MINUTES OF THE FIFTH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE, HELD AT 10 AM ON TUESDAY 11 NOVEMBER 1986 IN THE 7TH FLOOR BOARDROOM OF THE MACARTHY TRUST BUILDING, LAMBTON QUAY, WELLINGTON

PRESENT

Dr R C Riseley (Chairman)
Mr R C Griffith
Professor I R Edwards
Dr P D Bamford
Mr J H Berry
Mr D E Buckle
Mr R L Brock)
Miss J R Burke) (Secretaries)

IN ATTENDANCE

Mr R Withington
(Items 7-10 only):-
Dr J Donovan
Dr S M Martindale
Mrs S Combly

1 APOLOGIES

None.

2 CHAIRMAN'S REMARKS

Dr Riseley explained to the committee that Dr Boyd was now the Acting Manager of the Primary Health Care Programme. Dr Riseley was now the Principal Medical Officer of the Medicines and Benefits unit and had been appointed as Chairman of the Medicines Classification Committee. Dr Boyd will continue to chair the Pharmacology and Therapeutics Advisory Committee. Dr Riseley introduced Miss Burke and explained that she was receiving secretarial training from Mr Brock.

3 MINUTES OF THE MEETING OF 11 MARCH 1986

These were accepted subject to the following amendments:

Page 5, item 4(9), change "oestrogen" to "progestogen".
Page 6, item 5(2), correct 'Nicobrevin".

4 MATTERS ARISING

(1) Barbiturates

The committee studied tabulated data which showed that sales of barbiturates are dropping steadily. The department had met with representatives of Eli Lilly (NZ) and Co and May and Baker (NZ) Ltd. These companies had stated that they would not voluntarily withdraw sedative and hypnotic oral barbiturates from sale, but added that it may be uneconomical to continue distribution if sales continue to decline. They did not object to the proposal to make these barbiturates generally unavailable.

Dr Riseley reported that the department had received some responses from the medical profession on the proposal. General practitioners were in agreement with it if certain patients were permitted to continue receiving barbiturates. Some psychiatrists had reported the need for an urgent supply of barbiturates to sedate manic patients. The committee agreed to seek the opinion of the College of Psychiatrists on the proposal. The Minister may approve this exemption as a special dispensation.

Veterinary surgeons have been reminded to keep secure their supplies of Nembutal (phenobarbital sodium). This product is not sterile as it is used only for euthanasia in animals. It is available in a multi-dose bottle.

The legislative changes necessary to make sedative and hypnotic oral barbiturates generally unavailable will be promulgated by an Order in Council. The proposal is to move barbiturates from Part IV of the Third Schedule to the Misuse of Drugs Act 1975 to Part I (with cannabis leaf and plant). Barbiturates will then only be supplied with the permission of the Minister. As with amphetamines, the authority for this approval will be delegated to the Department of Health. Such exemptions would be granted to specific doctors for specified patients for supply through a hospital pharmacy.

The committee questioned the practicality of supply through hospital pharmacies only, but agreed that the aim of the proposal was to remove barbiturates from community pharmacies. Existing stocks held by pharmacies could either be destroyed, collected by hospitals or continue in stock. The Pharmaceutical Society will alert pharmacists to keep stocks to a minimum. Barbiturates could be sent through the mail by registered or insured post. The committee agreed that in certain situations, eg remoteness from a hospital, it may be desirable for a community pharmacy to continue to dispense barbiturates. This has happened with amphetamines.

Dr Riseley added that Professor Edwards' paper on weaning the elderly from barbiturates will be published in the equivalent of the Therapeutic Notes Series.

(2) Undecenoic acid and its salts (Pedisan)

Mr Brock reported that the Boots Company (NZ) Ltd had removed boric acid from the formulation of Pedisan at the committee's suggestion and now requested that the committee recommend the revision of the scheduling of undecenoic acid and its salts to allow the open sale of this medicine. The committee agreed to recommend that medicines containing more than 2.5 percent by weight of undecenoic acid and its salts (in total) should be pharmacy-only medicines. This will permit the open sale of Pedisan.

(3) Codeine

The committee examined sales figures for codeine containing analgesics and noted that sales of Panadeine had declined and that there was a decrease in the proportion of sales of larger pack sizes. The committee agreed that pharmacies are controlling sales of codeine containing analgesics well. There had been a disturbing increase in armed hold ups of pharmacies in Auckland. The committee noted that the Drugs Advisory Committee had not made any new recommendations on codeine.

(4) Silver Salts

Mr Brock explained that, as the committee had previously noted, lawyers acting for a distributor of an anti-smoking preparation which contains silver salts had challenged the classification of these products as medicines, according to the definition in the Medicines Act 1981. The department's view was that this challenge would be difficult to refute, so all anti-smoking preparations which contain silver salts can now be sold freely.

(5) Processing of Amendments to the First Schedule to the Medicines Regulations 1984

Mr Brock explained that there has been further delays in processing the amendments to the scheduling of medicines as recommended by the committee. He will endeavour to insure that the recommendations from this and the last two meetings are drafted as soon as possible.
Mr Griffith commented that only one revision of the regulations per year could now be expected, due to the heavy workload of the department's legal staff.

5 NEW MEDICINES TO BE SCHEDULED

(1) Selegiline (Eldepryl)

This is a selective MAO-B inhibitor which potentiates the effect of levodopa. It is indicated in the treatment of Parkinson's Disease. It was recommended for classification as a prescription medicine.

(2) Typhoid vaccine (Typhoral)

This is an oral vaccine for active immunisation against typhoid fever. A pharmacy-only classification was proposed by the distributor, but the committee considered that patients may believe the vaccine to be 100 percent effective when it is not. It was recommended for classification as a prescription medicine.

(3) Varicella virus vaccine (Varirix)

This vaccine is for protection against Varicella virus. It was recommended for classification as a prescription medicine.

(4) Ifosfamide (Holoxan)

This has antiproliferative action and is indicated for the treatment of various tumours. It was recommended for classification as a prescription medicine.

(5) Carboplatin

This is a platinum coordination compound with antitumour properties. It was recommended for classification as a prescription medicine.

(6) Terodiline (Mictrol)

Terodiline is a secondary amine with antichol inergic and calcium blocking properties. It is indicated in the treatment of bladder disorders and incontinence. The committee recommended that it be classified as a prescription medicine.

(7) Nedocromil sodium (Tilade)

This compound inhibits the release of inflammatory mediators and is indicated in the treatment of reversible obstructive airways disease. It was recommended for classification as a prescription medicine.

(8) Mesna (Uromitexan)

Mesna is indicated for the prevention of toxicity on the urinary passages by oxazaphosphorines. It was recommended for classification as a prescription medicine.

(9) Goserelin (Zoladex)

This is an agonist of luteinising hormone releasing hormone, which is indicated in the treatment of prostate cancer suitable for hormonal manipulation. It was recommended for classification as a prescription medicine.

(10) Loratadine (Claratyne)

This is an oral antihistamine which is indicated for relief of the symptoms of seasonal allergic rhinitis. The distributors had proposed a pharmacy-only classification. The committee considered that the warning on the packet was rather limited - there was no mention of drowsiness and the statement on pregnancy might imply that other medicines were safe. The product also stains urine. The committee resolved not to recommend a classification for loratadine until the new medicine application has been considered by the Medicines Assessment Advisory Committee (MAAC).

(11) Hexamidine isethionate (Medi Pulv)

Hexamidine isethionate has bactericidal, bacteriostatic and fungicidal properties. It has replaced clioquinol in the formulation of Medi Pulv foot powder. It was recommended for classification as a pharmacy-only medicine in medicines for external use.

(12) Dextran 1 injection (Promit)

Dextran 1 is a polysaccharide which is indicated in the prophylaxis of serious anaphylatic reactions with the infusion of other dextrans of higher molecular weight. The committee noted that other dextrans were also unscheduled and recommended that dextrans be classified as pharmacy-only medicines.

(13) Recombinant plasminogen activator (Actilyse)

Recombinant human tissue type plasminogen activator is a glycoprotein which is indicated for fibrinolytic therapy in acute thrombotic coronary artery occlusion. It was recommended for classification as a prescription medicine.

(14) Metergoline (Liserdol)

Metergoline has antiprolactin activity as is indicated in the prevention and suppression of postpartum lactation and the treatment of hyperprolactinaemic amenorrhea. It was recommended for classification as a prescription medicine.

(15) Mequitazine (Primalan)

This is an antihistamine indicated for the treatment of hayfever and other allergic conditions. The committee noted that it is a prescription medicine in the United Kingdom. The committee agreed to defer making a recommendation on its classification until the new medicine application has been assessed by the MAAC.

6 SUBSTANCES PROPOSED FOR RE-SCHEDULING

(1) Pamabrom (Midol)

Pamabrom is a diuretic and is an ingredient of Midol which is intended for the treatment of premenstrual syndrome. The committee was concerned at the lack of data on the use of pamabrom in early pregnancy, where premenstrual symptoms can still occur. Members considered that the Medicines Assessment Advisory Committee would be unlikely to make a favourable recommendation on the combination product. The committee agreed that more information on the safety and efficacy of Midol was required and resolved not to make a recommendation on the classification of pamabrom until a report was received from the MAAC on its safety in early pregnancy.

(2) Bufexamac (Paraderm)

Bufexamac 5 percent cream and lotion is a non-steroidal anti-inflammatory agent used in the topical therapy of inflammatory skin conditions. The distributors had requested that it be reclassified from restricted medicine to pharmacy-only medicine. The committee agreed to recommend that bufexamac, in medicines for external use containing 5 percent or less of bufexamac, be reclassified as a pharmacy-only medicine.

7 NATIONAL POISONING STATISTICS

Dr John Donovan, First Assistant Secretary, (Therapeutics Division) of the Commonwealth Department of Health entered the meeting at this point, accompanied by Dr Martindale and Mrs Combly.

The committee examined the tables of poisoning statistics which are produced annually by the Department of Health. Mr Griffith explained that notifications on poisonings are sent to district health offices where they are coded. Data are then sent to head office for tabulation. Mr Griffith said that he considered that the statistics for poisonings by multiple substances are not of much use. Professor Edwards added that 25-30 percent of poisoning notifications to the National Poisons Centre are for multiple substances. Mr Griffith proposed that if the poisoning information was coded at head office, brand names would be available. He suggested single substances only be tabulated. Dr Riseley added that this approach would be more useful in determining whether or not the products were in safety packaging. Professor Edwards stated that there were no trends in multiple poisonings. He had noted that carbon monoxide poisonings had declined after a recent resurgence.

Dr Bamford stated that at Dunedin Hospital, those poisoning cases not sent to intensive care were now held overnight without formal admission. This will affect the national poisoning statistics.

Professor Edwards suggested that with multiple substances, the statistics should record the individual substances involved in multiple substance poisonings. He added that the National Poisons Centre receives about two thirds of the total poisons notifications. He suggested that the department compare their presentation with overseas statistics. Canadian tables are similar to the New Zealand ones, but without combinations. He stressed the need for an alert if particular combinations are especially dangerous.

In summary, the committee recommended that the department study poisons statistics from the United States, Canada, Australia and the United Kingdom. The statistics should meanwhile continue in their present format, with a reassessment as to how combination poisonings could be monitored.

8 PROPOSED AMENDMENT TO THE FIRST SCHEDULE TO THE MEDICINES REGULATIONS

(1) Nonylic acid

Mr Withington explained that nonylic acid itself is not a medicine. The committee recommended that the entry under pharmacy-only medicines be amended to: "Nonylic acid, derivatives of". The committee noted that Finalgon Cream is the only medicinal product on the New Zealand market which contains a derivative of nonylic acid.

(2) Triamcinolone

The committee supported Mr Withington's proposal and recommended that the entries in Parts I and III of the First Schedule be amended to: "Triamcinolone; and its derivatives". Triamcinolone has no salts. The committee also recommended the addition, under the pharmacy-only entry, of: "in packs of not more than 10 tablets".

(3) Sorbide/isosorbide dinitrate

The committee considered a letter from the Dominion Analyst which explained that isosorbide dinitrate is not a salt of sorbide or isosorbide. The committee therefore recommended that the entry under pharmacy-only medicines for "Sorbide; and its salts" be deleted and "Isosorbide dinitrate" substituted, along with "Isosorbide mononitrate".

9 AMPHETAMINES

The committee had received a letter from the Drugs Advisory Committee seeking advice on the scheduling of 5 amphetamines: N-ethylamphetamine, fencanfamine, fenproporex, mefenorex and pyrovalerone.

A sixth substance, propylhexedrine, is already classified as a prescription medicine. These substances were referred for consideration for classification in accordance with the World Health Organisation's Convention on Psychotropic Substances. The Drugs Advisory Committee had not initially recommended a listing for these substances under the Second Schedule (Class B Controlled Drugs) to the Misuse of Drugs Act 1975 because some may prove to be of therapeutic use and because of propylhexedrine's classification.

The committee noted that some of the amphetamines under consideration are used as stimulants or anorexiants in Europe. None are available in New Zealand and the products which contained propylhexedrine are no longer available. The committee recommended that these amphetamines be referred back to the Drugs Advisory Committee for listing under the Second Schedule and that propylhexedrine be deleted from the First Schedule to the Medicines Regulations.

10 ANALGESICS

Dr Donovan commented that in Australia paracetamol is available from non pharmacy retail outlets in small pack sizes. Larger packs are available from pharmacies. Dr Donovan, Dr Martindale and Mrs Combly then left the meeting.

Members suggested that the sale figures for paracetamol in the agenda papers were incorrect in that there was an inexplicable difference in the sales between the years 1984-85 and 1985-86.

With reference to the submission from Sterling Pharmaceuticals (NZ) Ltd calling for the open sale of paracetamol, Dr Bamford stated that the committee must produce a strong justification should it recommend that this proposal be declined. He continued by saying that New Zealand is out of step with the United States, United Kingdom, Australia and Canada in restricting paracetamol to pharmacy-only. A pack size limit of 20 tablets would be appropriate for open sale.

Professor Edwards added that the committee should recommend a restriction on the pack size of aspirin available on open sale. He would favour the restriction of aspirin to pharmacy-only if this were feasible. Mr Berry commented that aspirin and paracetamol were available on open distribution overseas for historical reasons. He considered that an advertising war over analgesics would occur if the availability of paracetamol were liberalised. New Zealand is correct in classifying paracetamol as a pharmacy-only medicine. Pharmacies provide both a good availability and good control of analgesics. Withdrawal of any product is easily accomplished in New Zealand, whereas in the United

Kingdom he had noted that children's aspirin remained on grocery shelves after withdrawal was announced. Tylenol capsules had been subject to tampering in the United States.

Mr Berry continued that sale through pharmacies limits the availability of medicines for abuse. If paracetamol were on open sale, people would be encouraged to buy more of it than they needed. Analgesics are generally not now on open display in pharmacies. There had been no great public pressure to re-schedule paracetamol. He noted that paracetamol is more dangerous than aspirin in moderate overdosage. Both products should be under proper control. If paracetamol were available on free sale, more toxic effects would be experienced. There is little difference in cost between the two analgesics. He was aware that Sterling-Winthrop in the United Kingdom had had a preparation of paracetamol plus methionine ready to market, which suggested they were concerned at the use of paracetamol in suicides.

Professor Edwards replied that in situations where paracetamol is as freely available as aspirin the overall morbidity and mortality is unchanged, but the detailed content differs. He emphasised that problems occur with aspirin at therapeutic dose levels. The committee noted from the national poisoning statistics that there were no deaths from paracetamol in 1984.

On the subject of Reye's Syndrome, Professor Edwards stated that the association with aspirin was not proven, but there was public concern about it. With new therapeutic use of aspirin as well, it might be timely to advise the public of the potential dangers of aspirin. Mr Berry commented that pharmacists consider a patient's needs and would not sell a medicine if this was the appropriate course.

Mr Griffith stated that aspirin and paracetamol on open sale should be in restricted pack sizes and strengths and carry appropriate cautionary statements. These would refer to gastric distress for aspirin and warn not to exceed the recommended dose for paracetamol. Professor Edwards added that child proof containers should be used. Mr Berry asked whether blister packs were insufficient and Mr Griffith replied that they were as good or better than childproof screw tops. Professor Edwards commented that poisoning in children is always associated with lower socio-economic status where the medicines were likely to be bulk packs with screw caps.

Mr Berry then asked Professor Edwards for a statement of his proposal. Professor Edwards replied that it would be best to restrict both aspirin and paracetamol, but this might not be immediately acceptable to the public. He therefore proposed to replace aspirin on the open market with paracetamol and at a later date return paracetamol to pharmacy-only. Dr Riseley stated that the public may argue that if the committee was concerned at the safety of both substances, they should make one decision on restriction now. Professor Edwards suggested that the problems with aspirin use with children and with

paracetamol in overdose justify pharmacy-only status. This should be presented to the public. Members commented that both analgesics would still be available at stores situated 10 km or more from a pharmacy.

Mr Buckle commented that retailers would need reasonable warning if aspirin were withdrawn from open sale.

Dr Riseley summarised the four options for the scheduling of aspirin and paracetamol:

(1) both pharmacy-only medicines (although available in other retail outlets if these were 10 km or more from a pharmacy);

(2) paracetamol on open sale and aspirin pharmacy-only;

(3) aspirin on open sale and paracetamol pharmacy-only; and

(4) both on open sale.

Professor Edwards commented that the Toxic Substances Board had banned the advertising of tobacco with little public opposition. The committee should propose that both aspirin and paracetamol be pharmacy-only medicines and gauge public reaction. Mr Berry and Mr Buckle agreed that the Pharmaceutical Society would publicise the proposal.

Both analgesics will be available from other retail outlets situated 10 km or more from a pharmacy.

Mr Berry commented that paracetamol and aspirin were more toxic than any other open selling medicine.

Dr Riseley stated that there would be a problem of availability of analgesics over the 24 hour period and weekends that pharmacies could not completely cover. At the very least he thought that very small packs (2-4 tablets) of aspirin and paracetamol should be available through other retail outlets.

Mr Berry suggested members plan the details of the proposal for discussion at the next meeting. Dr Bamford stated that the committee's proposal should be publicised immediatey to gauge reactions. Professor Edwards suggested that the Consumers Institute and the manufacturers be invited to appear at the next meeting. Mr Griffith suggested that the committee needed a second proposal if opposition to the first was too great. Professor Edwards stated that this should be equal treatment of paracetamol and aspirin on open sale, with restrictions on both dose and pack size and warning statements. Mr Berry commented that this would double the problems in the community and Professor Edwards replied that the warning statements would channel people to use each medicine appropriately. Submissions, both personal and written, would provide the best advice to the Minister. Mr Berry added that the fall back position should not be rigidly determined before the next meeting.

Dr Riseley commented finally that in Italy all antipyretic analgesics for paediatric use are now prescription medicines.

11 OTHER BUSINESS

(1) Supply of syringes to drug addicts

Dr Bamford expressed surprise that the committee had not been asked to examine the issue of the supply of syringes to drug addicts to reduce the risk of AIDS transmission. Dr Riseley replied that the AIDS Advisory Committee was responsible for recommendations on this matter, which falls under the Misuse of Drugs Act. He commented that it is legal to carry a syringe for a purpose other than the abuse of drugs.

(2) Sale of medicines at Auckland International Airport

Mr Withington stated that the Minister of Health had recently wanted to buy a nasal decongestant at Auckland International Airport prior to travelling overseas. When he was unable to do so he had complained to the department. The district advisory pharmacist had previously directed the shop to withdraw pharmacy-only medicines from sale. Mr Buckle commented that the shop at Auckland International Airport had in the past had an exemption to sell pharmacy-only medicines and Mr Withington agreed to look into the matter further.

(3) Dates of meetings for 1987

These were set for 10 March and 22 September 1987, commencing at 10.00 am.

The meeting closed at 4.00 pm

10.3.87.