MINUTES OF THE THIRTEENTH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE HELD IN MEETING ROOM GO6 ON THE GROUND FLOOR OF THE MINISTRY OF HEALTH BUILDING, 133 MOLESWORTH STREET WELLINGTON ON THURSDAY 26 MAY 1994 COMMENCING AT 10:30am

PRESENT

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

IN ATTENDANCE

Dr R Boyd (till 11:25am)
Ms A Surman
Ms A Cossar
Ms L McLauchlan (for local anaesthetics)

1 WELCOME

Dr Martindale declared the meeting open at 10:30am and welcomed members to the thirteenth meeting.

2 APOLOGIES

There were no apologies.

3 CONFIRMATION OF THE MINUTES OF THE TWELFTH MEETING

The minutes of the twelfth meeting were confirmed by the committee and signed by the chairperson.

4 MATTERS ARISING

i Legislation review update

Copies of the discussion paper on the review of the medicines legislation entitled *Medicines & Medical Devices* were distributed to members. Dr Martindale announced that the paper had been launched the previous week. The philosophy behind the changes was outlined briefly and Dr Martindale went on to explain the 3-month consultation period which would follow the publication of the document and the nature of the public meetings planned for each of the Regional Health Authority areas. She explained that submissions would be analysed at the end of the consultation period and that the results of the analasys were to be reported to cabinet by the beginning of December. It was desirable that approval to draft new legislation could be granted before the commencement of the parliamentary recess. Dr Martindale said that the Minister had indicated a desire to take the new legislation to the House in 1995.

There was brief discussion about the proposed restrictions on advertising in the new legislation and Dr Martindale acknowledged that this would be contentious. She pointed out that C P I (Consumer Product Information) would not be considered as advertising.

ii Prescribing Rights Discussion Paper

Dr Martindale informed members that the discussion paper on Prescribing Rights prepared by Professor John Shaw was due for publication in mid-June. She explained that the Ministry did not yet have a position as to whether or not prescribing rights should be widened. However, she pointed out how a widening of prescribing rights could be accommodated in the new legislation if required. She said that a new role in the new legislation had been proposed for the Medicines Classification Committee in considering the prescribing rights of a wider range of practitioners and suggested that members might wish to consider ways of dealing with this.

A copy of the completed Prescribing Rights discussion paper was promised to members when it became available.

iii Classification Impact Study

A brief memo outlining the study and prepared by Ms Ewen, the project manager, was distributed to members and read out by the secretary. It was noted that the study was already under way. Dr Martindale explained that the medicines selected for the survey were those most likely to have a sufficiently high sales volume to allow a valid study to take place. She briefly outlined the structure of the study and the method of selecting consumers for the consumer survey part of the study. She also explained the role of Health Research and Analytical Services who were conducting the study. Members were promised the results of the study when they became available. This was expected to be by the end of the current financial year.

v Comparison with Australian Scheduling

Dr Martindale reported that she had attended the first meeting of the restructured Australian scheduling committee now known as the National Drugs and Poisons Schedule Committee and which reported to the Australian Health Minister's Advisory Council. She informed the committee that there were now industry and consumer representatives on this committee along with doctors, a Pharmaceutical Society nominee and a number of State or Territory Health Department administrators as well as technical experts, such as toxicologists on both State and Territory level. She said that it had been interesting to observe the interactions of the membership of the restructured body and she felt that some effort would be required to make the committee work in a positive manner.

Consultants had been commissioned to review and make recommendations on streamlining the administration of the committee and Dr Martindale felt that there could be elements of the review from which the NZ Ministry of Health could benefit. One particular area to be examined is the possibility of using electronic means to deal with out of session work so that the committee would not need to meet as frequently.

Dr Martindale reported that the exercise to compare item by item the classification of medicines in the Australian and NZ schedules had been completed. She said there were about 200 medicines classified differently and that about 17 of these were more restrictively classified in NZ. It was now up to the Ministry to put some work into deciding how best to deal with these differences. She said that it was desirable to harmonise where practicable and that industry was generally in favour of this especially for packaging reasons. At this point the question of the difference in classification of inhaled bronchodilators was raised. Dr Martindale was of the opinion that the two countries would never harmonise completely and she did not feel that they should necessarily do so.

Dr Martindale said that the Ministry would report back to the committee when it had developed a strategy to deal with the scheduling differences.

vi Codeine update

Dr Boyd reported that he had attended a meeting of a joint committee of Police, Customs and Health and had explained that one of the manufacturers had found a paracetamol/codeine combination from which it was not easy to extract the codeine. He added that the company was working on the formulation in Australia. He said that the police were no longer pressing for change of classification after loss of a court case in Christchurch and for other reasons, and that the parties involved were happy to await the results of the company's testing. Dr Boyd saw no change in availability or pack size in the foreseeable future.

5 SUBMISSIONS FOR RECLASSIFICATION

i Edetic Acid

Dr Martindale advised that the Ministry had discovered that this medicine, currently classified prescription medicine, was present in a number of products which would not be appropriately classified as prescription medicines. In a paper circulated before the meeting the Ministry had suggested a way of rescheduling edetic acid to rectify the problem.

Dr Martindale pointed out that there was a need to schedule this medicine at low concentration levels. She explained that the initial Ministry proposal circulated to members would not cover all preparations and that a new proposal had been prepared. This was tabled and outlined by Dr Martindale.

The committee considered levels present in different forms of chelation therapy. Dr Wilcox pointed out that chelation was usually conducted under medical supervision.

Members could see no problems with the 0.25% cut-off point suggested in the revised Ministry proposal. They recognised that injectable medicines containing 0.25% and less would automatically become pharmacy-only medicines under the blanket cover for injectable medicines. They agreed that the matter could be returned to the committee for further discussion if problems arose.

Recommendation

That edetic acid be classified as a prescription medicine when in strengths greater than 0.25% except when in contact lens solutions.

That edetic acid be classified as general sale medicine when in strengths of 0.25% or less and when in contact lens solutions.

ii Contact Lens solutions

Some of these had been found to contain edetic acid and other scheduled medicines which would exclude their sale through optometry practices. Dr Martindale suggested that the matter not be discussed at the meeting as the scheduled medicines present in contact lens solutions were also used in a variety of other ways. The committee agreed that the approach suggested in the Ministry paper did not require change but could be dealt with at an administrative level within the Ministry.

Dr Martindale suggested that in principle contact lens solutions be scheduled as general sale medicines. If other scheduled medicines were to be included in contact lens solutions they should not effect the scheduling of these.

Dr Boyd explained the historical reason for categorising contact lens solutions as medicines and pointed out that these reasons would probably not be applicable today. He added that contact lens solutions would not be considered as medicines under the new legislation.

The item was removed from the agenda.

iii Pregnancy Test Kits

At the last meeting the committee decided to consider these for possible scheduling as general sale medicines. The Ministry was to investigate.

Dr Martindale said that under the new legislation pregnancy test kits were likely to be considered as devices and unlikely to be subject to any form of scheduling. She added that in Australia a decision had been made to put these and ovulation kits into the general sale category.

Members could see no virtue in asking companies to change their labelling when they were likely to be required to change again in the near future particularly as none of the companies seemed especially eager for a classification change.

Recommendation

That pregnancy test kits remain pharmacy-only medicines.

iv Local Anaesthetics

Dr Martindale pointed out that since the reclassification exercise of 1990 there had been a number of inconsistencies in the classification of these medicines. Confusion had arisen from the fact that some local anaesthetics had been scheduled individually whereas others had been scheduled only under the blanket entry for local anaesthetics. Consequently some parenteral forms had been classified as pharmacy-only although the intention of the committee was for parenteral forms to be classified as prescription medicines.

Ms Linda McLauchlan, who had been asked by the Ministry to review the scheduling of local anaesthetics, presented her findings to the committee. It was noted that a change of classification would be required for those local anaesthetics which had parenteral forms and which had not been scheduled individually. These were cinchocaine, mepivacaine, prilocaine and procaine. Of these only prilocaine required an exemption from prescription status to allow use by dental therapists. Benzocaine also required individual classification but this would involve no change to present classifications.

The committee also agreed to Ms McLauchlan's suggestion that there be a cut-off point of 30 milligrams per dose form for local anaesthetics in throat lozenges. Members saw the local anaesthetic as becoming an internal use by ingestion above that point. The 30 milligram limit would bring NZ into line with Australia in this respect. The change would not affect products already on the market.

Recommendation

That Ms McLauchlan's recommendations be implemented for local anaesthetics.

That all local anaesthetics be scheduled individually and that the blanket entry be removed from the first Schedule of the Medicines Regulations.

That throat lozenges containing local anaesthetics should contain not more than 30 milligrams per dose unit if they are to be classified for general sale.

That the following entries be made in the schedule to accommodate Ms McLauchlan's recommendations:

Benzocaine

for external use in medicines containing more than 2%	*POM*
for external use in medicines containing 2% or less; in throat lozenges containing 30 milligrams or less per dose form	*GS*

Cinchocaine	
for parenteral use	*PM*
for external use in medicines containing more that 2%	*POM*
for external use in medicines containing 2% or less	*GS*
Mepivacaine	*PM*
Pramocaine (pramoxine)	
for external use in medcines containing more than 2%	*POM*
for external use in medicines containing 2% or less	*GS*
Prilocaine	
for parenteral use except when used by a dental therapist	*PM*
for external use in medicines containing more than2%	*POM*
for external use in medicines containing 2% or less	*GS*
Procaine	
for parenteral use; for internal use	*PM*

v Local anaesthetics for Optometrists

The New Zealand Association of Optometrists had requested the addition of lignocaine and oxbuprocaine to the group of local anaesthetics exempt from prescription classification when used in practice by registered optometrists. These two medicines had been left out of the joint submission by optometrists and ophthalmologists dealt with at the last meeting. The Ophthalmological Society was in agreement that optometrists should have access to these two medicines but wanted specific wording in the schedule to outline the circumstances in which the medicines could be used.

The committee did not feel that it was the business of MCC to ensure that optometrists carried out their profession in an appropriate manner. Nor did it consider the medicines schedule the appropriate place to specify this. They felt that the wording in the schedule seemed a little narrow to allow reasonable use of local anaesthetics by optometrists and were happy to see this wording relaxed by the removal of the wording "to facilitate the examination of the eye". This would then allow optometrists to use the products for other purposes permitted in the course of their normal practice.

Members agreed to recommend that lignocaine and oxybuprocaine should have an exemption from prescription status for the use by optometrists in the course of their normal practice. They were happy to allow therapeutics staff to determine suitable wording to that effect to be used in the schedule.

Recommendation

That lignocaine and oxbuprocaine be exempt from prescription status when used by optometrists in the course of the normal practice of optometry.

vi Zopiclone (Imovane, Rhone-Poulenc Rorer)

A proposal from the Pharmaceutical Society for reclassification of Zopiclone as restricted medicine was turned down in May 92 on the grounds that it was still too early in its use in NZ to assess potential problems. The company was now making a submission for OTC sale as a pharmacy-only medicine. Mr Griffith observed that the company submission, lacked depth and substance. He felt that the removal of chloral hydrate from the market may have been behind the submission for the reclassification of zopiclone.

Mr Griffith reported on the research he had done into misuse of zopiclone. He said he had found little public material available to show misuse although a small number of private reports of misuse were available. Of these most were related to people with psychiatric problems. He concluded that it would be reasonable to suppose that abuse would increase with increased use of the medicine.

Mr Caves commented that pharmacists would like to have some form of sedative to offer those who needed it.

Ms Egan reported that hospital pharmacists had appeared very much against reclassification of zopiclone at their recent special interest group meeting because of reported cases of abuse.

There was general agreement that diazepam had probably been regarded as having low abuse potential when it was first used.

Members discussed the medicine with reference to the criteria for reclassification and although the medicine fulfilled most requirements satisfactorily the committee was not convinced that the potential for abuse was low. Most felt that there was still not enough information available in this area. They noted that zopiclone was not available over the counter in any developed country. It was also noted that elderly people may need a lower dose. Mr Griffith pointed out that the company study provided on experience in thousands of patients with the medicine covered a very short period and was not particularly informative.

Concerns were also expressed about possible advertising leading to increased and inappropriate use should the product be reclassified.

The committee decided that they would not be happy to recommend zopiclone for reclassification at this stage as they felt that a longer period of wider use was necessary to see if problems would emerge. They suggested that the company might wish to make a more detailed submission in perhaps three years time and that they might consider an even smaller pack size of say 2 tablets.

Recommendation

That zopiclone remain a prescription medicine.

vii Ibuprofen syrup (Nurofen Junior , Boots)

The company was seeking pharmacy-only status for ibuprofen syrup when in concentrations of 100 milligrams per 5 millilitres and in pack sizes of less than 200 millilitres. Members noted that the medicine was available over the counter in Britain but not in the USA.

The committee felt that their main concern with this medicine was the problem with use in volume depleted children. It was noted that the problem did not occur with paracetamol. Members acknowledged that this might effect only a small percentage of users but recognised it as a safety issue which needed to be addressed. Dr Wilcox said that in NZ ibuprofen syrup was used mainly as a second line treatment for rheumatism so that use here would not have been as wide as in Britain. Dr Herbert pointed out that due to climatic conditions, children were more likely to become dehydrated in NZ. He felt that GPs should be encouraged to use ibuprofen in favour of paracetamol so that it could be more widely tested. Mr Griffith pointed out that the evaluator's report showed concern about how effective pack warnings might be especially in respect of use for children with asthma. Some time was spent discussing this issue.

The committee also discussed the company's practice of comparing ibuprofen to other medicines in advertising claims. They concluded that the claim was unlikely to constitute a safety issue in this case and that if the problem were to be tackled it would need to be dealt with on a much wider scale.

Mr Caves pointed out a discrepancy in the company submission that although the medicine was contraindicated in children under 12 months of age, doses were given on the labels for children from 6 to 12 months. Members agreed that ibuprofen syrup should not be available OTC for children under 12 months.

Members queried the contraindication against use in pregnancy when the dose instructions were for children up to 12 years only. They noted that the standard of material submitted by the company was poor.

After discussion, members concluded that their concerns could probably be dealt with through labelling. They agreed to recommended ibuprofen syrup for sale as a restricted rather than as a pharmacy-only medicine. However they felt there should be additional warnings to those already included by the company on the labelling. These should include warnings against use for children with diarrhoea or dehydration and any known gastric problems. Appropriate wording would be determined by the Therapeutics Section.

Recommendation

That ibuprofen syrup be available as a restricted medicine when for children over 12 months of age.

That in addition to the warnings suggested by the company, the labels should include warnings against use in children with dehydration, diarrhoea or any known gastric problem.

Secretary's Note

Subsequent to the date of the meeting it became evident to the Therapeutics Section that if the above recommendation were implemented ibuprofen liquid in strengths of up to 100 milligrams in 5 millilitres and in packs of less than 200 millilitres would be available OTC for use for children. However, the same strength of the medicine, in packs of 200 millilitres would be available only on prescription for adults. This would seem to be an anomolous situation. Members were consulted by phone and agreed that a wider overview should be taken of liquid ibuprofen. They agreed that liquid ibuprofen in both the available presentations should be reviewed for possible reclassification as restricted medicine before the above recommendation was implemented. The Boots Company would be consulted and Therapeutics Section would undertake a review of liquid ibuprofen for adult use. The resulting data would be sent to members for consideration prior to a recommendation being reached by telephone consultation.

viii Clotrimazole 10% vaginal cream preparation (Canesten 10 VC, Bayer)

The company was seeking consent for a single dose preparation of 10%. As the highest strength cream currently available was 2% the matter had been referred to the committee to confirm that the current classification of restricted medicine was still appropriate.

Ms Egan commented that there would obviously be better compliance with a one dose treatment. Mr Griffith pointed out that a 500mg dose tablet was already available as a single dose vaginal presentation.

Members agreed that this was suitable for sale as restricted medicine.

Recommendation

That clotrimazole for vaginal use at a strength of 10% should be classified as restricted medicine

ix Polymixin B sulphate/Bacitracin (Polysporin Ointment, Wellcome)

This was the fourth time this medicine had been considered by the committee for reclassification to OTC status.

Dr Wilcox distributed copies of an article from the Diagnostic Laboratory Newsletter(undated) entitled *Topical Antibiotic Agents*. The article illustrated Dr Wilcox's observation that polymixin and colistin were the only antibiotics which were effective against pseudomonas infections. He therefore saw it as unsuitable for wide use on cuts and scratches and felt there was a good public health argument for not derestricting the sale of the medicine.

Dr Martindale noted that although the company had requested a classification change for Polysporin ointment, the material submitted was for Polysporin powder.

Dr Wilcox pointed out that the submission did not discuss the matter of pseudonomas resistance. He said that resistance to polymixin gave immediate cross resistance to colistin. He added that pseudonomas infections were a major problem in NZ, especially in Auckland and among lower socio-economic groups where there was a lot of otitis externa. He observed that this problem might not necessarily occur in other countries where Polysporin was already available OTC.

Mr Griffith said he had not been aware of the problem before the meeting. He said that there were a number of other topical antibiotic preparations available and could therefore see no compelling reason to derestrict the product.

Other members agreed that the product should retain a prescription classification. It had an important place especially with pseudonomas infections of the skin and external ear as well as a potential for cross resistance with colistin. There were a number of other products available for skin infections.

Recommendation

That polymixin, and therefore Polysporin ointment, remain a prescription medicine.

x **Kenoid Ointment** (Bristol-Myers Squibb)
(Triamcinolone, nystatin, lignocaine)

and

xi **Kenacomb Cream and Ointment**
(triamcinolone, nystatin, neomycin, gramicidin)

A change to restricted medicine was requested for all three products. Dr Martindale observed that there was not a lot of information from the company in support of the application and this was generally agreed by other members.

Mr Griffith considered the criteria for reclassification with regard to Kenoid rectal preparation and could find no compelling reasons either to reclassify or to recommend against reclassification.

Dr Herbert disagreed. He pointed out that there was a great potential for misuse in that anal pruritis was a difficult condition to treat, could result from a variety of causes and was best treated under medical supervision.

Dr Herbert and Dr Wilcox were against the reclassification of triamcinolone as it was a fluorinated steroid and significantly more potent than hydrocortisone.

Members agreed that the medicines should not be recommended for reclassification.

Recommendation

That there be no change to the prescription classification of Kenoid and Kenacomb cream and ointment as there was insufficient safety data to support the submissions.

xii PHARMAC Policy Statement

Dr Martindale reminded the committee that at the last meeting they had been interested to know whether or not there was a relationship between the classification of a medicine and the decision to fund under the Pharmaceutical Pricing Schedule. Pharmac had replied that there was no automatic change to the subsidy status of a pharmaceutical when the classification was changed.

She pointed out that in the last paragraph of their reply Pharmac had invited the committee to comment on whether or not they thought RHAs should be able to subsidise pharmacy-only medicines for which there was no prescription. Dr Martindale said that she did not feel it was appropriate for the committee to be involved in those issues because the Medicines Classification Committee was a technical advisory committee and should not get drawn into the question of funding. She said that the Ministry proposed to reply to Pharmac saying that Ministry Personal Health Services would be happy to talk to them about funding issues.

6 NEW MEDICINES FOR CLASSIFICATION

i Galactose (Echovist)

Members agreed unanimously that galcatose should be treated in the same way as dextrose and fructose which are unclassified medicines. However, they acknowledged that Echovist would be classified pharmacy-only as it was an injectable medicine and would be caught under the blanket entry for injectable medicines. It was noted that although Echovist was a contrast agent it was not a radio-contrast agent.

Recommendation

That galactose be a general sale medicine

ii Topical(transdermal) ibuprofen (Ibuprofen Gel/Cream Boots)

Dr Martindale explained that ibuprofen for external use had not previously been classified although a 5% topical preparation had been granted consent to market. Mr Griffith pointed out that the Ministry had recently received an application for a 10% preparation. He said that the schedule had been changed to accommodate external use of other NSAIDs but that this had been overlooked for ibuprofen. Members agreed there would be no problem with use on the skin of a 10% preparation. Mr Griffith pointed out that the content of an entire tube would be equivalent to only one maximum daily oral dose. It was agreed that ibuprofen for external use should be pharmacy-only in line with other external NSAIDs.

Recommendation

That ibuprofen for external use be classified as pharmacy-only medicine.

iii Recommended for Classification by MAAC

The committee noted that the following had been recommended as prescription medicines by the Medicines Assessment Advisory Committee:

rocuronium bromide
nefazodone
lansoprazole
gabapentin
cefepime

acrivastine had previously been recommended for a prescription classification by MAAC. The company had objected to this classification on the grounds that other similar antihistamines were classified as pharmacy-only medicines and that the medicine had been available for many years in Britain. MAAC had agreed to amend its recommended classification to pharmacy-only medicine.

7 CORRESPONDENCE

i Emergency Contraceptive.

The committee was provided with copies of of a letter of 30 March which advised that although they are still in favour of OTC availability of the emergency contraceptive pill, the Family Planning Association does not intend to pursue the matter. The secretary had also received letters from Women For Life against OTC availability and the Pharmacy Guild which was in support of OTC sale.

ii The NZ Society of Gastroenterology Incorporated had expressed concern in a letter of 14 April about the rescheduling of H2 receptor antagonists for the reasons given in their 1993 submission. They also expressed reservations about the proposal to establish a recommended dose limit for OTC sale as they were anxious to see the medicines used in an appropriate dosage rather than in a reduced dosage. It was decided that the secretary should write to the society to assure them that the evaluation system will ensure that the appropriate dose will need to be justified before any H2 would be able to be sold as a restricted medicine.

8 SUGGESTED ITEMS FOR THE NEXT MEETING

Emergency contraceptive pill

Although the Family Planning Association was keen to see the emergency contraceptive available OTC it no longer intended to make a submission to MCC. The Ministry planned to prepare a submission for a meeting later in the year. It was suggested that at least the following bodies be consulted for input:
-companies who market the emergency contraceptive
-Family Planning Association of NZ
-The College of General Practitioners
-The College of Obstetricians
-Contraceptive Choice
-NZ Nurses Association

Dr Martindale told members that the committee would look at the technical aspects of reclassification but that the Minister would also need to seek advice from others on moral and ethical issues.

Oral contraceptives

A media release on 26 January 1994 stated that the Ministry would be asking the Medicines Classification Committee to investigate the question of whether or not oral contraceptives in general should be made available OTC. Dr Martindale said that the Ministry had already commissioned the Family Planning Association to prepare a paper on the topic. Consultation should be as for the emergency contraceptive. Dr Martindale suggested that trends in Britain and the USA be examined. Mr Griffith suggested that some different combinations of hormones might be preferable to others.

9 General Business

Due to a recent review of ministerial advisory committees, a number of issues had arisen.

i Dealing with the media

Dr Martindale said that the Ministry view was that ministerial advisory committees should not require media spokespersons as these committees should be reporting only to the Minister through the Ministry. The Ministry would therefore be responsible for fielding any media enquiries.

ii Committee spokesperson

For the reasons above, Dr Martindale said that it was not necessary to appoint a committee spokesperson.

iii Handling individual queries on behalf of MCC

Dr Martindale stressed that members should not discuss in-committee matters with others and should exercise judgement when responding to questions as members of the committee. She recommended that queries should be referred to the secretary to be dealt with by the Ministry.

iv Presentation and content of submissions

The secretary informed the committee that more than forty communications had been received in recent months from people who had discovered that individuals were able to make submissions to the MCC. However, none of these communications contained the kind of information required in a submission.

Dr Martindale suggested that there was a need for the Ministry to assemble and publicise better information on requirements about the submission process for those seeking classification change. She added that meanwhile all queries about the content or format of submissions should be channelled through the secretary who would be able to provide direction.

v **Operation of the committee**

As a result of Ministry of Health requirements for accountability and performance measures the secretary had prepared a questionnaire seeking members' responses on their level of satisfaction with the servicing of the committee and on ways in which improvements could be made. Members were not required to attach their names to the questionnaire. Dr Martindale explained the Australian method of presenting agenda papers and asked for suggestions for improvements in the MCC system. Members voiced general satisfaction with the servicing of the committee and did not wish to have their agenda material bound.

Date for the Next Meeting

It was agreed that the second half of October would be a suitable time for the next meeting. This would be the latest possible date for making a submission on the legislation review discussion paper.

The meeting closed at 3.30pm