MINUTES OF THE FOURTH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE, HELD AT 10.15 AM ON TUESDAY 11 MARCH 1986 IN THE 7TH FLOOR BOARDROOM OF THE MACARTHY TRUST BUILDING, LAMBTON QUAY, WELLINGTON

PRESENT

Dr G R Boyd	(Chairman)
Mr R C Griffith	
Dr P D Bamford	
Mr D E Buckle	
Mr J H Berry	
Mr R L Brock	(Secretary)

IN ATTENDANCE

Dr R C Riseley	(Items 1, 2, 3(1), 3(3) and 3(4) only)
Mr R Withington	
Mrs C Van Der Lem	
Mrs S Combly	
Dr K H Goh	

1 APOLOGY

An apology for absence was accepted from Professor I R Edwards.

2 MINUTES OF THE MEETING OF 17 SEPTEMBER 1985

These were accepted subject to the following amendments:

Page 4, item 5(16)
amend the spelling of "Betaxolol" and change "a miotic agent" to "an agent".

Page 4, item 6(2), 5th line
amend "reports".

3 MATTERS ARISING

(1) Barbiturates

The chairman reported that no reply had yet been received from Eli Lilly (NZ) and Co and May and Baker (NZ) Ltd to the department's proposal that these companies

voluntarily withdraw sedative and hypnotic oral barbiturates from the New Zealand market. There had been no discussions as yet with the New Zealand Medical Association, but their opinion will be sought.

Dr Riseley tabled sales figures of barbiturates to pharmacies for the period to December 1985. There was a continued decline in sales, which was faster than expected for some brands. He also reported that almost 7 percent of new admissions to drug dependency clinics resulted from barbiturate abuse and 14 percent of patients had used barbiturates at some stage. He estimated that about 1500 patients are currently prescribed barbiturates.

The chairman commented that when barbiturates become generally unavailable, it is probable that only the tail end of overseas production runs would be imported and that these would not be safety packaged. This would therefore require an amendment to the Medicines Regulations.

The committee agreed that barbiturates should become generally unavailable on 1 April 1987. Exceptions would be by ministerial approval delegated to the Department of Health and would require the prescriber's justification. The department could also request a second opinion. A register of patients on barbiturates would then be kept. This system will be similar to that currently used for amphetamines.

Medical practitioners will be informed soon of this plan. The publicity will emphasise that a strong attempt should be made to remove all patients from barbiturates.

The proposed starting date of 1 April 1987 would provide a better launching time for the new initiative. The Pharmacology and Therapeutics Advisory Committee will decide whether to remove barbiturates from the Drug Tariff. Nothing in the aforegoing shall apply to phenobarbitone.

(2) <u>Undecenoic Acid and Boric Acid (Pedisan)</u>

The Department of Health had received a changed medicine notification from The Boots Company (NZ) Ltd which confirmed the formulation of Pedisan to contain:

salicylic acid	2.0%
boric acid	6.0%
zinc undecenoate	2.0%
undecenoic acid	0.5%

This is the formulation currently sold through retail outlets. Boots requested that it become unscheduled.

Members commented that boric acid had been scheduled because of its use in baby powders. A baby had died in the 1950s from having baby powder put on open lesions.

The committee resolved to inform The Boots Company (NZ) Ltd that their request for the change in the classification of undecenoic acid and its salts would be considered only if boric acid were removed from the formulation of Pedisan or reduced to 2 percent or less.

(3) Nabilone

This synthetic cannabinoid was referred to the Drugs Advisory Committee (DAC) for consideration as a controlled drug. At its meeting of 5 March 1986, the DAC resolved to recommend to the Minister of Health that nabilone be scheduled as a controlled drug under Part III of the Second Schedule to the Misuse of Drugs Act 1975.

(4) Codeine

Dr Riseley presented tables showing sales of codeine containing analgesics to pharmacies and admissions to drug dependency clinics due to home manufactured morphine. The rate of increase in sales of codeine containing analgesics was slower for 1984-85 than for previous years, but the market is still expanding. There has been a small decrease in sales of the large pack sizes and a major decrease in sales of Codral Forte, due to the tight controls on the sale of this product.

Members reported that the Pharmaceutical Society would shortly issue further information to pharmacists, with the suggestion that those under particular pressure could remove all codeine containing analgesics from sale or keep a register of sales.

(5) Nitrous Oxide

This anaesthetic gas was recommended for classification as a prescription medicine at the last meeting. The chairman reported that Entonox, which is 50 percent oxygen and 50 percent nitrous oxide, is used by podiatrists as well as ambulance officers. The prescription medicine classification may be too restrictive. A restricted medicine can be sold to professionals from pharmaceutical wholesalers, while sales from pharmacies would be registered. The committee agreed to recommend that nitrous oxide be classified as a restricted medicine.

(6) Tramadol

The secretary reported that there had been no further information on this analgesic from Schering (NZ) Ltd. The committee agreed to take no further action until a reply was received.

(7) Diclofenac (Voltaren Emulgel)

The committee considered further information on the topical formulation of this non steroidal anti-inflammatory agent. It was agreed to recommend that

diclofenac and its salts, in preparations for dermatological use, be reclassified as a pharmacy-only medicine.

(8) Silver Acetate ("Call It Quits")

The chairman tabled a letter from the legal representatives of the distributor of this smoking deterrent, which claimed that "Call It Quits" was not a medicine as it exerts no physiological effect. He also stated that the active ingredient is apparently present in insignificant quantities. Dr Bamford suggested that the silver acetate may exert a physiological effect on the taste buds.

The committee noted that the department's acceptance that "Call It Quits" is not a medicine had implications for the anti-smoking chewing gum "Healthbreak", but that this contained much more silver acetate. The committee recommended that no change be made to the classification of silver acetate.

(9) Processing of Amendments to the Medicines Regulations

The secretary reported that the scheduling changes recommended by the previous meeting had not yet been enacted, but that those of the current meeting would be added and the amendment processed rapidly. An attempt would be made to make the amendments cumulative.

4 NEW MEDICINES TO BE SCHEDULED

(1) Methionyl Human Somatotrophin (Somatonorm)

This is a human growth hormone indicated in the treatment of short stature due to an insufficiency of pituitary growth hormone. It was recommended for classification as a prescription medicine.

(2) Cyclopropane

This is an anaesthetic gas. It was recommended for classification as a prescription medicine.

(3) Sulbactam Sodium (Unasyn)

This is a penicillin antibiotic. It was recommended for classification as a prescription medicine.

(4) Mithramycin (Mithracin)

This is an antineoplastic agent proposd for the treatment of certain cancers. It was recommended for classification as a prescription medicine.

(5) Etodolac (Lodine)

This is a nonsteroidal anti-inflammatory agent with analgesic and antipyretic properties. It was recommended for classification as a prescription medicine.

(6) Doxazosin Mesylate (Cardura)

This is a vasodilatory agent which is indicated for the treatment of hypertension. It was recommended for classification as a prescription medicine.

(7) Nonoxynol-9 (Today)

This is a spermicide, for use with a vaginal contraceptive sponge. The committee recommended that it remain unscheduled.

(8) Dequalinium Chloride (Dequacaine)

This is an antibacterial and antifungal agent which is already scheduled as a pharmacy-only medicine. The secretary apologised for the oversight.

(9) Gestodene

This is an oestrogen hormonal contraceptive. It was recommended for classification as a prescription medicine.

(10) Bupivacaine Hydrochloride

This is a local anaesthetic. The committee noted that there was a past history of problems with its use as a local block, with some deaths. It is more powerful than lignocaine. It was recommended for classification as a prescription medicine.

(11) Acipimox (Olbetam)

This is an antihyperlipidaemic agent used in the management of blood lipid disorders. It was recommended for classification as a prescription medicine.

(12) Enprostil (Gardrin)

This is a synthetic prostaglandin analogue which is indicated for the relief of gastric pain and the treatment of ulcers. It was recommended for classification as a prescription medicine.

(13) Bevantolol Hydrochloride (Ranestol)

This is a synthetic cardioselective beta-adrenoceptor blocking agent which is indicated for the long term management of patients with hypertension or angina pectoris. It was recommended for classification as a prescription medicine.

(14) Enoxacin (Gyroquin)

This is an antibacterial agent which was recommended for classification as a prescription medicine.

(15) Human Coagulation Factors II, IX and X (Prothrombinex)

Prothrombinex is used to achieve haemostasis in patients suffering from a deficiency in one or more of these factors. It may be used therapeutically or prophylactically. Human coagulation factors were recommended for classification as prescription medicines (factor IX is already scheduled).

(16) Murine Moab Anti-CD3 Human T Cell Blocker (Orthoclone OKT*3)

This is a murine monoclonal antibody to the T3 antigen of human T cells. It is indicated for the reversal of acute allograft rejection in renal transplant patients. It was recommended for classification as a prescription medicine.

5 SUBSTANCES PROPOSED FOR RE-SCHEDULING

(1) Naproxen Sodium (Naprogesic)

Syntex Laboratories Ltd had submitted a proposal that naproxen sodium be reclassified from prescription to pharmacy-only medicine for dysmenorrhoea. Members stated that if this was accepted, the Pharmaceutical Society would issue guidelines to pharmacists to encourage them to be involved in the sale of this product and to counsel patients to seek medical advice if the condition did not resolve.

The committee recommended that naproxen and its salts be reclassified to pharmacy-only medicine when in solid dose forms of 250 mg or less and with a pack size limit of 15 tablets or capsules. The committee noted that it had accepted the submission because of suitable labels, small pack size and patient leaflet. Any future applications to the department from other distributors to market naproxen or its salts for this indication as a pharmacy-only medicine should be considered on their merits, with these factors in mind.

(2) Quinine (Nicobrevin)

Nicobrevin is an aid to smoking cessation. The committee noted that the product claims physiological effects and can therefore be considered a medicine. The committee resolved to defer further consideration of the reclassification of quinine until (and unless) the new medicine application for Nicobrevin is approved.

6 PROPOSED AMENDMENTS TO THE FIRST SCHEDULE TO THE MEDICINES REGULATIONS 1984

The committee considered amendments proposed by Mr Withington.

(1) Hexoprenaline

The committee agreed to recommend the deletion from Part 1 of the First Schedule, the item:

"HEXOPRENALINE; and its salts";

and the substitution of the following item:

"HEXOPRENALINE; and its salts; in medicines for inhalation or for parenteral use".

This amendment is necessary if consistency is to be achieved with the item in Part III of the First Schedule, viz

"HEXOPRENALINE, except in medicines for inhalation or for parenteral use".

The following amendment was also recommended:

delete from Part III of the First Schedule the item

"HEXOPRENALINE, except in medicines for inhalation or for parenteral use";

and substitute the following item:

"HEXOPRENALINE; and its salts; except in medicines for inhalation or for parenteral use".

This amendment is necessary if consistency is to be achieved with the newly amended item in Part 1 of the First Schedule, as above suggested.

(2) Penicillin

The committee recommended that Benethamine Penicillin be added to Part 1 of the First Schedule, rather than a general entry for Penicillin derivatives.

(3) Salbutamol

The committee recommended the deletion from Part 1 of the First Schedule, the item:

"SALBUTAMOL; and its salts; in medicines for inhalation or for parenteral use";

and the substitution of the following item:

"SALBUTAMOL; and its salts; and its esters; in medicines for inhalation or for parenteral use".

This brings it into line with the item in Part III of the First Schedule, by including reference to the esters of salbutamol.

(4) Stramonium

The committee recommended the deletion from Part III of the First Schedule, the item:

"STRAMONIUM; alkaloids of; in medicines containing less than 0.15 percent of the alkaloids of stramonium calculated as hyoscyamine";

and the substitution of the following item:

> "STRAMONIUM; alkaloids of; and their salts; in medicines containing less than 0.15 percent of the alkaloids of stramonium, calculated as hyoscyamine".

This brings it into line with the item in Part II of the First Schedule, by including reference to the salts of the alkaloids of stramonium.

(5) Streptomycin

The committee recommended the addition to Part I of the First Schedule, in its appropriate alphabetical order, the item:

> "STREPTOMYCIN; and its salts".

This is consistent with the inclusion of other specified antibiotic substances in the Schedule.

(6) Tiaprofenic Acid

The committee agreed that the change of the word "acid" to upper case should be done when the regulations are redrafted and not as an amendment.

(7) Triamcinolone

The chairman explained that the entry in Part I of the First Schedule referred to one particular product containing triamcinolone acetonide, for which a new medicine application had not been received. The committee agreed to recommend that the entry remain unchanged.

7 DATE OF NEXT MEETING

At the members' request, this was changed to Tuesday 11 November 1986.

The meeting closed at 1.20 pm.

Ralph Rowe
11.11.86