

Provisional

Minutes of the 128th meeting of the Drug Control Committee

The 128th meeting of the Drug Control Committee was held on 23.4.86 at 11.30 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Prof. Waliullah, the chairman of the Drug Control Committee.

The following members attended the meeting:

1. Prof. A. Jabbar
2. Prof. Mofazzal Hossain
3. Mr. Kazi Abdul Fattah
4. Dr. Humayun K.M.A. Hye.

Proceedings and Decisions

1. The minutes of the 127th meeting were confirmed.
2. Matters arising out of the minutes of the last meeting.

Further to decision about processing of import registration of veterinary products taken in 56th meeting of DCC held on 24.5.84, it was confirmed that after recommendation by the Drug Control Committee, as per normal procedure, the samples of the veterinary products will be tested in the Drug Testing Laboratory. ^{with human samples} In specific cases such samples may also be ^{also} sent to some experts for opinion if so desired by the veterinary expert of the Committee.

3. The following recipes of essential drugs were placed and decisions taken are as follows:

Firms/Brands

Decisions.

Colloid Lab. Dhaka.

Coloferum-F Cap.
(ferrous fumarate 200mg
+ folic acid 0.5mg)

Approved with condition to delete light liquid paraffin, give indication as per BNF, as prophylaxis in pregnancy and give dose as 1 to 3 capsule per day only.

Indocol cap
(indomethacin 25mg)

Approved with condition to give indication as anti-inflammatory analgesic only.

Olvit-B cap.
(vitamin B-complex)

The recipe may be resubmitted by the firm after amendment as per approved standard and deleting tartaric acid & sodium lauryl sulphate.

Tetracycline-C cap, 250mg.

Approved with condition to add 5% overage, delete lactose and give indication as per BNF. The quantity of starch may be increased to adjust the volume.

Cologram cap.
(nalidixic acid 250mg)

The recipe may be resubmitted for 500mg capsule deleting lactose.

Ibn Sina, Dhaka.

Metsina susp.
(benzoyl metronidazole)

The recipe may be resubmitted with simplified formula, generic name of the excipients, which are expressed in brand name and specify colour yellow and flavours.

Approved
Waliullah
30/4/86

<u>Firms/Brands</u>	<u>Decisions</u>
<u>Ibn Sina, Dhaka.</u>	
Sinapol Liquid (paracetamol)	The recipe may be resubmitted with simplified formula.
Sinaferron syrup (ferrous sulphate)	-do-
<u>Chemico, Rajshahi.</u>	
Kamocyclin cap. (tetracycline HCl)	Rejected because of wrong formula.
<u>Polychem, Dhaka.</u>	
Metron susp. (benzoyl metrenidazole 6.4%)	Approved.
<u>Opgonin, Barisal.</u>	
Ampexin cap. (ampicillin trihydrate compacted, 500mg)	Approved with condition to give indication as per BNF.
Ampexin dry syrup (ampicillin trihydrate 250mg/5ml)	Rejected because not required in this strength.
Chemotrim tab. (cotrimoxazole 100mg+20mg)	-do-
Chemotrim tab. (cotrimoxazole 800mg +160mg)	-do-
Metryl 500mg tab. (metronidazole 500mg)	250mg & 500mg May be allowed if the existing 200mg & 400mg strength of the brand is withdrawn.
Metryl 250mg tab. (metronidazole 250mg)	
Solrin tablet (acetyl salicylic acid 300mg soluble)	Approved with condition to give indication as per BNF.

4. a) The Committee recommended for cancellation of registration of the following medicinal products which have been recommended for deletion from the next Import Policy Order.

<u>Generic name</u>	<u>Brand name</u>	<u>Manufacturer</u>	<u>Regn. No.</u>
Cimetidine tab.	1. Histodel tab.	Chemical Works of Gedeon Richter, Hungary.	63-1959-83
	2. Haldin tab.	R+N Pharmaceuticals, Greece.	120-1914-83
	3. Altramet R tab.	LEK Pharmaceuticals, Yugoslavia	142-1940-83
	4. Tagamet tab.	S.K. & F., U.K.	62-1320-78
	5. Citius tab.	Lab. Prodes. Spain	172-1924-83
Piroxicam	1. Piroxim cap	R+N Pharma. Greece	120-2025-84
	2. Fansider tab.	Hoffmann La-Roche, Switzerland	54-988-77
Ranitidine	1. Randin tab.	R+N Pharma, Greece	120-2111-85

30/4/86

<u>Generic name</u>	<u>Brand name</u>	<u>Manufacturer</u>	<u>Regn.No.</u>
I N H	2. Zantac tab.	Glaxo, U.K.	105-1927-83
	1. Isoniazid tab. 100mg.	Ciba-Geigy, Switzerland	87-331-77
	2. Isonicid tab. 50mg	Chemical Works of Gedeon Richter, Hungary.	63-37-75
	3. Isonicid 100mg	-do-	63-1331-78
	4. Rimifon tab.	Hoffmann-La-Roche, Switzerland	54-1019-77
	5. Isoniazid tab. 100mg	Sopar S.A. Belgium	101-688-76
	6. Isoniazid tab. 50mg	-do-	101-689-76
Chloroquin	7. Rimicid tab. 100mg	Pharmachim, Bulgaria	145-1706-80
	1. Haloquine inj.	Hese & Loss, W. Germany	71-1395-78
	2. Chloroquine Diphosphate inj.	Sidus, Italy.	93-1348-78
Rifampicin	3. Chloroquine Diphosphate inj.	Waldemar Weimer, W. Germany	14-1334-76
	1. Rimactane cap. 150mg	Ciba-Geigy, Switzerland	87-338-76
	2. Rimactane cap. 300mg	-do-	87-339-76
	3. Rimactane tab. 650mg	-do-	87-1831-81
	4. Rimactane tab. 600mg	-do-	87-1920-83
	5. Ricactane syp 2%	-do-	87-1918-83
	6. Rifadin cap. 150mg	Gruppo Lepetit, Italy	89-1672-80
	7. Rifadin cap 300mg	-do-	89-1673-80
	8. Rifocin 250mg inj.	-do.	89-1735-80
Saccharin sodium	9. Tibirim cap. 300mg	Ranbaxy, India	134-1816-81
	1. Sweetex Fellet.	Boots Co. U.K.	4-765-76
O R S	2. Marco-Sweet tab.	Marcopharma, Denmark	57-1399-78
	1. Crasaline sachet	Jina Brothers, USA	188-1947-83
Hyoscine N Butyl Bromide inj.	1. Buscopan inj.	Boehringer CH, W. Germany	5-958-77
	2. Busoclysin inj.	Pharmachim, Bulgaria	112-1056-77
	3. Hyoscine N- Butyl Bromide Inj.	Pharmadrug W. Germany	132-2089-35
L-Hyoscyamine	1. Levsin tab.	Kremere Urban, U.K.	53-589-76
	2. Levsin inj.	-do-	53-591-76
	3. Levsinex timecap	-do-	53-589-76
Methscopolamine Bromide	1. Pamine Bromide tab.	Upjohn, USA	90-302-76

Contd.....F/4

Approved
AS-21
30/11/86

<u>Generic name</u>	<u>Brand name</u>	<u>Manufacturer</u>	<u>Regn. No.</u>
Ampicillin inj.	1. Penbritin inj. 250mg	M/s. Eoecham, Singapore	89-892-77
	2. Fenbritin inj. 500mg	-do-	89-889-77
	3. Ampicillin inj. 250mg	LEK, Yugoslavia	152-1863-82
	4. Ampicillin inj. 500mg	-do-	152-1862-82
	5. Ampicillin inj. 1 gm	-do-	152-1871-82
	6. Roscillin inj. 250mg	M/s. Ranbaxy, India	134-1816-81
	7. Servicillin inj. 250mg	Ciba-Geigy, Switzerland	87-2037-84
	8. Servicillin inj. 500mg	-do-	87-2038-84
	9. Servicillin inj. 1gm	-do-	87-2064-85
	10. Omnipen N 250mg inj.	Wyeth, U.S.A.	42-999-77
	11. Omnipen N 250mg inj.	-do-	42-900-76
	12. Omnipen N-500mg inj.	-do-	42-901-76
Amoxycillin inj.	1. Ampicyn inj.	M/s. BBI, Italy	120-2003-84
	2. Ibi amox inj. 250mg	-do-	142-1795-81
Hydrochlorthiazide	1. Seryithiazide tab.	Ciba-Geigy, Switzerland	82-2063-85
	2. Lexon tab.	Lemon Pharma, USA	93-1806-81
Cephalexin tab./cap.	1. Ceporex cap. 500mg	Glaxo, U.K.	105-1182-77
	2. Ibilox cap. 250mg	I.B.I. Italy	124-1775-81
	3. Ibilox cap. 500mg	-do-	124-1776-81
	4. Ibilox syp.	-do-	124-1777-81
	5. Palitrex cap.	Bristol Myers, USA	69-1000-76
	6. Pyassan cap.	Chemical Works of Gedeon Richter, Hungary.	63-2013-84
Diazepam inj.	1. Valium inj. 10mg	M/s. Hoffmann LA-Roche, Switzerland	54-1031-77
	2. Valium inj. 50mg	-do-	54-1718-80
	3. Dialag inj.	Lagan SA, Switzerland	571804-81
	4. Seduxen inj.	Chemical Works of Gedeon Richter, Hungary.	63-1095-77
	5. Calmpose inj.	Ranbaxy, India	134-1813-81
	6. Diazepam inj.	Pharmadrug, W. Germany	132-2090-85
Nitrazepam	1. Somnite tab.	Norgine., U.K.	7-1812-81
	2. Mogadon tab.	Hoffmann La Roche, Switzerland	54-1008-77
Trifluoperazine	1. Stelazine tab. 1mg	M/s. SKF, UK	62-256-76
	2. Stelazine tab. 5mg	-do-	62-260-76
Acetazolamide	1. Acetazolamide tab.	M/s. Fliva, Yugoslavia	34-1379-78
Spironolactone	1. Spironolactone tab.	Pharmachemic, Belgium	34-1379-78
	2. Aldactone tab.	G.D. Searle, U.K.	12-420-76
Cyclandolate	1. Venela cap.	Modhida, Japan	36.860-77
	2. Cyclobral cap.	Norgine, UK	7-1858-82

Contd.... P/2.

Approved
 W. A. L. L.
 28/10/86

Minutes of the 129th meeting of the Drug Control Committee.

The 129th meeting of the Drug Control Committee was held on 20.4.86 at 11.30 a.m. in the Chambers of the Director, Drug Administration under the Chairmanship of Prof. Waliullah, the chairman of the Drug Control Committee.

The following members attended the meeting :-

1. Prof. A. Jabbar
2. Prof. M. G. K. Talukder
3. Dr. Md. Jahangir,
4. Dr. Humsyun K.M.A.Hye.

Proceedings and Decisions:

1. The minutes of the 128th meeting were confirmed.
2. Matters arising out of the minutes of the previous meeting.

The Director, Drug Administration informed the committee that provisional registration have been given to the veterinary medicines of M/s. Alvetra GmbH, West Germany which were recommended by DCC in its 127th meeting held on 16.4.86. Subject to the condition that the concerned samples must conform to the standard in laboratory test and confirm the efficacy of the drugs used clinically failing which the corresponding registration will be cancelled without further notice. The registrations were issued provisionally to enable the party for signing the contract of the DCC grant for these drugs within the deadline period (~~7.4.86~~).

The rest of the agenda was kept pending.

The meeting ended with vote of thanks to the chair.

Waliullah
21.5.86

MINUTES OF THE 130th MEETING OF DRUG CONTROL
COMMITTEE HELD ON 21 MAY 1986 AT 11.30 AM

MEMBERS PRESENT:

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

MEMBERS NOT PRESENT:

Dr. Syeda Feroza Begum, Dr. Munawara Binte Rahman &
Dr. A.T. Siddique.

CHAIRMAN:

The meeting was presided over by Dr. Waliullah.

AGENDA 1:

Confirmation of the minutes of the 129th meeting of DCC
held on 30.4.86:

The minutes of the 129th meeting of DCC held on 30.4.86
were confirmed.

AGENDA 2:

Matters arising out of the minutes:

None.

AGENDA 3:

Consideration of transfer of approved recipes of IV. fluids &
Metronidazole infusion of Opsonin Ltd. to Opsosaline Ltd.

The prayer of Opsosaline Ltd., Barisal dated 5.5.86 informing
that the IV fluid section of Opsonin Ltd., Barisal has been separated
from the parent company and the new company (i.e. Opsosaline Ltd.)
has taken over this part of the business, was discussed. The approval
of D.G., Industries and ~~Controller~~ ^{Registrar} of the Joint Stock Companies have
been obtained in this matter.

In view of this and in response to the prayer of Opsosaline Ltd.,
it was decided to allow transfer of the following approved recipes of
Opsonin, Barisal to Opsosaline, Barisal.

- i) Dextrose IV. infusion 5%
- ii) Normal saline IV. infusion 0.9%
- iii) Sodium chloride 0.9% with Dextrose 5% IV. infusion
- iv) Metryl injection (metronidazole 0.5%)

Subject to fulfilment of other requirements, the above products
may be registered as products of Opsosaline Ltd., Barisal.

AGENDA 4:

Discussion about realisation of fees for covering expenses of DCC

The subject of realisation of some fees to cover various expenses
of DCC was discussed. It was pointed out by several members that the
~~attendance of DCC meetings was not satisfactory. This could be improved
if a token remuneration could be paid to the members for attendance.~~
Besides from time to time expert opinion has to be sought by DCC on
individual drugs from experts within and outside the Committee.
Remuneration should be paid for such expert opinion.

an honourarium should be paid to the members
to cover expenses for attendance
contd....2

Approved
Waliullah
4.6.86

The DCC is a statutory body, but there is no budgetary provision for covering the various expenses of the DCC. Because of this, it is very difficult to carry out the functions of the Committee properly and timely.

In view of these discussions, it was decided that a fee of Taka 100.00 (Taka One hundred only) may be realised for each recipe to be evaluated in addition to the usual fees paid by treasury chalan. The fee may be realised by Drug Administration on behalf of DCC in the form of Bank Draft against properly signed receipts. The Member-Secretary of the Committee will keep the account of receipts and expenditure and a quarterly report of the accounts will be submitted to DCC for their scrutiny and approval. This could be a temporary arrangement until regular budgetary provision is made by the Government for covering the various expenses of DCC. The Government may be informed of this decision.

AGENDA 5:

Consideration of recipes of drugs not included in essential drug list

The following recipes were placed and decisions taken.

Firms/Brands

Decisions

Squibb, Dhaka

Princimox paediatric drops
(amoxicillin 100 mg/ml)

Approved with condition to market in 15 ml pack size with calibrated dropper to measure 1.25, 1.0, & 0.65 ml.

K.D.H. Lab., Dhaka

Lopamide capsule
(loperamide 2 mg)

Approved with condition to give indication as 'for control of diarrhoea' only and dosage as per BNF.

City Pharms, Ctg.

Milk of Magnesia
(magnesium hydroxide 8%)

Approved with condition to delete liquid paraffin & chloroform from excipients.

Vitamin-C syrup 2%

The firm may resubmit the recipe with a stable formulation.

Doctors, Bogra

D-Cee syrup
(vitamin C 2%)

The firm may resubmit the recipe with stable formulation and changed name.

Dentine tablet
(ranitidine 150 mg)

The firm may resubmit the recipe with a formula for film coated tablet.
and change name

Degram tablet
(nalidixic acid 500 mg)

Approved with condition to give indication as 'ⁱⁿused in ⁱⁿnalidixic acid sensitive ~~infection~~ only. ^{organism} + change name'

Greenland, Dhaka

Vinozyme capsule
(pancreatin 325 mg)

Rejected because not required any more.

Skylab, Comilla

Tincture Hyoscyamus BP

Rejected because not required.

Tincture Belladonna BP

-do-

Glaxo, Ctg.

Ceporex capsule
(cephalexin 500 mg)

Approved.

contd....3

*Approved
W. Waller
3/6/76*

: 3 :

Mukti, Dhaka

Sulphadiazine-M tablet Rejected because not required.
Furaz tablet (furazolidone) -do-

Unique, Dhaka

Moxillin capsule Rejected because the firm do not have
(amoxycillin) Biological licence.

Eureka, Ctg.

Eugel liquid (antacid) Rejected because of wrong formula.

AGENDA 6:

Consideration of prayers for import registration

Prayer for import registration of the following essential drugs recipes were placed and discussed. Decisions taken are as follows.

MSD, Pakistan

Blocadren tablet Rejected because same brand of USA
(timolol maleate 10 mg) origin registered.

Decadron plain ocumeter (dexamethasone) -do-

Decadron Neomycin ocumeter -do-

Cipla Ltd, India

Asthalin inhaler Referred for opinion to Prof. A. Rouf
(salbutamol 200 meter dose) of IDCH & Lt. Col. Ziauddin of CMH.

Help Ltd, Greece

Helpogen cream Rejected because not required.
(betamethasone+gentamicin+tolnaftate)

H. Lundbeck, Denmark

Clopixol injection (clopenthixol 10 mg/ml) Approved.

Saroten injection (amitriptyline 10mg/ml) Approved.

Cedona, Netherland

Cedocard tablet 5 mg, 10mg & 20mg Rejected because not required.
(isosorbide dinitrate)

Cedocard retard tablet 20 mg -do-

Cedocard 10 ml IV injection Approved.
1mg/ml

Astra, Sweden

Bricanyl tablet (terbutaline 5 mg) Approved.

Bremer Pharma, W. Germany

Indigestion powder (vet.) Rejected because not required.

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

Approved.

Waliullah
(Prof. Waliullah) 4/6/86
Chairman,
Drug Control Committee.

MINUTES OF THE 131ST MEETING OF DRUG CONTROL
COMMITTEE HELD ON 4TH JUNE 1986 AT 11.30 A.M.

MEMBERS PRESENT:

Dr. A. Jabbar, Brig. Anis Waiz, Dr. M. Q. K. Talukder & Dr. Humayun K.M.

MEMBERS NOT PRESENT:

ni ha
W
24/6
~~Dr. Syeda Firoza Begum, Dr. Munawara Binte Rahman, Dr. A.T. Siddiqui,
Dr. Mofazzal Hossain, Dr. Md. Jahangir & Mr. Kazi Abdul Fattah.~~

CHAIRMAN:

The meeting was presided over by Dr. Waliullah.

AGENDA 1 :

Confirmation of the minutes of the 130th meeting of DCC held on 21.5.86

The minutes of the 130th meeting of DCC held on 21.5.1986 were confirmed.

AGENDA 2:

Matters arising out of the minutes.

None.

AGENDA 3 :

Consideration of transfer of 21 (twenty one) registered products of
M/s. Copenin, Barisal to M/s. Crescent Pharmaceuticals, Dhaka .

The prayer of Crescent Pharmaceuticals, Dhaka 1.6.86, a group company/sister concern of Copenin Chemicals, Barisal, informing that the ~~txka~~ later has decided in their board meeting to transfer 21 (twenty one) of their registered biological and non-biological products. (tab./cap./dry syrup/cusp.) from the Drug Manufacturing licence to that of Crescent Pharmaceuticals was discussed. Copy of the minutes of the meeting of the Board of Director of Copenin endorsed by Notary Public, certificate of incorporation from Registrar of Joint Stock Companies, Memorandum of Articles of Crescent, agreement of ownership transfer and inspection reports of Crescent supporting facilities for manufacture of the said biological and non- biological medicinal products were available.

In view of this and in response to the prayer of Crescent it was decided to allow transfer of the ~~following~~ registered medicinal products ^{stated below} from manufacturing licence of Copenin to that of Crescent, subject to the fulfilment of the conditions stated below:

The products are :-

Sl.No.]	Brand name	Generic name	LAC No.
1	Tab. Riboflavin	Riboflavin D.F.5mg	029-20-39

Contd...P/2.

Sl.No.	Brand name	Generic name	DAC No.
2.	Tab. Sulphadiazine	Sulphadiazine BPC 500mg	025-21-59
3.	Cap. Moxin	Amoxycillin BP 250mg	025-52-60
4.	Moxin Dry Syrup 100ml	Amoxycillin B.P. 2.5gm	025-53-60
5.	Cap. Opsocycline	Oxytetracycline BP 250mg	025-56-60
6.	Tab. Aminophylline	Aminophylline BP 100mg	025-27-18
7.	Tab. Solas 100mg	Memendazole USP 100mg	025-31-55
8.	Susp. Solas	Memendazole USP 2gm/100ml	025-48-55
9.	Tab. Tubranin	Pyrazinamide BP 500mg	025-46-58
10.	Tab. Carbanin	Diethyl Carbamazine Citrate BP 50mg	025-50-55
11.	Tab. Cimetid	Cimetidine BPC 200mg	025-64-29
12.	Tab. Opsodexon	Dexamethasone BP 0.5mg	025-96-50
13.	Tab. Fulmolin	Salbutamol BP 2mg	025-98-18
14.	Tab. Frobanin	Propentheline Bromide	025-104-15
15.	Tab. Metocol	Metaclopramide HCL BP 10mg	025-105-32
16.	Tab. Otosil	Promethazine HCL BP 10 mg	025-106-28
17.	Otosil Elixir	Promethazine HCL BP 100mg/100ml	025-107-28
18.	Tab. Solas 500	Mebendazole USP 500mg	025-144-55
19.	Tab. Vasodic 40	Verapamil HCL BP 40mg	025-119-17
20.	Tab. Vasodil 80	Verapamil HCL BP 80mg	025-120-17
21.	Cap. Opsozyme	Pancreatin (Enteric coated Granules) BP 325mg	025-117-36

The conditions are:-

- i) Crescent will pay all fees including recipe evaluation fees, sample testing fees and inclusion fees ^{etc.} for these products
- ii) When these medicinal products are included in the licence of Crescent, simultaneously the same will be deleted from the licence of Opsonin

IV *(1)* The products under the name of Opsonin as manufacturer must be exhausted ^{or withdrawn} from the market before the products under the name of Crescent as manufacturer are ~~marketed~~ *allowed to market*

III Sample of first batch of all products must be submitted to Drug Administration for approval of presentation and packaging and for test in Drug Testing Laboratory.

- v) If any of these products are found substandard, they will be withdrawn without further notice.

Further, it was decided to allow change of name of the following products of Opsonin to avoid confusion.

Sl.No.	Products	New proposed name allowed to Crescent
	Cap. Opsocycline	Cremycin
	Tab. Opsodexon	Creson
	Tab. Frobanin	Antispa
	Cap. Opsozyme	Crezyme.

Contdiii: P/3.

SPD/10
W
2/15

AGENDA-4:

~~To consider recipes of essential drugs.~~

~~Was not considered.~~

AGENDA -5 :

To consider prayer of import registration

Prayer for import registration of the following five (5) Veterinary drugs were discussed.

The Committee approved the products subject to recommendation by Mr. Kazi Abdul Fattah, the Veterinary expert of the Committee. The party may be informed about the decision after such recommendation is obtained.

Firm/Brand

M/S. Alvetra GmbH W. Germany	Antelmint comp. powder (vet)	200mg levamisole HCl + 500mg piperazine citrate/g.
	Triplesulf special bolus	1,583mg Sulphadiazine + 1,583mg Sulphamerazine + 1,583mg Sulphapyridine + 313mg Streptomycin sulphate
	Triplesulf forte bolus	1,666 mg sulphadiazine + 1,666mg Sulphamerazine + 1,666mg sulphapyridine
	Phosol 500 solution for injection for i.v & and i.m. injection.	3.75 g calcium hypophosphite + 10.00 g calcium gluconate + 1.60 g Boric acid + 5.00 g magnesium chloride + 6.65 g Glucose/100ml.
	Trichlorofen Inj. solution for injection	500 mg Dimethylester of (2,2,2 - trichloro-n-hydroxyethyl + 0.5% atropine sulphate per 1 ml.

AGENDA-6

Miscellaneous

- a) To review recipe of Lantagon tablet (mianserin HCl) of Organon.

The Committee noted the adverse reports on mianserin HCl in different countries as reported in the WHO Drug Bulletin.

In view of above, the recipe of ~~Lantagon~~ tablet of Organon and decision about the matter was withheld for the time being for further study.

Approved
W. S. S. S.
24/1/68

Contd.....P/4.

- b) Consideration of permission to import and manufacture Chinese Traditional medicine and establishing a Hospital Complex in this respect.

The memo No. S-DA/D-18/86/419 dated 1.6.86 of Ministry of Health and Family Planning requesting for the opinion of the committee in respect of above was discussed.

It was decided to convene a full DCC meeting with the members of the traditional side on 2nd July, 1986 to discuss about the matter.

- 13th July 1986 at 9.30 DMC
- c) It was observed by the chairman of the Drug Control Committee that some of his patients vomited after taking Lactameal Suspension, an antacid product of Beximco. Also, bad taste and bad odour were reported for the product.

In this connection it was observed by the committee that decisions already were taken to delete milk and change name of Lactameal tablet, but no action seems to have been taken. It was further observed that the formulation of the suspension should also be changed to improve stability, and taste of the product. It was again confirmed that the name 'Lactameal' both for tablet and suspension should be changed as it confuses with 'Milk'.

The meeting ended with vote of thanks to the chair.

Approved

(Prof. Waliullah)
Chairman,
Drug Control Committee.

write

Waliullah

- b) Consideration of permission to import and manufacture Chinese Traditional medicine and establishing a Hospital Complex in this respect.

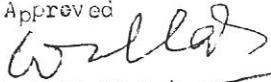
The memo No.S-DA/D-18/86/419 dated 1.6.86 of Ministry of Health and Family Planning requesting for the opinion of the committee in respect of above was discussed.

It was decided to convene a full DCC meeting with the members of the traditional side on 13th July, 1986 at 9.30 a.m. at Dhaka Medical College conference room to discuss about the matter.

- c) It was reported that certain antacid preparations e.g. Lactameal suspension of Beximco are found unstable and unpalatable causing nausea and vomiting to some patients. It was noted that ~~microbial~~ count for such preparations should not exceed the USP limit. In this connection it was observed that a decision was taken regarding Lactameal (tablet & suspension) to omit milk from the product and to change the name. It appears that the decision has not been adhered to ^{in respect of change of name} and it should be followed forthwith. It was also decided that henceforth no milk will be allowed in antacid preparations.

The meeting ended with vote of thanks to the chair.

Approved


(Prof. Waliullah)
Chairman,
Drug Control Committee.

Minutes of the 132nd meeting of Drug Control Committee
held on 26th June, 1986 at 11.30 A.M.

Member present:

Prof. A. Jabbar, Brig. Anis Waiz, Dr. Kazi Abdul Fattah & Dr. Md. Jahangir.

As Dr. Humayun K.M.A. Hye, Director, Drug Administration & Member-Secretary, Drug Control Committee was abroad, Major A. Rouf Mahmood, Deputy Director, Drug Administration attended the meeting as an observer.

Chairman:

The meeting was presided over by Prof. Waliullah.

Agenda - 1:

Confirmation of the minutes of the 131st meeting of Drug Control Committee held on 4.6.86

~~XXXXXXXXXX~~

The minutes of the 131st meeting of Drug Control Committee held on 4.6.86 were confirmed.

Agenda-2:

Matters arising out of the minutes.

- i) While discussing about agenda 6(b) regarding consideration of permission to import and manufacture Chinese Traditional Medicine and establishing a hospital complex in this respect, it was decided that the full DCC meeting with the members of traditional side will be held on 13th July, 1986 (instead of 2nd July, 1986) at 9.30 a.m. at Dhaka Medical College, Conference room to discuss about the matter.
- ii) The decision about agenda 6(c) regarding stability of antacid suspension e.g. Lactameal was requested to be rewritten.

Agenda 3:

Consideration of recipes of following essential drugs.

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

Firms/Brands

Decisions

M. H. Chemical, Dhaka
(Efersons)

Compain syrup
(paracetamol 2.4%)

Efergon syrup
(promethazine HCl 0.1%)

Ircon syrup
(ferrous sulphate 0.4%)

Approved with condition to delete overage, change name and delete ethanol & citric acid from excipients.

Approved with condition to change name and delete ascorbic acid and butyl parahydroxy benzoate from excipients.

Approved with condition to delete overage and citric acid, saccharin sodium, glycerine, butyl para hydroxybenzoate and caramel colour from excipients, and reduce quantity of ascorbic acid to 100mg.

*Approved
Waiz
2.7.86*

Contd.....F/2.

Elizol susp.
(benzoyl metrodidazole 6.4%)

Approved with condition to delete overage and ~~overage~~ and aluminium magnesium silicate & propylene glycol from ~~overage~~. *ex up. w/ly*

Benzenul emulsion
(benzyl benzoate 25%)

Approved with condition to delete overage and 'pediculosis' from ~~indication~~. *with proper care*

Efercin syrup
(chlorpheniramine maleate 0.04%)

Approved with condition to delete propylene glycol from excipient and delete overage.

Whitfield's ointment
(solicylic acid 3% + benzoic acid 6%)

Approved with conditions to delete overage.

Jayson, Dhaka.

Nibaron
(soluble aspirin 300mg)

Approved with condition to delete overage and give warning 'not for children under 12 years' and change name.

avoid specific medical advice

UCPL, Chittagong.

Frusamide tab.

Rejected because of non-implementation of Govt. directive to shift the factory to new premises and nonfulfillment of other recommendations as mentioned in last inspection report dated 28.11.83.

Sulpadoxine with Pyrimethamine tab.

-do-

Salbutamol tab.

-do-

Nifedipine tab.

-do-

Vitamin B-Complex tab.

-do-

Sulbutamol elixir

-do-

Agenda 5 : Miscellaneous

- a) To discuss about prayer of B.P.I (memo No.MKK/ARB dt. 3.6.86 about some veterinary products)

The Committee noted the prayer of BPI dt. 3.6.86 addressed to the Director, Deptt. of Livestocks and copy endorsed to the Director, Drug Administration about purchase of veterinary medicines against E.P.C. tender No.2205.

- b) To consider prayer of Bikalpa Frienda Pharmaceuticals dt. 15.6.86 requesting to consider their 15(fifteen) recipes on priority basis.

The Committee directed to put up the recipes in next meeting for decision

Contd....P/3.

*Approved
W. J. Williams
2.7.86*

- c) The Committee recommended to issue N.O.C. for import of 10 ampoules of Isoket Inj. (isosorbide dinitrate) free of cost without involvement of any foreign currency in favour of Dr. ^{Hasina} ~~Sazaya~~ Banoo, Asstt. Professor of Cardiology, IPGMR for research purpose.

The meeting ended with vote of thanks to the chair.

Approved



(-Prof. Waliullah)
Chairman
Drug Control Committee.

Minutes of the 133rd meeting of the Drug Control
Committee held on 2nd July, 1936 at 12 noon.

Members present

Prof. A. Jabbar, Prof. Mofazzal Hossain, Brigadier Anis Haiz, Mr. Kazi Abdul Fattah, Dr. Md. Jahangir & Dr. Humayun K.M.A. Hye.

Chairman

The meeting was presided over by Prof. Waliullah.

Agenda-1:

Confirmation of the minutes of the 132nd meeting of the Drug Control Committee held on 26.6.36.

The minutes of the 132nd meeting of the Drug Control Committee held on 26.6.36 were confirmed.

Agenda-2:

Matters arising out of the minutes: nil

Agenda -3

Consideration of recipes of import substitute drugs.

The following import substitute recipes were placed and decisions taken.

Firms/Brands

Decisions.

Ambee, Dnaka.

Nalidex tablet
(Nalidixic acid 500mg)

Approved with condition to cancel registration of Nevirgron capsule and suspension as soon as Nalidex tablet and suspension is registered. *marked*

Nalidex suspension
(nalidixic acid 3%)

-do-

Agenda-4:

Consideration of recipes of essential drugs.

The following recipes of essential drugs were placed and decisions taken.

Popular, Fatukhali

antacid suspension

The recipe may be resubmitted after *correction*.

Paracetamol syrup 2.4%

~~approved~~, approved with condition to reduce quantity of sodium saccharin to 25mg.

Polyferon (F) liq.
(ferrous gluconate)

The recipe may be resubmitted after *corrections* and change of name.

Contd... F/O.

Approved
Wali
13/7/36

A.P.C. Chemical, Mhulna

Butamol syrup
(salbutamol sulphate 2mg/5ml)

Approved with condition to delete
"Status asthmaticus and "severe" from an
indication and ~~from~~ change name.

Skylab, Comilla.

Skycid tab.
(antacid)
Skycid susp.
(antacid)

Kept pending

-do-

/ for inspection

Agenda 6: Miscellaneous

- a) To discuss the problem of Reye's syndrome in respects of use of aspirin in children and action taken in UK.

The Drug Control Committee considered new information about the use of aspirin in children and decided that:

- 1) Director, Drug Administration is advised to issue a public notice advising people not to use aspirin in children below 12 (twelve) years without specific ^{medical} advice and supervision of doctors.
- 2) Manufacturers of Aspirin is to be directed to amend their inserts, including warning about Reye's Syndrome and advice not to use aspirin in children below 12 years without doctor's advice.
- 3) Children aspirin preparations should not be registered or licensed. Earlier approval of Drug Control Committee regarding such items is withdrawn.
- b) Consideration of prayer of Bikalpa Friends Pharmaceuticals dated 15.6.86 requesting to consider their recipes submitted on 10.4.86 on priority basis.

Drug Control Committee considered the following recipes of Bikalpa Friends Pharmaceuticals, a new pharmaceutical manufacturing projects.

Decisions taken are as follows:

<u>Brand</u>	<u>Decisions.</u>
Nelodin syrup (levamisole HCl 944mg/100ml)	approved.
Paracetamol-F syrup 2.4%	Approved with condition to put "F" in prefix of name (i.e. F-Paracetamol).
B-Flex cap (vitamin B ₁ 5mg + B ₂ 2mg + B ₆ 2mg + Nicotinamide 20mg per capsule)	Approved with condition to delete lactose and adjust quantity of starch.
Neutragerl tab. (aluminium hydroxide 250mg + Magnesium trisilicate 500mg)	approved.

Approved
Wadhwa
12/7/86

Nalox susp. (benzoyl metronidazole 6.4%)	Approved.
Furox susp. (furazolidone)	Rejected because not required any more.
Nutragel susp. (aluminium hydroxide compressed gel equivalent to 4 g aluminium oxide + magnesium trisilicate 5 g per 100ml)	Approved.
Tetracycline-F cap. 250mg	Approved with condition to put "F" in prefix (i.e. F-Tetracycline)
Chemocide tab. (sulphamethoxazole 400mg + trimethoprim 80mg per tab.)	Approved with condition to change name, delete 'chronic' & 'infections associated with urinary tract' from indication and replace 'thrice by twice' in dosage.
F-Thiamine tab. (thiamine HCl 100mg)	Approved.
Nalox tab. (metronidazole 400mg)	Approved with condition to replace 'anti- Bacterial' by 'against anaerobic infection' in indication and give dosage as per DNF.
Riboflavin-F tab. 5mg	Approved with condition to put "F" in prefix of name, give indication as "Riboflavin deficiency state" and reduce lactose to 50mg and adjust quantity of maize starch.
Paracetamol-F tab. 500mg	Approved with condition to put "F" in prefix of name (e.g. F-Paracetamol)
Diopen cap. (ampicillin 250mg)	Approved.
Hb Flus suspension 2.9% (ferrous fumarate)	Approved with condition to delete vitamin - A from excipients, replace emerald by any suitable colour and change name.
Novoprin tab. (acetyl salicylic acid 300mg)	Approved with condition to change name and give warning as "not to be used in children under 12 years of age without specific medical advise"; delete avicel and change quantity of lactose & maize starch as 100mg and 76mg respectively.

In this connection it was decided that from now on, recipe of 100% new projects will be given priority in serial if satisfactory inspection report is available and other prior requirements are met.

c) To review the registration of some recipes of United Chemical & Pharmaceutical Ltd., Chittagong.

Prayer for fresh registration of 3 (three) products (e.g. Almsil NF liq., Paracetamol liquid and Theophylline liq.) of U.C.F.L., Chittagong, registration

approved
Wallas
13/7/80

Contd..... F/4.

-: 4 :-

WJH

due to WJ

of which ~~or~~ were cancelled (under different brand name) ^{due to} violation of the
suspension order issued while the products were found substandard, ~~were~~
was considered. ~~Fresh approved recipes were and satisfactory test reports of~~
~~fresh sample are available for these products.~~ *WJ*

The committee decided to keep the matter pending until the factory is moved to
new premises.

The meeting ended with vote of thanks to the chair.

approved
WJH
13.7.88

Minutes of the 134th Meeting of the Drug Control
Committee held on 13th July, 1986.

Members present:

Prof. A. Jabbar, Prof. A.T. Siddique, Prof. M.Q.K. Talukder, Prof. Mofazzal Hossain, Brig. Anis Waiz, Dr. Kazi Abdul Fattah, Dr. Md. Jahangir, Kabiraj Shah Islamullah Chisti, Hakim Hislamur Rahman, Hakim Aatur Rahman, Dr. Chamsul Alam Talukder, & Kabiraj Chitta Rajjan Nath & Dr. Humayun K.M.A. Hye.

Chairman :

The meeting was ~~presid~~ presided over by Prof. Waliullah.

Agenda-1 to 3:

Decision recorded under separate sheet.

Agenda-4:

Confirmation of the minutes of the 133rd meeting of the Drug Control Committee held on 2nd July, 1986.

The minutes of the 133rd meeting of the Drug Control Committee held on 2.7.86 were confirmed.

Agenda-5:

Matters arising of the minutes

None.

Agenda-6:

Consideration of the following recipes which are not included in the list of essential drugs.

The following recipes which are not included in the list of essential drugs were placed and decisions taken.:

~~XXXXXXXXXXXXXX.~~
Firm/Brand

Decision.

Pioneer, Dhaka.

Neomycin ointment
(neomycin 500mg +
bacitracin 50,000 units
per 100 g)

Approved with condition to delete the indication for use in burn & skin abrasion and add "and other sensitive skin infection."

United Lab. Co.

Pentazyme granules
(Pancrestin)

Rejected because not required any more.

Bengali Chemica, Dhaka.

Doxamin capsule
(doxycycline HCl 100mg)

Rejected because not required any more.

Kaysons Pharma, Dhaka.

Chloral elixir
(chloral hydrate 4%)

Rejected because such preparation needs to be freshly prepared ~~only for use~~

before use.

Contd.... F/2.

23/7/86

Waliullah
approved
23/7/86

Fisons, Dhaka.

Feginta cream
(gentamycin sulphate 0.3%)

Approved

Feginta HC cream
(gentamycin sulphate 0.3%
Hydrocortisone acetate 1%)

approved.

Feginta HC ointment
(gentamycin sulphate 0.3%
Hydrocortisone acetate 1%)

Approved.

Kaysons, Dhaka.

Cee Drops
(ascorbic acid 50mg/1ml)

Approved.

Boximco, Dhaka.

Iscxsuprine HCl tab.
10mg.

Kept pending for opinion of Prof. M.A. Mannan, IFGMR & Col. D.M. Sayeed Hussain, GMR.

Iscxsuprine HCl tab. 20mg

-do-

Ketoconazole tab. 200mg

Approved.

Dental Research, Barisal.

Laxut sachet
(ispaghula Husk 3.5g)

Approved with condition to give indication as per IMF

Central, Dhaka.

Mabacid susp.
(magnaldrate)

Rejected because not required any more

Mabacid tab.
(magnaldrate)

-do-

Microbe, Bogra

Riboflavin tab. 5mg

Approved.

S K & F, Dhaka.

Zentel F/C tab.
(albendazole)

Kept pending till shifting of the factory to new premises.

Macroclantin cap.
(nitrofurantoin)

-do-

Improfen cap.
(ibuprofen)

-do-

Acelol cap
(acebutolol)

-do-

Agenda-7:

Consideration of prayers of import registration

Prayer for import registration of the following recipes were placed and discussed. Decision taken are as follows:-

Boehringer Mannheim, West Germany.

Bezslip coated tablet
(bezafibrate 200mg)

Referred to Brig. A. Malek of ICVD and Prof. ARMA Awal of IFGMR for opinion.

M.A.
Sally
23.7.81

Geofman, Pakistan.

Snowplast adhesive plaster
(zinc oxide)

Impost
Rejected because not required.

Oxytocin inj., 10 iu/ml

-do-

Naphazolin nasal spray
(naphazoline + ephedrine +
fluoroprednisolone)

-do-

Shichi Pharma, China

Chloramphenicol eye drops 0.5%

Impost
Rejected because not required any more.
WZ

May & Baker, U.K.

Embacycline L₁ (vet) soln.
for deep injection,
multidose in 50ml & 100ml
(oxytetracycline dihydrate
equivalent to 200mg base per
ml as the magnesium complex
in a sterile aqueous solution)

Approved.

Embacillin for intramammary
infusion
(ampicillin sodium 75mg +
cloxacillin sodium 200mg per
syringe)

Approved.

Park Davis, Pakistan.

Ponstan tab.
(mefenamic acid)

Rejected because ~~not required~~ Local
product ^{being} available

Pharmachien, Bulgaria.

Nalidix tablet
(nalidixic acid 500mg)

Impost
Rejected because not required any more.

Procaine injection 1% & 2%
in 1ml ampoule

-do-

Psychoforin tab.
(imipramin 25mg)

-do-

Feloran tab.
(diclofenac 25mg)

-do-

Felevan tab.
(diclofenac, 50mg)

-do-

Medimpex, Hungary.

Septimetine cap. (vet)
(chloramphenicol 0.19 +
sulfadimidine 6.0g +
boric acid 6.0g +
citric acid 3.0g)

Rejected because not required.

Ciba-Geigy, Switzerland

Rimactazid 150 + Z sugar
coated tablet.
(rifampicin 150mg +INH 100mg x 3
+pyrazinamide 500mg x 3 in blister packs
for a daily requirement of a
patient of 50kg body weight)

~~Rejected because not required.~~

Approved
Wullat
23.7.86

approved with
condition that the price
of combination pack
does not exceed the
cost of 1/4 rimactazid
corresponding
Wullat 23/7/86

Rimactazid 300 + Z sugar coated tablet.
(rifampicin 300mg + INH 150mg/ x 2 + Pyrazinamide 500mg x 4 for a daily requirement of a patient of 50kg and above body weight)

~~Rejected because not required.~~

approved with condition as above

Medimpex, Hungary.

Halider tab.
(bencyclan hydrogen fumarate, 100mg)

Rejected because not required.

Halider inj.
(bencyclan hydrogen fumarate 50mg/2ml amp.

-do-

Teperin coated tab.
(amitriptyline HCl 25mg)

-do-

The meeting ended with ~~vote~~ of thanks to the chair.

*approved
Waller
23/7/86*

Minutes of the meeting of the Drug Control
Committee held on the 13th July, 1986.

A meeting of the Drug Control Committee was held on the 13th July, 1986 in the Conference Room of the Dhaka Medical College, Dhaka. Prof. Waliullah, Chairman, Drug Control Committee presided. The following members attended the meeting.

1. Prof. Waliullah
2. Prof. A. Jabbar
3. Prof. Mofazzal Hossain
4. Prof. A. T. Siddique
5. Prof. A. Q. M. Talukder
6. Brig Anis Waiz
7. Dr. Kazi Abdul Fattah
8. Dr. Humayun K.M.A. Hye
9. Dr. Md. Jahangir
10. Kabiraj Shah Islamullah Chisti
11. Hakim Hasmur Rahman
12. Hakim Ataur Rahman
13. Dr. Shamsul Alam Talukder
14. Kabiraj Chitta Ranjan Nath

Chairman welcomed the members of the Drug Control Committee and read out the agenda for confirmation.

Then the following agenda items were taken up in the meeting.

Agenda item No.1:- Proposal for the Introduction of Chinese Traditional
Medicine & Treatment in Bangladesh.

The proposal of Messrs. China Manzala Corporation regarding the introduction of Chinese system of Medicine was discussed elaborately.

The members expressed their views against the proposal, stating inter alia that :-

- (a) The introduction of the Chinese traditional medicine will adversely affect the promotion of the existing traditional systems of medicines, namely, the Unani and the Ayurvedic systems of medicines
- (b) The development of Unani, Ayurvedic and Homoeopathic systems of medicines should get priority over any proposal for introduction of a new system of medicine which is completely unused and not tested in this country.
- (c) The avowed policy of the Govt. is to attain, as early as possible, self-sufficiency in the field of health care. The introduction of Chinese traditional medicine directly counters such a policy.

Contd..... P/2.

proved
Waliullah
22/7/86

- (d) The efficacy and usefulness of the Chinese traditional medicines proposed to be introduced are yet unknown and not scientifically established. Over and above, there is no professional practitioners to prescribe such medicines.
- (e) It has been gathered from some visitors to China that the use of traditional medicines is very limited even in that country and used only in remote areas.
- (f) The traditional systems of medicine of Bangladesh are older and better established than that of China and as such, the local systems deserve better attention. Introduction of Chinese traditional medicine is not likely to help the health care system of the country in the least. After a thorough discussion the Committee unanimously decided the introduction of Chinese traditional medicine may not be allowed in this country at this stage. It was also decided that the Government may be requested accordingly not to accept on principle such an idea or proposal.

* G. Adoption of such foreign system will open the flood gate for similar other systems which are not in the agenda item No. 2 :- Miscellaneous

(a) Packing Size of Homoeopathic medicines.

Introducing the subject, the member- secretary informed the Committee of the difficulties being faced by the dealers in Homoeopathic medicines since the packing sizes of liquid Homoeopathic medicines has been limited upto a maximum of 60ml. on the recommendation of the Drug Control Committee. The traders have submitted several representations for withdrawal of such restrictions. It was also observed that prices of imported medicine go up considerably if the packing size is limited to 60ml. Similarly, marketing of locally produced medicines are being adversely affected by the order since rural homoeopathic practitioners mostly demand 1/2 or 1 litre pack sizes. The subject was referred to Chairman, Bangladesh Homoeopathic Board who recommended that the limitation might be withdrawn in respect of all types Homoeopathic medicines, locally manufactured or imported.

After elaborate discussion the Committee unanimously decided that the limitation of the packing sizes for imported Homoeopathic medicines be modified. Import and local manufactures ~~of finished forms~~ for retailing may be allowed in packing sizes of finished forms upto 1(one) litre. Manufacturers however, may be allowed to import any packing size for repacking or processing locally.

(b) Registration of Homoeopathic medicines - Opium, Cannabis and dilutions there of.

The member- secretary introduced the subject saying that opium Cannabis Sativa and Cannabis Indica being narcotic materials, no medicine or dilution can be prepared under law from substances without narcotic licences. As such, the registration of medicines given earlier on the recommendation of the Drug Control Committee might be cancelled. The Committee held that the subject being an important one, needed further study by the

Handwritten notes and signatures on the left margin.

members.

It was, therefore, decided that subject might be taken up in a subsequent meeting of the Committee and in the meantime-

- i) Opinion of the Chairman Bangladesh Homeopathic Board may be obtained ; and
- ii) Pending decision of the DCC on the subject, registration and production of these medicines may be kept under suspension.

(c) Banning of "SREEPURER BARI"

Some members drew the attention of the Committee that a medicine locally prepared which is known as "Sreepurer Bari" is a harmful one and many cases of harmful effects of the preparation had been reported. It was observed that the so-called "Sreepurer Bari" is an unauthorised product being illegally manufactured and sold by some unscrupulous persons.

It was decided that the matter may be investigated and legal action be taken against such persons. The public may also be informed of the subject through mass media.

(d) Maintenance of Shastriya principles in the approval of recipes and manufacture of medicines.

It was reported that in some cases Shastriya principles and standards are not being maintained in the matter of approval of recipes and manufacture of medicines. An example was liquid form of Jawaresh Jalinus, which is in fact a violation of such standards.

It was decided that such cases might be brought to the notice of the Licensing Authority so that the cases can be examined and action taken on the recommendation of experts.

Approved
Waliullah
23/7/86

Waliullah
(Prof. Waliullah) 23.7.86
Chairman,
Drug Control Committee.

Minutes of the 135th meeting of the Drug Control Committee held on 23.7.86.

Members present:

Prof. A. Jabbar, Prof. Mefazzal Hossain, Brig. Aniz Waiz, Mr. Kazi Abdul Fattah, Dr. Md. Jahangir & Dr. Humayun K.M.A.Hye.

Chairman :

The meeting was started under the chairmanship of Prof. Waliullah. When Prof. Waliullah left on some urgent business, Prof. A. Jabbar presided over the meeting.

Agenda-1 :

Confirmation of the minutes of the 135th meeting held on 23.7.86.

The minutes of the 134th meeting of the Drug Control Committee held on 13.7.86 were confirmed.

Agenda-2:

Matters arising out of the minutes.

- a) The Committee reconsidered the decision about the recipe of Doxgin cap. (doxycycline HCl. 100mg) of Bengal Chemical, Dhaka and approved the same.
- b) Decision about the recipes of Rimactazid 150 + Z S/C tab. (rifampicin 150mg + INH 100mg x 3 + pyrazinamide 500mg x 3) and Rimactazid 300 + Z S/C tab. (rifampicin 300mg + INH 150mg x 2 + pyrazinamide 500mg x 4) of Ciba-Geigy, Switzerland were also reconsidered and approved with condition that the price of commercial pack will not exceed the corresponding Rimactazid tab.

Agenda-3:

Consideration of the following recipes which were kept pending earlier for Quality Control facilities.

The following recipes which were kept pending on 21.6.84 & 3.2.85 for Q.C. facilities were placed and decisions taken:

<u>Firm/Brand</u>	<u>Decision</u>
<u>Ibne Sina, Dhaka.</u>	
Sinatrim tab. (sulphamethoxazole 400mg + trimethoprim 80mg)	Approved with condition to give indication as per BNF & delete overage.
Sinasprin tab. (aspirin 300mg)	Approved with condition to delete overage and give warning as "not to be used in children under 12 years of age without specific medical advice."
Sinadrox tab. (dried aluminium hydroxide gel 400mg + magnesium hydroxide 350mg)	Approved with condition to delete overage and omit imitation milk flavour from excipients.


30.7.86

Contd....1/2.

Cestab tablet
(ascorbic acid 250mg)

Approved with condition to change name
(e.g. sinacee) and give indication as per DNF.

Diasin tab.
(glibenclamide 5mg)

Approved with condition to delete overage.

Helsina tab.
(levamisole HCl. 40mg)

Approved with condition to delete overage.

Tensina tab.
(diazepam 2mg)

Rejected because such strength is not required.
*2mg is not a
sanctuary use*

Tensina tab.
(diazepam 5mg)

Approved with condition to give indication as per
DNF,

Sinaprel tab.
(propranolol HCl 40mg)

Approved with condition to delete overage and
give indication as per DNF.

Grisosin ~~tab.~~
(griseofulvin micronized, 125mg)

Approved with condition to delete overage
& change name

Hyosin tab.
(hyoscin butyl bromide 10mg)

Approved with condition to delete biliary &
renal colic (~~by cholecystitis from indication~~) & omit
overage.

Rifsina 300 cap.
(rifampicin 300mg)

Approved with condition to give indication &
dosage as per WHO recommendations & give
indication in tuberculosic and leprosy only
(i.e. myco-bacterial infections only.)

Rifsina 150mg
(rifampicin 150mg)

Change name

Agenda-4:

Consideration of the following recipes for reconfirmation which were approved
before the promulgation of the National Policy (NP). *Drug Control*

The following ~~the~~ recipes, which were approved before 1982 were placed for reconf-
firmation in light of National Drug Policy and decisions taken. *continued 1982*

Pharmachemie, Dhaka.

angugal tab.
(griseofulvin 125mg)

The firm may resubmit the recipe with the
following amendment:-

- i) change name
- ii) add overage
- iii) griseofulvin to be used in microdispersed form
(4-5 micron maximum particle size)

Robinsons, Chittagong.

Dand-O' anti-dandruff hair lotion. Rejected because safer substitute available.
(thymol 0.1g + coaltar soln.
50% 3.3g per 100g)

Comilla Lab, Comilla.

Comolax tab.
(phenolphthalein, 225mg)
(LAR No. 105-13-31)

Rejected under criteria of guideline No. 11 of
of the National Drug Policy as ^{it is} unbacked,
useless & harmful drugs.

Contd... 1/3.

MJ
30.7.86.

Agenda-5:

Consideration of the following resubmitted recipes:

The following recipes which have been resubmitted were considered and decisions taken.

Colloid, Dhaka.

Olvit-B cap.
(vitamin -B complex)

The recipe may be resubmitted with standard formula as nicotinamide 20mg + pyridoxine Hcl 2mg + riboflavin 2 mg + thiamine Hcl. 5mg per capsule.

Cologram cap.
(naldixic acid 500mg)

Approved with condition to change name.

Pharmaco, Dhaka.

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

The recipe may be resubmitted after getting overage.

Doctor's Chemical, Bogra.

Fressine tab.
(propranolol Hcl 10mg & 40mg.)

Approved with condition to change name and market in different coloured strips for

diff dose

Ibn Sina, Dhaka.

Metsina susp.
(benzoyl metronidazole 6.4%)

Approved with condition to delete overage.

Singferon syrup.
(ferrous sulphate 4%)

Approved with condition to delete overage, 450ml packsize and delete ~~Hy~~ phosphorous acid from excipients.

Sinapol liq.
(paracetamol 2.4%)

Approved with condition to delete overage, and omit saccharin sodium from excipients.

Sinatrim susp.
(sulphamethoxazole 4g
+ trimethoprim 0.8g
per 100ml.)

Approved with condition to delete overage.

Oasis Lab., Sirajgonj.

Amoxbis cap.
(amoxicillin 250mg)

Approved with condition to give indication as per BNF and change name.

Chloromacis cap.
(chloramphenicol 250mg)

Approved with the condition to change name

City Pharmaceuticals, Ctg.

Vitamin -C syrup 2%

The recipe was kept pending until facilities are available.

MJ
40.7.86

Agenda- 6 :-

Consideration of the following recipes of a 100% new firm on priority basis.:

The following recipes of a 100% new firm were placed and decision taken.:

Union Pharma, Kishoreganj.

Lemasol liq.
(levamisole HCl 944%)

The recipes were kept pending until full mechanization as per project is completed for total project implementation i.e. full facilities as per project is created.

Furadin susp.
(furazolidone 0.5%)

-do-

Ferston liq.
(ferrous sulphate 4%)

-do-

Unimol liq.
(paracetamol 2.5%)

-do-

Agenda- 7 :

Consideration of the following other recipes of essential drugs.:

The following recipes of essential drugs were placed and decisions taken.

Ibn Sina, Dhaka.

Multising Drops
(vitamin A palmitate 0.67g
+ Vitamin B2 0.83ml +
thiamine HCl 0.167g +
pyridoxine HCl 0.209g
+ nicotinamide 0.933g
+ riboflavin -5 phosphate
sodium 0.286g per 100ml.)

Approved with condition to give indication to give indication as multivitamin deficiencies in infants only.

Antasina susp.
(aluminium hydroxide gel,
10% oxide 40g + magnesium
hydroxide 8 g per 100ml.)

Approved with condition to omit overage, change name, delete propylene glycol & chloroform, use chlorinated water and should conform to usp in terms of microbial count.

Helsina tab.
(mebendazole 500mg)

The firm to resubmit the recipe with 100mg strength, simplified excipients and changed name.

Helsing susp.
(mebendazole 2%)

The firm to resubmit the recipe with change name, & simplified formula.

Agenda-9 : Miscellaneous.

a) Decision about disbursement of Drug Control Committee fund.

The Committee was informed about the collection of fees for various expenses of Drug Control Committee with effect from 1st July, 1986.

It was decided that the fund will be disbursed at the following rates. :

MJ
30.7.86

Contd.....F/O.

- a) Honourarium for, expense, of the attendance to the chairman and other members.
- @ Taka 150/- per meeting.
- b) Honourarium to the accountant -
- @ Taka 150/- per month.
- c) Honourarium for ~~de~~ling Assistant
- @ Taka 100/- per month.
- d) Honourarium to the experts ^{outside} for evaluation of a ~~one~~ ^{new drug}.
- @ Taka 150/- per drugs.

e) ^{Other expense, the committee,}
The meeting ended with vote of thanks to the chair.

as and when reqd

Read and Confirmed

M. Jabbar
20/7/86

Minutes of the 136th meeting of the Drug Control Committee held on 30.7.86.

Members present:

Prof. A. Jabbar, Prof. M.Q.K. Talukder, Prof. Mofazzal Hossain, Brig. Aniz Waiz,
Dr. Kazi Abdul Fattah, Dr. Md. Jahangir and Dr. Humayun K.M.A. Hye.

Chairman :

The meeting was presided over by Prof. A. Jabbar.

Agenda-1:

Confirmation of the minutes of the 135th meeting of the Drug Control Committee held on 23.7.86.

The minutes of the 135th meeting of the Drug Control Committee held on 23.7.86 were confirmed.

Agenda-2:

Matters arising out of the minutes

None

Agenda-3:

Consideration of the recipes of the following import substitute drugs

The following recipes of import substitute drugs were placed and decisions taken:

<u>Firm/Brand</u>	<u>Decisions.</u>
<u>Gaco, Dhaka.</u> Silver Sulphadiazine cream	Approved with condition to give indication and packsize as per BNF.
<u>Acme, Dhaka.</u> Ranitidin tab. (ranitidine Hcl 300mg)	<i>change name to ranitidine</i> The firm may resubmit the recipe with separate formula for core tablet and coating and mentioning the tab. as a coated tab.
Rifamzid cap. (rifampicin USP 300mg + isoniazid USP 150mg)	<i>amputation</i> Such combination will not be allowed in capsule form. The firm may resubmit the recipe coated tab. In this connection it was decided that all the existing similar products in capsule form will have to be changed to coated tablet form.
<u>Apcco, Dhaka.</u> Sweetage tab. (saccharin sodium 12 mg)	Approved with condition to change name.
<u>Jayson, Dhaka.</u> Dyrin tab. (ranitidin Hcl 150mg)	The firm may resubmit the recipe with separate formula for core tablet and coating material and changed name.
Sudanol oint. (silver sulphadiazine 1%)	Approved with condition to give indication and packsize as per BNF.

Opsonin, Darisal.

Metherspan inj. Approved.
(methyl ergometrine
maleate 200 mcg/1ml amp.)

Gonoshasthaya, Dhaka.

G-Cloxacillin inj. 250/vial Approved.
G-Cloxacillin sodium 500mg/vial approved with condition to give different
coloured labels for different concentrations/
strengths.

Opsonin, Darisal.

Tablet Ranitid-300mg The firm may resubmit the recipe with formula
(ranitidine Hcl 300mg) for coated tablet. They are also to change
the existing Ranitid 150mg tab. in coated
tablet form.

Beximco, Dhaka.

Amitriptyline Hcl 5/G tab. 25mg Approved.

Amitriptyline Hcl Approved.
f/c tab. 10mg.

Square, Pabna.

Rifazid 150 f/c tab. approved with condition to change name.
(rifampicin 150mg +
isoniazid 100mg)

~~Gonoshasthaya, Dhaka.~~
Gonoshasthaya, Dhaka.

G-Diclofenac inj. IM. Approved.
25mg/ml in 3-ml amp.
(diclofenac sodium)

G-Diclofenac tab. 25mg, enteric Approved.
coated

G-Ergometrine inj. Approved.
IM/IV, 500mcg/1-ml
amber colour amp.
(ergometrine maleate)

G-Rifampicin-Iso tab. The firm may resubmit the recipe with
(rifampicin 300mg + isoniazid 150mg) formula for coated tablet showing coating
materials separately. *or in capsule*

Hoechst, Chittagong.

Sofradex E/E oint. approved.
(framycetin sulphate
0.5% + dexamethasone
0.05% + gramicidin 0.005%)
in 5 g.

Sofracycin eye oint. Approved.
(framycetin sulphate 0.5%)
in 5 g.

Beximco, Dhaka.

INH-Rifampicin s/c tab. approved.
(rifampicin 150mg
+ isoniazid 100mg)

Pfizer, Dhaka.

antichol 5mg tab.
(oxyphenonium bromide 5mg)

Approved with condition to delete overage.

Ergomet tab.
(ergonovine maleate USP 0.5mg)

Approved with condition to either change name or resubmit the recipe with formula for methyl ergometrine maleate coated tablet like the injection form. The same brand name will not be allowed for two different salts.

Ergomet IM/IV inj. 0.2mg/ml
in 1-ml ampule.
(methyl ergonovine maleate USP
20mg/100ml.)

approved.

Agenda -7 : Miscellaneous.

- a) Consideration of recommendation to manufacture basic raw materials of aluminium Hydroxide Dried & Compressed Gels by M/s. Hydroxide Ltd., Dhaka.

The prayer of M/s. Hydroxide Ltd., Dhaka to manufacture the following basic

Raw materials were discussed and recommended. With the hope that the material Al(OH)₃ might be prepared locally in due time

Sl.No.	Raw material	Starting materials.	Remark.
1.	aluminium Hydroxide dried gel. USP	Aluminium sulfate	} Must conform with USP regarding Microbial content.
2.	Aluminium Hydroxide compressed gel. USP (Pharmaceutical grade)	aluminium sulfate	

- b) Statement about disbursement of DCC fund.

The Drug Control Committee noted the monthly statement of receipts & payment of account of Drug Control Committee fund for the month of July, 56.

- c) Evaluation of new projects.

It was observed that under the new Industrial Policy, person can apply for issuance of a drug manufacturing licence directly to the Drug Administration without approval of a project by the D.C. Industries, if the firm is established with own investment.

In the above circumstances, it was decided that a guideline will be approved by the Committee as a prior requirement to be met for approval of such licences. It was decided that Drug Administration will prepare such guideline and put up before the Committee for approval in the

next meeting
The meeting ended with vote of thanks to the chair.

Read
Confirmed
M. J. Islam
13/8/56