

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

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সংক্রান্ত.....সালে

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চিঠিগত্র/টোক/নিতাকর্ম

বিষয়:—

প্রবর্তা সংক্রান্ত

প্রবর্তা সংক্রান্ত

Minutes of the 137th meeting of the Drug Control Committee held on 13.8.86.

Members present:

Prof. A. Jabbar, Prof. Mefazzal Hossain, Brig. Anis Waiz, Dr. Md. Jahangir, Dr. K.A. Faruk & Dr. Humayun K.M.A. Hye.

Chairman:

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

Agenda-1:

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

The minutes of the 136th meeting of the Drug Control Committee held on 30.7.86 were confirmed.

Agenda-2:

Matters arising out of the minutes.

The decision about allowing rifampicin + isoniazid combination only in coated tablet form was reviewed by the Committee. It was observed that U.S.P. recommends only capsule form for such combination and WHO also recommends the capsule form. In view of the observation it was decided that capsule form as well as coated tablet form of rifampicin and isoniazid combination will be allowed. Thus recipe of Rifanzid cap. (rifampicin usp 300mg + isoniazid usp, 50mg) of M/s. Acme, Dhaka was approved with condition to use coated granules of the drugs.

Agenda-3:

Consideration of the recipes of the following import substitute drugs.

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

Firm/Brand

Decision

Acme, Dhaka.

Anginal cap. (dipyridamole 50mg)

The firm may resubmit the recipe in coated tablet form and change name.

Nalidix susp.
(nalidixic acid 6%)

Approved with condition to change name. They are also to change name for the capsule form of this product which was approved earlier.

Rifanzid 250mg cap.
(rifampicin coated granules
USP 150mg + isoniazid coated
granules USP 100mg)

Approved with condition to change name and delete overage for isoniazid.

Agenda-4:

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

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

Hudson, Dhaka.

Folcof syrup
(pholcodine 0.1%)

Approved with condition to change name in generic ~~xxxxxxx~~ form, replace amaranth colour with any other suitable coloring agent, give indication as antitussive only, give warning as not for children as they have ~~xxxx~~ no other cough ~~xxxxxxx~~ syrup approved as only one cough syrup will be allowed to a firm.

Green Lab., Comilla.

Greenoruboint
(vaporab)

Approved.

Skylab, Comilla.

Sulpamin powder
(sulphanilamide +
Sulphathiazole)

Rejected because not permissible under
National Drug Policy.

Ceparol cap.
(cephalexin 250mg)

Kept pending for inspection report.

Kaysons, Dhaka.

Kadryl elixir
(diphenhydramine Hcl
250mg/100ml.)

Approved.

City Pharmaceutical, Ctg.

Cetazol powder
(sulphathiazole)

Rejected because not permissible under National
Drug Policy.

Flucin oint
(fluocinolone acetonide)

May be kept pending till the factory moves to
a new suitable premises.

Betmethason oint.
(betamethasone dipropionate)

-do-

Corticod oint
(betamethasone valerate)

-do-

Casten oint
(clotrimazole)

-do-

Theophylline syrup

-do-

Phenobar drop
(phenobarbitone)

-do-

Jayson, Dhaka.

Dysentrin tab.
(furazolidone)

Rejected because no more required.

Dysentrin susp.
(furazolidone)

-dp-

Ascosen inj.
(sodium ascorbate equiv. to 500mg
ascorbic acid per 5ml ampoule).

Approved with condition that the filling should
be done under nitrogen gas/atmosphere.

Fisons, Dhaka.

Betanol 100mg tab.
(atenolol)

Approved.

Betanol 50mg tab.
(atenolol)

Approved.

Cardigin tab.
(digoxin, 0.250mg)

Approved with condition that bioavailability
report to be submitted before registration.

This condition will also be applicable in case
of other firms for such products.

Cardigin inj.
(digoxin 0.250mg per 1-ml ampoule)

-do-

Quantity of the excipients should be expressed
in enemil (ml)

Contd....P/3.

W. S. S.
27.5.88

ardioptin f/c tab.
Verapamil 80mg)

Approved.

6

ardioptin f/c tab.
Verapamil 40mg)

Approved.

Harmachemie, Dhaka.

ymellica syrup
ascorbic acid 2%)

The recipe may be resubmitted with a stabiliser and change name.

B. A. Co., Dhaka.

Eracillin inj.
(benzyl penicillin sodium
5 lac units)

Approved.

*change name with
Prescriber's name
Penicillin
WJ 27/8*

Eracillin inj.
(benzyl penicillin sodium
10 lac units)

A-approved.

Ben(dural)-LA Inj.
(benzothine penicillin
6 lac units).

Approved.

Bendural-LA inj.
(benzathine penicillin 12lac units)

Approved.

Beximco, Dhaka.

Vitamin -C drops.

The recipe may be kept pending.

*Resubmit
with
proper
name*

Cenarizine tab. 25mg

Approved.

Metoclopramide HCl tab. 10mg

Approved.

Nescapine HCl.
Cough linctus 0.6%.

Approved with condition to change name as 'Nescapine syrup' delete chloroform, give condition as 'antitussive' only delete children dose, give warning as 'not for children' and that they do not have any other cough syrup approved because a firm will be allowed only one cough syrup.

*Rejected
to come in
own &
been allowed
to
WJ 27.8.82*

Square, Patna.

Stigin tab.
(neostigmin bromide 15mg)

Approved with condition to change name.

SQ-Cycline E/E oint.
(oxytetracycline HCl 0.05%
+ polymyxin B sulfate 10 lac unit)

~~Rejected because such combination is not required.~~

*Approved
WJ 27/8*

Agenda-6: Miscellaneous.

The review petition of I.C.I. to allow manufacture Kemadrin tab. (procyclidine HCl 5mg) with brand name of Wellcome Foundation as an under licence drug was considered. It may be mentioned that the recipe was approved earlier (125th meeting held on 2.4.86) with condition to manufacture the product in their own brand name without any third party agreement. The firm mentioned that D.E. Industries has allowed them to manufacture the drug under third party licence which is valid till 1988.

The Committee rejected the prayer and upheld their earlier decision.

WJ 27.8.82

Handwritten: Pending 27/8/80
Initials: AV

-: 4 :-

A prayer of M/s. Healing Pharma to set up their factory temporarily in the residential area of Green Road was discussed. The project was approved to set up the factory at Demra. The firm mentioned in their prayer that they have already made some investment on the proposed temporary premises.

The Committee rejected the prayer and decided that, i) they should follow the original approved scheme and advised to shift to Demra as per approved scheme or shift to a better place out side metropolitan/residential area and follow the guidelines which will be approved by the Committee.

- c) It was observed that the products namely, Aminomal R tab. (aminophyllin, 193-2068-85) and Coroxin 75 tab. (dipyridamole, 193-2087-85) of Malesci, Itali, are imported in packsize of 5000's (Hospital pack) in addition to the 20's, 40's, 100's & 1000's in the registration certificate.

It was felt that such big packsize of 5000's is not necessary and will lead to misuse and deterioration of the drug for long storage in the market.

In view of the above it was decided that only upto 1000's packsize will be allowed for the said drug and the ^{5000 packsize} rest may be deleted from the corresponding registration certificates.

The meeting ended with vote of thanks to the chair.

Handwritten: Walled 27/8/80

Minutes of the 138th meeting of the Drug Control Committee held on 27.8.86

Members present:

Prof. A. Jabbar, Prof. Mofazzal Hossain, Brigadier Anis Waiz, Dr. Kazi Abdul Fattah & Dr. Humayun K.M.A. Hye.

Chairman

The meeting was presided over by Prof. Waliullah.

Agenda-1:

Confirmation of the minutes of the 138th meeting of the Drug Control Committee held on 27.8.86.

The minutes of the 137th meeting of the Drug Control Committee held on 27.8.86 were confirmed.

Agenda-2:

Matters arising out of the minutes

Decision about the following recipes/prayers were reviewed.

Firm/Brand

Decision after review

Acme, Dhaka.

Rifampid cap.
(isoniazid HSP +
rifampicin USP)

Agreed to delete "coated granules" as per prayer of the firm, since, these drugs are not mentioned as coated granules in the pharmacopoeia, thus, coating not necessary in capsule.

GA Co., Dhaka

Eracillin inj.
(benzyl penicillin)

The name to be changed preferably with a pen at the end.

Beximco, Dhaka.

Vitamin-C drops.

Cinarizine tab.

Metoclopramide tab.

The recipes may be resubmitted with the proposed brand name.

Noscapine cough linctus.

Rejected because one cough syrup (dextromethorphan) has already been allowed to the firm.

Square, Pabna.

SQ-Cycline E/E oint
(oxytetracycline 0.05%
polymyxin B sulfate 10 lac unit)

Approved, as, such preparation is available in the market (terracyclin E/E oint of Pfizer)

Healing Pharma, Dhaka.

Decision about their prayer was kept pending.

because of selection of
side not as per approval
scheme

Approved
Waliullah
3/9/86

Agenda-7 : Miscellaneous.

a) Discussion on reply of Beximco about decision on Lactameal tab/suspension.

The letter of Beximco dated 18.8.86 regarding the brand name 'Lactameal' was placed. The committee carefully considered their prayer. The Committee observed that brand names are integral part of the drug itself. It should not be an imitation of, or substitute for, or resembles in a manner likely to deceive another drug or food. In this respect the name LACTAMEAL stands for, lactamilk and meal-food. As the product being an antacid has nothing to do with the milk or food, therefore, such name will be misleading and confusing to the consumers. The Committee feels that, although trademarks are covered by the Trade Marks Act, 1940, they have the jurisdiction to give opinion and recommend change or deletion of brand name of any drug that may be misbranded or confusing. The committee also feels that the names which are misleading, confusing and misbranded goes against the spirit of the National Drug Policy.

(Lactin for milk)

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

Frank's prayer is rejected. The prayer. The D.C.C. has authority to approve or reject name which are integral part of label of drug. As this particular name "Lactameal" contains in it the word Lactin (Latin for milk) which a drug should not have or it is a meal (food) the name may confuse or deceive the consumers.

The meeting ended with vote of thanks to the chair

Wally
3/9/86

Minutes of the 139th meeting of the Drug Control Committee held on 3.9.86.

0-1

Members Present:

Prof. A. Jabbar, Prof. M.Q.K. Talukder, Prof. Mofazzal Hossain, Brig. Anis Waiz,
Dr. 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 138th meeting of the Drug Control Committee held on 3.9.86.

The minutes of the 138th meeting of the Drug Control Committee held on 27.8.86 were confirmed.

Agenda-2:

Matters arising out of the minutes

Nil

Agenda-3:

Consideration of the following recipes of import substitute drugs.

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

Firm/Brand

Decision

Crescent, Dhaka.

Iopac tablet
(iopanoic acid 500mg)

Kept pending till marketing of the previously approved drugs ~~are~~ completed.

Volrin tablet
(diclofenac sodium 25mg)

Resubmit for enteric coated tablet when marketing of the previously approved drugs are completed.

Corotin tablet
(dipyridamole 75mg)

Resubmit with formula for coated tablet showing excipients for core tablet and coating material separately when marketing of the previously approved recipes are completed.

Agenda-4:

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

Drugland, Bogra

Paracetamol syrup.

The recipes were kept pending until mechanization is completed as per project, sufficient water supply is ensured and storage facilities is improved.

Approved
Waliullah
17.9.86

Phenargin syrup
(promethazine Hcl 0.1%)

The recipes were kept pending until mechanization is completed as per project, sufficient water supply is ensured and storage facilities is improved.

Mebendazole susp 2%

-do-

Acicel susp.
(antacid)

-do-

Metrozol susp.
(benzoyl metronidazole 2.5%)

-do-

Darlin susp.
(furazolidone)

-do-

Glucoton syr.
(ferrous gluconate)

-do-

Stars Pharmaceuticals, Dhaka.

Methacin-S cap.
(indomethacin 25mg)

Approved with condition to change name with '-S' in pre-fix and give indication as per BNF.

Nalic-S cap.
(nalidixic acid 500mg)

-do-

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

Approved with condition to change name.

Amoxicillin -S cap.
(amoxicillin)

Kept pending till facilities are created.

Ampicillin -S cap.
(ampicillin)

-do-

Tetracycline -S cap.
(tetracycline)

-do-

Piperaz-in-S liq.
(piperazine)

~~Kept pending for further review.~~
Approved with condition to change name to S. to prefix in BNF.

Antacid-S liq.
(antacid)

Kept pending for microbiological facilities.

B-complex-S cap.
(vitamin B-Complex)

The recipe to be resubmitted with standard formula as, thiamine Hcl 5mg + riboflavin 2mg + Pyridoxin Hcl 2mg + nicotinamide 20mg per tablet/capsule and with '-S' in the prefix in the name.

Ferron-S liquid.
(ferrous sulphate)

Approved with condition to delete 454ml. packsize and put '-S' in the prefix of the name.

Contd....P/3.

Approved
Wadood
17.9.86

Histanin-S liq.
(chlorpromazine Hcl 0.5%)

The recipe to be resubmitted with changed name and proper indication as per BNF.

Levamisole-S liq.
(levamisole 0.8%)

Approved with condition to market in 30ml packsize only, put 'S' in prefix of name.

Cetamol-S liq.
(paracetamol)

The recipe may be resubmitted after deleting 450ml packsize, with strength as 2.4%, reducing quantity of propylene glycol changing name and giving indication as per BNF.

Nidazole-S liq.
(benzoyl metronidazole 6.4%)

approved with condition to delete 454ml packsize and give correct specification of benzoyl metronidazole. *& change name.*

Methoprim-S liq.
(trimethoprim 0.8%
+ sulphamethoxazole 4%)

The recipe may be resubmitted after deleting 60ml packsize, giving ^{ca}indication as per BNF changing name and mentioning preservative in chemical/generic name not in brand name.

A.P.C. Chemica, Khulna.

Apemisole syrup
(levamisole HCl)

Approved with condition to give strength as equivalent of 40mg levamisole base/5ml, delete sodium benzoate and mention preservative in chemical/generic form, not in brand name.

Apelose powder
(glucose monohydrate)

Approved.

City Pharmaceuticals, Ctg.

Rifampicin syrup.

Kept pending till the factory is shifted to to a better place.

Chloramphenicol oint

-do-

Pentocil susp.
(antacid)

-do-

Agenda-7:

Decision about registration of the two Hepatitis -B vaccines, e.g. HB-vaccine of Green Cross, Japan and Hepavex -B vaccine of Korea Green Cross, Korea.

It was observed by the Committee that the above two Hepatitis-B vaccines could not be tested in the DTL due to lack of facilities, none of the parties could submit two more Free Sale Certificate besides the country of origin to meet the requirement for registration. The HB-vaccine (Green cross, Japan) is now under

*Approved
Walla
17.9.86*

Contd....P/4.

20

-: 4 :-

process of registration in more than eight countries. The party also submitted a copy of a brief of a clinical comparative study report of the drug with similar product of ~~parsteur~~ Instt. of France and has been found comparable in efficacy and safety.

The Hepavex-B vaccine (Koren Green Cross) is also under way of registration in some countries and has submitted copy of some clinical trial report and test report about the brand. But it was observed by the Committee that though the brand Hepavex-B vaccine is not yet registered, it is being offered for commercial sale by the party.

In view of above, the Committee recommended for provisional registration of the HB-vaccine of Green Cross, Japan for one year with condition to submit Free Sale certificates from two ^{more} countries within one year.

As for Hepavex-B vaccine, it was decided to investigate how the party has imported this unregistered product and offering for commercial sale. *and submit the report within two weeks from 17.9.86.*

Agenda-8: Miscellaneous.

- a) To decide about chronological list for chairmanship of the meetings of the Drug Control Committee (DCC).

It was decided that in absence of Prof. Waliullah, Prof. Jabbar, will preside over the meeting of the DCC. In absence of both of them, Brig. Anis Waiz will preside over the meeting.

The meeting ended with vote of thanks to the chair.

*Approved
Waliullah
17.9.86*

Minutes of the 140th meeting of the Drug Control Committee held on 17.9.1986.

20

Members present:

Prof. A. Jabbar, Prof. A.T. Siddique, Prof. Mofazzal Hossain, Dr. Kazi Abdul Fattah, and Dr. Md. Jahangir.

Chairman:

The meeting was presided over by Prof. Waliullah.

Agenda-1:

Confirmation of the minutes of the 139th meeting of the Drug Control Committee held on 3.9.86.

The minutes of the 139th meeting of the Drug Control Committee held on 3.9.86 were confirmed.

Agenda-2:

Matters arising out of the minutes:

1. Decision about the recipe of Piperazine-S liquid of Stars Pharmaceuticals, Dhaka was reviewed and the recipe was approved with condition to change name with 'S' in the prefix of the name.
2. While discussing about the decision on agenda-7, it was further added that the investigation report about marketing of the unregistered drug Hipavex-B Vaccine of Kores Green Cross, Kores to be submitted before the Committee within two weeks from 17.9.86.

Agenda-3:

Consideration of the following recipes of import substitute drugs:

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

Firm/Brand

Decision:

Bexinco, Dhaka.

9 Sodium Fusidate cap. 500mg.

Fusidate Cortisone oint.
(sodium fusidate 2% +
hydrocortisone acetate 1%)

Fusidic acid susp. 5%

INH-Rifampicin 300 tab.

The recipe may be resubmitted with proposed ~~brand~~ name: *Either generic brand name or generic name if they want to do market it in generic name. in what name they want to market it*

-do-

Pfizer, Dhaka.

Rifnax cap. 600mg: 150mg
(rifampicin 300mg +
isoniazid 150mg)

Approved with condition to delete coverage for isoniazid.

Rifnax capsule 150mg: 100mg
(rifampicin 150mg + isoniazid 100mg)

-do-

*approved
AS/MS
2/9/86*

Agenda-4:

Consideration of the following resubmitted recipe.

The following resubmitted recipes were placed and decisions taken:

General, Dhaka.

Suprapen-400 f/c. tab. (bacampicillin 100mg)	Approved with condition to decrease overage to 2.5%.
Tenoloc-50 f/c. tablet (atenolol 50mg)	Approved with condition to delete overage.
Tenoloc-100 f/c. tablet (atenolol 100mg)	-do-

Agenda-5:

Consideration of the following other recipes:

The following other recipes were placed and discussed.

General, Dhaka.

Tetragen cap. (tetracycline HCl. 250mg)	Kept pending till report about manufacturing facilities of antibiotics is obtained.
Genoxytet cap. (oxytetracycline HCl 250mg)	-do-
Genacillin cap. (ampicillin 250mg)	-do-
Genacillin Dry. syrup (ampicillin 2.5%)	-do-
Genaclox cap. (cloxacillin 250mg)	-do-
Genopen V Dry syrup (penicillin V 2.5%)	-do-
Genaplex cap. (thiamine Hcl 5mg + riboflavin 2mg + pyridoxine Hcl. 2mg + nicotinamide 20mg)	Approved.
Getrim tablet. (sulphamethoxazole 400mg + trimethoprim 80mg)	Approved.
Getrim susp. (sulphamethoxazole 4% + trimethoprim 0.8%)	Approved.
Genapam tablet 5mg (diazepam 5mg.)	Approved with condition to give indication as per BNF.
Genacort oint. (hydrocortisone acetate 1%)	Approved.

ContdP/3.

*Approved
W. S. S. S.
24.9.86*

Beximco, Dhaka.

Melphin-2 chewable tab. 312.5mg.
(pyrantel pamoate)

The recipe was kept pending.
The firm ^{is to} justify the introduction of such strength and inform about availability of such strength in other country.

Ampicillin Paediatric drops
100mg/lml in 15ml bottle with calibrated dropper.

Approved.

Cephalexin paediatric drops
100mg/lml in 15 ml. bottle with calibrated dropper.

Approved.

Amoxycillin paediatric drops
100mg/lml in 15ml bottle with calibrated dropper.

Approved.

Resubmit with proposed name brand name or generic

Square Pabna.

Cotrim-DS tablet
(sulphanithoxazole 800mg + trimethoprim 160)

Rejected because not required in this strength.

Cardipro f/c. tab
(atenolol 100mg)

Approved with condition to delete overage.

Agenda-7:

Consideration of prayers for import registration.

The Committee considered the following review petitions and decisions taken:

Firm/Brand

Decisions:

Shanghai, Pharma, China.

25% Dextrose inj. 20ml.

Review petition of Chinese Embassy was considered and earlier decision of rejection of the drug (taken in 111th meeting held on 9.10.85) was upheld with reason to stop further import of the drug to encourage the local brands those are being manufactured.

Medimpex, Hungary.

Gordox inj.
(aprotinin)

The review petition against with-holding of the drug because its effectiveness is not substantiated was considered. The Committee upheld their earlier decision.

Jumex tablet
(seleginine 5mg)

The drug was rejected in 117th meeting as 'non essential & unnecessary drug' The review petition along with the clinical paper about its use in parkinsonism was considered and the earlier decision was upheld.

Norcolut tab.
(norethisterone)

The recipe was ~~rejected~~ in 120th meeting. The review petition stating that similar drugs e.g. "Primolut-N tablet of schering is allowed to import in higher price was considered. The earlier decision was upheld.

approved: with bid to c to manufacture locally
Contd.....P/4.

*approved
WZL
24/9/86*

28

-: 4 :-

Agenda-8: Miscellaneous:

Consideration of prayer of Healing Pharma dated 7.9.86.

The prayer was advised to put up in next meeting with all other similar cases.

The meeting ended with vote of thanks to the chair.

Approved
Walker
24.9.86