MINUTES OF THE EIGHTH 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 10.00AM ON FRIDAY 6TH DECEMBER, 1991

PRESENT

Dr S Martindale (Chairperson)
Mr R Griffith
Ms L McLauchlan
Mr G Caves
Dr J Wilcox
Dr M Herbert
Mrs C Smith (Secretary)
Mrs B Cavanagh (Assistant Secretary)

IN ATTENDANCE

Dr R Boyd (part of the afternoon session)

1 WELCOME

Dr Martindale welcomed the members to the meeting and explained that this meeting was both a continuation of and a tidy-up from the last meeting as well as an opportunity to deal with new business. In addition, Dr Martindale pointed out that this meeting was also a chance to plan for the next meeting in view of the desire expressed by the Minister to free up a greater number of medicines for availability over the counter.

2 APOLOGIES

There were no apologies.

3 CONFIRMATION OF MINUTES OF THE SEVENTH MEETING

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

p 5 para 2 for "words of similar meaning" substitute "words of similar intent"

p 6 replace "except than" with "except for".

p 11 replace "lignocaine" heading with "hydrocortisone".

p 13 under entry for Selenium, "does not exceed" should be "exceeds".

p 17 8(3) second to last line, replace "read" with "accepted or declined".

p 19 Broxyquinoline Current Classification should be POM.

p 30 Cyanocobalamin entry should read "in doses of more than 50mcg per daily dose". Entry under Current Classification should read POM

p 31 Cyanocobalamin delete "except" from the lower dosage

p 52 Hydroxocobalamin requires a qualifying statement for doses of 50 mcg or less per daily dose and a second entry to classify daily doses of more than 50mcg as PM.

p 54 Indomethacin should have an entry as Part II Pharmacy for external use.

p 58 Ketoconazole should have the words "except in dermatological medicines. There should be a further entry with POM as the current classification and to cover ketoconazole for dermatological use.

p 60 Lignocaine the Current Classification should have a POM entry not PM.

p 63 Mefenamic acid for dysmenorrhoea should be R for Current Classification.

p 71 Nicotinamide an entry is required for higher dosages. This should be consistent with those for Nicotinic acid and Nicotinyl alcohol. The higher strengths for all three should be Restricted rather than Prescription Medicine.

p 102 Triamcinalone. The second entry should specify 35mcg not 25mcg.

p 104 Tubocurarine should be classified PM

4 MATTERS ARISING

(1) Preparation Fee

Dr Martindale announced that a preparation fee of $50 per hour would be paid to members. A log of time spent should be kept and submitted with the claims form for other expenses. She said that a locum fee would also be payable where applicable and members should submit that claim in the same way.
Members were informed that an improved claims form was being prepared. They were asked to provide a GST number where possible as the Department was then able to recover part of this cost.

(2) Nomenclature for classification categories

Dr Martindale told the committee that the Department had not proceeded with the proposal to change the terms used to describe the various categories of medicines classification. She explained that this change would require a change of legislation before the new terminology could be implemented. However, she added that the concept had not been lost as a review of the Medicines Regulations was proposed over the next twelve months and that as harmonisation with Australia was to be a consideration in the review, the matter of terminology for classification would not be overlooked.

Ms McLauchlan asked if labelling would differentiate between Part I and Part II Pharmacy medicines. Dr Martindale replied that the difference would be identifiable in the Regulations but not necessarily in the label statement as it would be impossible to harmonise with Australia if a specific statement was required.

Mr Griffith commented that a good structure would be necessary to ensure that the differentiation between Part I and II Pharmacy medicines was handled appropriately.

Dr Martindale concluded that there will be consultation when the Regulations are reviewed, that Dr Martindale herself will be involved and that the Therapeutics Section will have carriage of the revision. The Minister has also given support.

(3) General Sales List

Dr Martindale told the Committee that although an end-point to this project was not yet in sight, the issue had not been neglected. She explained that the Secretary was working on a database of the classification of all medicines. This database will allow General Sales medicines to be extracted. However, this list may not be exhaustive. Dr Martindale commented that there is no General Sales List at the moment. She added that the revision of the Regulations may facilitate the compiling of such a list.

Ms McLauchlan asked if companies would be consulted on this and Dr Martindale replied that a list of interested parties would be consulted.

(4) Clindamycin

It was noted that a submission had been received from Upjohn and that this would be dealt with later on the agenda.

(5) Anti-fungals for vaginal use

The Committee was happy with the suggestion from the Department that the maximum pack size available as a Restricted Medicine should be a pack equivalent to one course of treatment.

(6) Atropine and Hyoscine

Dr Martindale pointed out that when the database was being compiled it became evident that inconsistencies existed for eye preparations. The Committee agreed that eye preparations should be classified as Prescription Medicines and that no exemption statement should be included for optometrists. It was agreed that homatropine should also be included here.

Mr Griffith stated that some preparations containing atropine were available over the counter and that a dose limit should be set for Pharmacy-Only medicines containing belladonna alkaloids.

The Committee agreed that medicines for oral use containing up to 0.35mg of the alkaloids of belladonna should be Pharmacy-Only. Those above that strength should be Restricted Medicines.

(7) Liquid Ibuprofen

Dr Martindale explained that although a submission for this had been expected it had not eventuated. Dr Wilcox thought that a submission might well be submitted soon as he had been approached by a person from Boots on this subject.

Dr Wilcox stressed his previous reservations about derestricting this medicine as he is particular concerned about its use for acutely dehydrated children. He asked that the Committee bear this in mind for future decisions.

Dr Herbert commented that ibuprofen might well be safer than paracetamol but that this had yet to be satisfactorily proven.

(8) Ketoconazole

Janssen-Cilag was upset with the decision to reclassify ketoconazole for dermatological use as a Prescription Medicine and wished for this to remain Pharmacy-Only. Dr Wilcox pointed out that there had been an omission from the list of medicines at the last meeting and that ketoconazole should also have an entry for dermatological use.
It was noted that this should be added to the amendments to the minutes of the last meeting.

The Committee decided to consult Dr Richard Meech, Consultant Physician of Napier Hospital. They agreed that if the consultant considered that ketoconazole for dermatalogical use should be Pharmacy-Only they would recommend that classification. If Dr Meech considered the classification should be Prescription Medicine the company would be given a further opportunity to comment on the reasons given for such restriction.

(9) Hydrocortisone

It was noted that the Committee may have inadvertently changed the classification of the 0.5% strength and that they would return to this item later on the agenda.

(10) Nicotine

It was noted that there were several submissions and that the Committee would return to these later on the agenda.

(11) Phenolphthalein

It was noted that a letter had been written to the Pharmaceutical Society as decided at the last meeting. Ms McLauchlan said that pharmacists had been advised to discourage the use of this medicine.

(12) Sulphacetamide/Sulphadiazine

It was noted that letters and courses of action decided upon at the last meeting had been attended to.

(13) Triamcinalone

Dr Martindale reported that Bristol-Myers Squibb had agreed to make Kenalog in Orabase available as a Pharmacy-Only medicine. She said that this had been implemented in the gazette notice of 26 September but pointed out that the 25mcg quoted on p 102 of the minutes of the last meeting should be 35mcg as in the UK and that this should be amended in the minutes.

(14) Amyl nitrate

Dr Martindale explained that the Department had not proceeded with the proposal to reclassify this as further restriction would limit its availability to possum trappers. She pointed out that their suppliers are able to get a licence to supply Pharmacy-Only medicines but would not be able to supply Restricted Medicines in the same way.

Dr Martindale added that a control mechanism is already in place to license suppliers and that records of sale are kept.

(15) Fenoterol for oral use

The Committee agreed that there was no reason to restrict this medicine more severely than other medicines for the same indications as the information causing caution with fenoterol was related to the inhaled dose form.

(16) Plasma volume expanders/substitutes

It was agreed to allow the classification of Polygeline to revert to Pharmacy-Only for consistency and ease of access for St John's Ambulance staff.

(17) Camphorated oil

There were several submissions concerned with the proposal to relax the availability of camphorated oil. However, the committee did not consider a change from Restricted Medicine to Pharmacy-Only would make it any more readily available. Ms McLauchlan said that the toxicity could be explained as easily by a sales assistant as by a pharmacist. The Committee adhered to its original decision to classify camphorated oil as a Pharmacy-Only Medicine.

(18) Phenylephrine in eye preparations

The Committee agreed that a low strength should be available as a General Sales Medicine. It was decided that a strength of 0.12% or less could become a General Sales Medicine while greater strengths should remain Prescription Medicine. For consistency it was agreed that some other eye preparations should be given General Sales status for low dose preparations and that the matter would be revisited later in the meeting.

OTHER MATTERS ARISING

Ms McLauchlan raised two other matters which arose from the minutes of the last meeting.

(1) Amphotericin

Unlike other antifungal medicines amphoterincin had not been derestricted in lozenge or oral suspension form for the treatment of fungal infections of the oral muçosa. The Committee agreed to consult with Dr Richard Meech and bring the matter back to the committee only if he was not in agreement with amphotericin being made consistent with other antifungal medicines.

(2) Naproxen

At the last meeting naproxen for dysmenorrhoea was derestricted to Pharmacy-Only in limited pack sizes. Ms McLauchlan would like to see this available for other indications. The Committee decided to consider this later in the meeting along with ketoprofen.

5 RECONSIDERATION OF PREVIOUS RECOMMENDATIONS

(1) **Hyoscine** (availability to optometrists)

The Committee decided that this should remain a Prescription Medicine with no qualifying statement for optometrists. Members agreed that there were more suitable medicines of shorter duration available for diagnostic purposes and this medicine was more suited to therapeutic practices which were inappropriate for optometrists.

(2) Terfenadine

Dr Martindale explained that the Department had not proceeded with the decision at the last meeting to make terfenadine a General Sales Medicine. She said that the Department had reservations in that if this medicine became General Sales then natural therapists could manufacture without licensing control of their premises. However, the Committee was in favour of the reclassification and it was decided to make this a General Sales Medicine with a restriction of five days' supply (ie packs of 10 tablets.) The Committee also decided to seek submissions from companies with regard to a similar declassification of Claratyne(loratidine) and Hismanal(astemizole).

(3) Nicotine gum

The Committee agreed that there should be no change to the present classification of Pharmacy-Only Medicine for nicotine in both gum and patches. However, they would like to see it available through clinics or where counselling is provided and would like the Department to look for a way, before the next meeting, of making this possible.

(4) Hydrocortisone

Dr Martindale pointed out that the reclassification of the 0.5% strength to Restricted Medicine may have been inadvertent. This was generally acknowledged although Dr Wilcox felt that 0.5% hydrocortisone should never have been available as Pharmacy-Only. Mr Griffith said that a good reason was needed to make a medicine less readily available and that he could see no good reason in this case. Mr Caves and Ms McLauchlan thought that recording the sale was a drawback though there was general agreement that the guidance of a pharmacist was desirable. Ms McLauchlan suggested that the Pharmaceutical Society should be involved and it was agreed that the 1% strength should remain Restricted and the 0.5% revert to Pharmacy-Only. The Department would write to the Pharmaceutical Society requesting that pharmacists be involved in the sale of hydrocortisone and giving reasons for this request.

(5) Chloroform

It was decided that no scheduling was required for chloroform as it has no therapeutic purpose and would be better dealt with under toxic substances legislation.
The Secretary is to write to the Secretary of the Toxic Substances Committee drawing it to their attention in case they wish to schedule it. Chloroform is to be deleted from the medicines schedules.

(6) Mupirocin

The Committee considered both the Canterbury Area Health Board submission against the derestricting of mupirocin to Restricted Medicine and the Department paper in favour of this reclassification. Members decided that use should continue as decided at the last meeting and mupirocin should continue as a Restricted Medicine.

(7) Ketoprofen

As the company was seeking Pharmacy-Only status for the 25mg dose the Committee thought that some other NSAIDs should be considered alongside ketoprofen. It was decided that:

i) Naproxen up to and including 250mg or equivalent
ii) Diclofenac and its salts up to and including 25mg
iii) ketoprofen and its salts up to and including 25mg

each with a pack size restriction of not more than 30 tablets or capsules should be Restricted medicines. This would mean a reversal of a decision at the last meeting to make naproxen for dysmenorrhoea available as a Pharmacy-Only Medicine and the company should be notified immediately to avoid possible problems with new packaging. The 25mg strength of naproxen would not be limited to use for dysmenorrhoea only.

It was also decided that:

iv) Mefenamic acid for dysmenorrhoea should remain Pharmacy-Only.

v) Ibuprofen up to 200mg in each dose form should remain Pharmacy-Only at present with no restriction on pack size but that the secretary would write to those companies that market ibuprofen asking for reasons why ibuprofen should remain Pharmacy-Only.

The decision concerning ibuprofen was based on the fact that there has been considerable use of ibuprofenon an over-the-counter basis. However, Dr Wilcox referred to papers throwing doubt on the safety of ibuprofen.[1,2,3,4]. It was agreed that copies of these articles should be sent to the companies when requesting their submissions. Any submissions received would be considered in consultation with Dr R Walker of Christchurch Hospital.

1 Non Steroidal Anti Inflammatory Drugs: Monitoring to Help Prevent Serious Adverse Effects. Barbara Cardario MSc and Allan A McKinnon MEd (British Columbia Drug and Poison Info Ctr) *Canadian Family Physician* Vol 37: 171-180 (January 1991)

2 *Pain Control and the Use of Non-Steroidal Analagesic Anti-Inflammatory Drugs.* G Nuki (Dept of Medicine, Rheumatic Diseased Unit, University of Edinburgh) *British Medical Bulletin* (1990) Vol 46, No 1 pp 262-278 (Published by the British Council)

3 *Potential for Renal Damage with long-term OTC Analgesic Use.* Dr R Walker, Dept of Medicine, Christchurch Clinical School, Univ of Otago. *NZ Medical Journal* 104: 182-183 8th May 1991

4 *Focus on Rheumatology - Patient Management New Zealand* vol 20 (9) pp15-18 *NSAID-Induced Disease - An Emerging Epidemic* Dr R R Grigor

6 NEW SUBMISSIONS FOR CLASSIFICATION CHANGE

(1) Diclofenac for dysmenorrhoea

This was covered under discussion for ketoprofen.

(2) Sodium cromoglycate for nasal administration

The Committee agreed to the Department's submission to reclassify this as a Restricted Medicine

(3) Retin-A (tretinoin)

Dr Martindale pointed out that it was not clear exactly what classification the company was seeking in its submission. However, it was agreed that this should be classified as Restricted but only in respect of an acne preparation. If a new indication were sought the matter would need to be brought back to the Committee to ascertain whether or not the Restricted classification was appropriate for the new indication. The Department will need to vet the new packaging and labelling for Retin-A with particular reference to warning statements in pregnancy.

(4) Beta Carotene

The Committee decided that the cut-off level for the classification of this medicine should be a maximum daily dose of 18mg. Medicines containing up to 18mg per daily dose should be General Sales and those above 18mg should be Prescription Medicines.

(5) Flucortalone (Doloproct, Schering)

The request to have this medicine reclassified as a Restricted Medicine was not recommended on the grounds that this is a fluorinated steroid and no good reason could be found to derestrict its use.

(6) Clindamycin (Upjohn)

The Committee agreed that clindamycin for topical use could be reclassified as Restricted Medicine subject to advice on the issue of resistance from Dr Richard Meech that derestriction was appropriate.

(7) Steroid hormones with anabolic activity

Dr Martindale explained that it was proposed to make a group entry in Schedule I to cover this group of medicines so that it would be possible to control sports medicine abuse in those medicines not covered by the present androgen-type headings.

The Committee agreed on the following wording for two entries:

Steroid hormones: either natural or synthetic, which exhibit anabolic activity.

and:

Anabolic steroids: either natural or synthetic, which exhibit anabolic activity.

(8) Quinine (Nicobrevin)

The Committee decided that a maximum daily dose of 50mg would be a suitable cut-off point for the restriction of this medicine. A daily dose of up to 50mg could be classified as a General Sales Medicine and strengths greater than this should remain Prescription.

(9) Physostigmine for optometrists

It was agreed that this should remain a Prescription Medicine but that an exemption should be made for use by a registered optometrist for the purpose of use in his practice as an optometrist.

(10) Lignocaine for eye use

A decision was made that this should also remain a Prescription Medicine but should have an exemption for optometrists as above. It was noted that proxymetacaine should be treated in the same way.

(11) Fluorescein eye preparation

The Committee decided that this should retain its Pharmacy-Only classification.

(12) Gastrolyte

Members agreed they they would like to see Gastrolyte solution available for general sales but recommended that potassium chloride remain a Pharmacy-Only Medicine. It was suggested that the Department worked out a qualifying statement for the potassium chloride entry to the effect that it remained Pharmacy-Only except in medicines for oral rehydration therapy.

(13) Folic acid and Zinc

The Committee saw no harm in altering the cut-off point for these medicines in order to bring them into line with Australian regulations. It was recommended that folic acid in medicines with a recommended daily dose of up to 500mcg become a General Sales Medicine and strengths greater than this become Pharmacy-Only. Similarly, the recommendation was made to increase the cut-off point for zinc so that medicines containing up to 25mg per daily dose of elemental zinc become General Sales and those above this strength remain Prescription.

7 NEW MEDICINES FOR CLASSIFICATION

Dr Martindale explained that the Medicines Assessment Advisory Committee had already recommended a classification for some of these. The following classifications were recommended:

4-hydroxyandrostenedione	PM
apraclonidine hydrochloride	PM
azithromycin	PM
botulinium toxin	PM
calcipotriol	PM
carvedilol	PM
cefazolin; and its salts	PM
cefodizime	PM
cefpodoxime proxetil	PM
cetirizine; and its salts	PM
cisapride	PM
clarithromycin	PM
clodronic acid disodium salt	PM
colfosceril palmitate	PM
dexfenfluramine	PM
didanosine (DDI)	PM
edoxudine	PM
epoprostenol	PM
esmolol; and its salts	PM
etidionate disodium	PM
fenoldopam	PM
filgrastim	PM
fluoxetine	PM
fluticasone; and its esters	PM
formoterol	PM
fosinopril	PM
fotemustine	PM
gadopentetate demeglumine	PM
gestrinone	PM
granisetron; and its salts	PM
halofantrine	PM
hydrocortisone 17 butyrate	PM
hydrocortisone sodiumsuccinate	PM
ilomedin	PM
ioversol	PM
isradipine	PM
itraconazole	PM
L- asparaginase	PM
lacidipine	PM
lamotrigine	PM

levocabastine	R
lomefloxacin; and its salts	PM
menthyl valerate	G
mercaptoethane sulphonate sodium(mesna)	PM
molgramostim	PM
mometasone; and its esters	PM
moricizine; and its salts	PM
nafarelin; and its salts	PM
nicergoline	PM
nilutamide	PM
nisoldipine	PM
paroxetine	PM
perindopril	PM
permethrin; 1% or less	G
permithrin; more than 1%	PM
pinacidil	PM
pipecuronium bromide	PM
pravastatin; and its salts	PM
quinapril	PM
ramipril	PM
remoxipride	PM
roxithromycin	PM
salmeterol	PM
septomonab	PM
sodium detiocarb	PM
sumatriptan; and its salts	PM
tazobactam	PM
temafloxacin	PM
terazosin hydrochloride	PM
terbinafine; for external use	POM
terbinafine; except for external use	PM
thymoxamine; except when used by an optomestrist for use in his practice as an optometrist	PM
tolrestat	PM
tropisetron	PM
vigabatrin	PM

Key		
	PM	Prescription Medicine
	R	Restricted Medicine
	POM	Pharmacy-Only Medicine
	G	General Sales Medicine

8 PROPOSALS FOR DERESTRICTION

Dr Martindale asked the Committee for proposals for classes of medicines which could be considered for derestriction at the next meeting.

She suggested that desoxyriboneuclease could be considered.

Ms McLauchlan produced a written submission from the Pharmaceutical Society.

Dr Wilcox asked that, in view of increased doctors' and prescription fees, the matter of a warrant system or an extended supply system for prescribing be reconsidered. Members agreed that the Department would contact interested parties and put forward a proposal at the next meeting.

Ms McLauchlan queried the decision on colchici
ne at the last meeting but agreed to stick with the Prescription Medicine classification.

9 GENERAL BUSINESS

Codeine

Dr Wilcox was concerned with abuse problems and thought that all medicines containing codeine should be Prescription Medicines. He mentioned a remit to the November/December meeting of the Medical Association Council by the Nelson/Marlborough division of the Medical Association. This remit proposed that all medicines containing codeine become Prescription Medicines even when in combination with paracetamol Dr Boyd said that this remit had not yet been brought to the notice of the Department. Ms McLauchlan reported that the Pharmaceutical Society would not support further restriction of these medicines and she was of the opinion that making them Prescription Medicines would not solve the problem of abuse.
It was agreed that the matter should be put on the agenda for the next meeting.

Travel sickness preparations

Dr Martindale pointed out that there was a lack of consistency at the moment in that not all travel sickness medicines had an exemption from the Pharmacy-Only classification that allowed them to be sold at transport terminals. However, members decided that some travel sickness medicines were not considered suitable for such derestriction and that the status quo should be maintained.

Cyanocobalamin/Hydroxocobalamin

Dr Martindale pointed out a lack of consistency in the entries on the classification schedules between these two medicines. It was agreed that another entry should be made to the Pharmacy-Only schedule for hydroxocobalamin above 50mcg per daily dose.

The meeting closed at 4:25pm