MINUTES OF THE NINTH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE HELD IN THE FIRST FLOOR CONFERENCE ROOM OF THE DEPARTMENT OF HEALTH BUILDING 133 MOLESWORTH STREET, WELLINGTON COMMENCING AT 10:30 AM ON THURSDAY 28TH MAY, 1992

PRESENT

Dr S Martindale (Chairperson)
Mr R Griffith
Ms L McLauchlan
Mr G Caves (from 10.50am)
Dr J Wilcox
Dr M Herbert
Mrs C Smith (Secretary)

IN ATTENDANCE

Dr R Boyd (Morning session only)
Mr M Rowland (Morning session only)
Ms M Ewen

1 WELCOME

Dr Martindale declared the meeting open at 10:45am and welcomed members.

2 APOLOGIES

There were no apologies.

3 CONFIRMATION OF THE MINUTES OF THE EIGHTH MEETING

The minutes were confirmed and signed subject to the following amendments:

p4 Atropine and hyoscine. The words "per recommended dose" should be inserted after "0.35mg".

p4 Liquid ibuprofen. "use for acutely dehydrated children" should be "use in acutely dehydrated children".

p9 Ketoprofen. The last line of the first paragraph should refer to the 250mg strength of naproxen not the 25mg strength.

p11 Anabolic steroids. The words "which exhibit anabolic activity" should be removed from the second entry.

p14 Septomonab, the proposed International Nonproprietary Name, should be replaced by nebacumab which is now the approved International Nonproprietary Name. The new name is subject to confirmation.

p14 Sodium detiocarb should be sodium ditiocarb.

4 OPERATION AND TERMS OF REFERENCE OF THE COMMITTEE

Dr Martindale reminded committee members that this committee functions in an advisory role under Section 9 of the Medicines Act. She pointed out that the Minister may not necessarily act on the recommendations of the committee and that all recommendations made should be regarded as confidential until such time as the Minister has made a decision.

Dr Boyd then spoke about personal liability. He informed members that the Department has insurance cover in this area so that members are not personally liable for recommendations made and have no financial liability. However, members may be called upon by a court of law to substantiate recommendations made. Dr Boyd pointed out that any recommendations made are open to challenge and that decisions should be recorded correctly. He added that committee members need to be mindful that there is often considerable financial impact on a company as a result of a classification change.

Dr Boyd also commented on the fact that the Nurses' Association is seeking prescribing rights for nurses. He pointed out that there is a proposal as part of the Health Reforms process for the broadening of prescribing rights as this would assist in reducing the government's fiscal risk. Committee members would need to consider the impact of such a change in prescribing rights when making its recommendations, as a Prescription Medicine classification might no longer restrict the use of a medicine to a medical practitioner.

5 MATTERS ARISING

(1) Berberine

Although this had been declared obsolete at the 1990 meeting it has been found to be present in Murine eye drops. The committee recommended that it should not retain its previous Pharmacy-Only status but should become a General Sale Medicine to be consistent with other quarternary ammonium compounds.

(2) Hydrocortisone

Dr Martindale observed that there were two issues involved here.

The first related to the use of hydrocortisone in combination with other active ingredients. Dr Martindale pointed out that the words "with no other active ingredient" as stated in the second amendment to the Medicines Regulations when hydrocortisone was first derestricted had been omitted, probably inadvertently, during the 1990 reclassification exercise. This had led to some companies marketing hydrocortisone in combination with another active ingredient as a Restricted Medicine.
Ms McLauchlan said that she had advised pharmacists that this was now acceptable.
Dr Wilcox was happy to see hydrocortisone available as a Restricted Medicine when in combination with antifungals but was not so happy about antibacterials.
Mr Griffith expressed reservations about certain combinations

The second issue related to the 3M submission that the 15ml restriction was not sufficient for a lotion. The company requested that 100ml be the cut-off point for lotions as Restricted Medicine.
Dr Wilcox was against the use of large quantities of hydrocortisone without medical supervision.
Ms McLauchlan was for increasing the amount of lotion which could be made available but against increasing the cut-off point for cream.
Mr Griffith could see no difference between lotion and cream.

The committee decided that the 15ml cut-off point for hydrocortisone lotion should remain.

They recommended that the products containing hydrocortisone in combination with antifungals which are currently available over the counter should retain their present status. However, products containing hydrocortisone in combination with any active ingredient other than an antifungal should be a Prescription Medicine.

The decision could be open to review. Mr Griffith suggested that members keep an eye on Australia where the 0.5% strength of hydrocortisone is permitted without prescription in quantities of up to 30 grams.

(3) Nicotinamide, nicotinic acid and nicotinyl alcohol

The committee decided to accept the recommendation of the Department. All three should be classified as follows:

General Sale for 100mg and less per dose form
Restricted Medicine in doses above 100mg per dose form

No special provision need be made for sustained release forms as these would be obtainable through a pharmacy.

(4) Ketoconazole

As agreed at the last meeting, a letter was written to Dr Meech seeking his view on ketoconazole for dermatological use. Dr Meech was in favour of the committee's recommendation that the status remain Pharmacy-Only and this was notified in the New Zealand Gazette of 2 April.

(5) Amphotericin

Dr Meech was consulted and agreed with the committee that it is appropriate for amphote
ricin to be consistent with other antifungals. This was gazetted on 2 April as a Restricted Medicine when used for treatment of the oral mucosa.

(6) Clindamycin

Dr Meech concurred with the committee's recommendation to classify clindamycin as a Restricted Medicine when for topical use. This has been notified in the New Zealand Gazette of 2 April.

(7) Terfenadine

The decision at the last meeting to recommend that terfenadine become a General Sale medicine was withheld on grounds of possible cardiac effects. This information came to the notice of the Department after the last meeting of the MCC from the minutes of the 176th meeting of the Australian Adverse Drug Reactions Advisory Committee.

The Medicines Adverse Reaction Committee is to consider the matter and it was decided that any recommendation to reclassify should be deferred pending further information.

(8) Loratidine

As the company had been invited to submit a proposal for reclassification of loratidine on the basis that terfenadine had been recommended for general sale, the committee decided that loratidine should remain Pharmacy-Only at present.

(9) Astemizole

This should remain Pharmacy-Only for the same reason as loratidine.

(10) Nicotine Gum

The Secretary has sent a memo to Dr Martindale suggesting that ways be investigated to make nicotine in both gum and patches available through clinics where appropriate counselling is provided and that this be considered when revising the Medicines Regulations. Dr Martindale said that the matter would be addressed but that no mechanism had yet been determined for enabling this type of distribution to be set in place.

(11) Hydrocortisone

A letter has been written to the Pharmaceutical Society requesting that pharmacists be involved in the sale of hydrocortisone.

(12) Chloroform

Chloroform was removed from the list of scheduled medicines and a letter has been written to the Secretary of the Toxic Substances Board drawing this to their attention.

(13) Naproxen

Syntex was unhappy with the the reclassification of naproxen at the last meeting where the company lost the Pharmacy-Only availability of naproxen for dysmenorrhoea in limited pack sizes. Syntex wishes to retain both this Pharmacy-Only classification as well as the Restricted Medicine classification for wider indications.

Dr Boyd pointed out that products for dysmenorrhoea are readily available over the counter in Australia.
Mr Griffith was in favour of the Pharmacy-Only classification.

The committee decided to allow a Pharmacy-Only pack of naproxen for dysmenorrhoea in strengths of up to 250mg of naproxen per dose form and containing not more than 20 dose forms per pack.

The committee agreed that this decision will also apply to other companies who make similar applications.

(14) Ibuprofen

Discussion was deferred as the Boots company has requested extra time in which to prepare a submission.

(15) Codeine

The New Zealand Medical Association has requested that the sale of over-the-counter medicines containing codeine be banned because of the problem of "homebake" particularly in the Marlborough area.

Dr Wilcox pointed out that Panadeine is the only medicine from which codeine can readily be extracted and that the company might be able to do something about the formulation of the product to make extraction more difficult.

Mr Griffith stated that there was no point in pharmacists recording the sale of codeine containing medicines if there was no follow-up. He was of the opinion that over-the-counter availability is in the public good.

Dr Herbert said that there was a therapeutic role for codeine and that it should be left to pharmacists to take care in areas where abuse is known to occur. Ms McLauchlan and Mr Caves replied that this happened already and that there were informal networks in place which kept an eye on abuse. Ms Mclauchlan pointed out that abuse would continue no matter what action was taken.

The committee agreed that the classification of codeine should remain unchanged A letter is to be written to Sterling Pharmaceuticals requesting that they attempt to reformulate Panadeine in order to make the codeine less readily extractable.

(16) Warrant System

Dr Martindale stated that no further action had been taken in this area. Dr Boyd pointed out that this might be the right time to look at the matter in view of the rate of change in health reform. He said that the matter of prescribing rights for prescription medicines was being reviewed and that the outcome could result in a widening of the occupational groups who are able to prescribe.

The topic was deferred to the end of the meeting.

(17) Implications of reclassifying medicines

Although this had been discussed earlier in the meeting, Dr Martindale brought the Upjohn letter to the notice of the committee as an example of the type of situation which could occur when a medicine was reclassified. She stressed that care was necessary. She also explained that the Department was required by legislation to consult with companies before changing the Medicines Regulations and it was the intention that reasonable notice of classification changes be given.

Mr Caves pointed out that a time-lapse was necessary between the agreement to make classification changes and their being notified in the Gazette so that pharmacists could be informed before the changes came into effect.

Dr Boyd explained that the committee was now answerable to the Director-General under powers delegated by the Minister. He suggested that a period be allowed between the acceptance of the committee's recommendations and their notification in the Gazette. The Department should consider objections and refer them back to the committee only in cases where the objections contained new or significant material.

The committee accepted this proposal.

5 SUBMISSIONS FOR CLASSIFICATION CHANGE

(1) Hydrocortisone with natamycin and neomycin

Hydrocortisone with natamycin was covered under earlier discussion and has already been recommended as Restricted medicine.

Ms McLauchlan suggested that there was also a place for over-the-counter hydrocortisone with an antibiotic.

Dr Wilcox thought that antibiotics should be kept separate. He observed that there had not been a chance yet to observe results from the derestriction of mupirocin.

Dr Herbert agreed with this and added that there was a possibility of local sensitivity rash with neomycin.

Mr Griffith expressed reservations about multicomponent preparations because of problems relating to misapplication and diagnosis.

The committee declined to recommend that hydrocortisone with neomycin become available over the counter.

(2) Polymixin and bacitracin with or without neomycin

The committee decided that they would not proceed with the proposal to make these medicines available over the counter. It was considered that problems of resistance could occur and that there appeared to be no specific need for these products.

(3) Beclomethasone dipropionate

Ms McLauchlan saw a use for this for continuing therapy and supported a Restricted classification.

Dr Wilcox saw problems relating to potentially serious recurrent reinfection and to systemic absorption. When used for chronic rhinitis he said there could be problems with underlying asthma and the related steroid dosage.

Dr Herbert saw a case for a warrant-type system for the long-term use of this medicine. He added that people who use nasal sprays tend to over-use.

Mr Griffith also favoured a warrant system.

The committee agreed not to change the Prescription Medicine classification but that the minutes should record this medicine as a possible candidate for a warrant system.

(4) Chloramphenicol

After some discussion the committee decided to consult with the Opthalmological Society and to reconsider the matter at the next meeting.

(5) Midazolam

Mr Caves requested that pharmacists be able to supply 2 day's treatment with midazolam as a hypnotic in cases of emergency.

Dr Herbert was strongly against this on the grounds of potential abuse.

Dr Martindale pointed out that due to misuse and abuse benzodiazepines are being listed increasingly as drugs which governments are required to control. Although this is not yet the case in this country, New Zealand is required to provide documentation when supplying benzodiazepines to countries where they are controlled.

Dr Herbert commented that dependency is very fast.

The committee decided to recommend that midazolam retain its Prescription Medicine classification.

Ms McLauchlan requested that the the minustes record that pharmacists would like to be able to supply a sedative.

(6) Zopiclone

The committee agreed that zopiclone should remain a Prescription Medicine as it is still too early in its use in New Zealand to assess potential problems.

(7) Trimethoprim

There was divided opinion over whether or not trimethoprim is appropriate for over-the-counter sale for short-term use.

The committee decided to seek the comments of Dr Ross Bailey of Christchurch and of the company, Wellcome, and to return to this matter at the next meeting.

(8) Quinine

The committee recommended that quinine become a Restricted medicine when indicated for cramp, in dose forms of up to 200mg and in pack sizes of up to 5 day's supply.

(9) Corticosteroid scalp preparations

As these preparations are for the long term treatment of chronic conditions the committee felt that corticosteroid scalp preparations would be suitable products for a warrant system. They recommended that the Prescription Medicine classification be retained.

(10) Prochlorperazine

Ms McLauchlan requested a 3 day's supply of prochlorperazine for the treatment of nausea associated with migraine. This was supported by Mr Caves.

Dr Herbert was against the use of prochlorperazine for vomiting because of the extrapyramidal side effects which have been seen after only one dose. He added that it usually has no effect in established migraine. He and Dr Wilcox agreed that migraine sufferers were usually equipped to deal with the problem of nausea.

Ms Ewen explained that there is a real problem for migraine sufferers in that the only product available at present over the counter to treat nausea associated with migraine is metaclopromide in combination with paracetamol. She pointed out that a sufferer who had already dosed heavily on paracetamol would be in danger of overdosing if the combination product were then taken for nausea.

Members agreed that although prochlorperazine should remain a Prescription Medicine, metaclopromide would be suitable for derestriction.

(11) Metaclopromide

The committee recommended that metaclopromide should be available as a Restricted Medicine when indicated for the treatment of migraine and when sold in packs of not more than 10 tablets or capsules.

(12) Desoxyribonuclease

There was general agreement that desoxyribonuclease for external use should be classified as a Pharmacy-Only Medicine. It was noted that this should be covered later when dealing with the prescribing powers of nurses.

(13) Cimetidine

Members agreed that this product is for long-term treatment and that there could be difficulty identifying appropriate patients. They could see no relevance in the short-term pack proposed by the company for derestriction. Members also saw problems relating to interaction with other medication. The product was regarded as one better suited to supply under a warrant system to patients already under medical supervision.

The committee recommended that cimetidine effervescent tablets remain a Prescription Medicine.

(14) Choline salicylate and alcohol (Bonjela)

The committee agreed that this product was suitable for general sale. Choline salicylate should be reclassified as a General Sale Medicine and the Department would be left to look at a way of rewording the entry for alcohol to allow it to be used as a General Sale Medicine in this case.

(15) Flunisolide

Members agreed that this should be dealt with in the same way as beclomethasone, that is, it should remain Prescription Medicine but that the minutes record that it was considered suitable for use under a warrant system.

(16) Naproxen

This was dealt with earlier.

(17) Cetirizine

The recommendation was for this to remain Pharmacy-Only as for terfenadine, loratidine and astemizole.

(18) Erythromycin

Members decided to seek views on resistance from both Roche and from Dr Richard Meech before making a recommendation on the classification of erythromycin for topical use.

(19) Sennocides

The committee stood by its earlier decision to classify sennocides as Pharmacy-Only Medicine on the grounds that these are not appropriate for long-term use as would be implied by supermarket availability and that the use of bulk laxatives should be encouraged.

(20) Benzoyl peroxide

Members agreed that they required more supporting evidence. A recommendation will be deferred to the next meeting and Reckitt and Colman will be asked to supply evidence that the 10% strength is as safe as the 5% strength

(21) Cholestyramine resin

It was agreed that this could be recommended for sale as a Restricted Medicine. There should be some warning on the pack that this should be used under medical supervision.

(22) Calciferol

The committee agreed that this should remain a Prescription Medicine. A letter of explanation should be written to Mr Farquharson.

(23) Hydroquinone

This has already been classified as Pharmacy-Only over 2%.

6 NEW MEDICINES FOR CLASSIFICATION

Foscavir	Prescription Medicine
Oxiconazole nitrate	Pharmacy-Only Medicine

7 SUGGESTED ITEMS FOR CONSIDERATION FOR RECLASSIFICATION AT THE NEXT MEETING

No new medicines were suggested.

Warrant system

Members decided that a significant portion of time should be set aside at the next meeting for the discussion of a warrant system for prescribing medicines. Dr Martindale thought it advisable for members to comment before then in view of the speed of health reforms and invited members to send their comments to the Department as soon as possible The Department of Health would prepare background information on how this matter is dealt with in other countries.

If there was an opportunity to discuss the topic at the next meeting members agreed that they would consider whether or not the decision to supply medicine under a warrant system was best left to be decided between doctor and patient or whether a schedule of suitable medicines should be compiled by the committee.

The committee decided to consider also who should prescribe and what training requirements should be necessary.

A target date of mid-July was set for committee members to return their postal comments.

6 GENERAL BUSINESS

(1) Natamycin

The committee decided that this should be consistent with other antifungals. They recommended that natamycin be reclassified as Restricted Medicine when for vaginal use or when used for treatment of the oral mucosa.

(2) Phenylephrine for nasal use

Members recommended that this be classified as for xylometazoline, that is, Pharmacy-Only Medicine except at an airport.

(3) Duofilm

The committee agreed that this product should not be reclassified from Pharmacy-Only to Restricted because of the ether content. It was left for the Department to determine suitable wording for ether when it was not used for a therapeutic purpose.

(4) Next meeting.

Thursday November 5th was set as the day for the next meeting.

The meeting closed at 4:35pm.