MINUTES OF THE SIXTH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE, HELD AT 10AM ON TUESDAY 10 MARCH 1987 IN COMMITTEE ROOM 1, 14TH FLOOR, NATIONAL PROVIDENT FUND BUILDING, 1 THE TERRACE, 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 (Secretary)

IN ATTENDANCE

Dr K H Goh (items 1-3 only)

1 APOLOGIES

None

2 MINUTES OF THE MEETING OF 11 NOVEMBER 1986

These were certified as correct subject to the following comments:-

P2 item 4(1), 3rd paragraph, change "phenobarbital sodium" to "pentobarbital sodium"

P3 item 4(4), 7th line, insert "those" between "all" and "anti-smoking"

P4 item 5(2), 5th line, replace "not" with "very much less effective than this"

P6 item 6(1), add after final sentence: "The company will be advised to make its submission on this to the MAAC."

P9 item 10, 3rd paragraph, replace "detailed content" with "pathology"

P9 item 10, 5th paragraph, last sentence should read:

"Professor Edwards commented that in the United Kingdom poisoning in children has been associated with lower socio-economic status where the medicines were likely to be bulk packs with screw caps."

P10 item 10, 3rd paragraph, option (1), add "and appropriately licensed" after "pharmacy"

P10 item 10, 4th paragraph, 1st sentence, changed "had banned" to "had recommended a ban"

P10 item 10, 4th paragraph, delete sentence beginning "Mr Berry and Mr Buckle agreed ..."

P10 item 10, last paragraph, 8th line insert "second proposal" between "this" and "should"

3 MATTERS ARISING

(1) Barbiturates

Mr Brock reported that no reply had yet been received from the College of Psychiatrists concerning the need for barbiturates for the parenteral sedation of manic patients. Dr Riseley stated that the proposal to make sedative and hypnotic oral barbiturates generally unavailable had been forwarded to the Legal Unit of the Department of Health for drafting as an Order in Council. Because of the workload of this unit, it was unlikely that the proposed date of 1 April could be met. The Order in Council would be promulgated later in the year.

(2) Silver salts in anti-smoking preparations

Dr Bamford asked whether any of these preparations were sold other than through pharmacies and Mr Brock replied that at least one was sold through mail order. The committee discussed the definition of medicine. This covers the prevention of disease, which includes addiction. The secretary will write to the department's Legal Unit to query whether the definition of medicine is applicable in the case of anti-smoking preparations which contain silver salts. Mr Griffith added that the department did not require evidence of efficacy for these products.

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

Mr Brock reported that a draft cumulative amendment had been prepared. This included those changes enacted by the First Amendment. The recommendations of the current meeting would be added to this and it would then be forwarded to the Legal Unit for legal drafting.

(4) Loratadine (Claratyne)

Classification of this antihistamine was deferred from the last meeting pending assessment by the Medicines Assessment Advisory Committee (MAAC). Mr Griffith reported that the MAAC had requested further data on this medicine.

(5) Mequitazine (Primalan)

Classification of this antihistamine was also deferred from the last meeting. The MAAC has not yet considered this medicine.

(6) National Poisoning Statistics

Dr Riseley reported that single substance poisonings are now held on computer. The data are derived from hospital accident and emergency presentations and coroner's reports. Currently codes for groups of medicines are used, but these will be extended to individual codes for each medicine. Dr Riseley continued to say that Dr Martindale will be visiting the United Kingdom in April and will report on the collation and analysis of poisoning statistics there. Mr Griffith will contact the National Health Statistics Centre for their advice on what happens in Australia.

(7) Analgesics

The committee discussed the letter received from the Minister of Health. Mr Berry expressed concern at the mention of pharmacy deregulation. Professor Edwards added that the Minister had made no mention of the committee's proposal about small pack sizes in retail outlets. The Minister had suggested that they should change their professional opinion for political reasons.

Dr Riseley stated that the Medicines Classification Committee and similar committees were advisory in function only. Ministers can make their own final decisions. The Minister had asked the committee to provide compelling evidence that open sale of aspirin and paracetamol would present a substantial danger to the public and that restriction to a pharmacy-only classification would overcome the problem. Mr Berry commented that the current deregulatory situation might overwhelm any scientific arguments. The committee agreed that it was necessary to restate the reasons for its proposal to restrict aspirin in more concrete terms. Dr Bamford and Mr Buckle suggested that the committee should also now examine the alternative proposal of open sale for paracetamol.

Dr Bamford stated that in many individuals aspirin has more toxicity than paracetamol in normal dosage. Dr Riseley suggested that the public may be familiar with aspirin, but Professor Edwards stated that hospital admissions still occur with aspirin induced peptic ulcers. Mr Berry added that paracetamol is now widely used and probably came into major use in New Zealand 20-25 years ago. Dr Riseley read an extract from the Federal Register which stated that paracetamol was first reported on as an analgesic in 1893.

Dr Bamford suggested that the committee should write to the Minister, spelling out in greater detail the reasons behind the proposal of the last meeting. Opinions should also be sought from the manufacturers and public. The letter to the Minister should also state that if the proposal to restrict aspirin is unesccessful, paracetamol should be placed on open sale. Mr Griffith stated that he considered that public reaction was not a scientific basis for making a decision.

Professor Edwards stated that the proposal to restrict aspirin and paracetamol was made on the basis of the morbidity from use of these analgesics. An advantage of restriction would be that professional advice would be available for the safe use of these medicines. Mr Berry added that there was no chance of intervention at supermarkets whereas pharmacies provided a potential oversight of sales.

Dr Riseley asked that were the Medicines Adverse Reactions Committee to make a restrictive ruling on aspirin because of Reye's syndrome, where would analgesics for children and teenagers be available? Mr Berry replied that pharmacies have a network of rostering for emergency dispensing.

Professor Edwards stated that the professional ideal was for restriction on both aspirin and paracetamol. The alternative was restricted pack size and label warnings for both.

In response to a query from the committee as to whether the Paediatric Society had given a recommendation on Reye's Syndrome, Dr Goh replied that they had stated that Reye's Syndrome is rare in New Zealand and had made no recommendation.

Professor Edwards expressed concern that non-steroidal anti-inflammatory medicines were becoming increasingly available when serious adverse effects were associated with this group of medicines. The committee should restrict their availability.

Dr Riseley suggested that the Minister was representing the public who do not want to pay to obtain prescriptions or the higher prices of pharmacy over other retail outlets. Consumers now desire more medicines to be freely available and more information on them.

Dr Bamford expressed concern at the use of the trade name "Disprol" for paracetamol when "Disprin" is an aspirin product, and "Hedex" for paracetamol in the UK and aspirin in New Zeland.

He stated that 20 tablets was a realistic pack size for open selling paracetamol.

Dr Bamford agreed that the committee should write to the Minister to explain its proposals. Mr Berry said that there was no point in entering into a political argument, but that the Minister should be told the grounds for the committee's proposal to restrict aspirin to pharmacy-only. Approaching the public and the manufacturers on this would produce a large volume of adverse comment. The letter to the Minister should mention all of the reasons for the proposal, including Reye's Syndrome. Dr Bamford commented that it was probably unrealistic to propose the removal of aspirin from general sale. Mr Berry added that there were precedents in Australia and the United Kingdom with regard to pack size limits.

Dr Bamford said that the letter should express the committee's concern at the inherent toxic effects of aspirin and that a safer product (in normal dosage), paracetamol, should be available on open sale.

Mr Berry said that the proposed pack size limit would satisfy reasonable immediate requirements, but would avoid a price war with analgesics. Twenty tablets per pack would be reasonable for both aspirin and paracetamol. It would be inadvisable to encourage the public to purchase more medicines than they required.

Mr Griffith commented that a reduced pack size would not reduce the risk of adverse effects at normal doses. Professor Edwards said that led back to the argument for pharmacy-only aspirin. Very clear warning statements should appear on the packs.

Mr Berry stressed that his arguments were not based on keeping medicines in pharmacies for economic reasons. He asked whether paracetamol should replace aspirin on open sale, but added that the labelling should be examined in any case for aspirin and paracetamol. Professor Edwards commented that the use of aspirin in the new cardiac indication was a further argument for aspirin in pharmacy.

Mr Buckle suggested that aspirin would be scheduled as a prescription medicine if it were considered a a new medicine. This was not possible, but people could be encouraged out of danger by putting hurdles in their way. Dr Riseley commented that the public resents these hurdles. Professor Edwards said that consumers should be provided with reasons for the restrictions.

The committee agreed to present to the Minister option 4 from the last meeting, that aspirin and paracetamol should both be available on open sale, with restricted pack size and suitable warning statements. Dr Riseley added that the committee cannot afford to ignore public opinion.

Mr Berry stated that the committee's letter to the Minister should express concern at the toxicity of aspirin in normal dose, gastric irritation and Reye's Syndrome. Mention should also be made of the safety of paracetamol in normal dosage and of the dangers of overdosage.

Dr Riseley suggested that the committee should consider liquid analgesic preparations for children. Mr Berry said that these should not be available outside pharmacy. There is a British precedent in having pharmacy-only paediatric medicines, with tablets available outside pharmacy. There is no problem in New Zealand with the current situation of supply. The committee agreed that paediatric patients were currently adequately provided for. It was noted that the minimum age limits for aspirin OTC sales, arising from consideration of Reye's Syndrome, were 12 years in the UK, 16 in the USA and 20 in Australia.

Mr Griffith said that he thought that the maximum amount per pack for aspirin and paracetamol should be stated in grammes rather than the number of tablets or capsules. Mr Berry commented that there were already some problems of underdosage with aspirin. The committee agreed to recommend limits of 10g per pack for both aspirin and paracetamol. Both will be limited to 500mg per solid dose form. The effect of these restrictions would be to prevent manufacturers offering for promotional reasons increasing higher dosage strengths.

The committee then considered label warnings. The current statement required for aspirin and paracetamol by regulation 22(3) of the Medicines Regulations 1984 is: "Warning-Prolonged or excessive use may be harmful. Do not give to children under 2 years of age except on medical advice" or words of similar meaning. Mr Griffith informed the committee that the recommended warning for paracetamol in the USA was: "Do not exceed recommended dosage because severe liver damage may occur." Mr Griffith suggested that the word "severe" may unduly discourage people from taking paracetamol. Members agreed with this.

Professor Edwards and Mr Buckle pointed out that the reference to children under 2 in the New Zealand warning statement applies to aspirin. The committee agreed not to recommend its inclusion for paracetamol. The committee therefore recommended the following warning statement for paracetamol.

"Warning - Do not exceed the recommended dosage because liver damage may occur."

For aspirin, the committee agreed to recommend that the statement: "Do not take this product if you have indigestion, ulcers or bleeding problems" should precede the other two warning sentences given by regulation 22(3). This recommendation would be subject to any recommendation concerning Reye's Syndrome made by the Medicines Adverse Reactions Committee (MARC) at its meeting of 11 March 1987. (Secretary's note: the MARC made no recommendation on this subject at its meeting).

The recommended warning statement for aspirin is therefore:

"Warning - Do not take this product if you have indigestion, ulcers or bleeding problems. Prolonged or excessive use may be harmful. Do not give to children under 2 years of age except under medical advice."

4 NEW MEDICINES TO BE SCHEDULED

(1) Nitrendipine (Baypress)

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

(2) Nizatidine (Axid)

This is an H2-receptor antagonist indicated in the treatment of duodenal ulcer. It was recommended for classification as a prescription medicine.

(3) Ciprofloxacin (Ciproxin)

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

(4) Lisinopril (Prinivil and Zestril)

This is an angiotensin converting enzyme (ACE) inhibitor which is indicated in the treatment of essential hypertension, renovascular hypertension and congestive heart failure. It was recommended for classification as a prescription medicine.

(5) Flumazenil (Anexate)

This is a benzodiazepine antagonist which is indicated for reversal of the centrally sedative effects of benzodiazepines. It was recommended for classification as a prescription medicine.

(6) Ofloxacin (Floxan)

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

(7) Felodipine (Plendil)

This is a calcium antagonist which is indicated in the treatment of hypertension. It was recommended for classification as a prescription medicine.

(8) Omeprazole (Losec)

This is an inhibitor of the gastric proton pump. It is indicated in the treatment of duodenal ulcer and Zollinger-Ellison syndrome. The committee recommended that it be classified as a prescription medicine.

(9) Zidovudine (Retrovir)

This is an antiviral agent which is indicated for the management of serious manifestations of human immunodeficiency virus (HIV) infections in patients with the Acquired Immune Deficiency Syndrome (AIDS) or AIDS-Related Complex (ARC).

Dr Riseley explained that he had first contemplated recommending this medicine for consideration as a controlled drug, as supplies to New Zealand will be limited, and apportioned in relation to the number of AIDS cases notified to the World Health Organisation. There may be a security risk at hospital pharmacies. The distributors will treat it like a controlled drug and it will only be distributed to certain hospital pharmacies for prescription by certain doctors. Hospital pharmacists will also be expected to treat it like a controlled drug. However, Dr Riseley considered that this situation would be a temporary aberration as production of zidovudine would be increased and more effective medicines for AIDS developed.

The committee recommended zidovudine for classification as a prescription medicine.

5 MEDICINES PROPOSED FOR RECLASSIFICATION

(1) Mefenamic acid

The committee considered a submission from Parke Davis Pty Ltd that mefenamic acid should be reclassified from prescription medicine to pharmacy-only medicine to allow self treatment of primary dysmenorrhoea.

Professor Edwards declared that he had a Parke Davis Research Fellow on his staff. He commented that mefenamic acid is frequently prescribed for dysmenorrhoea and is similar to ibuprofen in terms of its relatively low toxicity.

The committee recommended that mefenamic acid be reclassified as a pharmacy-only medicine when in solid dose forms of 250mg or less and with a pack size limit of 20 capsules or tablets. The committee noted that the Department of Health would assess any future applications from other distributors to market mefenamic acid as a pharmacy-only medicine for dysmenorrhoea with careful attention to labelling and pack size.

(2) Oil of tansy

Dr Riseley explained that this is one of the essential oils, which are toxic when taken in excess. They are not herbal medicines, which must consist of the crushed or dried plant. Professor Edwards commented that the Australian list of controlled herbs consisted of toxic plants.

Dr Riseley read the definition of essential oils from Martindale's Extra Pharmacopoeia, 28th Edition:

"Essential oils are volatile odorous principles which are soluble in alcohol but only to a very limited extent in water. Chemically they are mixtures of esters, aldehydes, alcohols, ketones, and terpenes."

He commented that there would be a long list if all essential oils were scheduled by name. All contain toxic compounds. Oil of tansy and some others are prohibited as flavouring agents in the United Kingdom. The committee agreed to defer consideration of oil of tansy because many essential oils were probably of equal toxicity. The whole group should be dealt with together and further information would be required.

(3) Pregnancy testing kits

In response to Mr Brock's question regarding supply of pregnancy testing kits by mail order, Mr Berry replied that pharmacies would supply them by mail if requested, but were unable to advertise this service.

6 MEMBERSHIP

Dr Riseley explained that the members' 3 year terms would expire before the September meeting. Nominations or re-nominations would be called for from the New Zealand Medical Association and the Pharmaceutical Society of New Zealand. Members could be reappointed to serve a further three years. Mr Berry stated that he would now retire from the committee, having served on it and its predecessors for 18 years. Dr Riseley, on behalf of the Committee and the Department, thanked him for his valuable contribution.

7 OTHER BUSINESS

(1) Thrombin

Dr Riseley explained that the entry for thrombin under prescription medicines reads: "Thrombin, dried human". However, a bovine thrombin is available which is technically unscheduled. The committee agreed to recommend the deletion of the words "dried human" to cover this.

The meeting closed at 2.45 pm.