MINUTES OF THE FIRST MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE HELD AT 10.30 AM ON TUESDAY 13 NOVEMBER 1984 IN THE LARGE BOARDROOM OF THE MACARTHY TRUST BUILDING, LAMBTON QUAY, WELLINGTON

PRESENT

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

IN ATTENDANCE

Mr R Withington
Dr R C Riseley (agenda items 1-6 (1), 6 (3) and 10 (4) only)
Dr C Sri-Ananda
Dr H Goh

The Minister of Health, the Hon. Dr Michael Bassett and his Private Secretary, Miss E Soper, attended morning tea before the meeting to meet the committee members. They were present for items 1-4 and 6 (1).

1 APOLOGIES

There were no apologies.

2 INTRODUCTORY REMARKS

The chairman explained the terms of reference and conditions of appointment. He stated that the Department of Health can assume the role of the Minister in referring matters to the committee.

3 DATES OF NEXT MEETING

These were set as 19 March and 17 September 1985.

4 CORRESPONDENCE RECEIVED

The committee considered a letter from Mrs C Conn of the Anti-Vivisection Society to members of the Restricted Drugs Committee. This concerned LD50 tests. The chairman agreed to write to Mrs Conn to state that the committee was sympathetic to her views up to a point. While no formal LD50 tests are carried out in New Zealand, some toxicological testing on animals is necessary as there is no satisfactory alternative.

5 MINUTES OF THE SECOND MEETING OF THE RESTRICTED DRUGS COMMITTEE

The minutes were accepted subject to the following amendments:

Page 3 item 5 (7) add "or injection" after "except when packed for inhalation";

Page 5 item 8 (3), paragraph 2, amend the spelling of Codral Forte;

Page 5 item 9 (1) replace "as a Pharmacy-Only Medicine" with "for marketing only through pharmacies."

6 MATTERS ARISING FROM SECOND MEETING OF RESTRICTED DRUGS COMMITTEE

(1) Barbiturate Sales Volumes

The committee examined final sales figures received from Lilly Industries (NZ) Limited for the period 1981-3. It was suggested that the slight increase in sales of the heavier sleeping pills Amytal Sodium and Tuinal 200 mg in 1983 was due to a market shortage in 1982.

Dr Riseley presented his tables and graphs which showed that barbiturate prescribing had decreased from 24 million doses in 1969 to 1.6 million in 1984 (year to 31 March). He stated that 80 percent of the elderly can be weaned off barbiturates. The committee noted that this may result in a decrease in suicides as barbiturates can produce severe CNS depression in overdose, whereas non-barbiturate sleeping pills tend to produce abnormal behaviour.

The committee recommended a 3 pronged approach to the further control of barbiturates.

(a) Education. Professor Edwards offered to revise his article on how to wean the elderly from barbiturates.

(b) No new patients should be prescribed barbiturates.

(c) There will be a deadline of 31 December 1986 to make specified prescription barbiturates unavailable.

The secretary will advise the Department of Health of these recommendations.

(2) Nicotine Chewing Gum

The committee noted that an application for consent to market this product has now been lodged.

(3) Terfenadine (Teldane)

This was recommended for classification in the Second Schedule (now Pharmacy-Only Medicine) by the Restricted Drugs Committee. The manufacturer desires that it should be made a Prescription Medicine. They had refused to put a modified warning statement on the packet. The committee recommended that it should remain a Pharmacy-Only Medicine.

(4) Naltrexone Hydrochloride (Naltrexone)

The Drugs Advisory Committee (DAC) will consider whether this should be a Controlled Drug in their meeting on 15 November 1984. It was noted that Naltrexone is stated in the literature to be very similar to Buprenorphine. The committee agreed that if the DAC does not recommend control, then it should remain a Prescription Medicine.

(5) Diphenoxylate/Atropine Sulphate Combinations (Diastop)

Pacific Pharmaceuticals Limited have agreed to the Restricted Drugs Committee's recommendation that bulk supplies of Diastop should be strip packaged.

7 MEDICINES TO BE SCHEDULED

(1) Sumithrin (Sumithrin Powder)

This is a synthetic pyrethroid pediculicide. It was recommended for classification as a Pharmacy-Only Medicine.

(2) Antihaemophilic Factor (Human) (Hemofil "T")

This is a protein necessary for blood clot formation which is indicated in haemophilia A (classical haemophilia) for the prevention and control of haemorrhagic episodes. It was recommended for classification as a Pharmacy-Only Medicine.

(3) Butoconazole Nitrate (Butoconazole Nitrate 2% Cream)

This is an imidazole derivative indicated for treatment of vulvovaginal mycotic infections caused by Candida species.

The following classification was recommended:

Butoconazole; and its salts; except in dermatological medicines - as Prescription Medicines, and Butoconazole; and its salts; in dermatological medicines - as Pharmacy-Only Medicines.

(4) Amsacrine (Amsidyl)

This is a cytotoxic agent for use in specialised oncotherapy. It was recommended for classification as a Prescription Medicine.

(5) Ceftazidime Pentahydrate (Fortum)

This is a bactericidal cephalosporin antibiotic, which was recommended for classification as a Prescription Medicine.

(6) Nabumetone (Relafen)

This is a non-steroidal anti-inflammatory agent indicated for a variety of conditions requiring anti-inflammatory and analgesic effect. It was recommended for classification as a Prescription Medicine.

(7) Vincamine (Oxygeron)

This is an alkaloid obtained from Vinca minor. It is indicated in the treatment of psychobehavioural disorders of cerebral ageing. It was recommended for classification as a Prescription Medicine.

(8) Leuprolide Acetate (Lucrin)

This is a synthetic nonapeptide analogue of gonadotrophin releasing hormone, indicated in the palliative treatment of advanced prostatic cancer. It was recommended for classification as a Prescription Medicine.

(9) Epidoxorubicin Hydrochloride (Pharmorubicin)

This is an anthracycline anti-tumour agent indicated for the treatment of breast cancer. It was recommended for classification as a Prescription Medicine.

(10) Levobunolol Hydrochloride (Betagan Eye Drops)

This is a noncardioselective beta-adrenoceptor blocking agent. It is indicated for the control of intraocular pressure in chronic open angle glaucoma and ocular hypertension. It was recommended for classification as a Prescription Medicine.

(11) Ciclopirox Olamine (Batrafen Cream)

This is a broad spectrum antifungal agent. It was recommended for classification as a Prescription Medicine except in dermatological medicines and as a Pharmacy-Only Medicine when in dermatological use.

(12) Piroctone Olamine (Octopirox)

This is an antidandruff agent. Medicines containing over 1 percent of piroctone olamine were recommended for classification as Pharmacy-Only Medicines.

(13) Albendazole (Zentel)

This is an anthelmintic agent which is indicated in the control of intestinal parasites. It was recommended for classification as a Prescription Medicine.

(14) Cefonicid (Monocid)

This is an antimicrobial agent which was recommended for classification as a Prescription Medicine.

(15) Cefotetan (Apatef)

This is a broad spectrum bactericidal cephamycin parenteral antibiotic. It was recommended for classification as a Prescription Medicine.

(16) Imipenem (Zienam)

This is a thienamycin becta-lactam antibiotic. It was recommended for classification as a Prescription Medicine.

(17) Cilastatin Sodium (Zienam)

This is a specific enzyme inhibitor that blocks the metabolism of imipenem in the kidney. It was recommended for classification as a Prescription Medicine.

(18) Mitoxantrone Hydrochloride (Novantrone)

This is a cytotoxic synthetic anthracenedione indicated for carcinoma of the breast. It was recommended for classification as a Prescription Medicine.

(19) Aztreonam (Azactam)

This is a monobactam, synthetic monocyclic beta-lactam antibiotic with bactericidal activity against gram negative aerobic pathogens. It was recommended for classification as a Prescription Medicine.

(20) Famotidine

This is a histamine H_2 receptor antagonist indicated for duodenal and benign gastric ulcers and hypersecretory conditions. It was recommended for classification as a Prescription Medicine.

(21) Mefloquine Hydrochloride (Fansimef)

This is an antimalarial agent indicated particularly for the therapy of Plasmodium falciparum resistant to other antimalarials. It was recommended for classification as a Prescription Medicine.

(22) Pseudomonic Acid (Bactroban)

This is indicated for the topical treatment of skin infections. Consideration of its classification deferred until the next meeting, by which time it will have been before the Medicines Assessment Advisory Committee. (Secretary's note: pseudomonic acid is now called mupirocin).

(23) Meptazinol Hydrochloride (Meptid)

This is indicated as an analgesic for mild to moderate pain in acute and chronic conditions. It was recommended for classification as a Prescription Medicine.

(24) Benzonatate (Tessalon Perles)

This is a non-narcotic antitussive for the symptomatic relief of cough. No recommendation was made as to its classification as the application for consent to distribute it has been declined.

8 MEDICINES FOR RESCHEDULING

(1) &
(2) Polymyxin B Sulphate and Bacitracin Zinc (Polysporin)

The committee raised two objections to this product being available over the counter. Firstly, it might encourage the development of resistant strains, and secondly, being antibiotics, the two ingredients should be Prescription Medicines.

The committee will seek the opinion of the National Health Institute, dermatologists and the Animal Remedies Board. It is necessary to determine how frequently these substances are used for animals and for serious conditions in humans. The possibility of cross resistance and the effects of the omission of neomycin will also be investigated. Wellcome New Zealand Ltd will be asked to contribute on these issues. The committee will consider thereschedulingagain at the next meeting.

(3) Loperamide Hydrochloride (Imodium)

This is an anti-diarrhoeal agent. The committee supported the application to change the classification of loperamide and its salts from Restricted Medicine to Pharmacy-Only Medicine.

(4) Comfrey

This has been scheduled in Victoria as a substance extremely dangerous to human life. The committee reviewed publications on comfrey and Professor Edwards reported his experiments in Africa which showed dose-dependent cardiac suppression on isolated heart preparations by comfrey.

The committee resolved to issue the following statement:

"The committee is aware of animal studies which show danger, particularly to the liver. In view of this and a lack of evidence of benefit to humans, the committee could not recommend the use of comfrey."

9 AMENDMENTS TO SCHEDULES OF MEDICINES REGULATIONS

The committee proposed the following amendments to the Schedules of the Medicines Regulations 1984.

(1) "Ketoconazole; and its salts. " (Currently Prescription Medicine)

The committee agreed that the proposed introduction of Nizoral Cream, containing 2 percent of ketoconazole, warrants the following changes in keeping with other antifungal medicines in this general group.

Prescription Medicine : "Ketoconazole; and its salts, except in dermatological medicines."

Pharmacy-Only Medicine : "Ketoconazole; and its salts; in dermatological medicines."

(2) Glucagon; and its salts

This is a hyperglycaemic agent which is administered parenterally, and as such would be caught up by the item "INJECTABLE MEDICINES, not specified elsewhere in this Schedule" as a Pharmacy-Only Medicine. Although Lilly (NZ) Ltd have proposed that Prescription Medicine is more appropriate, the committee felt that Pharmacy-Only Medicine is the correct classification.

(3) Indamide

This had been omitted and should appear under Prescription Medicines.

(4) Aluminium clofibrate

The committee agreed that this appears correctly under Prescription Medicines.

(5) Pancreatin. (Pharmacy-Only Medicine)

This should be changed to "PANCREATIN; for internal use."

This will allow optometrists to sell some contact lens solutions.

(6) Quaternary Ammonium Compounds. (Pharmacy-Only Medicine)

This entry was intended for antiseptics and should read: "QUATERNARY AMMONIUM ANTISEPTIC COMPOUNDS."

(7) Bismuth Subcitrate

"BISMUTH SUBCITRATE" should be added under Pharmacy-Only Medicines. While De Nol is scheduled as tripotassium dicitrato bismuthate, other bismuth compounds are scheduled separately under bismuth.

(8) "CARDAMOM compound; tincture; ... " (Pharmacy-Only Medicine).

This should read "CARDAMOM; compound tincture;... "

(9) Hydrocortisone (Pharmacy-Only Medicine)

Insert after the word "base" the words : "with no other active ingredient." Although the recommendation of the Poisons Committee was on the basis of no other active ingredient, this was not included in the schedule. While proprietary combinations can be controlled by new medicine application and changed medicine notification pharmacists may promote their own combinations.

(10) Lignocaine. (Pharmacy-Only Medicine)

The entry should read : "LIGNOCAINE; and its salts; except in medicines for external use containing 2 percent or less of lignocaine."

(11) Metrizamide

This should be deleted from Prescription Medicines as it is covered by Restricted Medicines, under radiographic contrast media.

10 ANALGESICS

(1) Re-scheduling of Ibuprofen (Nurofen)

The committee felt that the submission by the Boots Company (New Zealand) Ltd contained adequate technical data. Concern was expressed as to how the Boots Company

intend to promote Nurofen, as the committee felt that an advertising war would result between the manufacturers of analgesics.

The committee considered that the statement : "Nurofen is gentler on the stomach than aspirin and is as well tolerated as paracetamol" should not appear on the packaging.

The committee also felt that there should be restrictions on strength and pack size of ibuprofen if it was made a Pharmacy-Only Medicine. A limit of 24x200 mg was suggested.

These concerns will be communicated to the Boots Company and their submission will be reconsidered at the next meeting.

(2) Aspirin and Paracetamol

The committee suggested that it was illogical to have aspirin on general sale when paracetamol and ibuprofen are as safe. The scheduling of these analgesics and the issue of maximum strengths and pack sizes will be examined at the next meeting.

(3) Dextropropoxyphene

Discussion of this item was deferred until the next meeting because of a lack of time.

(4) Codeine

Dr Riseley stated that the bulk of new admissions to the Auckland Drug Dependency Clinics are now due to home manufactured morphine. Codeine and the other chemicals necessary for its manufacture are being stolen.

The committee noted the sales of codeine-containing analgesics are increasing, but that advertising of Panadeine and Pirophen would have led to the increase in sales of these products. The committee will write to the Pharmaceutical Society to ask them to approach Sterling Pharmaceuticals (NZ) Ltd to remove large packs (100's) of Panadeine from sale and to stop advertising codeine-containing analgesics.

Members expressed the opinion that abuse of medication occurs in New Zealand because few other drugs are available. Control of any substance results in the transfer of abuse to a new one. The committee did not consider that a change in the scheduling of codeine was warranted.

The committee noted that the Pharmaceutical Society continues to draw its members' attention to the problem of codeine-containing medicines. It was agreed that it would be impractical to keep a register of sales of other codeine products in addition to Codral Forte.

11 GENERAL BUSINESS

(1) Camphor

The committee noted that a booklet called "The Cold War" issued by Vicks Vaporub advocates putting camphor in a baby's cot to combat colds. This was referred to the Department of Health for action because of the potential toxicity.

The meeting closed at 4.35 pm.

19/3/85