drugs Consultative Committee.
Agenda Item - 17 Amendment of item 10(ii) of Schedule K of the Drugs and Cosmetics Act, 1945 so as to exclude the scope for exemption of Glucose-D from the provisions of the Drugs and Cosmetics Rules.	The question was raised that Sugar of Milk which is largely used in Homoeopathy cannot be controlled in regard to quality in view of the specific exemption provided for it in entry number 10 of Schedule K. Similarly the question also arose whether Glucose or Dextrose which is marketed without making any therapeutic claims would fall within the purview of the Drugs and Cosmetics Act. The Chairman stated that Glucose when marketed as 'Medicinal Glucose' containing therapeutic claims made on the labels should be controlled under the provisions of the Drugs and Cosmetics Act. On the other hand, if glucose lactose etc. are marketed in a manner as not to give an indication that they could be used as drugs, they need **not** be brought under the regulations of the Drugs Act. The same position would hold good in respect of preparations of protein hydrolysate with or without vitamins where no claims are made as to its therapeutic efficacy or where no indications are given which may lead to its use as a drug.	In view of the certain comments since received in this Directorate the Questions will be discussed at the next meeting of the Drug Consulative Committee.
Agenda Item - 20 The question whether the requirement of Rule 65(6)(7) of the Drugs & Cosmetics Rules could be insisted upon in the event of a dealer surrendering a licence.	Shri Rangnekar referred to certain firms in his State which had secured valid sale licences under the Drugs Act after complying with all the requisite conditions and that after transacting sales for a short period had voluntarily surrendered the licences. Subsequently, it transpired that during the period when the firms carried on sales activity some contraventions of the Drugs Rules had been committed. In order to investigate the matter the State Drug Control Administration needed the records maintained by the firms the persons connected with the firms have however taken cover under the plea that since they did not hold any sale licence at present, they were not bound to produce the record maintained when they operated against the sale	The matter was referred to the Ministry of Law for their views as to whether it would be in order to insist upon the production of records after cancellation of the Sales licence voluntarily surrendered by the licensee. The views of the Ministry of Law are reproduced below :- 1. Under rule 65(6) of the Drugs and Cosmetics Rules, 1945 a duty is cast on "the licensee" to produce for inspection by an Inspector on demand

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	licence. Shri Rangnekar wished to know from the Committee whether it would be in order for Maharashta Drug Control Administration to insist upon the production of records at this stage. The question, it was felt by the Committee, required to be examined by legal experts, Shri Rangnekar, at the instance of the Chairman, agreed to supply particulars for further examination by the Central Government.	all registers and records maintained under the Rules for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed. The Drugs and Cosmetics Act or the Rules made thereunder do not define the word "licensee" In the absence of any special meaning given to that word the ordinary meaning has to be taken. The ordinary meaning would be a person who at present holds a licence. Since the persons concerned here have surrendered their licence, they are no longer licensees and no liability contemplated under Rule 65(6) is cast on them. 2. It is true that under Rule 65(7) the registers and records maintained under these Rules have to be preserved for two years. But the Rules do not say that they have to be preserved even after the licensee ceases to hold the licence. The two years are to run from the date of the last entry therein. The two years period may be covered when the licensee still holds the licence. The expression "two years from the date of the last entry therein" finds full meaning in the period when the licensee still holds the licence and hence there is no implication that the records must be preserved even after the licensee Ceases to hold the licence

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		3. Under the circumstances an Inspector can ask for production of registers and records under rule 65 (6) only during the time that the licensee holds the licences. In the light of what has been stated above by the Ministry of Law, no further action is required in this regard.
Agenda Item - 21 Consideration of the question whether Deodorants and Antiperspirants should be deemed to be cosmetics or 'New Drugs'.	The question was raised by Shri Rangnekar whether deodorants and anti-perspirants which contained aluminium hydroxychloride which is a powerful astringent and a mild bacteriostatic, could be considered as a drug, especially as that ingredient affected the function of the body by interfering with the function of the sweat glands. Some members were of the view that ruling on this subject by the F.D.A. in Washington were available. The Chairman stated that the question had to be examined carefully in the light of the claims made and in the light of the decision taken in the F.D.A. Washington. An examination of the issue would be done, if Shri Rangnekar forwarded full particulars.	The proposal was examined in the light of the particulars forwarded by Shri Rangnekar, Director Drugs Control Administration, Maharashtra. It was decided that preparations which are marketed as 'Deodorants and Antiperspirants' creams may be considered as drugs under the provisions of the Drugs & Cosmetics Act and the rules thereunder. The decision was conveyed to the members vide this Directorate letter No.53-26/67-D dated 16th December, 1967.
Agenda Item - 24 Consideration of the amendment of rules 65(3) to provide for dispensing of drugs in accordance with the prescription.	It was explained that a suitable draft amendment to rule 65 (3) was being considered in this connection.	The proposal to amend rules 65(3) was considered by the Drugs Technical Advisory Board at its meeting held on the 14th July, 1967 and it agreed to it. In the circumstances the Ministry of Health & Family Planning have been requested to publish the following drafts amendment to the Drugs and Cosmetics Rules in the Gazette

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		for eliciting comments from the public after consulting the Ministry of Law :- "In the Drugs and Cosmetics Rules in rule 65 after sub-rule (3) the following new sub-rule shall be inserted :- 3-A No drug shall be supplied against demand or prescription which is **not** of the same nature, substance and quality and which is not marketed by the same manufacturer as the one demanded or specified in the prescription.
Agenda Item - 25 The question whether products marketed as 'Hair Fixtres' should be considered as cosmetic.	The question was raised whether 'Hair Fixters' which contained gum and colour should be considered as a cosmetic. In order to ensure safety and in order to enable exporters to obtain a certificate to the effect that the preparations are manufactured under a licence and that their quality was all right, the Committee felt that 'Hair Fixters' should be considered as a cosmetic though unnecessary restrictions need not be imposed on them under the Act, particularly if the exporting authorities had no objection to accepting them.	The offices of the Central Drugs Control Organisation at the ports have been requested that export consignments of 'Hair Fixters' may be dealt in the light of the decision taken by the Committee.
Agenda Item - 26 Suggestion that where a dealer changes his place of business, the current licence should be deemed to be valid for a maximum period of three months from the date on which	The subject arising out of the discussions at the Tenth Drugs Conference held in Calcutta on 14th & 15th of March, 1967 where then considered. The Chairman referred to the representation made by the dealers at the Drugs Conference that when a dealer shifted to a new premises the same licence that was valid for the old premises should automatically be deemed to be valid for a period of three months to ensure that there is no disruption of business and desired to know the views of the committee on this respect.	The decision taken at the meeting of the Drugs Consultative Committee has been conveyed to the members of the Drugs conference.

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the change takes place, unless in the meantime a fresh licence has been taken from the licensing authority in respect of the new place of business.	After discussion the Committee felt that shifting of premises cannot be done overnight and since licensing of sale premises will have to be done only after ensuring that the premises are adequate and are equipped with the requisite storage conditions it would not be advisable to grant any such concession as asked for by the dealers. Any such concession was likely to be misused and it would be extremely difficult to take action against any contraventions under the Drugs Rules on the part of the dealer during the three month period.	
Agenda Item - 27 Recognition of pharmacopoeias for the purpose of standards for drugs.	The question as to what should be the status of a drug which is not covered by the latest edition of the I.P. but which is included in the earlier edition of the same pharmacopoeia was discussed. It was agreed that the standards for the drug as given in the latest edition in which the item is included should be accepted. The same position would hold good for drugs covered by the earlier editions of other pharmacopoeias.	A draft amendment to entry 5 of the Second Schedule to the Drugs Act according recognition to the edition of the Indian Pharmacopoeia for the time being in the case of drugs included therein and to the edition of L.P. immediately preceeding the one for the time being in the case of drugs including therein but not in the latest edition and similarly in the case of drugs not included in the I.P. the edition of such pharmacopoeia for the time being and the one immediately preceeding it, is under examination of the Ministry of Health & Family Planning in consultation with the Ministry of Law.
Definition of the term 'Componding' and 'Dispensing'.	The Chairman stated that suggestions were made at the Tenth Drugs Conference to the effect that the terms 'compounding and dispensing' should be defined and that the question whether experience of sale across the counter could be deemed to be adequate to consider a person as 'qualified person' under the Drugs Rules should also be examined. It was agreed that these two matters should be examined by the Sub-Committee constituted under item number ten of the Agenda.	The matter has been referred to the Sub-Committee of the Drugs Consultative Committee for examination. The minutes of the Sub-Committee held on the 20th September at Baroda will be placed at the next meeting of the Drugs Consultative Committee.

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Question regarding declaration of samples of Cholera Vaccine not of standated quality by the Govt. Analyst in West Bengal.	Dr. Sarkar stated that certain samples of cholera vaccine maufactured in West Bengal had been declared not of standard quality by the Govt. analyst on the ground that the vaccine did not contain 8,000 micro-organisms per ml. As these organisms undergo lysis after manufacture this test in his opinion would not be a correct indication of the potency of the vaccine. The Chairman stated that the Biological Products Sub-Committee of the Indian Pharmacopoeia will be examining this aspect.	The matter has been referred to the Biological Products Sub-Committee of the Indian Pharmacopoeia for examination.
Grant of I.T.C. Licenses for Raw Material - difficulties raised.	Shri Nair said that I.T.C. Licences for raw material are not being granted to the firms in his State on the basis of his recommendation and that he had been experiencing difficulties in settling such matters with the authorities concerned. The Chairman stated that he would look into the question if full particulars were supplied.	The State = Drugs Control authorities, Kerala have been requested to furnish the full particulars to this Directorate for further action. The particulars are awaited.
Amendment of Rule 49 of the Drugs Rules.	Shri Ramana Rao desired that the Drugs inspectors functioning in the States for inspections of Schedules C and C(1) drugs from the time the Drugs Rules came into force should be protected and that Rules 49 of the Drugs Rules should be suitably amended for this purpose. It was explained to him that the case had been under discussion with the legal department and that it looked as though an amendment of Rule 49 was inescapable. Shri Patel mentioned in this connection that the provisions of the prevention of Food Adultration Rules which are almost similar to the Drugs Rules have been recently amended so as to ensure the continuance of Inspectors who were appointed in a provisional capacity in the initial stages of the enforcement of the Act. He promised to send particulars so that the amendment of Rule 49 could be considered.	The following amendment has been referred by the Ministy of Health & F.P. to the Drugs Technical Advisory Board for its consideration. "In the Drugs and Cosmetics Rules, 1945 for the first and second provisos to rule 49, the following shall be substituted, namely :- 'Provided that Inspectors with three years' experience in the manufacture and testing of drugs specified in Schedule C or Inspectors whose training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be necessary, a reasonable guarantee of adequate knowledge and competence to

(1)	(2)	(3)
		inspect the manufacture of items mentioned in Schedule C may be appointed to inspect the manufacture of items mentioned in Schedule C".

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ANNEXURE II
Item No.30 of the 12th D.C.C. Meeting

"Principles for institution of Prosecution under Drugs Act"

Institution of Prosecution :

The weapon of prosecution should be used sparingly and judiciously.

As a prudent measure, prosecution should be launched where administrative measures have failed to have desired effects. Minor contraventions which are either due to ignorance of are unintentional, should not be recommended for prosecutions.

The persistent defaulter should be prosecuted but trivial ommissions should not form the basis of prosecutions. For guidance of officers a broad classification of cases in which prosecutions should be launched and in cases where they should not be launched is given below :

Prosecutions should be launched in cases :

(1) Where spurious or misbranded drug is manufactured, sold or stocked or exhibited for sale or is distributed.

(2) Where drugs are manufactured without a valid licence and where such manufacture is not due to ignorance of law.

(3) Where a drug manufactured, sold, stocked or exhibited for sale or distributed does not, on test and analysis carried out by the Government Analyst, give even qualitative tests for the presence of active therapeutic ingredient, or the active ingredient is practically absent.

(4) Where a parenteral preparation is reported by the Government Analyst to be non-sterile, pyrogenic and toxic and which, on enquiry, is found to be sub-standard due to total absence of any quality control in the manufacturing premises and where previous warning has been issued.

(5) Where a person is found stocking or exhibiting for sale, selling or distributing drugs without a valid licence provided such person is sufficiently warned in writing for committing the same offence.

(6) Where a licensee, who has ben previously and sufficiently warned for contravention of conditions of licence or any Rule or whose licence has been suspended or cancelled for violating conditions of licence or committing breach of the

Rule, is found again continuing or committing the said violation. For example selling Schedule 'H' and 'L' drugs without precription and in absence of qualified person, inspite of several warnings.

(7) Where a licensee is being prosecuted or is involved in manufacture, sale, distribution, etc. of spurious durgs, and his registers and records are not found complying with provisions of Drugs Rules 1945 or conditions of licence, and when such discripancies are likely to prove the conduct of the licensee and thereby help the main case of spurious drugs.

(8) Where the Police or other departments of the Government have carried out searches under Acts enforced by them, and where they have referred cases to this Directorate for taking action for contraventions of provisions of the Drugs Act, 1940, and Rules thereunder suspended or detected by them during their course of enquiry.

Provided the case papers forwarded by police or such other departments show a prima facie case under the Drugs Act, 1940.

Prosecutions are not ordinarily warranted in the following cases :

(i) Where the sample reported by the Government Analyst is not of standard quality because thermolabile active ingredients are below the prescribed limit or where the deficiency in the active ingredients is due to improper storage and not due to any fault of the manufacturer, and where the control sample of the same batch preserved by the manufacturer is of the standard quality.

(ii) Where the manufacturer, or a dealer, situated outside the State, has sold, distributed a drug not of standard quality and which is not counterfiet. In such case full facts should be communicated to the Director, so as to enable him to take up the matter with authorities of the State in whose jurisdiction the said manufacturer or dealer is located.

(iii) Where a licensee is found contravening provisions of Section 18 (a) (iii) and 18 (a) (iv) or 18 (a) (v) of the Drugs Act, 1940 and such contraventions, an enquiry, are found to be unintentional and due to inadvertant ommissions. For example, an Ayurvedic or Unani Medicine which also falls within the meaning of word 'Drug' is stocked or exhibited for sale or sold or distributed.

(iv) Where foreign matter is found in a product. For example, glass piece or piece of rubber in an Antibiotic vial or some such matter in liquid oral preparations.

While investigating cases under the Drugs Act if contraventions or offences under other Act, like Prohibition Act, Poisons Act, etc. are disclosed then such offences should be reported to authorities concerned. For example Superintendent of Prohibition and Excise for Prohibition Act, Drugs (Control) Act, etc.

In complicated cases, or where it is felt necessary to deviate from the broad principles referred above, the Director, Drugs Control Administration should be informed in detail about full facts of the case together with the officers' remarks and opinion of the Police or Public Prosecutor as the case may be, the Director's order for Prosecution must be obtained in every case".

Standards for Petroleum Jelly **ANNEXURE III**

Item No.34 (9) of 12th D.C.C. Meeting

No. DCA/GMP/13493-13527/ of 68
Directorate of Drugs Control
Administration, Maharashtra State,
127, Mahatma Gandhi Road, Fort,
Bombay - 1. 11th September, 1968.

To

All Manufacturers of Petroleum Jelly,
of Pharmacopoeial quality in the State.

Subject : - Standards for oils to be used in the manufacture of Petroleum Jelly White and Yellow of Pharmacopoeial quality.

Dear Sirs,

Our recent visits to the units manufacturing Petroleum Jelly in the State, have revealed that there is no proper control over the oils that are being used in the manufacture of Petroleum Jelly. It was observed that oils which are generally marketed as spindle oils, transformer oils, pale oils, etc. are used in the manufacture of Yellow Petroleum Jelly. As far as manufacture of White Petroleum Jelly is concerned, it was found that the mere creteria on which any oil was used was its colour and if sufficiently colourless material was available, no other specifications were insisted upon. The visits also revealed that addition of Microcrystalline Wax varies from 6% to 20% and that there is no uniformity.

You are aware that Petroleum Jelly manufactured in this country is not manufactured by the fractional distillation of crude oils but is manufactured by merely blending oils with certain proportion of waxes. The pharmacopoeial specifications in I.P., B.P. or U.S.P. are therefore, based on the hypothesis that Petroleum Jelly is manufactured by the fractional distillation process. These standards evidently cannot, therefore be taken to be as sufficient guarantee that a Petroleum Jelly manufactured by the blending process would be really of a good quality. No standards have so far been established for Petroleum Jelly manufactured by the blending process. It is necessary therefore that quality control is exercised in using raw materials of proper quality and in proper proportions. You will appreciate that these two factors will have a vital bearing on the quality of the finished product. With a view therefore that the Petroleum Jelly manufactured in the State is of gooc

quality, this Directorate after consultation with experts in the field feels that good quality of Petroleum Jelly is likely to be obtained if manufacturers use oil of the following specifications and adopt the suggestions given below :

Specification for White Oils to be used in the Manufacturer of White Petroleum Jelly I.P.

The oil shall be a mixture of liquid hydrocarbons obtained from Petroleum.

Description : A transparent, colourless, oily liquid, free from fluorescence by day-light almost odourless when cold; tasteless.

Solubility : Practically insoluble water, and in alcohol; soluble in chloroform, and in solvent ether; miscible with fixed and volatile oils.

*** Weight per ml :** At 20, 0.830 to 0.873 g (page 917)

Kinematic Viscosity : At 37.8 not greater than 30 centistokes (Page 919)

Sulphur Compounds : Mix 4 ml. with 2ml of ethyl alcohol and 2 drops of a clear, saturated solution of lead monoxide in solution of Sodium Hydroxide, and heat at 70 for ten minutes with frequent shaking; the mixture remains colourless.

(* Pages refer to pages of Indian Pharmacopoeia, 1966)

Specification for oils to be used in the manufacture of Yellow Petroleum Jelly

The oil having the following specification shall be used only in the manufacture of Yellow Petroleum Jelly :

Colour	1 Max.
(Light Colour preferred)	
Sp. Gravity @ 60° F.	|
SUS @ 100°	330 Min.
SUS @ 210° F	60 AUR
USR	97 MIN.
POUR	30 MAX
COC FLASH	400 MIN.

Microcrystallin Wax : Manufacturers may continue to use Microcrystallin Wax which is available from the oil companies, The Percentage of Microcrystallin Wax, however, in White or Yellow Petroleum Jelly must not be less than 10%.

Batch Size : Batch size should be commensurate with the capacity of the vessel used and each such batch must be tested for quality, purity and strength.

I am sure, manufacturers in the State would cooperate with the Administration in ensuring to the consumer products which are really of good quality purity and strength. Action taken in the matter may please be communicated to this Directorate.

Please note that if you are found using oils of any inferior grade or deviating from the above instructions this Directorate would be constrained to take stern action in the matter.

Yours faithfully,

Sd/-
Director
Drugs Control Administration

ARO/loQ ... No.DCA/GMP/13528-13597 of 68
Bombay - 1 11th Sept. 1968

1. Copy forwarded to All Associations of manufacturers in the State of Maharashtra.
2. Copy forwarded to All Officers of Drugs Control Administration for information and guidance. When officers visit manufacturers of Petroleum Jelly, they should keep an eye on the quality of oils that are used.

Sd/-
Director
Drugs Control Administration.

No.MFG/GMP/15906-93/ of 68
Directorate of Drugs Control
Administration, Maharashtra State,
127, Mahatma Gandhi Road, Fort,
Bombay - 1

14th October, 1968

To

All Manufacturers of Petroleum Jelly
of Pharmacopoeial quality in the State.

Subject : Standards for oils to be used in the manufacture of Petroleum Jelly White and Yellow of Pharmacopoeial quality.

Sirs,

Reference this Directorate Circular Letter No.DCA/GMP/13493-13527, dated 11th September, 1968.

Querries have been received by this Directorate seeking clarification on certain points in the circular Similarly some typographical errors have crept in the circular already issued. With a view, therefore, to correct these errors, and with a view to clarify various points raised by manufacturers, this circular is being issued.

The following corrections may be made in the circlar already issued.

On page 2, under the heading Kinematic viscosity read as "at 37.8° not less than 30 centistokes" instead of "37.8° not greater thatn 30 centistokes". Under the heading SUS @ 210° F the specifications should be read as '60 AVR' instead of '60 AUR'.

Certain manufacturers have asked for clarification regarding the various short forms used and regarding standards. The following clarification is given:

The letter 'SUS' stand for Seybolts Universal Seconds' the letter 'USR' stand for Unsulphonated Residue'. The letter 'COC' stand for Cleveland open cup' method, 'MIN' and 'MAX' stand respectively for minimum and maximum and the short form 'AVR' stands for 'Average'.

A question has been raised as to whether equivalent ISI specifications are available. It may be stated here that the specifications given in the Circular already issued are according to ASTM standards and the equivalent ISI specifications wherever available are given below :

Test	-	IS specifications.
Colour	-	IS 1448 P.12, 1967
Viscosity	-	IS 1448 P.25
Pour	-	IS 1448 P.10
COC Flash	-	IS 1448 P.21 (closed cup method)

While issuing the earlier circular it was not considered necessary to give specifications for the microcrystalline wax used in the manufacture of Petroleum Jelly, it is however, now felt that the same should also be given for guidance of manufacturers. These are as follows :-

Grade	Melting Pt. Min. ASTM D127-49	Penetration at 77° (ASTM D 1321-54T)	Colour	Viscosity Seybolt Universal @ 210°C.
White	Min.160°F	20/35	White Opaque	80/90
Light Yellow	Min. 160°F	20/35	2 Maximum	80/90

It is hoped that these standards would enable manufacturers to use proper quality of microcrystalline wax. Manufacturers are also informed that White oil required for manufacture of White Petroleum Jelly is being manufactured by M/s Fastern Petroleum Private Ltd., Bombay and manufacturers may therefore approach the said firm for their requirements of White Oil.

Yours faithfully,

Sd/-
Director
Drugs Control Administration

ARQ/1210

NOTE ON PETROLEUM JELLY

We had recently inspected the following firms manufacturing Petroleum Jelly of pharmacopoeial quality, in view of the complaints received regarding the quality of Petroleum Jelly, from Drugs Controller (India) as well as from some of the manufacturers. The object of this visit was to find out the exact manufacturing conditions existing in these manufactories and to have first hand information as regards the nature and quality of the raw materials used by them in the manufacture of Petroleum Jelly, and also to find out what quality control measures are exercised by these firms. The whole idea was to find out as to what steps could be taken to improve the quality of Petroleum Jelly manufactured and sold in the State. Dy. Drugs Controller (India) and Drugs Inspector, Shri Dolas, were associated in this probe.

In all we visited the following firms :

1. M/s. Bharat Petroleum Products,
   Sainath Industrial Estate No.2
   Shed No.10, Off Aarrey Road
   Goregaon (East),
   Bombay - 62.

2. M/s. Kela Co (India) Pvt. Ltd.
   Wagle Industrual Estate
   Thana.

3. M/s. Lyka Laboratories,
   47 Quarry Road
   Malad (East)
   Bombay - 64

4. M/s. Savitha Chemicals Pvt. Ltd.,
   34-A Kurla - Andheri Road
   Bombay - 59

5. M/s. Trichem Laboratories
   14 Katrak Road
   Lalwani Industrial Estate
   Block 11, 2nd Floor, Wadala
   Bombay - 31.

6. M/s. Nymph Laboratories
Tulsi Pipe Road
Opp. Phoenix Mills
Bombay - 13

7. M/s. Punkaj Petroleum and Chemical Industries,
Aghadi Estate, Marol Village
Maroshi Road, Bombay - 59

8. B. Tex Ointment Manufacturing Co.,
Kandivli Industrial Estate.

9. Franco Italian Co.,
Kandivli Industrial Estate, Bombay - 67

10. M/s. Kirti Kumar Chandulal and Co., Bhandup

All these firms are manufacturing Yellow Petroleum Jelly as well as White Petroleum Jelly. There is practically no quality control exercised over the manufacture of Yellow Petroleum Jelly. The oils commonly used for manufacture of Yellow Petroleum Jelly are :

1.	Indrex 10	4.	Security 118
2.	BOC 40	5.	Security 44
3.	Coray 40	6.	Harmony 40 (German Pale oil)

These oils, as we were given to understand, are spindle oils and are marketed by I.O.C., Burma Shell ESSO, and Caltex. It is not customory with the manufacturers to test these oils but they only go by the brands, purchase in bulk and use them in the manufacture of Yellow Petroleum Jelly. We examined all these oils and we found all of them had strong kerosenic odour and highly fluroscent. These oils are not subjected to any treatment before the are taken up for use in the manufacture of Petroleum Jelly.

Micro-Crystalline Wax (ML 445 Yellow and W 445 White)

This Wax is imported and is supplied through I.O.C. or brought under import licence. The common brand of the Micro Crystalline Wax that is used for the Petroleum Jelly are as follows :-

Grade	Melting Pt. Min. ASTM D127-49)	Penetration ASTM D-1321-54T	Colour	Viscosity Saybolt Universal @ 210° C.
W 445	165° F	25/85	White	80/90
ML 445	165° F	25/35	Pale Yellow	80/90

Brand Name	Colour	M. Pt.	A S T M O F
Stanvac Microwax 190Y	Yellow	109-95	
S/V Cerese Wax AAA	Light Tan	170	
S/V Product 2305	Light Yellow/ White	160	
Stanvac Micro Wax 455W	White	165	

HARD PARAFFINE WAX

This is the other ingredient which is used in the manufacture of Petroleum Jelly. This is supplied either by BOC or Indequip.

Our enquiries reveal that this does not pass the pharmacopoeial tests. These two firms have got monoply of supplies in respect of this raw material.

WHITE PETROLEUM JELLY :

For the manufacture of white petroleum jelly, the manufacturers have necessarily to use an oil which is colourless. The manufacturers of Petroleum Jelly treat the pale oils with acid and alkalies to make it colourless but no standards have been laid down by these manufacturers before these can be used in the manufacture of Petroleum Jelly.

The manufacturers are mainly interested in colourless oils and so long as they get such oils they do not bother about any other specifications. We found

that even these oils though colourless were found to have some kerosine odour and some flourescence.

METHOD OF MANUFACTURE

The method of manufacture differs from manufacturer to manufacturer in as much as some manufacturers are using jacketted vessels for heating oils with stirring arrangements, whereas some have direct heating arrangements with no stirring.

The process essentially consists in heating the oil to about 100°C and then adding. Micro Crystalline Wax and Hard Paraffin Wax in certain proportion. There is also no fixed proportion in which these waxes are added to the oil. Our enquiries have revealed that the same varies from 6% to 20%. There is no uniformity in this regard. Hard Paraffin Wax is added so that the total percentage of Wax in particular batch comes to around 20 to 25%. We, however, found that there is a tendency amongst the manufacturers to use less of Micro Crystalline Wax and compensate it by adition of hard paraffin wax since Micro Crystalline Wax is a costly item.

The mixture is then stirred for a period of 2 to 3 hours and allowed to cool. Samples from this lot are drawn and sent for test and analysis. It may be worthwhile here to mention the process of manufacture of petroleum jelly, In this country it essentially consists in blending of oils with Micro Crystalline Wax and other waxes, whereas in U.S. Petroleum Jelly is obtained after distillation of other fractions of the Crude Oil and material which is remaining at the bottom of the distilling stills is then subjected to various purification treatment and for removal of impurities and then marketed as of pharmacopoeial quality. According to certain experts the important property of the Petroleum Jelly is due to the proto substance that is present in the Petroleum Jelly manufactured by this process. It has not been so far possible to isolate this substance. It is, therefore, implied by these authorities that the Petroleum Jelly made by any other method as is being done in our country is not likely to have the same properties and quality as the one obtained from distillation process. There is a tendency in such a petroleum jelly to separate out because it is a sort of mixture that is found by blending of the oils and the waxes.

QUALITY CONTROL

As stated above quality control is not properly exercised over the raw materials used in the manufacture of Petroleum Jelly. Even on the finished products, we observed that there is no uniformity in the matter of testing. In one case the manufacturer was marketting the production of one entire month as one batch so as to minimise the expenditure of testing. This practice more or less is being followed by other manufacturers though not to the extent as the one referred to above. We have advised all manufacturers to test each load of the oil taken in the tank for manufacture of Petroleum Jelly as one batch for purposes of test and analysis.

With a view to find out whether the products come upto the Pharmacopoeial specifications we drew informal samples of all Petroleum Jellies manufactured by all the manufacturers whose premises were inspected by us. We took samples both of Yellow Petroleum Jelly as well as White Petroleum Jelly, wherever available. The same were sent for test and analysis to Government Analyst for testing it according to I.P and U.S.P. Specifications. The official results from the Government Analyst have not been received yet but from unofficial reports that we have received, it is seen that all samples of Yellow Petroleum Jelly manufactured by various manufacturers pass I.P. specifications except the one manufactured by M/s. Kela and Co., This product of this company failes in yellow colouring matter test. As regards U.S.P. tests we have information that all the samples are passing the U.S.P. specifications but Government Analyst is not in a position to undertake "congealing temperature" and consistency test as he does not have necessary equipment for carrying out these tests. It will be seen from the above that a petroleum jelly manufactured by the licensed manufacturers does monoply with I.P. and U.S.P. specifications.

It may, however, be mentioned that this does not mean that the products manufactured by these manufacturers are really good, because the limits given in the I.P. as well as in B.P. are very broad and so long as the manufacturer uses a particular grade of oil, adds some quantities of waxes, it is bound to pass the pharmacopoeial specifications. It may also be mentioned here that the standards that have been laid down in I.P. and B.P. are based on the assumption that Petroleum Jelly that would be available would be from the distillation of crude oils

and not from the blending of spindle oils and waxes. Essentially, therefore, these specifications cannot guarantee that the petroleum jellys are really of good quality. It may also be worthwhile here to mention that in the manufacture of Petroleum Jelly by the distillation of crude oil method, the resultant product is yellow petroleum jelly and after bleaching this petroleum jelly, white petroleum jelly is obtained. It is therefore clear that yellow petroleum jelly is a sort of Crude Petroleum Jelly with certain colouring matters and other impurities. It may be worthwhile here to mention that U.S.P. XVII does not include yellow petroleum jelly and there is monograph only on white petroleum jelly. The point, here for consideration is, if in the country we are goint to manufacture petroleum jelly by the blending process then whether it is necessary to include yellow petroleum jelly in the pharmacopoeia since this involves less control on quality of the oil that is used and it is definitely inferior product. Both these white and yellow petroleum jellies have to be manufactured separately and it is not that one results from the other. We have therefore a feeling that it would be necessary to examine whether yellow petroleum jelly should at all find a place in I.P.

The above would give a picture of the conditions existing in the state as far as manufacture of petroleum jelly is concerned. We had occasion to discuss various aspects of the manufacture and quality control of petroleum jelly with experts in this field. There was unanimity of opinion that unless we lay down certain specifications for oils that are used in the manufacture of Petroleum Jelly, it will be difficult to exercise any control over the finished product.

We then discussed as to what could be the minimum specifications for the oils that are presently being used in the manufacture of Petroleum Jellies. It was generally agreed that for a good quality petroleum jelly the ideal pale oil would be one complying with the specifications laid down in the I.P. for "light liquid Paraffin". However, if light liquid Paraffin is used for the manufacture of Petroleum Jelly the cost of production would be prohibitive. It was also pointed out that many of the mineral oils available are quite suitable for the manufacture of good petroleum jelly. While these oils conform to all the specifications laid down in the I.P. for light liquid Paraffin they do not pass the test for "Readily carbonizable substances". We feel that this particular test has no significance so far as the manufacture of Petroleum jelly is concerned. Since the price differential between such oils and light liquid paraffin is significant, we are of the view

that rather than insisting on the use of light liquid Paraffin. We may insist on oils being used which conform to all the tests laid down for light liquid paraffin except the test for "Readily corbonisable substances". As the prices of such oils are not very high the insistance of the use of these oils should not affect the prices of petroleum jelly. As regards Microcrystalline wax, we may insist on the manufacturers that the same should not be less than 10% in the batch of Petroleum Jelly. we may not insist on the uniformity of process of the manufacture and leave the same to the individual manufacturer. We may also ask manufacturers to conduct experiments to find out the grade of oil that they are able to get by using the spindle oil that they are going to use and then finally lay down the specifications.

PRICE :

Our enquiries reveal that the prices of Yellow Petroleum Jelly vary anywhere from Rs.1.75 per kilo to Rs.2.50 per kilo and that of White Petroleum Jelly varies from Rs.2.75 to Rs.3.50.

YELLOW PETROLEUM JELLY

This is made out of crude spindle oil that is available in the market. We have discussed this with some experts in the field and they have suggested that we may insist that the oil having the following specifications should only be used :

Col : (Lightest colour preferred)	1 Max :
Sp. Gravity @ 60° F	0.850/0.900
SUS @ 100° F	330 Min.
SUS @ 210° F	60 AVR
USR	97 MIN
POUR	30 MAX
COC FLASH	400 MIN

The conditions regarding addition of Micro Crystalline wax have remain the same.

In summary we have to say as follows :

1. The question of deletion of Yellow Petroleum Jelly from I.P. should be considered.

2. Drugs Controller (India) to issue directive to Drugs Controllers in other States laying down the minimum specifications of the oils and the percentage of Micro-Crystalline Wax to be used in the manufacture of Petroleum Jelly so long as the same is manufactured by the blending process.

ANNEXURE - IV
Item 34 - 10 of 12th D.C.C. Meeting

MINIMUM SUGGESTED REQUIREMENTS FOR MANUFACTURE OF OPHTHALMIC OINTMENTS.

I. PREMISES

1. The area of the Section should be adequate enough to provide for free moving space after taking into account the volume of production, area occupied by the equipment and the number of workers in the Section.

2. The flooring, walls and ceiling should be smooth and washable. The floor should be tiled. The walls should also be preferably tiled.

3. Two airlocks should be provided at the entrance to the Section (Three in case where a Manufacturer has no separate facilities for changing street clothes into factory uniforms for workers).

The first airlock should be used for changing factory uniforms, washing of hands and feet and for dipping hands and feet in antiseptic solution anc the second airlock should be used for putting on sterile overalls, masks and footwear. In the second airlock also antiseptic solution should be kept for washing hands again.

4. Pencillin ointments, must be manufactured in an area specially reserved for the purpose in the Section. Separate equipment and Air Conditioners should also be provided for Pencillin Ointment. This arrangement is considered necessary to minimise penicillin contamination.

Ointments other than Penicillin ointments must be manufactured in other area of the Ophthalmic Ointment Section and must not be manufactured in Penicillin Section.

5. The Section should be provided with sufficient number of germicidal lamps of sufficient intensity which would be useful in maintaining sterile conditions in the Section.

II. EQUIPMENT

The following equipment is considered necessary for manufacture of Ophthalmic Ointments.

1. Micropulveriser

2. Bantam Mill - On passing through Bantam Mill through 0.13" HB sieve and thereafter through 0.20" HP sieve particle size on an average is reduced to 15u maximum particle size is 75u.

3. Fitz Mill - Passing the material through No.000 size sieve, 10 to 20 u is achievable. Oversize particle - 50 u.

4. Ball Mill - On ball milling certain materials for 48 to 72 hours particle size upto maximum 50 u an average of 5 to 10 u is achievable.

5. Balances.

6. Brushes mounted on motors for brushing the tubes to free them from metal particles.

7. Compressed air system for air cleaning of tubes.

8. Equipment for sterilisation of tubes.

9. Aluminium trays with air-tight lids for storing tubes.

10. Jacketted stainless steel tank with thermostatic control.

11. Stainless stell scoops.

12. Jacketted stainless steel tank fitted with Hobart type mixer.

13. Triple Roller Ointment Mill.

14. Adequate number of Stainless steel tanks for storage of ointment with air-tight lids.

15. Equipment for filling and sealing tubes.

16. Autoclave for sterilising overalls etc.

III. TEST FOR METAL PARTICLES IN COLLAPSIBLE TUBES

It is recommended that the empty tubes should be tested for limit of metal particles as per method given in British Standards Institute Specification BS 4230-1967.

The Method essentially consists in expressing ointment from tubes and filtration of the contents of the samples of 50 clean tubes filled with eye ointment

base and examination of the filter paper for metal particles. The metal particles content is assessed by giving each metal particle a score, as follows and adding the scores together.

Particles 1 mm and above	50
Particles 0.5 mm but less than 1 mm	10
Particles 0.2 mm but less than 0.5 mm	2
Particles less than 0.2 mm	0

If the total score is less than 100 points, the batch of tubes passes the test; if the total score is more than 150 points the batch fails the test. If the total score is between 100 and 150 points inclusive, the test is repeated on a further sample of 50 tubes and the batch passes the test if the sum of the total scores in the two tests is less than 150 points.

IV. BASE STERILISATION

Separate area near the Ophthalmic Ointment Section is recommended to be provided for sterilisation of petroleum base. The base should be first melted, filtered and then sterilised at 150°C for not less than one hour. Some arrangement should be made for directly transfering the sterile base into the mixing tank or into previously sterilized containers. In case of non-baseline bases, suitable method of sterilisation should be adopted.

V. PREPARATION OF CONTAINERS

1. It is suggested that Empty tubes should first be cleaned by inserting the open end of the Tube on small vertical brushes mounted on motors. It is expected that this will help in removing and loosening of the foreign material adhering to the inside of the tubes. This has to be done carefully otherwise it may damage the ends of the tubes.

2. Thereafter compressed air jet should be forced into the tubes from the open end of the tubes. It is expected that this will ensure removal if foreign matter and dirt already loosened in the first step.

3. Tubes should then be sterilised in aluminium trays provided with tight fitting lids and by adopting any one of the following techniques :

It should, however, be understood that it is necessary to develop proper technique before any of these methods is adopted.

1. Treatment with specially denatured spirit followed by drying at 60° to 70° for sufficient time (Steam or water heated over is suggested for this purpose; but a manufacturer may use an electric oven for this purpose provided it is flame-proof and explosion-proof.

2. Heating the tubes at 150°C for at least one hour.

3. Continuous exposure to U.V. Radiation for a period of not less than four hours in Aluminium trays.

4. Treatment with formaldehyde

5. Exposure to Ethlene Oxide.

6. Any other method approved by the Administration.

Sterilised tubes should be stored in closed aluminium trays and should preferably be taken up for filling on the same day but in all cases within 21 hours of sterilisation of tubes.

VI. BATCH SIZE

Batch size of the Ophthalmic Ointment should be commensurate with one day's continuous filling operation, with the same set of workers.

VII. MANUFACTURING PROCEDURE

1. The equipment used must be sterilised by swabbing with specially denatured spirit/or by flaming.

2. The medicament to be used in the manufacture of Ophthalmic Ointments must be finely ground material which would give an average particle size of less than 50 microns in the finished product. No particle should however be more than 75 micron size.

If the material used is not of proper particle size, steps should be taken to ensure that the finished product will comply with the particle size requirements in the finished product.

3. It is also desirable to pass the entire ointment mass through a triple roller mill for even distribution of medicament in the ointment.

4. The finished product should be stored in air tight stainless steel tanks until it is taken for filling.

5. Aseptic condition should be maintained during the process of manufacture, storage and filling.

6. Fresh sterile ovealls should be used at the time of every entry into the filling section.

7. White soft paraffin IB/BP/USP is recommended for use in manufacture of Ophthalmic Ointments containing vaseline base.

8. Plate count of the section should be taken occasionally. If there seems to be an abnormal rise in the count, effective steps should be taken to subject the area to proper cleaning and disinfection operations before production of fresh batches is undertaken.

9. The Bactericidal lamps should be tested by a U.V. meter for measuring their efficiency. In case this is not possible a record should be maintained of the burning hours of the bactericidal lamps and the lamps should be replaced after their efficiency period as declared by the manufacturer/supplier of the lamps, is over.

VIII. QUALITY CONTROL OF OPHTHALMIC OINTMENT REQUIREMENTS

1. Petroleum Jelly manufactured by licensed manufacturers only should be used.

2. All the raw materials used in the manufacture of Ophthalmic Ointment should be tested irrespective of the test report from the manufacturer.

3. Samples for test shold be drawn ir sucha manner as to represent the entire day's filling of the batch.

4. Particle sizes

The average particle size in the medicament should not exceed 50 microns and no particle in the ointment should have size over 70 microns.

5. Finished product should be tested for potency, and net contents and for other requirements prescribed by Indian Pharmacopoeia and by Drugs Control Administration from time to time.

6. The finished product should be tested for absence of gross contamination as follows :-

Conduct of Gross Contamination Test

About 1 gm. of the material is dispensed on the agar surface and streaked in a zig-zag pattern with a sterilised rod. The plates are then incubated for 4 days at 25°C for stabouraud agar, and for 2 days at 33°C for Trypticase agar.

Interpretation

The sample passes the test if there are not more than 10 viable organisms/ gm. of sample used. The colonies should be typed for presence of gram negative rods.

7. The finished product must be free from Pseudomonas auriginosa.