MINUTES OF THE TWELFTH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE HELD IN THE FIRST FLOOR CONFERENCE ROOM OF THE MINISTRY OF HEALTH BUILDING 133 MOLESWORTH STREET WELLINGTON ON THURSDAY 25 NOVEMBER 1993

PRESENT

Dr S Martindale (Chair)
Mr R Griffith
Dr M Herbert
Dr J Wilcox
Mr G Caves
Miss U Egan
Mrs C Smith (Secretary)

IN ATTENDANCE

Dr S Jessamine
Ms A Surman (morning only)
Ms L Middleton (morning only)
Ms S Wellington (afternoon only)
Ms R Greenaway (afternoon only)

1 WELCOME AND OPENING REMARKS

Dr Martindale declared the meeting open at 10:30am and welcomed members to the twelfth meeting. She introduced Ursula Egan who had replaced Linda McLauchlan as one of the Pharmaceutical Society representatives on the committee.

The committees' attention was drawn to the new Members' Handbook which had been sent to members with the agenda material for the meeting. Dr Martindale suggested that it would be useful for members to refresh their memories about the terms of reference of the committee and other matters before each meeting. The secretary was thanked for the preparation of the Handbook.

Dr Martindale also pointed out the need for confidentiality of matters discussed at meetings. She stressed that this was a ministerial advisory committee and that until the Minister had seen the minutes and made a decision about the recommendations, the matters discussed at the meeting should remain confidential. Dr Martindale stated that the issue of confidentiality was becoming more complex and that she would expand on the subject later in the meeting.

2 APOLOGIES

There were no apologies.

Dr Martindale took the opportunity to introduce to committee members the observers at the meeting. She introduced Ailsa Surman and Sheree Wellington (present later in the meeting) the two new evaluators in the Therapeutics Section and Lesley Middleton from Research and Analytical Services. Dr Martindale explained that the Therapeutics Section had commissioned a survey of the operation of the three ministerial advisory committees that it services. The survey was being carried out by Lesley Middleton and Ruth Greenaway of Research and Analytical Services.

3 CONFIRMATION OF THE MINUTES OF THE ELEVENTH MEETING

It was noted that the new procedure was now in place to consult with members on the minutes closer to the time of the meeting. This had been done and any corrections had already been made. The minutes of the eleventh meeting were confirmed.

4 MATTERS ARISING

i Legislation review update

Dr Martindale reported that a discussion paper was being prepared and although progress had been made there was not a lot to add since the last meeting. Review in the context of wider health reforms had taken longer than anticipated and there had also been some delay due to the outcome of the election. Dr Martindale said that there was no date set for publication but that she hoped the paper would be published in the new year.

ii Confidentiality of Reports

Dr Martindale explained that special confidentiality considerations often applied to material supplied by other regulatory agencies. She said that this applied particularly to Australian material and that the Australians had not yet worked out their own rules. For that reason it had still not been determined what rules should apply in NZ. In the meantime confidential material would be marked as such and the confidentiality should be respected and should continue to be respected even after the Minister had made a decision on the matter concerned. The committee would be notified when there was any change to this approach.

iii Codeine update

Dr Martindale told the committee that this had been put on the agenda mainly so that the topic would not be overlooked. She explained how, after the Minister had received the recommendations made by MCC and the Drugs Advisory Committee, the Ministry had consulted with the companies concerned in early June about the possibility of making the codeine less readily extractable from their preparations. These replies had gone straight to the Minister. No outcome had been reported back to the Ministry before the election and a decision would not now be made until after the appointment of a new Minister. Dr Martindale hoped to be able to provide an update at the next meeting.

iv Prescribing Rights draft discussion paper

Dr Martindale informed the committee that this was a draft only and had been supplied on request for the interest of members. She asked that confidentiality be respected until such time as the final version was published and said that no date had been finalised for publication. Dr Martindale understood that the Ministry had already requested some changes and that it was intended that the paper be published as the work of John Shaw of the School of Pharmacy rather than as a Ministry document.

Some discussion followed in which members commented on the lack of direction indicated by the paper and the broad range of abilities covered by the range of practitioners discussed in the paper. However, it was agreed that it would be necessary to see the final version before making further comment.

v Reclassification Impact Study update

This study, commissioned with Research and Analytical Services, was at the planning stage and due to be completed by the end of the current financial year. Dr Martindale reported that it had not yet been established which products should be selected for inclusion in the study. She pointed out that this selection would affect the protocol of the study. Dr Martindale said she wanted to assure members that the matter had not been overlooked and would be dealt with by Therapeutics and Research and Analytical Services. She hoped to have more to report at the next meeting.

vi Reference list of specialist consultants

Dr Martindale said that there was a Ministry-wide list of specialists used. She called for suggestions for names to be included. Dr Jessamine said that he had a database of consultants used by the Therapeutics Section. It was agreed that Ministry sources would be used when it was considered necessary to seek specialist advice.

vii Non-sedating antihistamines

Dr Martindale summarised the situation to date. She reminded members that at the previous meeting the MARC had requested that terfenadine, astemizole and loratadine be reclassified as restricted medicines but that MCC had not thought the move to be appropriate in view of the limited information available. It had been agreed that the matter would be returned to the agenda and that Dr Martindale would update members on the situation from the most recent meeting of the Australian Drugs and Poisons Schedule Standing Committee.(DPSSC.)

Dr Martindale explained that in Australia loratadine was bound by the two-year rule relating to the classification of new chemicals and although the Australian Adverse Reactions Committee had asked that loratadine not be more restrictively classified than terfenadine and astemizole, the DPSSC were adamant about maintaining the two-year rule. However, they had agreed to look with favour on classifying loratadine in the same way as terfenadine and astemizole when the two-year period expired.

Members noted the article prepared for the *Prescriber Update* by Dr Tim Maling which had been supplied in support of the MARC request to reclassify the non-sedating antihistamines to restricted medicine.

After some discussion the committee agreed that there was still insufficient evidence to cause them to alter their recommendation at the previous meeting to leave the non-sedating antihistamines as pharmacy-only medicines. They felt it would be unwise to move loratadine to general sales at this time. It was agreed that non-sedating antihistamines should be returned to the agenda if new information came to hand.

Recommendation

That there be no change to the current pharmacy-only classification of terfenadine, loratadine and astemizole.

viii Claratyne syrup

Concern had been expressed by one of the members at the previous meeting about the possibility of use for children under two years. Dr Martindale reported that files showed the product was clearly labelled as contraindicated for use in children under 2 years of age. She added that unless the committee wished to consider reclassifying the product, the possible misuse of the properly labelled product was not within the brief of MCC.

ix H_2 receptor antagonists

Dr Martindale summarised the situation to date. She explained that the Ministry had felt it was appropriate to ask MCC to engage in a further round of consultation before proceeding with a recommendation. Given that various queries had been raised, it had seemed reasonable to prolong the consultation process. Dr Martindale said that the Ministry had supported in principle the reclassification of these medicines to OTC status with certain conditions attached. It was now necessary for the committee to provide the Ministry with principles which it would use when evaluating an application to approve an OTC pack. She said that a changed medicine notification would be necessary to gain approval for an OTC pack. She suggested that members first consider the comments arising from the consultation process and determine whether or not they had changed their earlier position on the proposed reclassification. Dr Martindale added that all companies involved with these medicines now appeared to be in favour of having an OTC presentation of their product. She stressed the importance of there being an OTC pack containing all the appropriate patient information in plain language, rather than having prescription packs broken down to suitable size by a pharmacist. She also pointed out that at the previous meeting it had not been possible to establish precise indications or dosages for specific products as the relevant material had not been available.

Reporting on events in Australia, Dr Martindale said that the Australians intended to reclassifiy these medicines and were about to publish their intention to do so. Because of their 2-year rule they would be able to consider cimetidine, famotidine and ranitidine but not nizatidine. The DPSSC had accepted the material from the June meeting of MCC and intended to use similar pack warnings. They also intended to include warnings for cimetidine concerning interactions with warfarin, phenytoin, and theophylline. Dr Martindale added that the Australian scheduling committee did not concern itself with indications when reclassifying medicines.

Dr Martindale also pointed out that the British indications, dosages and treatment periods were now available and should be considered. She suggested it might be sensible for NZ to adopt the 2-week limit of treatment accepted in Britain rather than the 10-day period suggested at the previous meeting. She added that Australia intended to do the same.

The committee considered and discussed the information presented by the companies and professional bodies and agreed it was in favour of proceeding with the proposed reclassification provided the medicines could be presented in approved OTC packs. It was agreed that rather than establish precise dosages, indications and warning statements, a set of principles should be agreed to and that these would be used by Therapeutics evaluators when assessing changed medicine notifications for OTC presentations.

The following framework was decided on and it was agreed that relevant details for each medicine would be finalised by evaluators in the Therapeutics Section at the time a changed medicine notification for an OTC pack was evaluated. Evaluators would work within the framework established by MCC. Some latitude would be allowed within the framework depending on the evidence supplied for each individual medicine. The medicines schedule would be worded in such a way as to allow these medicines to be sold OTC only when presented in approved OTC packs.

Recommendation

That cimetidine, famotidine, nizatidine and ranitidine become restricted medicines when they are sold in OTC-specific packs appropriately labelled. It is recommended that the medicines be used only for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity or on the recommendation of a doctor. The OTC pack must contain not more than 14 days' supply

That recommended dose limits be established for each medicine by Therapeutics Section evaluators as being suitable for the OTC indications specified and that these are supported by clinical data.

That comprehensive consumer information be provided in plain language. The consumer information must contain warnings and precautions worded in a manner considered appropriate by the Therapeutics Section of the Ministry of Health for each individual medicine. The warnings and precautions must cover the following:

i	*a warning not to use the medicine for any purpose other than that specified on the pack unless under the supervision of a doctor*
ii	*the need to consult a doctor if symptoms persist*
iii	*the need to consult a doctor if symptoms recur*
iv	*the need to consult a doctor if symptoms become worse*
v	*the need to consult a doctor if new or additional related symptoms occur*
vi	*a warning against use with non-steroidal anti-inflammatory medicines unless under the supervision of a doctor*
vii	*a warning to use with caution if over 40 years of age*
viii	*a warning not to use without medical supervision if warfarin, phenytoin or theophylline are being taken (for cimetidine only).*

x Nicotine for nasal use

Dr Martindale told the committee that since the last meeting when this had been given a restricted medicine classification, evaluators had expressed concern about the product and the matter was to be reopened. Dr Jessamine outlined these concerns which were contained in the copy of the Medical Advisor's Report provided for members. Dr Jessamine also pointed out that the company had initially requested a prescription classification for the product but had switched to wanting restricted status just before the last meeting.

It was noted that the product had not yet been approved for marketing.

Members concluded that, in light of the new information received, nicotine for nasal use was not an appropriate candidate for OTC sale at this stage. It was suggested that the three-year rule established as a criterion for OTC sale of a new chemical could also apply to a new route of administration.

Recommendation

That nicotine for nasal use be classified as prescription rather than restricted medicine.

5 SUBMISSIONS FOR RECLASSIFICATION

i Paramax (metoclopramide & paracetamol) SmithKline Beecham

Members agreed unanimously to the request of SmithKline Beecham to increase the size of the OTC pack of Paramax from 6 to 10 tablets.

Recommendation

That the Restricted Medicine entry for metoclopramide in the First Schedule of the Medicines Regulations be amended to read as follows:

> *Metoclopramide; when compounded with paracetamol and in a pack size of not more than ten tablets or capsules*

ii Opticrom (sodium cromoglycate) Fisons

This submission had been initiated by the Ministry so that access to the eye preparation could be improved. As Opticrom could be obtained only through a hospital pharmacy the nasal preparation was being recommended for use in the eye. Members agreed that this was inappropriate and could see no problems with OTC availability of the eye preparation. It was agreed that this would be most appropriately classified the same way as the nasal preparation.

Recommendation

That sodium cromoglycate for eye use be reclassified from prescription to restricted medicine.

iii Pregnancy Test Kits

Dr Martindale explained that under the present legislation these are medicines and have been classified as pharmacy-only under the heading of diagnostic medicines. However, she pointed out that these might not continue to be regarded as medicines under the new legislation.

Dr Martindale also said that it had been proposed at the DPSSC meeting in Australia the previous week that pregnancy test kits become general sale items.

It was noted that the products were well-labelled and reliable. Concern was expressed about possible inappropriate storage in some general sale outlets and also the lack of confidentiality involved in purchase through these outlets. Members also felt that there was often a need for counselling at the point of sale.

Dr Martindale pointed out that if pregnancy test kits were reclassified manufacturers would be required to relabel the kits.

It was agreed that before any recommendation was made to reclassify pregnancy test kits, consultation should be undertaken with those who would be affected by a reclassification.

iv Optometrists/Ophthalmologists joint submission

It was acknowledged that there had been some debate in the area concerning those prescription medicines which were suitable for optometrists to use in the course of their practice. The Ophthalmological Society of NZ and the NZ Association of Optometrists had jointly reached agreement on a suitable list of medicines for optometrists to use. They had also consulted with the Ministry about the matter.

Members agreed that it was reasonable to respect the consensus agreed to by the two bodies and accepted that the joint submission presented a clear picture of what the two bodies would like to see happen.

Recommendations

That the committee accept the recommendations contained in the joint submission from the NZ Association of Optometrists and the Ophthalmological Society of NZ.

That the following medicines should continue to have exemption from prescription status for use by optometrists in the course of their practice:

amethocaine proxymetacaine tropicamide

That the above medicines be used only for the purpose of facilitating examination of the eye and not for the purpose of treatment.

That all other medicines not mentioned above and which at present have an optometrist exemption in the prescription category of the medicines schedule should have that exemption removed from the schedule.

That any subsequent changes to the schedule concerning optometrist access to prescription medicines used in the eye should be made only after consultation with both the NZ Society of Optometrists and the Ophthalmological Society of NZ

v Phenylephrine for eye use

The submission from Professor Garner of the Department of Optometry at Auckland University requested optometrist availability for a 2.5% strength of phenylephrine for use as a mydriatic. The committee agreed that in light of the recommendation made in the joint submission from the optometrists and ophthalmologists they would refuse the request.

Recommendation

That there be no change to the classification of phenylephrine for use in the eye.

vi Potassium citrate

Dr Martindale explained that when potassium chloride had been reclassified from pharmacy-only to general sales when used in medicines for oral rehydration therapy, potassium citrate, which is also used in this way, had not been reclassified. Members agreed to recommend the reclassification.

Recommendation

That potassium citrate be classified as general sale medicine when used for oral rehydration therapy.

NEW MEDICINES RECOMMENDED FOR CLASSIFICATION BY MAAC

The following new chemicals were recommended for classification as prescription medicines by the Medicines Assessment Advisory Committee

Acrivastine	Cabergoline	Fluvastatin
Mivacurium chloride	Recombinant human DNase	

SUGGESTED ITEMS FOR THE NEXT MEETING

Contact lens solutions

Dr Martindale explained that there was a need to review the classification of these as a number of classification inconsistencies had come to the attention of the Ministry. She said that Therapeutics would investigate this and provide material for the next meeting.

Comparison with Australian scheduling

Dr Martindale said that the comparison between the scheduling of medicines in Australia and NZ was almost complete and that this would provide a source of new material for the committee. She said that there were about 130 medicines which were classified differently in the two countries but that some of these differences were not significant. She suggested that a list of scheduling differences be brought to the next meeting along with some proposed criteria for prioritising the review of the list. Dr Martindale continued that the outcome was unlikely to be complete harmonisation with Australia but that where NZ did differ from Australia, the committee needed to be comfortable with the reasons for that difference. She suggested that the committee might look first at amending those NZ scheduling entries it felt to be unsuitable. The Australian committee would then be provided with the updated list so they could consider amendments to Australian schedules.

Local anaesthetics

The secretary said that there appeared to be a number of discrepancies in the classification of local anaesthetics. She said that this would be looked at within the Therapeutics Section and, if necessary, brought to the committee at the next meeting.

GENERAL BUSINESS

Antazoline

It was brought to the notice of the committee that antazoline appeared to have been inadvertently granted an exemption from pharmacy-only status when sold at an airport for nasal use. Members agreed that this use was inappropriate and that there was no longer a nasal product available.

Recommendation

That antazoline for nasal use should remain a pharmacy-only medicine without an exemption for sale at an airport.

Other

Miss Egan suggested that MCC might wish to consider the reclassification of Lyclear(permethrin). The secretary explained that the Therapeutics Section had considered the matter and had made a decision not to bring Lyclear to this meeting of the committee. Dr Martindale explained that, ironically, making permethrin available OTC might well cause it to become less accessible to the consumer because of its high cost. This would occur if the product were to be removed from the Drug Tariff.

The committee wished to know if there was any link between the classification of a medicine and its place on the Drug Tariff. It was agreed that the secretary should write to PHARMAC seeking a policy statement on whether or not there was a relationship between the classification of a medicine and the decision to fund on the Drug Tariff.

The meeting closed at 2:30pm