

Members present:

Prof. A. Jabbar, Prof. A.T. Siddique, Prof. Mofazzal Hossain, Prof. M.Q.K.Talukder, Brig. Anis Waiz, Dr. Md. Jahangir, Dr. Kazi Abdul Fattah, & Dr. Humayun K.M.A. Hye.

Chairman:

The meeting was presided over by Prof. Waliullah.

Agenda No.1:

The minutes of the 140th meeting were confirmed.

Agenda No.2:

Matters arising out of the minutes of the 140th meeting held on 17.9.86.

nil

Agenda No.3:

Consideration of the following recipes of essential drugs.

The recipes of the following essential drugs were placed and decision taken.

| <u>Firm/Brand</u>  | <u>Decision.</u>  |
|--|---|
| <u>Ibn Sina, Dhaka.</u>  |   |
| Sinasol tab.<br>(salbutamol sulphate 2mg)  | Approved with condition to delete overage.                                    |
| <u>Modern Research, Jessore.</u>   |   |
| Tab. Levax, 50mg<br>(levamisole)   | The recipes were kept pending for upto date inspection report.                |
| Tab. Medanol 10mg/40mg<br>(propranolol)  | -do-  |
| Ferrum-M syrup<br>(ferrous sulfate 4%)   | -do-  |
| Tab. Griferin<br>(griseofulvin 125mg)  | -do-  |
| <u>Pfizer, Dhaka.</u>  |   |
| Allemine 4mg tab.<br>(chlorpheniramine maleate)  | Approved with condition to delete overage.                                    |
| <u>Standard Chemical, Dhaka.</u>   |   |
| Pethidine Inj, 100mg/2ml amp.  | Rejected as the firm donot have Narcotic licence.                             |
| Morphine inj.<br>0.25mg/1ml amp.   | -do-  |
| <u>City Pharmaceuticals, Ctg.</u>  |   |
| Levamisol syrup 944mg/100ml  | The recipe was kept pending till shifting of the factory to a suitable place. |
| Sefton lotion<br>(cetrimide 3% +<br>chlorhexidine gluconate<br>solution 20", 1.5ml/100ml). | -do-  |

Approved  
Waliullah  
1-10-86

Minutes of the 142nd meeting of the Drug Control Committee held on 1.10.66.

Kaysons, Dhaka.

B-Complex tablet  
(thiamine Hcl 5mg  
+ riboflavin 2mg  
+ pyridoxine Hcl. 2mg  
+ nicotinamide 20mg)

Approved with condition to change name.

Conoshasthaya, Dhaka.

G-Propranolol -80mg tab.

Approved.

G-Propranolol 160mg tab.

Approved.

Cpsonin, Barisal.

Cpsovit s/c tab.  
(nicotinamide 20mg  
+ riboflavin 2mg  
+ pyridoxine Hcl 2mg  
+ Thiamine Hcl 5mg).

Approved.

Acme, Dhaka.

Vit.-C effervescent tab. 250mg  
(vitamin C)

Rejected because not required in effervescent form.

UCPL, Chittagong.

Glibenclamide tab. 5mg

The recipe was kept pending till shifting of the factory to a suitable place.

Sabbath, Bagerhat.

Histalin liq.  
(promethazine Hcl 0.1%)

Approved with condition to change name and delete overage.

Feladel liquid.  
(ferrous gluconate 6%)

Approved with condition to add a sta-biliser.

Ulced susp.  
(antacid)

The recipe was kept pending for inspection to check facilities production & testing (microbial count.)

Fungacin oint.  
(salicylic acid 3%  
+ benzoic acid 6%)

Approved.

Womdel liq.  
(mebendazole 0.1%)

Rejected because strength not acceptable.

Paradel liq.  
(paracetamol 2.4%)

Approved with condition to delete overage,

change name

Paradel liq.  
(benzoyl metronidazole 6.4%)

Approved.

Ascadel liq.  
(benzoyl benzoate 25%)

Approved with condition to change name

Agenda No.4:

Consideration of the recipes of the following new firm on priority basis.

The recipes of the following firm were considered on priority basis and decision taken:-

Medikub, Dhaka.

Cap:XXXXXXXX

Approved  
W. S. M.  
1.10.66

Medilab, Dhaka.

|  |  |
|--|--|
| Cap. Amicin<br>(ampicillin 250mg)  | The recipe was kept pending for creating segregated and microbiological facilities.  |
| Medigel susp.<br>(antacid)   | -do-   |
| Erycin Dry syrup.<br>(erythromycin 2.5%)   | -do-   |
| Amicin Dry syrup.<br>(ampicillin 2.5%)   | -do-   |
| C-pen dry sryp<br>(penicillin VK 2.5%)   | -do-   |
| Seovil susp.<br>(griseofulvin 2.5%)  | -do-   |
| Oxytet cap.<br>(oxytetracycline 250mg)   | -do-   |
| Medoxin cap.<br>(doxycycline Hcl 100mg)  | -do-   |
| Cravit cap.<br>(thiamine Hcl 5mg +<br>riboflavin 2mg<br>+ pyridoxin Hcl 2mg<br>+ nicotinamide 20mg). | Approved.  |
| Feronex cap.<br>(ferrous fumarate 300mg<br>+ folic acid 300mcg.)                                     | Approved with condition to delete overage for ferrous fumarate and add 3% overage for folic acid and change name.                |
| Feronex syrup.<br>(ferrous sulphate 4%)  | Approved with condition to change name and add a stabiliser and reduce quantity of sodium benzoate to 300mg.                     |
| Parasol syrup<br>(paracetamol 2.4%)  | Approved.  |
| Derux liquid<br>(dextromethorphan HBr. 2%)   | Approved with condition to market in generic name (not in brand name) and add warning as "Not for children" on label and carton. |
| Histin syrup.<br>(chlorpheniramine maleate to<br>40mg/100ml.)  | Approved with condition to change name.  |
| Benzol lotion<br>(benzyl benzoate 25%)   | Approved.  |
| Parasule ca p.<br>(paracetamol)  | Rejected because not required in this dosage form (capsule).   |
| Milozide cap.<br>(amiloride & hydrochlorothiazide)   | -do-   |

Agenda No. 7: Miscellaneous:

a) Consideration of cancellation of some products of import origin.

The Committee reviewed the registration the medicinal products of import origin which are registered from more than one source. The registration of one source was retained and rest of the source(s) was/were cancelled as stated below:

*OPP/2012*  
*W. Saha*  
*1-10-86*

Minutes of the 142nd meeting of the Drug Control Committee held on 1.10.77

| Sl.No. | Brand  | Registration retained | Registration(s) cancelled.   |
|--------|--|-----------------------|--|
| 1.     | Sinemet tab.<br>(carbidopa + levodopa)                                 | MSD, U.S.A.           | MSD, Holland sinemet 10mg + 20mg tab.<br>(64-798-77 & 64-799-77).  |
| 2.     | Moduretic tab.<br>(amiloride + hydrochlorothiazide)                    | MSD, U.K.             | M.S.D., Pakistan Moduretic tab.<br>(21-1997-84)  |
| 3.     | Tryptonol tab.<br>(amitriptyline 10mg & 25mg)                          | MSD, USA.             | MSD, Pakistan<br>Tryptonol tab. 10mg.<br>(21-1974-83)<br>Tryptonol tab. 25mg<br>(21-1975-83)<br>Tryptonol tab. 75mg.<br>(21-1976-83) |
| 4.     | Penidur LA inj.<br>(benzothine penicillin)<br>(6 lac, 12 lac & 24 lac) | Wyeth, Holland        | Wyeth, USA.<br>Penidur LA inj. 6 lac (42-108-76)<br>12 lac (42-114-76)<br>24 lac (42-110-76)   |
| 5.     | Modeca-te inj.<br>(fluphenazine decanoate)                             | Squibb, U.K.          | Squibb, Egypt Modecate inj.<br>(96-204-85)   |
| 6.     | Kenalog inj.<br>(triamcinolone)  | -do-                  | Squibb, Egypt<br>Kenacort, A A M inj.<br>(96-2046-85)  |
| 7.     | Velosef inj.<br>(cephradine)<br>250mg & 500mg                          | -do-                  | Squibb, Egypt<br>Velosef inj. 500mg<br>(96-2103-85)  |
| 7.1    | Velosef inj<br>(Cephadrine 250mg)                                      | Squibb, Egypt         | Squibb, Greece<br>Velosef inj. 250mg (96-1401-78)  |
| 8.     | Negram tab.<br>(nalidixic acid)  | Winthrop, U.K.        | Winthrop, U.S.A.<br>Negram tab. (2.654-76)   |
| 9.     | Negram Paed susp.  | -do-                  | Negram Paed susp.<br>(2-643-76)  |
| 10.    | Neo-synephrine $\frac{1}{2}\%$ drops.                                  | -do-                  | Neo-synephrine $\frac{1}{2}\%$ Drop & spray<br>(2-652-76)  |
| 1.     | Neo-synephrine $\frac{1}{2}\%$ drops.                                  | -do-                  | Neo-synephrine $\frac{1}{2}\%$ drop & spray<br>(2-651-76)  |
| 2.     | Physohex emulsion<br>(hexachlorophene)                                 | -do-                  | Winthrop, U.S.A.<br>Physohex emulsion (2-660-76)   |
| 1.     | Furacin oint.<br>(nitrofurazone)                                       | SK & F, U.K.          | Eskayef, India<br>Furacin oint (62-1101-77).   |

Contd .....P/5.

Approved  
W. J. [Signature]  
1/10

- |   |                                 |   |
|---|---------------------------------|---|
| 14. Angised tab.<br>(glyceryl trinitrate)   | Wellcome<br>Foundatio-n<br>U.K. | Wellcome Foundation, Pakistan<br>Cicatrln Powder<br>(75-1092-77)      |
| 15. Cicatrln Powder<br>(neomycin +<br>bacitraclnzinc,<br>cysteine,<br>threonine, glycine) | -do-                            | Wellcome Foundation, Pakistan<br>Cicatrln powder<br>(75-1092-77)      |
| 16. Lanoxln tab.<br>(digoxln)   | -do-                            | Wellcome Foundation, Pakistan<br>Lanoxln tab. (75-1091-77)            |
| 17. Mix-Ovial solu<br>cortef inj.<br>(hydrocortlsone<br>sodium succlnate)<br>10mg/2ml.    | Upjohn, Belgium                 | Upjohn, USA.<br>Mix-C-vlal solu cortef inj. 100mg/2ml.<br>(90-400-76) |

b) Consideration of prayer of Healing pharma dated 7.9.86 and other similar case

The Committee considered the above prayer and advised to bring recipes of the firm along with the inspection report for further consideration.

c) Consideration of the report about Hepavax vaccine of Korea Green Cross, Korea.

The Committee considered the investigation report about the import of the unregistered drug, Hepavax vaccine (hepatitis B vaccine) of Korea Green Cross, Korea. It was mentioned in the report that the local agent, International agencies was allowed to import 50 vials of the drug for registration purpose, out of which 10 vials was submitted to the Drug Administration for test and analysis, one vial was short received and rest 39 vials were distributed free of cost to different persons/doctors, as claimed by the party. It was noted by the Committee that the whole stock which was imported for registration purpose was supposed to be submitted to the Drug Administration, as per condition given during allowing NCC for import and none of this stock is allowed for free or commercial distribution. Any form of distribution is violation of the condition of NCC permission.

In view of above, the committee decided to keep the issuance of registration of Hepavax vaccine (Hepatitis-B vaccine) of Korea Green Cross, Korea pending, and warn the local agent for the offence.

The meeting ended with vote of thanks to the chair.

The committee considered the evidence  
was not clear violation of NCC  
and vaccine for registration purpose  
by distribution to the said vaccine by  
to registration. and decided this to  
reject the registration.

Approved

11/01/86

Minutes of the 142nd meeting of the Drug Control Committee held on 1.10.86.

Members present:

Prof. Mofazzal Hossain, Brigadier Anis Haiz, Dr. Kezi Abdul Kattab &  
Dr. Md. Jahangir.

Chairman:

The meeting was presided over by Prof. Gullulgh.

Agenda:

Confirmation of the minutes of the 141st meeting held on 24.9.86

The minutes of the 141st meeting were confirmed.

Matters arising out of the minutes : nil.

Agenda-2.

Consideration of the following recipes of essential drugs:

The recipes of the following essential drugs were placed and <sup>the following were</sup> decisions taken:

| <u>Firm/Brand</u>   | <u>Decision.</u>  |
|---|---|
| ✓ <u>Seema, Dhaka</u><br>Profen-S tab.<br>(ibuprofen 200mg)                 | Approved with condition to put 'S' in the prefix of the name.   |
| ✓ <u>Scribb, Dhaka.</u><br>Spont C.T. tab.<br>(hyoscine butyl bromide 10mg) | Approved.   |
| <u>A.P.I. Ltd., Dhaka.</u><br>Rimabact s/c tab.<br>(rifampicin 450mg)       | The recipe may be resubmitted showing excipients for core tablet and coating material separately.   |
| <u>Salton, Dhaka.</u><br>Seapicillin cap.<br>(ampicillin 250mg)             | Kept pending for inspection report about facilities for antibiotic manufacture.   |
| <u>Tetra, cycline cap. 250mg</u>  | -do-  |
| <u>Toltsul cap.</u><br>(vitamin B-complex)                                  | The recipe may, <sup>be</sup> resubmitted with standard formula as, thiamine Hcl. 5mg, riboflavin 2mg, pyridoxine Hcl. 2mg and nicotinamide 20mg per cap. and changed name. |
| <u>Menocap cap.</u><br>(ferrous fumarate 200mg)<br>+ folic acid 1mg)        | The recipe may be resubmitted reducing quantity of folic acid (250mcg per cap) and indication as per ENF.   |
| <u>A.P.C. Chemical, Moulana.</u><br>Ezedi tab.<br>(propranolol Hcl.)        | Kept pending for upto-date inspection report about facilities for manufacture.  |

Apetryl-250 tab.  
(metronidazole 250mg)

Kept pending for upto-date inspection about facilities for manufacture.

Apetryl-400 tab.  
(metronidazole 400mg)

-do-

Apetrax tab.  
(mchendazole 100mg)

-do-

Apeglobin cap.  
(ferrous fumarate 300mg  
+ folic acid 300mcg.)

-do-

Tetracyp cap.  
(tetracycline Hcl. 250mg)

-do-

Apeclox cap.  
(cloxacillin Na 250mg)

-do-

Apecillin cap.  
(ampicillin trihydrate 250mg)

-do-

Doctor's Ch. Works Bonga:

✓ Pressine tab.  
(propranolol Hcl. 40mg)

Approved with condition to manufacture in different size and colour from that of 10mg tab. of the drug and give indication as per ENF.

✓ Haemodin tab.  
(ferrous fumarate 200mg  
+ folic acid 250mcg.)

Approved with condition to give indication as per ENF.

✓ D-Butanol liquid  
(salbutamol 40mg/100ml.)

Approved with condition to give indication as per ENF.

Cipla Ltd., Dogra:

✓ Ferromet cap.  
(ferrous fumarate 300mg  
+ folic acid 0.5mg)

Approved with condition to give indication as per ENF.

Gayatri Pharr., Babna:

✓ Gyno-miconazol vaginal cream  
(miconazole nitrate 2%)

Approved.

The Acne Lab., Ltd., Dhaka:

Tetra-plex cap.  
(tetracycline Phosphate complex)

The recipe to be resubmitted with condition to change name and justify the advantage of using "phosphate complex" of tetracycline.

Apcco, Dhaka:

Aspron soluble aspirin tab.  
(acetyl salicylic acid 300mg)

Approved with condition to change name and give warning as not to use in children below 12 yrs of age without a physician's supervision.

AtanGa-4:

Consideration of the following resubmitted recipes.

The following resubmitted recipes were placed and decisions taken.

with following in mind

.....

Standard Ch. Ind., Dhaka.

Inj. Calcium Gluconate 10%

The recipe was kept pending for inspection report confirming availability of facilities of manufacture.

Asiatic, Dhaka.

Tempol Elixir  
(paracetamol 2.4%)

Approved.

Nutrovita cap.  
(thiamine Hcl. 5mg  
+ riboflavin 2mg  
+ pyridoxine Hcl 2mg.  
+ nicotinamide 20mg)

Approved.

Medicon, Dhaka.

Ironin syrup  
(ferrous gluconate 4%)

Approved.

Casis, Sirajganj.

Ferasis cap.  
(ferrous fumarate 200mg  
+ folic acid 0.5mg)

Approved.

Zymosis cap.  
(pancreatin enteric coated  
granules 325mg)

Approved.

Vita-B cap.  
(thiamine 5mg  
+ riboflavin 2mg  
+ pyridoxine 2mg  
+ nicotinamide 20mg)

Approved.

Pharmaco, Dhaka, Gyzsyzs

Oraplex cap.  
(thiamine 5mg  
+ riboflavin 2mg  
+ pyridoxine 2mg  
+ nicotinamide 20mg)

Approved.

Popular, Barisal.

Antacid susp.

The recipe was kept pending for inspection report about facilities for manufacture and checking microbial count.

Multiferron syrup.  
(ferrous sulfate 4%)

Approved with condition to change name.

Pharmachenic, Dhaka.

Solu-Aspirin tab.  
(aspirin 300mg)

Approved with condition to give warning as not to use in children below 12 years of age without a physician's supervision.

Bio-chem, Dhaka.

Biodex oint.  
(iodine 4% + methyl  
salicylate 5%)

Approved.

Azad Pharma, Dhaka.

Vixerub oint  
(menthol 4% + camphor 6%  
+ thymol 1% eucalyptus, 2%)  
vial

Approved.

Doctor's Ch. Bogra.

D-Cee syrup  
(ascorbic acid 2%)

Approved.

Chamico, Rajshahi

Tetracycline cap. 250mg

The recipe was kept pending for inspection report confirming availability of facilities.

Beximco, Dhaka.

Ascobex drops.  
(ascorbic acid 10%)

Approved.

Meclomid tab.  
(metoclopramide Hcl 10mg)

Approved.

Mirroy, Dhaka.

Pethidine Hcl inj. 100mg/2ml amp.

The recipe was kept pending for update Narcotic Licence.

G. A. Co, Dhaka.

Unitac f/c tab.  
(ranitidine Hcl. 150mg)

Approved.

Agenda-5:

Consideration of the recipes of the following firm on priority basis.

The recipes of the following new firm were palced and discussed.

Healing, Dhaka.

Antacid-HP susp.

The recipe was kept pending for next meeting.

Heligan syrup  
(promethazine)

-do-

Supemycetin susp.  
(chloramphenicol)

-do-

Amomat susp.  
(benzoyl metronidazole)

-do-

Tritrim susp.  
(cotrimoxazole)

-do-

Fersolin syrup.  
(ferrous gluconate)

-do-

Tampacit liq.  
(paracetamol)

-do-

Hemapar syrup  
(levamisole)

-do-

Scab emulsion  
(benzyl benzoate)

-do-

Antacid-HP tab.

The recipe was kept pending for next meeting.

(tetra-HP cap.  
(tetracycline)

-do-

Helzyme cap.  
(pancreatin)

-do-

Whitfield's oint.

-do-

Agenda-6:

Consideration of prayers for import registration.

Johnson & Johnson, India

Velroc brand plaster  
of Paris Bandage

Approved as recommended by Prof. Anisuddin Ahmed  
of Sir Salimullah Medical College. *as expert*

Fama Italia, Italy.

Pharmarubicin inj.  
(epirubicin Hcl 10mg &  
50mg per vial)

Approved as recommended by Dr. M.N. Huda of  
Dhaka Medical College. *as expert*

Hoechst, West Germany

Claforan inj.  
(cefotaxime, 0.25g, 0.5g, 1.0g  
and 2.0g vials)

Approved as recommended by Prof. T.A. Chowdhury  
of IPGMR and Prof. Mofazzal Hossain of Dhaka  
Medical College and Prof. Motiur Rahman of IPGMR.

*as experts*

Tsingtao Fish Liver Oil  
Factory, China.

"Double whale" brand Fish  
Liver Oil capsule  
(vit. A & D)  
(196-2145-86)

Extension of the provisional registration for  
one year was recommended.

Agenda-8 : Miscellaneous

a) Review of registration of some non-importable drugs

The following drugs of foreign origin, the validity of registration of which  
are over and are being considered for renewal of the registration, but the  
drugs ~~are~~ not importable, were placed before the committee for decision as to  
whether the registrations <sup>shall</sup> be renewed and be processed for inclusion in  
the importable list. The decisions taken ~~are~~ as follows:

Item/Brand

Decision

Cyanide, USA

1. Artane tab. 5mg  
(trihexyphenidyl Hcl or  
benzhexol Hcl)  
(75-1789-81)

The registration may be renewed.

2. Artane tab. 2mg  
(75-1790-81)

*(circled)* -do-

*Recommend  
not to proceed  
JK/m*

MSD, USA

- 3. Cogentin inj.  
(benztropine)  
(64-279-76)

The registration may be renewed.

Upjohn, Belgium

- 4. Lincocin capsule  
(lincemycin)  
90-313-76
- 5. Lincocin inj.  
(lincemycin)  
(90-312-76)

-do-

-do-

Roche, Switzerland

- 6. Rivotril 0.5mg tab.  
(clonazepam)  
(54-1611-80)
- 7. Rivotril 2mg tab.  
(clonazepam)  
(54-1612-80)
- 8. Rivotril 1mg/ml amp.  
(clonazepam)  
(54-1623-80)

-do-

-do-

-do-

*Reference to Prof Rashid  
for Ref. Scam on  
& Prof Nazimuddin  
with a  
form.*

Cooper, USA.

- 9. Tearsol ophth. soln.  
(boric acid + methylcellulose)  
(150-2756-31)

-do-

*Specialists' drug.  
Ophthalmologist*

ISVI Sclavo, Italy

- 10. Gurevax Vaccine  
(rubella Vaccine)  
(57-1675-80)

-do-

Asta, West Germany

- 11. Honvan inj.  
(tetra sodium fosfestrol)  
(89-1350-78)
- 12. Honvan tab.  
89-1349-78

-do-

-do-

Ciba, Switzerland

- 1. Anturan 100mg tab.  
(sulphinpyrazone)  
(87-322-76)
- 2. Anturan 200mg tab.  
(87-325-76)

The registration may not be renewed.

-do-

Grauppo, Italy

- 3. Rifocin 250mg inj.  
(rifamycin SV)  
(89-1735-80)

-do-

MSD, USA.

- 4. Cogentin 2mg tab.  
(benztropine)  
(64-278-76)

-do-

Medimpex, Hungary

5. Plastubol spray  
(neomycin)  
(63-409-76)

The registration may not be renewed.

SK & F, UK

6. Dytide cap.  
(triamterene +  
benzthiazid)  
(62-242-76)

-do-

7. Dytac cap.  
(triamterene)  
(62-243-76)

-do-

Bayer, West Germany

8. Comital-L tab.  
(diphenyl hydantoin  
+ prominal + luminal)  
(61-1048-77)

-do-

9. Mitigal oint  
(mesulphen +  
precipitated sulphur)  
61-481-76

-do-

Kramer-Urban, USA.

10. Nitrol 2% oint  
(nitroglycerine)  
(53-1837-81)

-do-

Leo, Denmark

11. Vagilia cream  
(sulfoxazole)  
(93-1809-81)

-do-

Medimpex, Hungary

12. Hydrocortisone oint  
(63-1368-78)

-do-

Upjohn, USA

13. Cortef Acetate 1% oint.  
(hydrocortisone)  
(90-300-76)

-do-

14. Cortef Acetate 2.5% oint  
(90-301-76)

-do-

15. Neomedrol Acne lotion  
(methyl prednisolone  
+ sulfur + neomycin  
+ aluminium chlorhydroxide)  
(90-309-76)

-do-

Contd....P/8.

Asta, West Germany.

- |  |                                      |
|--|--------------------------------------|
| 16. Holoxan 2 g inj.<br>(Difosfamide)<br>(89-1338-78)            | The registration may not be renewed. |
| 17. Holoxan 1 g inj.<br>(89-1339-78)                             | -do-                                 |
| 18. Holoxan inj. 500mg<br>(89-1340-78)                           | -do-                                 |
| 19. Holoxan inj. 200mg<br>(89-1341-78)                           | -do-                                 |
| 20. Ixoten tab.<br>(trofosfamide)<br>(89-1342-78)                | -do-                                 |
| 21. Favistan tab.<br>(methyl mercapto imidazole)<br>(89-1351-78) | -do-                                 |

The following other decisions were taken about drugs of foreign origin as below :

Smith  
Wyeth, Australia

- |   |  |
|---|--|
| 1. Seropax 10mg tab.<br>(oxazepam)<br>(42-139-76) | The registration was cancelled, as, the same brands of USA origin are also registered. |
| 2. Seropax 15mg tab.<br>(oxazepam)<br>(42-140-76) | -do-   |

Shanghai, China.

- |   |  |
|---|--|
| 3. Insulin inj.<br>(147-1665-79)                  | Provisional registration of the drug was valid till 31.12.80. The party has applied for renewal of the registration. The Committee rejected the prayer for renewal. The registration may be cancelled. |
| 4. Protamin Zinc<br>Insulin inj.<br>(147-1664-79) | -do-   |

- b) To take decision whether combination antiasthmatic drug will be permissible.

Some locally manufactured combination antiasthmatic products (e.g. combination of ephedrine + promethazine + theophylline/aminophyllin or hydroxyzine) were placed before the Committee for decision as to whether such combinations will be permissible in light of the National Drug Policy.

The matter was kept pending.

- c) Consideration of prayer of Bulgarian Embassy about registration of some Bulgarian drugs to be imported through barter trade, which were earlier rejected by the Committee. The Committee rejected the prayer because the drugs under reference are not acceptable because of availability of enough substitutes, either locally manufactured or imported.

- d) Prayer of Alco Pharma to replace registrations of MSD products of USA origin by those of Pakistani origin.

The prayer was rejected because the quality of the USA source are more acceptable. X

- e) To take decision about Elastocrep bandage of Smith & Nephew, Korea manufactured by Sun IL Textile, Korea.

The matter was kept pending. ✓

- f) Test report of Ultraproct Cream of Schering.

The Committee was informed about the test report of the above mentioned drug which was found not to conform to the claim as reported by the Govt. Analyst.

The meeting ended with vote of thanks to the chair.

Approved

Chairman.

20/4/86

20

Minutes of the 143rd meeting of the Drug Control Committee held on 23.10.86.

The 143rd meeting of the Drug Control Committee was held on 23.10.86 at 10.30 A.M. in the office chamber of the Secretary, Ministry of Health & Family Planning under the chairmanship of Mr. Manzurul Karim, Secretary, Ministry of Health & Family Planning.

The following members attended the meeting.

1. Prof. Nurul Islam
2. Brig. Anis Waiz
3. Prof. Abdul Mannan
4. Dr. Mobarak Ali
5. Prof. M.Q.K. Talukder
6. Dr. Humayun K.M.A. Hye
7. Dr. Zafrullah Chowdhury
8. Mr. Md. Anisul Islam
9. Dr. A.M.M. Khan
10. Dr. Md. Nurul Anwar.

At the start of the meeting, the chairman congratulated the members of the new Committee. A preliminary discussion was held without touching agenda. The Committee expressed their concern about the proliferation of adulterated/substandard drugs in the market and felt the necessity for a National Quality Control Laboratory.

The following decisions were taken:

- 1) The Committee decided to hold the meeting on every fortnight.
- 2) The Committee decided to distribute the working papers to members so that they could study them <sup>at</sup> home before attending the meeting.
- 3) The Committee decided to examine whether D.C.C.'s functions conflicted with those of any other Committee.
- 4) The Committee decided to circulate rules of exa<sub>l</sub>u<sub>g</sub>ation to individual members.

The meeting ended with vote of thanks to the chair.

*Prof. Nurul Islam*  
*confirmed*  
*20/11/86*

Minutes of the 144th meeting of the Drug Control Committee

70

The 144th meeting of the Drug Control Committee was held on 20.11.56 at 2.30 P.M. under the chairmanship of Mr. Manzoor-ul-Karim, Secretary, Ministry of Health & Family Planning in his office chamber.

The following members attended the meeting:-

1. Prof. Nurul Islam
2. Brig. Aziz ul-Hiz
3. Dr. Mubarak Ali
4. Prof. M.A.K. Talukdar
5. Dr. Humayun Kamal Hye
6. Dr. Asifur Rahman
7. Dr. Z. Faullah Chowdhury
8. Mr. Mansur Islam
9. Dr. Akmal Khan
10. Mr. M. Nurul Karim.

The following member could not attend the meeting.

1. Prof. A. Rahman

The following decisions were taken:

- 1) A group of fifty percent of the members (i.e. 5 members) will make the quota.
- 2) The meeting will be held on every 3rd & 4th day of the month at 9.30 A.M. in the office chamber of Director, Drug Administration, 90, Motijheel Commercial Area, Dhaka. To separate notice will be issued for the meeting from now on. If no meeting is held on a particular day, members will be informed accordingly. *can be held on a particular day, members will be informed accordingly.*
- 3) In the absence of Chairman, Prof. Nurul Islam, *and in his absence* the meeting will be presided over by *the members of the committee* *as per guidelines to be laid down by the Council of the Drug Control Committee.*
- 4) The Council should that the recipes of essential drugs from now on should be prepared by drug administration *and handed down by the Council of the Drug Control Committee.*
- 5) The Council should constitute a sub-committee consisting of Dr. Mubarak Ali and Mr. Mansur Islam to prepare the recipes before placing the same to the Drug Control Committee for *approval*.
- 6) The Council should examine minutes of the 142nd & 143rd meetings, with the following amendments in the minutes of 142nd meeting.

4:

1. Variation of strength of recipe  
 2. 500 mg, 1000 mg, 2000 mg, 4000 mg, 8000 mg, 16000 mg, 32000 mg, 64000 mg, 128000 mg, 256000 mg, 512000 mg, 1024000 mg, 2048000 mg, 4096000 mg, 8192000 mg, 16384000 mg, 32768000 mg, 65536000 mg, 131072000 mg, 262144000 mg, 524288000 mg, 1048576000 mg, 2097152000 mg, 4194304000 mg, 8388608000 mg, 16777216000 mg, 33554432000 mg, 67108864000 mg, 134217728000 mg, 268435456000 mg, 536870912000 mg, 1073741824000 mg, 2147483648000 mg, 4294967296000 mg, 8589934592000 mg, 17179869184000 mg, 34359738368000 mg, 68719476736000 mg, 137438953472000 mg, 274877906944000 mg, 549755813888000 mg, 1099511627776000 mg, 2199023255552000 mg, 4398046511104000 mg, 8796093022208000 mg, 17592186044416000 mg, 35184372088832000 mg, 70368744177664000 mg, 140737488355328000 mg, 281474976710656000 mg, 562949953421312000 mg, 1125899906842624000 mg, 2251799813685248000 mg, 4503599627370496000 mg, 9007199254740992000 mg, 18014398509481984000 mg, 36028797018963968000 mg, 72057594037927936000 mg, 144115188075855872000 mg, 288230376151711744000 mg, 576460752303423488000 mg, 1152921504606846976000 mg, 2305843009213693952000 mg, 4611686018427387904000 mg, 9223372036854775808000 mg, 18446744073709551616000 mg, 36893488147419103232000 mg, 73786976294838206464000 mg, 147573952589676412928000 mg, 295147905179352825856000 mg, 590295810358705651712000 mg, 1180591620717411303424000 mg, 2361183241434822606848000 mg, 4722366482869645213696000 mg, 9444732965739290427392000 mg, 18889465931478580854784000 mg, 37778931862957161709568000 mg, 75557863725914323419136000 mg, 151115727451828646838272000 mg, 302231454903657293676544000 mg, 604462909807314587353088000 mg, 1208925819614629174706176000 mg, 2417851639229258349412352000 mg, 4835703278458516698824704000 mg, 9671406556917033397649408000 mg, 19342813113834066795298816000 mg, 38685626227668133590597632000 mg, 77371252455336267181195264000 mg, 154742504910672534362390528000 mg, 309485009821345068724781056000 mg, 618970019642690137449562112000 mg, 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41538374868278621028243970633760768000 mg, 83076749736557242056487941267521536000 mg, 166153499473114484112975882535043072000 mg, 332306998946228968225951765070086144000 mg, 664613997892457936451903530140172288000 mg, 1329227995784915872903807060280344576000 mg, 2658455991569831745807614120560689152000 mg, 5316911983139663491615228241121378304000 mg, 10633823966279326983230456482242756608000 mg, 21267647932558653966460912964485513216000 mg, 42535295865117307932921825928971026432000 mg, 85070591730234615865843651857942052864000 mg, 170141183460469231731687303715884105728000 mg, 340282366920938463463374607431768211456000 mg, 680564733841876926926749214863536422912000 mg, 1361129467683753853853498429727072845824000 mg, 2722258935367507707706996859454145691648000 mg, 5444517870735015415413993718908291383296000 mg, 10889035741470030830827987437816582766592000 mg, 21778071482940061661655974875633165533184000 mg, 43556142965880123323311949751266331066368000 mg, 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5986310706507378352962293074805895248510699760029696000 mg, 11972621413014756705924586149611790497021399520059392000 mg, 23945242826029513411849172299223580994042799040118784000 mg, 47890485652059026823698344598447161988085598080237568000 mg, 95780971304118053647396689196894323976171196160475136000 mg, 191561942608236107294793378393788647952342392320950272000 mg, 383123885216472214589586756787577295904684784641900544000 mg, 766247770432944429179173513575154591809369569283801088000 mg, 1532495540865888858358347027150309183618739138567602176000 mg, 3064991081731777716716694054300618367237478277135204352000 mg, 6129982163463555433433388108601236734474956554270408704000 mg, 12259964326927110866866776217202473468949913088540817408000 mg, 24519928653854221733733552434404946937899826177081634816000 mg, 49039857307708443467467104868809893875799652354163269632000 mg, 98079714615416886934934209737619787751599304708326539264000 mg, 196159429230833773869868419475239575503198609416653078528000 mg, 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57896044625530045385385492504343953926634993304314154838614770557977786368000 mg, 11579208

Minutes of the 144th meeting of the Drug Control Committee

The 144th meeting of the Drug Control Committee was held on 20.11.86 at 12.30 P.M. under the Chairmanship of Mr. Manzoor-ul-Karim, Secretary, Ministry of Health & Family Planning in his office chamber.

The following members attended the meeting.

1. Prof. Nurul Islam
2. Brig. Aniz Waiz
3. Dr. Mobarak Ali
4. Prof. M.Q.K. Talukder
5. Dr. Humayun K.M.A. Hye
6. Dr. Azizur Rahman
7. Dr. Zafrullah Chowdhury
8. Mr. Anisul Islam
9. Dr. A.M.M. Khan
10. Dr. Md. Nurul Anwar.

The following member could not attend the meeting.

1. Prof. A. Mannan.

The following decisions were taken:

1. Presence of fifty percent of the members (i.e. 6 members) will make the quorum.
2. The meeting will be held on every 2nd & 4th Wednesday of the month at 9.00 a.m. in the office chamber of Director, Drug Administration, 80, Motijheel C.A., Dhaka. No separate notice will be issued for the meeting from now on. Prior information will be given to member if no meeting can be held in particular week.
3. In the absence of Chairman, Prof. Nurul Islam & his absence, any of one of the members as decided by consensus will preside over the meeting.
4. The Committee decided that recipe's of essential drugs from now on would be processed by the Drug Administration as per guidelines laid down by the Committee and approval would be taken from Drug Control Committee. Dr. Md. Nurul Anwar would scrutinize the recipes before placing the same to D.C.C. for approval.
5. The Committee confirmed minutes of the 142nd & 143rd meeting with the following amendment in the minutes of 142nd meeting.

A. Agenda-4:

- a) Consideration of resubmitted recipe:

Miramoy, Dhaka. Pethidine HCl. inj. 100mg/ml. Rejected.  
Reason: Allocation of pethidine from International Narcotic control is fixed and more fresh recipe would be approved

B. Agenda-6:

Consideration for import registration

Hoechst, West Germany, Claferran inj.  
(cefotaxime 0.25g, 0.5g, 1.0g & 2.0g vial) To be re-examined about price.

Tsingtao Fish Liver oil — Factory China Import not to exceed Tk. 1 million  
"Double whale" brand Fish  
Liver oil capsule  
(Reg.No.196-2145-86)

C. Agenda-8(a)

Review of registration of some non importable drugs.

Cynamide, USA Artane tab. 2mg Registration may not be renewed.  
Reg.No.75-1790-81

Upjon, Belgium

Lincocin cap. (lincomycin) Reg.No.90-313-76 -do-

Roche, Switzerland

Rivotril 0.5mg tab.  
Rivotril 2mg tab.  
Rivotril 1mg/ml cap.  
May be referred to Prof. Rashiduddin, Prof. S.G.M. Chowchury and Prof. Nazimuddin for opinion for renewal of their registration certificate with the following points:

- i) Whether they recommend or not with proper justification
- ii) Whether any substitute available
- iii) Cost ~~benefit ratio~~ *effectiveness*

Coper, U.S.A.

Tearsol oph. soln. (boric acid + methyl cellulose) Regn.No.150-1675.30) Must be used under supervision of ophthalmologist.

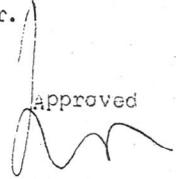
Insulin- China Regularization & renewal of provisional registration may be allowed.

Agenda-8(d)

Prayer of Glaxo Pharma to replace registration of MSD products of USA origin by those of Pakistani ~~ark~~ <sup>is not</sup> origin ~~may be~~ approved.

The meeting ended with vote of thanks to the chair.

Approved

  
Chairman

Drug Control Committee.

(2)

Minutes of the 145th meeting of the Drug Control Committee

The 145th meeting of the Drug Control Committee was held on 10.12.86 at 9 A.M. in the office chamber of Director, Drug Administration under the Chairmanship of Mr. Manzoor-ul Karim, Secretary, Ministry of Health & Family Planning.

The following members attended the meeting.

1. Prof. Nurul Islam
2. Brig. Aniz Waiz
3. Dr. Humayun K.M.A. Hye.
4. Dr. Azizur Rahman
5. Dr. Zafrullah Chowdhury
6. Mr. Anisul Islam,
7. Dr. A.M.M. Khan
8. Dr. Md. Nurul Anwar.

The following members could not attend the meeting.

1. Prof. A. Mannan
2. Dr. Mobarak Ali
3. Prof. M.Q.K. Talukder.

Minutes of the 144th meeting of the Drug Control Committee was confirmed.

During the course of discussion about approval of various recipes, it was revealed that great confusion and controversy existed regarding right, jurisdiction and responsibility of the Drug Control Committee and Drug Administration. Some members observed that unless detail of a particular firm was known and their capability was evaluated, it would be unwise to give clearance to their recipes.

Drug Administration observed that the mechanism did exist for control before issuing Drug Manufacturing Licence. It was also argued that Drug Control Committee should be content with the report of the Drug Administration about the capability of a particular Pharmaceutical Company. While submitting a recipe, Drug Administration should be satisfied that the particular company is capable of manufacturing the particular drug, in certain dosage form.

Finally it was agreed that a proforma should be prepared to be filled in and submitted by each company. This will be approved by the Drug Administration.

Decision in respect of the following recipes were taken as mentioned in the last column.

M/s. Ibn Sina.

1. Ampicillin Drops (Ampicillin)

Decision.

Initially it was decided to be resubmitted with reformulation and finally the recipe was rejected on the ground that the product in paediatric drop form would be costlier than syrup. Paediatric antibiotic drops shall not be allowed and others will be asked to withdraw the same from the market within six months.

Contd....P/2.

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*prepr. already available in m.s.*

2. Sina-col cap. (chloramphenicol)

Approved. *Production capacity already available exceeds the market demand.*

3. Sinacol susp. (chloramphenicol)

Rejected. *No. of manufacturers with their production capacity is already more than needed to avoid proliferation of the drug.*  
Reason: (The drug is toxic and non essential (No) further recipe will be allowed from now on. <sup>from</sup> ~~on.~~ *^* ~~chemical.~~ *In view of that it was decided to not to allow the proposal.*

4. Sinaflox cap. (Flucloxacillin)

Rejected.  
Reason: No advantage over cloxacillin and recipe's of similar drugs accorded approval earlier would be withheld.

5. Sinaflox drops (Flucloxacillin)

-do-

6. Sinaflox dry syrup. (do)

-do-

7. Ribosina tab. (riboflavin)

Approved.

8. Pyrosina tab. (pyridoxin HCl)

To be resubmitted with adjustment of excipients.

9. Calsina (calcium -D-Pantothenate) tab.

Rejected. *This drug has no evidence of any value.*  
Reason: ~~Not~~ *not* required. Similar item to be ~~be~~ *also be* withdrawn.

M/s. Gonoshasthaya, Dhaka.

1. G-Atenolol tab. (Atenolol)

To be resubmitted after adjusting extra excipient.

<sup>a</sup>  
The meeting ended with vote of thanks to the chair.

*M. Anwar* 22/12/86  
Member-Secretary  
Drug Control Committee.

Approved  
*[Signature]*  
Chairman  
Drug Control Committee