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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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MINUTES OF THE FIFTEENTH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 9TH AND 10TH MARCH, 1972.

Welcoming the members the chairman stated that though the meeting of the Drugs Consultative Committee is normally held in one of the States, it was being held at New Delhi due to the elections in the States. A programme for the training of Drugs Inspectors from the States had been arranged at Bombay under the Charge of an Officer on Special duty from February, 72 and that 16 drugs inspectors were receiving training at present. The programme was a continuous one and the next session would start after the monsoon. He stressed the fact that there was no short cut to tighten Drugs Standard Control other than to keep on inspecting the manufacturing and facilities. This meant that more experienced drugs inspectors should be available to exercise stringent quality control measures. In this context he appealed to the members to avail themselves of the training facilities. A similar training programme for the training of drugs analysts - was also proposed to be organised at the Central Drugs Laboratory Calcutta during 1972-73 and hoped that States Drugs Control Departments would make the best use of the arrangement.

Talking about the quality control in the field of drugs the Chairman referred to an impression that had been created amongst the members of the medical profession and the Government authorities that the quality control measures observed by the samll and medium scale sectors of the drugs industry cannot be depended upon. To dispel such wrong information, officers of the Drugs Control Organisation in States and Zones should exercise stringent quality control over these firms. He rieterated the earlier suggestion that firms which make supplies of drugs against D.G.S. & D tenders and firms engaged

in the manufacture of sensitive preparations such as antibiotic preparations including paedriatic and ophthalmic preparations and injectables should be subjected to more frequent and stringent scrutiny. He assured the States Drugs Control authorities of help in this direction from the Zonal Officers and their Inspectorates.

A common complaint voiced at the Inter-Ministerial meetings held by the Central Govt. was that statistical information about firms which are not registered under the Industries (Development and Regulations) Act was meagre and that any assistance to be given to that sector of the industry will depend upon the information available about the basic products manufactured by them, their turnover, the number of skilled and unskilled workers employed, the values of import licences granted to the, the nature of testing and other facilities available with them, etc. Although detailed information about small scale units located in states was called for the above aspects, the response from States has been very disappointing. He stated that the Zonal officers were collecting this information through their Drugs Inspectors and that the State Drugs Control authorities should undertake similar surveys. The claim should be to collect information about such firms within a period of one year.

Referring to the prevalence of sub-therapeutic preparations, the Chairman pointed out that such preparations constituted a positive hazard to public health and would strike at the root of the basic concepts of Drugs Control. Their manufacture was confined to a few states, but if their prevalence is not taken note of and proceeded with other States will be faced with the same problem on a considerably magnified scale. The U.P. Government had been fighting a writ petition on this score and all the States will have to co-operate in stamping out these preparations. He assured that the Central Drugs Standard Control Organisation will be glad to assist the States

in this Compaign. A similar problem was likely to be encountered with theraputically irrational combinations and that our efforts should be to keep a watch on the theraputical need and rationale of new combinations marketed only if the combinations are dictated by considerations of therapeutic necessity.

Expressing concern about the reported misuse of spiriteous tinctures and misuse of drugs by young healthy persons, the Chairman said that the Drugs authorities, cannot rest content on the ground that the issue concerned the public health administration more than the Drugs Control Administration.

Turning to the major developments in the Central Organisation, the Chairman informed the members that administrative sanction of the Central Govt. for the construction of a new C.D.L. building on the existing site had been received and the construction work has been entrusted to the CPWD and that the building might be completed within the next three years. A full fledged pharmacopoeial laboratory was also being constructed at Ghaziabad. During 1972-73, a target has been set for recruting 24 Inspectors in the Central Drugs Standard Control Organisation. The training programmes for Drugs Inspectors and Drug Analyst would be intensified for the benefit of the State Govts. An intensified Drugs Quality Control Programme has been started by the Central Drugs Laboratory, the object of which is to identify the products manufactured by licensed firms which are likely to deteriorate or which appear suspicious in quality and the regions where they move. The State Drugs Control authorities would be informed about the scope and results of the intensive sampling scheme, and also about the sampling schemes resorted to by the zonal officers so that the State sampling programmes could be designed in such a manner as not to overlap with the control programme and also to suit the capacity of their State testing laboratories.

The Chairman then suggested that members might like to apprise the Committee of (1) any outstanding organisational developments in their State Drugs Control Administration, (2) any progress or improvements in regard to the State analytical laboratory and (3) any other important issues which would require attention on an all India basis.

Before the State Drug Control authorities started the review on the three aspects mentioned by the Chairman, Shri. Rangnekar desired to highlight a few points arising out of the Chairman's introductory remarks. The specific points mentioned by him were :

(a) The Training Programme arranged for Drugs Inspectors by the Central Drugs Control Organisation was good but adequate notice for the subsequent sessions should be given to the States to enable them to obtain the sanction of the State Govt. and depute their Inspectors.

(b) The Zonal Officers/Inspectors of the Central Drugs Standards Control Organisation should work in collaboration with the States in the collection of information pertaining to the small scale units.

(c) To curb the manufacture and marketing of combination Drugs containing the constituent ingredients in subtherapeutic doses, apropriate rules should be incorporated in the Drugs & Cosmetics Rules.

(d) The Essential Drugs Committee, which is being reconstituted by the Central Govt. should be given a legal status so that the recommendations made by this committee could be implemented by the State Drugs Control authorities.

(e) The consumption of alcohol for the manufacture of spirituous preparations which could be misused as beverages should be drastically regulated by the State authorities. Guidelines for the release of alcohol for the manufacture of only those preparations which have a bonafide medical use and are demanded by hospitals, should be issued by the Ministry of Finance

at the Centre to the excise authorities at the State level. The manner in which the State Excise Departments and the State Drugs Control department could work in close unision to check the manufacture and misuse of spirituous preparations should also be drawn up for the guidance of the States.

(f) Special arrangements for training Drugs Inspectors and the State Drugs Control Authorities in so far as control over the quality of sera and vaccines is concerned, should be made. At present, the States are deficient in this field. Similar arrangements should be made for bulk drugs also.

Referring to the points raised by Shri Rangnekar, the Chairman stated that the misuse of spirituous preparations and combination of drugs figured as separate subjects in the agenda and could be discussed at length. Efforts would be made to arrange for a special training courses for sera and vaccines at Kasuali.

ITEM NO.1

Confirmation of the minutes of the last meeting of the Drugs Consultative Committee.

The minutes were confirmed.

ITEM NO.2

Action taken on the recommendations made by the Drugs Consultative Committee at its Fourteenth Meeting.

Quality of drugs supplied by firms to major drugs purchasing organisations

It was agreed that inspections will be conducted jointly by the States Drugs Inspectors and Central Drugs Inspectors of firms which supply drugs to major drug purchasing organisation.

A Control over Hospitals

Union Health Minister's letter to State Health Ministers emphasising the need for frequent and stringent examination of Hospital stores, Hospital Pharmacy, and manufacture of drugs by hospitals provide greater scope for action by Drugs Inspectors in this direction. If the conditions of manufacture in hospitals are such as to pose a positive threat to public health interests the Committee felt that it would be advisable for the Drugs Control Organisation to pass on to the State Administrative Medical Officer and to the State Government an opinion to that effect.

A suggestion was made that manufacture of drugs in hospitals should be licensed. Even if such licensing were to be provided for, the question of cancelling the licence of Committee was therefore of the view that the suggestion to licence hospitals to manufacture drugs was rather premature.

Amendment of Form - 34 of the Drugs & Cosmetics Rules

The recommendation made by the Govt. Analysts Maharashtra, Gujarat and Director, CDL that Form 34 should be amended so as to delete the entry 7 namely "Results of tests or analysis" and to replace it by new entry "7. remarks if any, was not agreed to by the Committee. It was felt that if the proposed amendment was accepted Govt. analysists might be inclined to express opinion on the samples of cosmetics after mere physical examination and without subjecting them to any analysis. The Committee

agreed that the Director, Central Drugs Laboratory and the head of the analytical laboratories in Baroda and Maharashtra should jointly meet the leading manufacturers of Cosmetics and discuss the nature of tests that could practically be carried out on cosmetics and suggest specific amendment to Form - 34 item 7 thereof.

Storage of Vitamins

Since a decision had been taken at an earlier meeting that stability studies on Vitamin preparations should be insisted upon by the State Licensing Authorities before manufacturing licence for them is granted and since the Drugs and cosmetics Rules are being amended requiring vitamin preparations to display the date of expiry of potency, the Committee agreed that vitamins need not be required to be stored in a cool place and that Schedule P should be suitably amended. A decision on the storage conditions of Antibiotics will be taken after the results of the all-India survey that is being undertaken are known.

Standards for Surgical Dressings

The subject of standards for surgical dressings that should be adopted as monographs in IP and also incorporated in the Drugs & Cosmetics Rules came up for discussion.

The consensus view of the members was that the standards for surgical dressings should be realistic enough so that the supply line is not adversely effected when these standards are enforced.

The Chairman suggested that the comments of State Drugs Control Authorities on the amendments to IP monographs on 'Absorbent Cotton Wool' and 'Absorbent lint' and on draft standards, on 'Absorbent gauge' and 'Bandage Cloth' which had been circulated by the Directorate to the State Drugs Control authorities should be furnished within a period of one month, after consulting the manufacturers of Surgical dressings in their states, so that the standards for surgical dressing could be finalised in the light of the comments received.

Central Drugs Control Organisation and the inspectorate the question how best the inspectors could assist the States in ensuring uniform and stringent enforcement of the provisions of the Drugs & Cosmetics Act and Rules thereunder.

It was agreed that a sub-committee consisting of the following members should suggest ways and means by which the Central Drugs Inspectors could play a more effective and meaningful role in assisting the states in exercising stringent quality control over drugs particularly those moving in interstate commerce :-

Shri M.K. Rangnekar, Chairman
Dr. A.C. Kar, Member
Shri R. Balasubramanyan - Convener

Consideration of the question whether blood transfusion Assembly receiving sets - disposal type should be considered as drugs.

The committee noted the legal difficulty in considering blood transfusion Assembly sets as 'Drugs' under the Drugs and Cosmetics Act but felt at the sametime that it was desirable to safeguard the consumer against the toxic effects of PVC or Polyethylene material. It was agreed that I.S.I. should be asked to lay down standards for these sets and to arrange for their certificate. Thereafter the State Administrative Medical Officers should be asked to buy only those sets which bear the I.S.I. certification mark.

ITEM NO.3 (a)

Use of paraphenylene diamine in hair dyes.

In the light of the available documents / references the Committee recommended the following safe limits for the content of paraphenylene diamine in hair dyes and also the standards for it :-

1. Maximum limit of 4.00% paraphenylene diamine in hair dyes marked in solution form.

2. When paraphenylene diamine is marketed in powder form it should be allowed to be sold in a concentration of 20% and in packings not exceeding 5 gm in weight.

3. Only the pure dye with a melting point between 145-147°C should be allowed to be marketed.

4. The material should be free from impurities such as pnitraniline and Organic chlorine compounds.

ITEM NO.4

Consideration of Suggestion from CBI and Police authorities that Police officers should be appointed as Drugs Inspectors under the Drugs & Cosmetics Act.

The consensus view was that offences under the Drugs and Cosmetics Act being cognizable, police authorities are free to investigate any offences and process the case upto the prosecution stage. The Act lays down that only prosecutions under it should be instituted by a Drugs Inspector. As such, the Committee did not consider it necessary to appoint Police Officers as Drugs Inspectors especially as the Police Officers should work for all purposes, under instructions of the Drugs Control authority of the State as the Controlling Authority **"vide** rule 50 of the Drugs and Cosmetics Rules.

Shri Patel stated that a separate legislation for controlling production distribution and use of psychotropic drugs may have to be enacted following the new United Nation convention on such drugs.

After discussion the following decisions were reached :

1. A sub-committee consisting of Dr. P.K. Mishra, Shri B.V. Patel and Dr. S.S. Gothoskar (Convener) should examine whether a separate legislation should be enacted or the existing provisions under the Drugs and Cosmetics Act would be adequate to regulate the quantitative production of psychotropic substances, to ensure their distribution through a limited number of dealers and against prescription from Registered Medical Practitioners and to make it mandatory on the part of manufacturers and dealers to maintain detailed records in the same manner, as in the case of narcotic drugs. If however, a separate legislation is considered necessary by the sub-committee draft legislation should also be suggested by it.

2. The State Drugs Control Organisations should maintain more frequent check over the sale of psychotropic drugs especially by dealers located near Schools, Colleges and Universities.

3. Sampling of 'Mandrex' to Medical practitioners should be stopped

4. Since the medical practitioners of the indigenous systems of medicine who had been recognised as Registered Medical Practitioners by some States Governments are reported to be indulging freely in the issue of prescriptions for psychotropic drugs, Health Ministry should be requested to write to State Governments concerned suggesting that such medical practitioners as have had no academic training in pharmacology and therapeutics of allopathic drugs should not be recognised as Registered Medical Practitioners for the purposes of the Drugs and Cosmetics Rules.

ITEM NO.5

Consideration of proposal from All India Manufacturers Organisation asking for relaxation in the enforcement of labelling provisions of Drugs & Cosmetics meant for export.

The consensus view was that in order to stimulate exports, the drug industry should be granted certain concessions in regard to labelling requirements especially when many manufacturers abroad specifically ask for supplies of drugs without particulars such as the name of the manufacturers, etc. being shown on the label. At the same time the Committee was firm that the concessions extended, should be such as not to compromise on the quality of drugs which are exported or will reflect on the indigenous industry's reputation. The Committee after discussion, agreed that wherever exporters wanted to show the information regarding the name of the manufacturer, the date of manufacture, the date of expiry of potency and the batch number in the form of a code on the label such a procedure may be agreed to in the case of exporters who are registered with the Basic Chemicals and Soap Export Promotion Council, provided the details of such codes are furnished to the State Licensing Authorities. Apart from this, particulars

of exports made under codes should be furnished by exporters to the State Licensing Authorities as and when the exports are made. The Central Drug Control Officers operating at the ports will also maintain separate statistics of such exports. It was further agreed that the implication of these decisions on the indigenous drug industry should be reviewed after some time.

As regards an earlier request made by the Basic Chemicals and Soaps Export Promotion Council that foreign firms should be allowed to operate in this country against loan licences exclusively for export purposes, the Committee felt that from the point of view of the Drugs & Cosmetics Act, there should be no objection to the proposal.

The third concession asked for by the Basic Chemicals and Soap Export Promotion Council was that drugs meant for export should not be made to show on the label the legend "Made in India". The Committee felt that this was a requirement under the Merchandise Marks Act which was administered by the Ministry of Foreign Trade and that the Council should be advised to approach that Ministry in this matter.

ITEM NO.6

Consideration of the measures that should be taken to prevent the misuse of spirituous Medicinal preparations.

The consensus opinion was that abuse of spirituous medicinal preparations could be restricted to the minimum if release of alcohol by State Excise Deptt. is confined to only those preparations which are necessary for medical practice.

The Chairman was asked to take up the matter with the Ministry of Finance at the Centre who should be asked to write to State Excise Deptts. advising them that when alcohol is in short supply for the manufacture of bulk drugs and other essential products, it would be worth while regulating its release for the manufacture of medicinal preparations which have become outmoded in medical practice or which are not very much in demand. State

Excise Deptts. should be advised to work in unision with State Drugs Control authorities not only for the release of alcohol but also for maintaining the maximum extent of quality control over the products processed with alcohol. It should also be stressed that a very liberal scale of wastage is allowed to manufacturers of drugs, that this affords scope for diversion of alcohol for purposes other than bonafide drug manufacture and that the scale of wastage should be reduced to the minimum.

It was further agreed that a sub-committee consisting of the following members should survey the conditions responsible for misuse of alcohol and suggest remedial measures :-

1. Dr. P.K. Mishra, Drugs Controller, Delhi Admn.
2. Adviser ISM, Ministry of Health & F.P.
3. Adviser Homeaopathy, Ministry of Health & F.P.
4. Dr. S.S. Gothoskar, Dy. Drugs Controller (I) (Convenor)

ITEM NO.7

Consideration of the use of Polyethylene containers for packing drugs.

The question of permitting the use of Polyethyelene containers for packing drugs and the directive issued to manufacturers in Maharashtra State by the Commissioner FDA, Maharashtra on the subject were considered by the Committee. The consensus view of the members was that any direction issued on the subject should be such as could be uniformly adopted in all the States. The Committee agreed to the recommendation that it would not be desirable to grant permission to pack liquid oral preparations in polyethylene containers irrespective of the density of the material used for fabrication of the containers as contained in the directive issued by the Commissioner, FDA, Maharashtra State.

The Committee also recommended the following lines of action in this connection :-

(a) Permission can be granted for use of high density polyethylene complying with ISI specifications, as well as low density polyethylene complying with code practice given in draft Indian Standards Institutions specification for packing Capsules and tablets subject to the following conditions :-

i. the containers are manufactured from the virgin raw materials.

ii. The containers should have the minimum wall thickness of 0.5 mm.

iii. In case of tablets or capsules packed in high density or low density polyethylene laminated film bags, the minimum thickness in case of low density polyethylene should be 300 gauge (75 microns) and in case of high density polyethylene the same should be 200 gauge (50 microns).

(b) The manufacturers in their own interest should obtain from polyethylene manufacturers and suppliers, certificates to the effect that the materials supplied by them conform to either draft Indian Standards Institution's specifications CDC-I7-I2 - or DOC-GDC-17 (4009) as the case may be and is inert and that the material complies with thickness requirements as stated above.

(c) Use of Low density polyethylene for strip packing of tablets or capsules may be permitted.

It was also agreed consequent on the finalisation of draft ISI specifications if any changes in regard to the above decision are necessary these will be examined and circulated to the State Drugs Control authorities.

As regards transfusion solutions, it was agreed that plastic container for these should comply with the USP, specifications.

ITEM NO.8

Nasal preparations containing Liquid Paraffin".

It was agreed that in view of the adverse effects that is associated with the use of liquid paraffin in nasal preparations, it should not be allowed to be used in such preparations.

ITEM NO.9

Consideration of the question whether products containing hexachlorophene be permitted to be manufactured and marketed in the country in view of reported toxicity of hexachlorophene through skin absorption.

The Chairman stated that there was adequate evidence that bathing of new born babies with 3% hexachlorophene solution was harmful. He added that Director General of Health Services had already issued a circular letter advising State Administrative Medical Officers to instruct the hospital under them not to use such solutions for total body bathing or wide spread applications.

The Chairman also informed the Committee that a decision had been taken by the U.K. authorities that cosmetics containing hexachlrophene such as tale, powder, cream lotions and emulsions should only be recommended for use on medical advice. Since this condition is not capable of being enforced in this country, the committee agreed that a rule should be introduced in the Drugs and cosmetics Rules prohibiting the use of hexachlorophene in Cosmetics preparations.

The Committee further discussed the use of hexachlorophene in drugs and felt that any cautionary note given on the label indicating that drugs contain hexachlorophene will not only scare the consumer but also raise serious doubts in the minds of the Registered Medical Practitioners. It will therefore be advisable for drugs manufacturers to use alternative bacteriostatics or antiseptics.

Since soaps do not fall within the purview of drugs or cosmetics,

control over the use of hexachlorophene in soaps cannot be exercised by drugs control organisations. As such the Committee recommended that hexachlorophene imports should be banned and that manufacturers of soaps should be asked to co-operate with Govt. by not using hexachlorophene in soaps. If the response from soap manufacturers is not adequate, the public should be educated of the ill effects of hexachlorophene.

ITEM NO.10

Deficiencies in State Drugs Laboratories engaged in the Manufacture of Biologicals.

It was agreed that the enforcement authorities in the States (licensing authorities and competent inspectors should be given an orientation course in matters relating to the manufacture and testing of sera & vaccines. Only through frequent and stringent inspections and follow up action, can improvement be expected in the manufacture and testing by State Government Institutions.

On Shri Narasimhan's raising a query as to what steps should be taken if manufacturers of sera and vaccine do **not** agree with the findings of Drugs Inspectors, the Chairman stated that Dr. Thomas, Director, C.R.I., Kasauli could be asked to undertake a second inspection of such manufacturing premises and give his recommendations.

Shri Kattishettar said that the deficiencies in the Mysore State Vaccine Laboratory may have to be set right and that if necessary he would seek the assistance of Director General of Health Services in the matter.

ITEM NO.11

Procurement of canalised items of raw materials by the State Trading Corporation and their distribution.

This was discussed separately vide the proceedings at Annexure I

ITEM NO.12

Manner in which the first five to the batches of drugs are to be permitted to be manufactured after testing under the supervision of the State Drugs Control authority.

It was agreed that if the licensing authority felt that the testing facilities available with a manufacturer are adequate and better than those available with "approved testing laboratories", sending of samples to the approved testing laboratory for rechecking may not be insisted upon.

ITEM NO.13

Proposal that repacking of drugs may be differentiated from manufacture.

Dr. Kar suggested that every drug repacked by a firm should bear on its label the words "Repacked by" followed by the name of the repacker so as to draw a distinction between a drug which is manufactured" by a firm and one which is 'repacked'.

The Chairman clarified that the conditions of licence to repack for sale or distribution of drugs (being drugs other than those specified in schedule C & C (I) require that the drugs repacked under the licence shall bear on their label, apart from other particulars required by the Drugs Rules, the name and address of the licensee and the number of the licence under which the drug is repacked preceeded by the words "Rpg. Lic. No."

ITEM NO.14

Proposal that in Section 19(3), the words 'A person' may be replaced by the words 'A licensee'.

The general view was that the suggested amendment was not necessary. Chairman however requested Dr. Kar to furnish particulars of the legal suits lost becuase of the deficiency in the section 19(3) of the Act.

ITEM NO.15

Proposal that a provision be made in the Rules for taking action against the sellers for wrongly supplying prescriptions.

The Committee was informed by the Chairman that a rule is being introduced in the Drugs & Cosmetics Rules enabling Govt. to take action against dealers for wrongful supply of schedule H & L Drugs. Shri Rangnekar stated that in Maharashtra action had been taken against the supplier of a wrongful drug under the provisions of the Indian Penal Code.

ITEM NO.16

Provision for maintenance of record in respect of "Stetrility Test" in Schedule U.

The Chairman informed Dr. Kar that necessary details in respect of maintenance of record for sterility test in Schedule U are already being introduced.

ITEM NO.17

Repacking of Schedule C1 drugs.

The Chairman stated that repacking of Schedule C1 drugs is not permitted under the Drugs & Cosmetics Rules. Besides in accordance with the ITC policy as laid down in the preamble to Appendix 19 of the Red Book for April - March, 1972 the drugs and medicines licensed to Actual users in terms of the import Trade Control Policy cannot be sold after repacking or rebottling. He suggested that cases where drugs imported against Actual user's licence are repacked, should be brought to the notice of the Jt. Chief Controller of Imports & Exports concerned.

ITEM NO.18

Incorporation of Good Manufacturing practices under the Drugs & Cosmetics Rules.

The Committee agreed that good Manufacturing practices should be given legal status by inclusion in the Drugs & Cosmetics Rules. The Chairman stated that a sub-committee was already engaged in this task and that its report was awaited. The amendments in the Drugs & Cosmetics Rules that will be necessary in this connection will be examined on receipt of the sub-committee's report.

ITEM NO.19

Repacking of technical grade of substances as drugs.

The Committee agreed that no item which is covered by the I.P./B.P. etc should be permitted to be repacked and marketed unless the repacked product is labelled as unforming to the relevant standards.

ITEM NO.20

Definition of the term 'Raw Material'.

The Committee was of the opinion that no specific definition of the term 'raw material' is necessary. It was further agreed that the term 'raw material' should include excipients, pharmaceutical aids and auxilliaries such as capsules etc. which are used for formulating medicines.

ITEM NO.21

Employment of one technical staff for each category of drugs in a manufacturing unit.

The Chairman stated that the proposal was likely to hit hard the small and medium scale units in the drugs industry. The present provision provided sufficient powers to the Licensing Authority to insist upon the appointment of more than one competent technical staff if the manufacturing activities wre spread out and warranted adequate supervision.

The committee, after discussion, agreed that for the present no

change in the Drugs Rules need be made on this account.

ITEM NO.22

Steps to control Microbial contamination in pharmacopoeial preparations.

The Chairman apprised the Committee that the question of laying down adequate standards to control microbial contamination in pharmacopoeial preparations was being examined by a sub-committee of the Drugs Tech. Advisory Board and that the report of the Committee be awaited.

ITEM NO.23

Enforcement of Test of Content uniformity and dissolution test.

The chairman stated that "Content uniformity" of tablets was capable of achievement and that the State Drug Control authorities should educate drug manufacturers that when "Good Manufacturing Practices" was incorporated as a condition of the manufacturing licence, firms should invariabl comply, with "content uniformity" of tablets. He stressed the need for Drug Control authorities adopting to educate the manufacturers in this regard.

As regards dissolution test, it was agreed that a paper circulated by the W.H.O. on the subject should be circulated to the members. (Annexure II)

ITEM NO.24

Inclusion of Drug Testing Laboratories in the Centrally sponsored schemes.

The Chairman explained the trend of the discussions that took place at the meeting of the Central Council of Health, held in Jaipur in October, 1971. The Planning Commission's view was that according to the decision taken by the National Development Council financial provision for State Analytical Laboratories should be made in the State sector of

the Plan Scheme. Although efforts had been made to pursuade the Planning Commission to extend financial assistance to States, nothing positive had materialised so far. The Union Health Minister will be writing again to the Minister for Planning in this regard. He assured that the question of cental financial assistance to States for setting up drug testing laboratories, will again be taken up with the Planning Commission in the Fifth Five Year Plan.

ITEM NO.25

Integrated sampling Plan.

The Chairman said that at this stage it was not feasible to conceive of a national plan for sampling of various drugs manufactured in the country. After discussion the Committee recommended that States should primarily concentrate on testing the drugs manufactured within its area. If financial provision for samples and the testing capacity of the state laboratories permitted samples of drugs manufactured in other States should also be got tested.

ITEM NO.26

Post import check of imported raw materials.

The Chairman conceded that there might be certain genuine difficulties in carrying out post-import check on the use of imported raw materials by manufacturers but he felt that such checks should continue to be carried out as they help in keeping a watch over the utilisation of raw materials imported from abroad.

ITEM NO.27

Control over the approved laboratories.

The Chairman suggested that it would be advisable to wait for the report of the sub-committee which is considering the question of exercising control over private labaratories which undertake testing of drugs from manu-

facturers who do not have their own testing facilities. Such laboratories should be licenced under the Drugs and Cosmetics Rules and conditions imosed on their functioning. Such a provision will facilitate the revocation of licences granted to these laboratories wherever considered necessary.

ITEM NO.28

Control over psychotropic substances.

The subject had already been covered under Item 4.

ITEM NO.29

Prevention of cross contamination.

The Committee agreed that for preventing cross contamination during manufacture of antibiotic formalations along with the other dosage forms, good manufacturing practices should be insisted upon.

ITEM NO.30

Friability Test for Tablets.

The Committee felt that when good Manufacturing practices were enforced, the friability test for tablets can also be insisted upon.

ITEM NO.31

Manufacture of Pain balm containing Ayurvedic and allopathic drugs.

In the context of the opinion given by the Adviser Indigenous system of Medicine, the Chairman said that it would not be possible to take the view that the ointments in question though they are covered by the I.P. or other recognised pharmacopoeias could be considered as allopathic drugs. It was however necessary that in such cases the State Drugs Controllers

should ensure that the ingredients used are pure and conform to pharmacopoeial standards if they are included in any pharmacopoeia.

Arising out of these discussions the Committee recommended that the Adviser in Indigenous system of Medicine should be asked to introduce a rule under Chapter IV A of the Drugs and Cosmetics Act to the effect that where ingredients such as Paraffin Jelly, Eucalyptus Oil, menthol etc are used for the manufacture of Ayurvedic (including siddha) and Unani medicines, the standards for such material should be those given in the pharmacopoeia recognised under the other chapters of the Drugs and Cosmetics Act.

ITEM NO.32

Use of Polyethylene containers for liquid oral preparations.

This subject had been discussed under item 7 of the Agenda.

ITEM NO.33

Rule 59 and 60 of the Drugs & Cosmetics Rules the question of granting a fresh licence for sale of drugs after a brief close down to petty chemist.

The Chairman informed Shri Gupta that a rule for imposing a penalty for delayed renewal of sale licences was likely to be published very soon.

ITEM NO.34

Rule 65 - Conditions of sale licence - Provision for obtaining photographs of qualified persons.

The Committee agreed that the licensing authorities should issue identity cards with photographs to those who are accepted as qualified persons "or Registered Pharmacist" under rule 65 of the D & C Rules and the latter should be made to carry the identity cards with the photographs on their

person. Such qualified persons should also be required to wear clean white overalls while working on the sale premises.

ITEM NO.35

Uniform Policy about Registered Medical Practitioners vis & vis the misuse of drugs.

The Chairman stated that he had already written to Punjab suggesting the exclusion of Vaids and Hakins from the definition of the term "Registered Medical Practitioner in the Drugs & Cosmetics Rules. As long as the name of a medical practitioner is borne on any Register maintained by a State Govt. he cannot be prevented from practising any system of medicine. In view of the reported misuse of drugs by the practitioners of indigenous systems of medicines in the Punjab, Committee desired that a similar communication may also issue to other States in the matter.

ITEM NO.36

Policy for approving the patent ayurvedic drugs containing poisons.

The Chairman informed Dr.(Mrs.) Khosla that a sub-committee of the Ayurvedic Drugs Technical Advisory Board was already examining the question and that the findings of the sub-committee should be awaited.

ITEM NO.37

Desirability of making a provision in the Drugs and Cosmetics Rules for making it binding on the part of the Regd. Medical Practitioners to write prescriptions as laid down in the Rule 65(10) of the Drugs & Cosmetics Rules.

The Committee felt that since Rules 65(10) spelt out the details that should be given on the prescription it was open to dealers to refuse supply against prescriptions which are incomplete. A provision requiring medical practitioners to write their prescriptions in a specified form would

be difficult to introduce in the Drugs and Cosmetics Rules.

ITEM NO.38

Desirability of amending Rule 161 of the Drugs & Cosmetics Rules suitably in regard to labelling of Ayurvedic Drugs.

The Chairman stated that Rule 161 relating to the manner of labelling Ayurvedic (including Siddha) or Unani drugs was made after careful consideration by the Ayurvedic and Unani Drugs Technical Advisory Board. Besides the select Committee, of the Parliament when considering the provision relating to Ayurvedic and Unani drugs specifically desired that the composition of the preparation should be given on the label. It was agreed that no amendment of Rule 161 need be made at present.

ITEM NO.39

Discussion regarding correct interpretation of clause 19 of the Drugs (Prices Control) order, 1970.

This item was taken up for discussion separately on 10.3.72 vide record note at Annexure III attached.

ITEM NO.40

Desirability of enforcement of Dangerous Drugs Act by a single administration.

The Chairman informed Shri Pany that the Central Govt. had already advised the State Govts. that Drugs Control authorities can take up the work relating to the enforcement of Dangerous Drugs Act from the State Excise Department if they so desired. In Kerala the enforcement of Dangerous Drugs Act is in the hands of the Drugs Control authorities.

ITEM NO.41

Discussion regarding test reports issued by Govt. Analysts on

cosmetic samples on which 'no opinion' has been given by the Govt. Analyst.

The decision taken under item 2 would cover this subject also.

ITEM NO.42

Question of laying down guide lines for the control of humidity and temperature for capsule manufacturing.

The Chairman promised to make available to the Delhi Drug Control Administration suitable guide lines in this regard.

ITEM NO.43

To consider the question whether the repackers may be allowed to repack drugs according to specifications of pharmacopoeias other than I.P.

This subject had already been discussed under item 19 of the agenda.

ITEM NO.44

Licensing of manufacture of drugs carried out by the Hospital.

The Chairman stated that so long as Hospitals manufactured drugs for the use of their own patients, it would be difficult to make them take out manufacturing licences under the Drugs and Cosmetics Act. It was however felt that following the letter written by the Minister of State for Health in the Union Health Ministry to State Health Ministers, it should not be difficult for the State Drugs Control authorities to inspect the manufacturing operations in Hospitals in a detailed manner and remedy the defects in them, if any.

ITEM NO.45

Proposal for amendment of Rule 51 Duty of Inspector.

The item was withdrawn by the Commissioner, F.D.A., Maharashtra State, Bombay.

ITEM NO.46

Amendment of Rule 65 - Showing of Batch No. on cash memo.

The Committee agreed to the suggestion that under Rule 65 (3)(f), it should be obligatory on the part of dealers to show the name of the manufacturer and the batch number in the case of Schedule H drugs as is the case with the drugs specified in the Schedule C or Schedule L.

ITEM NO.47

Amendment of Rule 65 - Deletion of the words in sub-rule (15).

The Committee did not agree to the suggestion to remove the words' on or before 31st December, 1959" from the proviso to rule 65(15).

The reason for this decision was that the process of approving qualified persons must be stopped on a specified date as otherwise tne basic objective of 'registered pharmacists' replacing qualified persons will not be fulfilled.

Shri Rangnekar, however, did not agree with this view.

ITEM NO.48

Amendment of Rule 65 (17) - Stocking of time expired drugs.

The Committee agreed that time expired drugs in a sales establishment should not only be stored separately from trade stock as per the proviso to Rule 65(17) but that a suitable warning that these stocks are not for sale should also be exhibited so that the stocks are not removed for sale or distribution through any misunderstanding. It was further decided that Rule 65(17) should be amended suitably.

ITEM NO.49

Amendents for loan licences.

The Chairman stated that the proposal to restrict the grant of loan licences subject to certain conditions is already under the consideration of the Ministry of Health and Family Planning Suitable changes in the Drugs & Cosmetics Rules would be made after the proposal is cleared by the Central Govt.

ITEM NO.50

Amendment of Rule 89 - Licence fee for test licences.

It was agreed that a licence fee of Rs.15/- should be made applicable for licences to manufacture drugs for examination test or analysis.

ITEM NO.51

Provision for suspending manufacture - when it is threat to public health.

The Committee agreed to the suggestion that in the Drugs & Cosmetics Rules a provision should be made enabling the licensing authority to direct a licensee to suspend or modify manufacturing activity or recall a drug distributed by a manufacturer if in the opinion of the licensing authority such a decision was warranted in the interests of public health. At the request of the Chairman, Shri Rangnekar agreed to suggest a suitable draft rule for this purpose.

ITEM NO.52

Colouring of pharmacopoeial drugs.

The Chairman clarified that addition of colours to pharmacopoeial preparations is not permitted as the Drugs & Cosmetics Act stands at present.

The existing Rule 127 of the Drugs & Cosmetics Rules is ultravirus of the Act and is being substituted by a rule setting out the colours that could be added to non-pharmacopoeial preparations.

ITEM NO.53

Standards of Oral Polio Vaccine :

The Committee agreed that standards of quality, purity and strength for Oral Polio Vaccine should be incorporated in Schedule 'F'.

ITEM NO.54

Good Manufacturing Practice - as a part of Schedule M.

This had already been discussed under Item 18 of the agenda.

ITEM NO.55

Blood grouping sera in Schedule C

The Chairman explained that the first entry in schedule C namely '1 sera' would cover Blood Grouping Sera and that no specific amendment of Schedule C is necessary for this purpose.

ITEM NO.56

Administration of Ayurvedic Drug - provision for

The Committee, agreed to the proposal that a provision on the lines of the section 17B of the Drugs & Cosmetic Act is required to be incorporated in the Act in respect of Ayurvedic Drugs. The Chairman said that a note of the proposal will be kept for incorporating the necessary provision in Act, when the Act is amended next time.

ITEM NO.57

Claims made for Ayurvedic and Homoepathic drugs - Drugs & Magic Remedies (Obj. Advt.) Act.

The Chairman stated that according to the advice given by the Ministry of Law at the Centre there should be no objection of Ayurvedic and Unani Drugs being described by names which are given in the Authoritative Books of the Indigenous System of Medicine, notwithstanding the fact that such names, might deem to suggest that the drug could be used for treatment of deseases covered by the Schedule to the Drugs and Magic Remedies (Objectionable Advertisements) Act. The Committee desired that Law Ministry's opinion should be circulated to state Drugs Control authorities.

ITEM NO.58

Amendment to Sec. 22(cc) - delete words "Mentioned in clause (c)".

The consensus view of the Committee was that deletion of words 'mentioned in clause (c)' appearing in Secion 22 (cc) would be tantamount to vesting in drugs Inspectors arbitrary and uncanalised powers which may not be desirable. In the course of the discussions it was brought to the notice of the Committee that the powers of Inspectors relating to seizure of documents do not apply to 'sale premises'. The Chairman agreed that when the Act is amended next, the scope of the relevant section be amplified in the Act to cover this aspect also.

ITEM NO.59

Section 22(c) - defect may be remedied by the possessor of the drug - this has to be amended. Defect can be remedied only by the manufacturer.

It was pointed out that seizure of drugs by Drugs Inspectors is applicable only if the possessor can remedy the defects. If the possessor of a drug is a dealer who cannot remedy the defects, the drugs should be

taken back by the manufacturer for rectification of the defects. The Committee was therefore of the view that the amendment to Section 22(c) as proposed by Shri Chandrasekharan Nair is **not** necessary.

ITEM NO.60

Drugs and Magic Remedies (Objectionable Advts.) Act - Publication of advertisement - jurisdiction to file complaint.

The question whether an offence is committed at the place where an advertisement is published or at the place of business of the advertiser was considered by the Committee. It was agreed that section of the Act read with the definition of the term taking any part in the publication of any advertisement" in the Act would clarify that the offence should be deemed to be committed at both the places i.e. where the advertisement is published as well as at the place of business or the place where the manufacturer is located.

ITEM NO.61

Who is to prosecute - A provision similar to Section 32 of Drugs & Cosmetics Act is lacking - Under Sec.9A - Police have powers to prosecute - whether a specific provision is to be introduced.

It was clarified that a Drugs Inspector appointed as a specific officer under Section 8 of the Drugs and Magic Remedies (Objectionable Advertisements) Act can also institute prosecution in accordance with the procedure set out in Code of Criminal Procedure. By virtue of Section 9A of the said Act, a Police Officer can also institute prosecution.

ITEM NO.62

No rules are framed after introduction of new section 8 of Drugs and Magic Remedies (Obectionable Advertisement) Act - the legal aspects of this may be discussed.

The Chairman explained that Section 8 of the Drugs and Magic Remedies (Objectionable Advertisements) Act does not make it mandatory on the part of Government to frame rules and that in case any rules have been framed, the provisions of those rules should be complied with.

Certain rules were operative before Section 8 was struct down by the Supreme Court, and amended subsequently. Since the pith and substance of the Section was not substantially altered at the time of its amendment, no additional rule was considered necessary consequent on the amendment of the section.

ITEM NO.63

Whether Drugs Inspectors have powers to Inspect and examine records and documents in hospitals relating to purchase storage, and issue of drugs.

Dr. Khosla stated that one of the major difficulties experienced by the Punjab State Drugs Control authorities was the checking of the consumption of narcotics and psychotropic substances by private nursing homes etc. who claim that they need not maintain records of consumption of such drugs vide the entry at 5-A of Schedule K.

The Chairman indicated that only hospitals or dispensaries maintained or supported by Govt. or local bodies or by charity or voluntary subscription would fall within the purview of the specific entry in schedule K and that private nursing homes could certainly be asked to produce the records etc. in this connection. Even the Registered Medical Practitioners are required to maintain records of sale of barbiturates, pethidine etc.

ITEM NO.64

Definition of wholesaler as per Drugs (Prices Control) Order, 1970.

The Chairman said that the status of wholesaler under the Drugs (Prices Control) order which had been issued under the Essential Commodities

The Chairman informed the Committee that a list of equipment required for manufacture of Ayurvedic / Unani products is being compiled by the Adviser, Indigenous system of Medicine.

Additional Items :

ITEM NO.71

Dr. Pitambar Dayal, Drugs Controller Rajasthan, stated that he received a request from a person having licensed shop at chachro, Distt. Tharparkar in Pakistan (now under control of Indian Army) to grant licence under the Drugs and Cosmetics Act and Rules to run a shop in area within Indian Territory so that he could dispose of drugs which are with him and desired to know whether the request can be granted. The condition of the drugs was reported to be good and the dealer wanted to sell drugs in this country before they became time-barried after obtaining a licence to sell drugs under the provisions of the Drugs and Cosmetics Rules.

The Committee felt that in case permission was granted to sell the drugs in the Indian Market, difficulties might arise subsequently, especially if there were to be complaints regarding their quality. At that stage, it would be difficult to recall the drugs from the market. Further, the view was also expressed that permission to sell such drugs may be used to pass on this country the drugs obtained on the other side of the border through illegal sources. The Committee therefore felt that rather than allowing the dealer to sell such drugs in the market, it would be advisable if Rajasthan Government after having satisfied itself about the quality of such drugs, could buy the drugs and make use of them in their hospitals. The Committee also felt that particulars of such drugs, the quantities bought, the quantities issued to hospitals, their Batch numbers and date of expiry of potency, etc. should be maintained by the State Government.

Items carried forward from the meeting of the Port & Zonal Officers held on the 3th March, 1972.

ITEM NO.72

It is observed that patent and proprietary preparations are being allowed by Drugs Control authorities of States without ascertaining the fact that there are proper methods to estimate the ingredients qualitatively and quantitatively. The Govt. Analyst sometimes finds it difficult to assay such products.

The Chairman impressed upon the members that the methods for the qualitative and quantitative assay of ingredients contained in patent and proprietary medicines should be called from the manufacturers and got verified before allowing such preparations to be manufactured. The suggestion was accepted by the members.

ITEM NO.73

Consideration of the question of the need for taking effective action regarding prohibition of manufacture of Pencillin skin ointment and tablets of sulphanilamide.

The Chairman stated that in view of the sensitivity reactions resulting from the use of Pencillin skin ointment, such preparations should be discouraged from being manufactured. The State Drugs Control authorities were asked not to recommend raw materials for the use of these preparations. He reiterated that manufacturers using sulphanilamide in their formulations should be asked to discontinue its use in formulations gradually since it was known to produce toxic symptoms and had ben superseded by more effective and less toxic sulpha drugs.

Before the meeting concluded, it was brought to the notice of the Chairman that Shri B.V. Patel who has been a member of the Drugs Consultative Committe almost from its inception, would be retiring from service very soon. The Chairman mentioned about the depth of technical knowledge of Shri Patel and his vast administrative experience in the field of drugs Control and allied services and said how time and again in matters relating to important decisions Shri Patel had played a valuable role in the

delibrations of the Committee. Shri Patel always believed in an educative approach in developing the drug industry but at the same time he would not tolerate deliberate remisness in quality control meaures.

Members endorsed the views of the Chairman and wished Shri Patel many long years of happy and healthy retired life. They also expressed the hope that Shri Patel would continue to take interest in the development of drug industry, drug Standardisation, pharmaceutical profession, hospital pharmacy etc. and give his uninhibited opinion on these subjects.

Thanking the Committee for the good wishes, Shri Patel said that he would endeavour his level best to continue serving the interests of the pharmaceutical industry, profession, education and research.

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

PART II

ANNEXURES TO THE MEETINGS

ANNEXURE - I

(Item No.11 of 15th D.C.C. Meeting)

Record Note on the discussions concerning the pattern of import and distribution of canalised items.

On the 10th March, 1972 the Drugs Consultative Committee discussed certain matters concerning the pattern of import and distribution of canalised items. The following representations from the Indian Drugs and Pharmaceuticals Ltd., and the State Trading Corporation of India were present at the discussions by special invitation :-

1. Dr. Prem Balwani, Chief Sales Manager, IDPL, New Delhi.
2. Shri M.N. Misra, Director, STC, New Delhi.
3. Shri K.V. Menon, Additional Chief Marketing Manager, STC, New Delhi.
4. Shri B.K. Key, Marketing Manager, STC, New Delhi.
5. Shrimati (Mrs.) A. Roy, Marketing Manager, STC, New Delhi.

The Chairman introduced the representatives of IDPL/STC to the members and stated that they had been invited to meet the Committee so that the problems relating to the Price Control Order and import and distribution of drugs by the STC and / or IDPL could be considered and solution found for them. The Chairman then invited Dr. Balwani to apprise the difficulties experienced by the IDPL to the State Drugs Control authorities.

Dr. Balwani had circulated a note regarding "Non lifting of drugs covering the following salient points :-

1. IDPL is releasing bulk canalised drugs to pharmaceutical units on a Quarterly basis based on the recommendations of the State Drugs Control authorities and that some of the

units do not generally lift the allocations made to them by the IDPL.

2. Non-lifting of pharmaceuticals by the parties results in huge accumulation of drugs and the situation becomes grave particularly with regard to products bearing date of expiry of potency.

3. It is essential that the off-take of imports planned by Govt. Agencies is ensured and it should be made binding on the part of actual users to lift the allocations made to them. In the state of Maharashtra, the procedure adopted is that while asking for the requirements from the individual units, an undertaking in writing is taken from the units to the effect that goods will be lifted as and when released. Other State Drugs Controller should also adopt a similar line of action.

4. The recommendations of the State Drugs Control authorities regarding requirements of pharmaceutical units should reach IDPL as early as possible so that the first quarterly release for the year 1972 - 73 is made in time.

Dr. Balwani referred to the points made in the note and expressed that it would be difficult for IDPL to make allocations unless the requirements of the whole country are known in time. The Chairman requested the members that the figures regarding past consumption and allocation of IDPL items for any financial year (based on past consumption) should be made available to the IDPL by the end of October of the preceeding year.

Dr. Balwani said that if a moral commitment from the manufacturing units to lift the drugs allocated by IDPL is taken as in the case of Maharashtra, it would help th IDPL to a great extent.

Dr. P.K. Mishra, Drugs Controller, Delhi Admn. stated that if the IDPL could assure regular supplies of canalised items by the due date upto the whole quantity recommended by them, the State Drugs Control

authorities would be justified in foreing the units to lift the material.

Shri P.V. Patel, Director DCA Gujarat stated that in case of cetain items specially those which IDPL required for their own use in formulations supplies to the extent of only 5% of the requirements of the actual users were made. Dr. Balwani assured the members that except for one or two items where there was shortage in the international market, IDPL would be in a position to meet the demands. He pointed out that there were certain cheaper sources which catered to the needs of the units and as such the IDPL drugs were not being lifted.

The Chairman said that IDPL items were imported after spending foreign exchange and the actual users should be made to fall in line with the discipline of purchasing them as and when allocations are made. Today they may obtain drugs from cheaper sources in the open market but sooner or later on, they would experience difficulty in getting supplies when these sources dry up. Should the units hesitate to lift the IDPL items, they may have to be warned that their demands for these items from IDPL would not be accomodated in future and that they should not complain when there is shortage. At the same time the Chairman emphasised that the IDPL also should not dictate terms to pharmaceutical units, compelling them to lift items not required by them and for which IDPL has no ready market. The Chairman said that he would be glad to take up with the IDPL authorities those cases where IDPL tries to palm off on manufacturers raw materials not needed by them.

The State Drugs Control authorities stated that if the quantities and the particulars of drugs lifted by the units were intimated to them, the latter would try and check up the quantities consumed by such units, and any external source of supply of raw materials, if any, procured from other sources, and utilised by these units. The Chairman pointed out that IDPL had been intimating particulars of supplies of raw material made to the actual users without indicating the quantities recommended for them by the State Drugs Control Authorities. This does not give a clear picture

of the actual supply position. Dr. Balwani promised to furnish the information in future.

Shri. Misra of STC who was then requested by the Chairman to explain his difficulties brought out the following points :-

1. Import plans for succeeding year are made in the preceding month of December. To come to the correct figures of requirements, consolidated recommendations in respect of all the A/US for each item from State Drugs Controllers are required before December.

2. STC brought it best if recommendations from all the States are sent to STC by the end of October.

2. State Drugs Controllers should fix a dead line beyond which recommendations should not be entertained for emergency releases.

3. STC has been saddled with many imported items imported as per requirements of the actual users as recommended by the State Drugs Controller but which have not been lifted by them. There should be some binding on the part of the actual users to lift the items as agreed to in the case of IDPL items.

4. The actual users should also be induced to maintain a pipeline stock of about 4 months and should not convert STC/IDPL into their inventory holders so that they can draw up materials on a monthly basis as and when required.

After discussion, the Committee agreed that recommendation from State Drugs Control authorities for allocation of STC imported raw materials for any specific financial year should be sent so as to reach the STC by the 31st October, of the preceeding year.

The Chairman agreed that the State Drugs Control authorities

should follow the same procedure as in the State of Maharashtra for obtaining a moral commitment on the part of actual users to lift the STC material which may be allocated to them from time to time. He said that STC should give a dead line say two months for receiving recommendations from States for distribution of items such as citric acid, iodine etc. If after the expiry of this period of 2 months, no allocation figures are received from States, the STC will be free to divert the stocks meant for the defaulting States to the firms of other States.

Shri Misra indicated that as regards citric acid, iodine, tartaric acid and hard gelatin capsules, STC would be guided by the DGTDs recommendations for firms borne on their list. The requirements of such units for these raw materials should be excluded from the State's figures as otherwise there might be duplicate of supplies, Shri Misra stated that figures in respect of consumptions of certain raw materials were pending with certain States and desired that these figures may be expedited. The Chairman requested the members to take note of the valuable suggestions made by Shri Misra and co-operate with STC by furnishing the figures of consumption of raw materials in time. The purpose he explained was to make advance provision for the imports so that the supply pipe line does not get dried up.

The Chairman then brought to the notice of Shri Misra certain important observations that the members had to make about the activities of STC. These points are summerised as under :-

1. The STC takes a long time to process the quotations, in respect of drugs, received by it from abroad. The stocks cannot be expected to be held indefinitely at our disposal by the oversea suppliers. Shri Misra agreed with the Chairman that reply will be given by STC within a week in such cases.

2. STC godowns at the ports do not possess adequate facilities for storage of antibiotics and vitamins products. Shri Misra informed the Chairman that the question of installing adequate storage accommodation to preserve the potency of sensitive

products which are being imported by STC through the ports is engaging their attention and that steps to create such facilities would be expedited.

3. The Chairman said that drugs imported at the ports were released to STC after taking samples for tests by the officers of the Drugs Standard Control Organisation against a written undertaking that the good would not be disposed of pending receipt of test reports. The purpose was to avoid delays in clearance. It was however observed that such drugs were distributed by the STC in certain cases before the results of the samples drawn in regard to the quality of drugs were received. He desired that drugs imported by S.T.C. should not be released to actual users pending receipt of test results.

   Shri Dey admitted that a few drugs imported by STC were released by them earlier and that the requirements of the Drugs & Cosmetics Act and Rules have since been brought to the notice of the officers concerned. Such lapses, he assured, would not recurr in future.

4. Certain drugs imported by STC and found to be deficient in labelling details had been released on a letter of guarantee executed by STC, so that the labelling deficiency could be rectified and the letter of guarantee cancelled thereafter. In actual practice however, it was observed that in many cases, neither the labelling corrections were carried out by STC nor the letter of guarantee got cancelled.

   Shri Misra stated that these matters will be looked into carefully.

5. Shri Rajyadhyaksha voiced the view of the industry that the prices of chlaramphenicol, vit C and Iodine fixed by STC were high.

   The Chairman asked Shri Rajyadhyaksha to furnish a note

on the subject so that the matter could be pursued with the STC and the Ministry of Petroleum and Chemicals.

6. A point was raised that the figures relating to the requirements of Iodine in respect of Actual Users to be supplied by State Drugs Control authorities, should be based on the average consumption of Iodine by the party during the last four years and not 2 years as laid down at present. This was agreed to.

7. It was also agreed that in respect of units having no past consumption but applying for canalised items for the first time, the basis of recommendation for items required for basic manufacture should be the capacity of production in a period of six months and, in the case of items required for manufacture of formulations, it should be 3 months' production capacity (on a single shift basis).

Summing up, the Chairman asked the representatives of STC/IDPL to maintain more frequent contacts with the States Drugs Control authorities so that the bottlenecks, if any, in the way of smooth distribution of canalised items could be settled quickly.

Shri Menon stated that the representatives of STC intended to visit Maharashtra once in two months and that STC intends to have regional meetings and would be glad if representatives from States Drugs Control administrations could attend such meetings along with representatives from drug industry. Such regional meetings could constitute an appropriate forum for exchange of ideas and for resolution of difficulties experienced by STC and the industry.

The Chairman thanked the representatives of STC/IDPL for participating in deliberations of the Committee.

The Meeting then terminated with a vote of thanks to the Chair.

ANNEXURE - II

(Item No.23 of 15th D.C.C. Meeting)

WORLD HEALTH ORGANISATION WHO/PHARM/70.459

ORGANISATION MONDIALE DE LA SANTE ORIGINAL : ENGLISH

THE INTRODUCTION OF A DISSOLUTION TEST IN PHARMACOPOEIAL SPECIFICATIONS

By

Dr. G.B. ENGEL
CANBERRA

During the last few years reports have appeared in the literature concerning drugs which either have not given the expected clinical results or which have caused unexpected toxic reactions. This has been more noticeable in patients who have been stabilized on drug for a period of time and, after taking a new batch or brand, have experienced a change in the clinical effectiveness of their medication. A suspected cause of malabsorption or enhanced absorption is the variation of release characteristics of the final product.

It has only been recently that sufficiently accurate analytical techniques have been developed to measure small amounts of drugs in blood, plasma and other tissues which have enabled workers to establish a relationship between drug levels in the blood and clinical effectiveness. Further work is required to establish values for minimum effective blood levels for many drugs and also to determine at what concentration toxic levels usually occur. Progress is taking place in these fields strengthening already established concepts of drug absorption and therapeutic safety of orally administered drugs. The methods for determining reliability of oral solid dosage forms are now described.

Disintegration tests

Over a period of years national pharmacopoeias have described

disintegration tests. Such tests measure the time for an intact dosage form to break up into smaller aggregates or particles and pass through a standard wire mesh under defined conditions of agitation. Although disintegration tests are useful for a large number of drugs in as much as they screen out poorly formulated products, they do not distinguish between product which is clinically effective and one which is not, especially in the cases where the drug is a relatively insoluble compound.

It is assumed that before a drug can be absorbed, it must be dissolved so that the passage of the drug may occur across the gastro-intestinal tract. A distntegration test does not measure the rate of dissolution of a drug but simply the phenomenon of breakdown of a single mass into smaller aggregates.

A measure of drug availability from a dosge form therefore depends not on disintegration but on the rate of dissolution. Most workers who have carried out comparative tests **in vitro** have shown that there is no consistent relationship between disintegration and dissolution of a drug dosage form.

The relationship between formulation and the rate of dissolution

A number of factors affect the rate of dissolution of drugs from tablets and capsules. These factors are complex and interrelated. An important aspect is that of particle size. Generally, the smaller the particle size of a drug, the faster is the rate of dissolution, However the particle size which is importance is that which exists after disintegration has occurred and this is difficult to measure and is often very different from the particle size of the starting material. Other factors which affect rate of dissolution are the type of crystals used (which depend upon the solvent used for crystallization and the temperature of crystallization), the presence of disintegrating agents, lubricants and other excipients. The method of processing - granulation, drying and compression also afects the rate of dissolution. A standard for a dosage form based on the particle size of the raw material alone is not adequate to guarantee clinical effectiveness.

With the knowledge to date, it appears that a performance test

such as a dissolution test is the method **in vitro** which best gives a reliable indication of the quality of the final product.

The relationship of dissolution tests to physiological availability

There is sufficient evidence to establish that the rate at which a drug dissolves from its dosage from after disintegration often controls the rate of absorption of a drug. There is also adequate evidence to conclude that **in vitro** dissolution tests can provide an explanation for the observed differences in clinical results obtained in animals or humans in many cases. A review of this topic is given by Wagner (Drug Intelligence, 4,32-37, 1970). In some cases, however it has yet to be shown that the rate of dissolution necessarily parallels absorption rates. More data are required to correlate results of dissolution tests with physiological availability.

Dissolution tests

There are a number of excellent reviews of dissolution tests in the literature (Wagner, J.G. Drug Intelligence, 4,92-96, 1970; Hersey, J.A., Man. Chemist, 32-35, Feb, 1969) There are probably as many dissolution tests as there are workers in the field. However, the most used methods are the Beaker Method (Levy, G & Hayes, B.A., New Engl. J. Med., 262, 1053-1058, 1960), the Rotating Flask Method (Poole, J.W. Drug Inform, Bull., 3, 8-16, 1969) and the Rotating Basket Method (Pernarowski, M., Woo, W. & Searle, R.O., J. Pharm. Sci., 57, 1419-1422, 1968). The latter method, with modifications, is used in the U.S.P./N.F. method which is the only official method to date.

It is not feasible to design an "ideal" apparatus to simulate **in vivo** conditions. All dissolution tests involve a choice of arbitrary conditions. These conditions should be related to the conditions obtaining **in vivo.** An essential requirement of a dissolution test which is to be used for official or regulatory purposes is that the results of such a test are reproducible. Also, a dissolution test should be able to distinguish between acceptable and non-acceptable formulations. Whether a formulation is acceptable can

only be determined in the first instance by clinical results. The dissolution test cannot be expected to predict clinical effectiveness but should be able to screen out unacceptable batches or formulations on the assumption that widely differing dissolution rates may affect the efficacy or toxicity of the product.

If further **in vivo/in vitro** studies are to take place, the usefulness of these will be dependent on the acceptance of one or two dissolution tests and accumulation of clinical data so that an assessment of a particular dissolution test can be made. Hence it is desirable to accept a dissolution method now even though the clinical implications of the test are not fully known. If this is not done, there is no starting point for comparative tests in various laboratories and countries.

The decision as to which drugs (and dosage forms) require dissolution tests depends upon a number of factors. It has been shown that changes in formulation may produce clinical hazards, e.g. increased toxicity of phenytoin with change of excipient; ineffective control of blood sugar with some brands of tolbutamide. The number of drugs and formulations where a dissolution test should included is probably not great. Where a patient is being treated for a chronic illness or requiring continuous replacement thereapy, a change in formulation between batches or brands may result in lack of clinical efficacy or in an increase in toxicity. Such drugs may include.

(i) Oral anti-inflammatory steroids (Prednisone; prednisolone);

(ii) Oral antidiabetic agents (Tolbutamide);

(iii) Oral anti-epileptic agents (Phenytoin);

(iv) Digoxin tablets;

(v) "Insoluble" intestinal antiseptics (iodochlorhydroxyquinolines, nitrofurantoin);

(vi) Oral anticoagulant drugs (dicoumarol, Phenindione);

(vii) possible some oral diuretics (hydrochlorthiazide);

At present different workers in different countries are continuing studies on dissolution tests and physiological availability. It is suggested that there be some co-ordination at international Level to avoid duplication of work and that an internationally. acceptable method be used as a standard dissolution test.

ANNEXURE - III

(Item No.39, 64 and 68
of 15th D.C.C. Meeting)

Subjects Relating to Drugs (Prices Control) Order, 1970 Discussed on the 10th March, 1970 at New Delhi.

On the 10th March, 1972 the Drugs Consultative Committee discussed the problems connected with the administration of the Drugs (Prices Control) Order, 1970. Shri R. Grover, Deputy Secretary, Ministry of Petroleum and Chemicals was present by invitation.

The Chairman, Shri P.S. Ramachandran, introduced Shri Grover to the members of the Drugs Consultative Committee and requested the State Drugs Control authorities to avail themselves of the opportunity and exchange ideas on matters relating to the price Control Order.

Shri Grover stated that the Drugs (Prices Control) Order, 1970 was promulgated by the Ministry of Petroleum and Chemicals with the object of rationalising the price structure of drugs. In this process, the prices of a few products might have gone up but the prices of a large number of products of various categories were brought down. The consumer, surely was benefited to the extent of a few crores of rupees.

Shri P.K. Mishra, Drugs Controller, Delhi Administration enquired from Shri Grover of the impact which the Drugs (Price Control) Order had made on the consumer. The benefit of the Price Control measure to the consumer, in his view, could be assessed in two ways (i) by investigating whether the cost of the drug bill in hospitals had come down as compared to the over-all drug bill of the hospitals for the same medicines prior to the enforcement of the Order and (ii) by examining whether the prices of common household remedies had been brought down.

Shri Grover stated that no study regarding the impact of the Order on the drugs bill of hospitals had been made by the Ministry of Petroleum and Chemicals. He however, said that since the order came into force,

production of drugs had been going up steadily while prices of formulations have still remained steady by for and large. The forces of competition had also contributed to a reduction in prices and that according to the study based on what the consumer had to pay now for the drugs, the findings of the Ministry of Petroleum and Chemicals were that consumer had been benefited.

The Chairman said that in order to find out whether hospitals and dispensaries stand to gain under the Price Control Order, a selected study of a few Hospitals should be under-taken. He suggested that such a study could be carried out at the Safdarjang or Irwin Hospitals or the CGHS where the consumption of drugs is heavy.

To facilitate such a study, Shri Grover agreed to depute one of the Cost Accountant to these hospitals to work out the details.

Shri M.V. Rajyadhyaksha, Assistant Commissioner FDA, Maharashtra stated that it was not possible for mofussil dealers to maintain a supply of all the essential drug because of the cut in dealers margin of profit. Many State Drugs Control authorities also represented that wholesale dealers are being denied the extra margin of profit which is allowed under Order with the result that the retail dealers in the mofussil or rural areas are not fed continually with adequate stocks. The Chairman agreed with the view expressed by the members and said that the surveys carried out by Drugs Control authorities in Tamil Nadu, Maharashtra and Gujarat confirm that retail dealers in the interior of the States had complained that while in the past wholesale dealers used to come to them, meet the requirement of drugs and in many cases offered credit facilities, the position obtaining to-day was that retail dealers have to go to the nearest town for replenishment of their stocks which they could do only once in a month or once in two months.

Shri Grover stated there was a difference between the definition of wholesaler as given in the Drugs and Cosmetics Act and that providfed under the Order. In the Order, the term "dealer" had been defined as a person carrying on the business of purchase or sale of drugs and includes a wholesaler

or retailer. The term retailer has also been defined in the Order. By way of inference, the term wholesaler meant a person who is **not** a retailer but who does not deal with the consumer directly. He stated that while under the Drugs and Cosmetics Act and Rules, the same dealer can have a wholesale as well as a retail licence, the intention under the Drugs (Price Control) Order, was that two types of discounts should not be made available to the same person. The definition of "wholesalers" under the Drugs Act was therefore not made applicable under the Drugs (Prices Control) Order. The intention of the order was not to interfere with the prevailing practices of the industry and trade prior to the, promulgation of the Order and the manufacturers were therefore specifically advised by the Ministry of Petroleum & Chemicals to continue the trade practices, that were existing prior to the promulgation of the Order.

Shri B.V. Patel and Shri Pany stated that they know of cause where manufacturers had considered certain dealers as "wholesalers" before the Price Control Order came into force, and that the status of such firms had been changed after the introduction of the Order. Supplies are now being made to those firms and the invoices are enfaced with rubber stamp "Supplies made against retail sale licence".

Shri Grover stated that if the names and particulars of such firms are brought to the notice of the Ministry of Petroleum and Chemicals, the matter would be taken up with manufacturer concerned.

Shri Rangnekar, Commissioner, FDA, Maharashtra State represented that certain manufacturers are said to have included charges such as insurance, freight, packing, forwarding etc. while supplying drugs to dealers outside the state and enquired whether such a practice was in consonance with the provisions of the Price Control Order. Shri Grover said that he would get the matter examined and inform the Committee of the legal position.

Dr. Mishra said that under the Order care had been taken to protect the interest of the manufacturer and the first wholesaler on the distribution line and that the ultimate retail price has been fixed ignoring

all other intermediary levels. It has been left to the trade to decide how the sales transactions between one wholesaler and another or between one retailer and another should be conducted. The net impact of this arrangement is that the consumer is hard put to obtain his requirements of drugs. He suggested that the differentiation between the dealer and the retailer may be done away with. Shri Rangnekar suggested that a minimum of 15% margin should be ensured for dealers after doing away with the differentiation between "dealer" and "retailer" in the existing Price Control Order. Shri Patel however was of the view that a 20% margin would be needed especially when dealers have to instal air conditioners, maintain cold storage arrangements for certain categories of drugs and all records. Shri Grover took note of the suggestions made and said that the suggestions would be taken into consideration when the order is amended next time.

Shri Rajyadhyaksha enquired whether the prices for bulk drugs fixed by Government would be the same in different parts of the country and desired to know whether a person would receive drug from outside Bombay at the same price at which he obtains it from Bombay market. Shri Grover stated that the prices are fixed in relation to drugs and therefore should be uniformly applicable through out the country.

Shri Rajadhyaksha also explained the difficulties experienced by small scale units in obtaining raw materials from manufacturers who hold the stocks of such material for their captive consumption and are not inclined to part with them to other formulators, especially to the small scale units. He desired to know whether the manufacturers can be made to part with the raw material under the provisions of the Order. Shri Grover said that under Para 5-A(3) of the Price Control Order it should be possible to make manufacturer of bulk drug to distribute the material to any category of formulators.

Dr. Mishra desired to know whether any action can be taken against the defaulting manufacturers in case such instances are brought to the notice of the Ministry of Petroleum and Chemicals. Shri Grover answered that manufacturers can be asked to explain by the Ministry of Petro-

leum and Chemicals and that the action taken against defaulting firms would depend upon the facts of each case.

Shri Rajadhyaksha said that in the case of bulk drugs Government only fix their prices and have not specified any specific commission to be paid by the manufacturers of bulk drugs to wholesalers. Replying to this question Shri Grover stated that in arriving at the prices of such bulk drugs Government provides sufficient margins for wholesale dealers. It was for the manufacturers to decide on the extent of commission to be paid to wholesalers.

Some of the State Drugs Controllers pointed out that the communications issued by the Ministry of Petroleum and Chemicals on the subject of Drugs Price Control are received by the trade much in advance of the State Drugs Control Administrations. Shri Grover assured the members that the Ministry of Petroleum and Chemicals maintained a list of all State Drugs Controllers and that all relevant communications are also despatched to them. It was however likely that there could have been some delay in the postal system.

Summing up, the Chairman said that about two years have passed since the promulgation of the Drugs (Prices Control) Order, 1970 came into force and that it was time that the Ministry of Petroleum and Chemicals made a survey of the impact of the Order on the various categories of manufacturers (small-scale, medium scale and the large-scale) and dealers (including wholesalers and retailers) and examine whether any changes are called for in the Order. There was every indication to show that shortage of drugs in the mofussil and rural areas was mainly the resultant effect of the changes made in the trade and distribution patterns by many manufacturers. The Ministry of Petroleum and Chemicals should be firm in dealing with such manufacturers. State Drugs Control Authorities would do well to bring such cases to the notice of the Central Drugs Control Organisation.

The discussions then came to a close with a vote of thanks to Shri Grover and the Chairman.