# MINUTES
# OF THE FIFTEENTH MEETING
# OF THE MEDICINES CLASSIFICATION COMMITTEE
# HELD IN CONFERENCE ROOM NORTH
# ON THE FIRST FLOOR OF THE MINISTRY OF HEALTH BUILDING
# 133 MOLESWORTH STREET WELLINGTON
# ON THURSDAY 30 NOVEMBER 1995
# COMMENCING AT 10:30am

**Present**

Dr Susan Martindale (Chair)
Mr Richard Griffith
Dr Jon Wilcox
Dr Murdoch Herbert
Ms Ursula Egan
Mr Glen Caves
Mrs C Smith (Secretary)

**In attendance**

Mr Mark Rowland
Dr Stewart Jessamine
Mr Mike Thompson (for clindamycin only)

## 1. WELCOME

Dr Martindale declared the meeting open at 10:30am and welcomed members to the fifteenth meeting. It was noted that Dr Herbert needed to attend another meeting at 3pm. Dr Martindale proposed that the item on emergency contraception be moved to the end of the agenda and members agreed to this.

## 2. APOLOGIES

There were no apologies.

## 3. CONFIRMATION OF THE MINUTES OF THE FOURTEENTH MEETING

The minutes of the fourteenth meeting were confirmed as an accurate record of the meeting and were signed by the chairperson.

## CONFIRMATION OF THE RECORD OF THE POSTAL CONSULTATION CONDUCTED IN MAY 1995

The record of the postal consultation was confirmed by the committee as an accurate record of the postal consultation conducted in May 1995 and was signed by the chairperson.

## 4. MATTERS ARISING

### i Potassium chloride in ophthalmic drops

The committee accepted unanimously the Ministry proposal to reword the entry for potassium salts in the first schedule to the Medicines Regulations. It agreed that potassium chloride in ophthalmic drops would be appropriately classified as a general sale medicine and acknowledged that the change of wording in the schedule entry would be easier to use and would not change the classification of any of other potassium-containing products already on the market.

*Recommendation*

That the entries for potassium salts in the First Schedule of the Medicines Regulations 1984 be replaced by the following entries for potassium:

**Prescription medicine**
potassium bromide
**Pharmacy-only-medicine**
potassium; except when specified elsewhere in this schedule; for internal use in slow release or enteric coated forms; in medicines containing more than 100 milligrams per recommended dose except in medicines for oral rehydration therapy.

### ii Oral Contraceptives

Dr Jessamine commented on recent worldwide reaction to reports of the results of several studies which claimed that low-dose oral contraceptive pills containing desogestrel and gestodene presented an increased risk of thromboembolism compared to other low-dose oral contraceptive pills. He explained that although Britain had decided to recommend that women using these pills change to other brands, the New Zealand Ministry of Health had recommended that there was insufficient evidence to justify a change of contraceptive. This had been reinforced by the similar decision made by the European Community's Medicines Expert Advisory Group. Dr Jessamine pointed out that although there had been worldwide reaction to the results of the studies, the studies themselves had not yet been published. He added that these were all sizeable studies following large numbers of subjects over considerable periods.

The World Health Organisation study and a Transnational study by W Spitzer were both due for publication on 15 December in *The Lancet* and *The British Medical Journal* respectively. A general practice research database study by H Jick and a Dutch study were also due for publication in the near future.

It was agreed that no further consideration should be given to possible reclassification of oral contraceptives until the studies had been published and the results examined. Copies of the Lancet and BMJ articles would be forwarded to members as soon as they could be procured by the Ministry.

***Recommendation***

That further consideration of the reclassification of oral contraceptives should be deferred until the results of the recent studies have been published and analysed.

**iii The Emergency Contraceptive Pill**

This item was discussed at the end of the agenda.

At the fourteenth meeting the committee had considered safety issues relating to the emergency contraceptive pill (ECP). Members had agreed that, on the evidence available, the ECP was sufficiently safe to warrant investigation into ways of making this medicine more readily accessible. The committee had requested further investigation of safety data and wider consultation. These two requests had been carried out by the Ministry.

Dr Jessamine advised the committee that further database searches had revealed no new safety data and that no new papers had been published over the last year.

Results of the consultation process indicated strong support for increased access to the ECP.

Dr Martindale reminded the committee of the Minister's interest in lowering access barriers to contraception and in developing measures to reduce the number of unwanted pregnancies.

Dr Martindale proposed that instead of reclassifying the ECP as a restricted medicine the committee might wish to consider recommending an amendment to the schedule which would retain the active ingredients as prescription medicines except when supplied by a pharmacist for post-coital contraception in a package approved by the Director-General of Health. This would remove the barrier of needing to have the sale recorded which was a requirement for restricted medicines. A similar mechanism had been used to allow optometrists access to certain medicines which were otherwise prescription medicines. The pack approved by the Director-General could be the existing Schering product, PC4, with OTC labelling but the schedule

entry would be sufficiently flexible to allow the pharmacists to provide alternative presentations in packaging approved by the Director-General.

Members agreed that the product would be best sold in OTC-specific packs so that the necessary labelling and package information could be supplied.

Availability through a pharmacy was seen as providing convenient access in that the counselling and the supply would occur at the same place.

Members felt that registered practice nurses or family-planning nurses should also be able to dispense the ECP but it was acknowledged that there might be difficulty in permitting this under current legislation. Dr Martindale advised the committee that a separate Ministry project was already under way on the issue of prescribing rights for nurses. The committee accepted that in the first instance the widening of the supply rights for the ECP needed to be done within the existing legislation and that it might not be possible for nurses to provide the ECP without further legislation change.

Cost was seen as a further barrier to access and the committee felt that ideally, the ECP should be free of charge. While realising that funding issues did not fall within their terms of reference, the committee recommended that the Minister consider mechanisms for reducing the cost of the ECP to consumers.

The committee agreed that publicity and education would be necessary if the ECP were to be available over the counter. This publicity should inform the public about the improved access rights and give advice on effective contraceptive use and the safe and appropriate use of the ECP.

It was agreed that anti-emetics should be available for supply with the ECP. Prochlorperazine and metoclopramide considered suitable for this purpose. Members agreed that one day's supply should be provided with the ECP and that anti-emetics should be scheduled in the same way as the active ingredients for the ECP.

The committee accepted the chairperson's proposal to set up a Ministry project to work through the implementation issues. This project would:

1. Define packaging and labelling requirements. The committee considered that:
   - one course of treatment only should be provided
   - the language should be English
   - consistency with the content of Consumer Medicine Information would be preferred
   - warnings about the efficacy should be included

2. Consider whether practice nurses and family-planning nurses could also be granted supply rights under curent legislation.

3. Recommend approved labelling for the anti-emetics to be supplied with the ECP.

*Recommendations*

That the active ingredients ethinyloestradiol, levonorgestrel and norgestrel be exempted from prescription status when sold by a pharmacist in a medicine for post-coital contraception and in a package approved by the Director-General of Health.

That a Ministry project would be initiated to :

- define packaging and labelling requirements for the ECP and anti-emetics
- investigate ways of allowing registered practice nurses and family-planning nurses to provide the ECP
- formulate appropriate wording for the scheduling of the active ingredients for the ECP and for the anti-emetics metoclopramide and prochlorperazine.

That there be a public information campaign to inform women of increased access and safe and appropriate use of the ECP and proper use of contraceptives.

That the Minister consider ways of reducing the cost barrier to access

## 5. SUBMISSIONS FOR RECLASSIFICATION

### i Beclomethasone 50mcg for nasal use

This Glaxo submission was for the reclassification from prescription medicine to pharmacy-only medicine of a new presentation indicated only for seasonal rhinitis. The medicine had been reclassified to a pharmacy medcine in Britain.

Dr Wilcox tabled a paper expressing his concerns with the submission. He felt there was insufficient research and that the papers provided were old. No post-marketing surveillance had been undertaken. None of the papers dealt with use with infections which Dr Wilcox saw as a significant problem in this country. He was surprised that the medicine had been reclassified in Britain but felt that the incidence of nasal infection might be higher in New Zealand due to climatic conditions. He felt that the medicine was more suited to a warrant system than to reclassification as an OTC medicine. Dr Martindale said that while there would be provision for this under the new legislation it was not possible under the existing legislation.

Dr Jessamine pointed out that according to the data sheet, infection was not a contraindication for this medicine and that use did not exacerbate infection. He also commented that beclomethasone was regarded as safer and more effective than decongestant nasal sprays and that most people knew when they had hayfever.

Dr Martindale asked whether members thought a pharmacist would be able to provide the required counselling and most members felt that pharmacists could provide this. However, as the committee was not in full consensus it was agreed to defer making a recommendation on the reclassification as a pharmacy-only or a restricted medicine until Glaxo had been asked whether they were able to supply any information on the use of beclomethasone with nasal or sinus infection. Other companies marketing this medicine would also be asked to comment.

*Recommendation*

That the proposal to reclassifiy nasal beclomethasone for the treatment and prophylaxis of seasonal rhinitis be deferred to the next meeting pending further information from Glaxo and other companies relating to use with infection.

**ii Carbetapentane**

The committee saw no problems in agreeing to the SmithKline Beecham submission to reclassify lower strengths of this medicine from pharmacy-only to general sale medicine in order to bring the classification into line with Australia.

It was recognised that this was an older-type medicine, developed in Europe and not widely used in the USA. Mr Griffith reported that database searches had not provided a great deal of information on the medicine.

*Recommendation*

That carbetapentane in strengths of 0.5% or less be reclassified as a general sale medicine.

**iii Clindamycin**

Mr Thompson presented his report on the Upjohn submission for the reclassification of topical clindamycin from restricted medicine to pharmacy-only medicine. The Ministry report recommended that topical clindamycin remain a restricted medicine because of the potential for the development of cross-resistance to existing or future antibiotics.

Dr Martindale advised the committee that a recent address by a visiting Danish microbiologist had raised concerns about the absence of a national policy on antibiotic use.

The Therapeutics Section had resolved to establish a working party to make recommendations on policies for antibiotic use. No time-frame had been set for the first meeting but it was likely to be early in the New Year.

Some time was spent discussing the findings in the Ministry report. Members agreed that the medicine was effective in the treatment of acne and that it was reasonably safe with only a small potential for the development of antibiotic colitis. Mr Griffith pointed out that as this was a transitional treatment between benzoyl peroxide and a systemic form of treatment, caution was warranted and the restricted medicine classification was appropriate. While the committee agreed that resistance to clindamycin per se was not a major problem, the matter which caused concern was that of the development of cross resistance. It was noted that a company involved in the development of new antibiotics had objected to the Upjohn submission on those grounds. It was also noted that two outside experts had presented opposing views on this question and that the issue would need to be addressed by the working party.

Members agreed that the company should be informed of the proposed working party and warned that the medicine might be reclassified as a result of the findings but that at present there should be no classification change.

***Recommendation***

That there be no change to the current restricted medicine classification of topical clindamycin.

**iv Pancreatin**

An article from *The Lancet* of 19 August 1995 entitled *Colonic strictures in children with cystic fibrosis on low-strength pancreatic enzymes* was tabled.

The Ministry submission for the reclassification of high-strength preparations to prescription medicine originated from recent reports of colonic strictures in cystic fibrosis children who had received high doses (over 20,000 units). The Ministry report also recommended reclassification to either pharmacy-only or restricted medicine for lower-strength preparations.

The matter had been considered by the Medicines Adverse Reaction Committee the previous day. This committee had had no new evidence to add to that already available but was in favour of the reclassification of high-strength preparations.

Members had considered the strengths of preparations on the market and had had difficulty determining a suitable cut-off point for high-strength preparations. In the absence of scientific evidence it was considered prudent to follow the lead of other regulatory bodies, particularly Australia, in establishing the cut-off point at 20,000 units.

The committee was reluctant to reclassify lower-strength preparations as there were known to be a number of dietary supplement products available which would be affected by a classification change. Members had no justification to support such a change.

*Recommendation*

That pancreatic enzymes in strengths of more than 20,000 units become prescription medicines and that pancreatic enzymes in strengths of 20,000 units or less remain general sale medicines

## 6. NEW MEDICINES FOR CLASSIFICATION

### i Nicotine for inhalation

The committee accepted the Ministry recommendation for a prescription classification for this medicine.

*Recommendation*

That nicotine for inhalation be classified as a prescription medicine.

### ii Medicines Classified by the MAAC

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

| | |
|---|---|
| abciximab | alendronate sodium |
| alglucerase | deflazacort |
| desflurane | follitropin |
| gametotrophin beta | losartan potassium |
| mycophenolate mofetil | ropivacaine hydrochloride monohydrate |
| sparfloxacin | tirilazad mesylate |
| ursodeoxycholic acid | valaciclovir |

*Recommendation*

That the above medicines be classified as prescription medicines.

## 7. FOR THE NEXT MEETING

### i Forthcoming agenda items

Members acknowledged the items already received for the agenda of the next meeting. It was requested that the Ministry check whether or not nedocromil sodium would qualify under the three-year period set as one of the criteria for OTC sale.

It was noted that the Ministry had received a New Medicine Application for a terfenadine metabolite that did not appear to have the same adverse effect profile as the parent compound.

### ii Suggested Items for Reclassification

The committee agreed that the following items should be added to the agenda of the next meeting:

- Antimicrobial mercurials for consideration for more restrictive classification. Members questioned whether or not these should be made unavailable. The Ministry would investigate their use. It was noted that their use as preservatives should also be considered.

- Nasal corticosteroids for consideration for OTC sale
  budesonide
  flunisolide
  betamethasone
  fluticasone

- Hydroxyzine. This was recently reclassified as a pharmacy medicine in UK for pruritis associated with accute or chronic urticaria, atopic dermatitis or contact dermatitis in people aged six years and over with limitations on doses and pack size. The Ministry would check the availability of Atarax as some members thought this was no longer available in New Zealand.

- Oral single dose fluconazole was recently reclassified as a pharmacy medicine in UK.

## 8 GENERAL BUSINESS

### i Results of Member surveys

The secretary reported that two suggestions for improved servicing of the committee had arisen from member surveys over the past two years. One suggestion was for a computer terminal to be made available for members to seek information during meetings. Dr Martindale commented that this was not feasible.

A second suggestion was for more uniformity of Ministry reports to the committee. The secretary referred members to the *Guidelines for Ministry Reports and Submissions to the Medicines Classification Committee* which had been compiled as a result of the survey. Dr Martindale said that members were invited to comment on this document.

Dr Martindale asked whether members found the Ministry report valuable or whether members would prefer to do their own analysis and research. It was agreed that not all members had access to literature references and that it would therefore be necessary to provide members with technical papers. There was, however, interest in members conducting their own analysis of the information provided. Under this scenario the Ministry could research the items, communicate with pharmaceutical companies and send the material to committee members for analysis.

One member queried whether the committee would be reimbursed for time spent. Dr Martindale said that she would look into the matter and discuss it with the Manager of the Therapeutics Section. She said that there would be no funds budgeted for this in the current financial year.

Mr Griffith pointed out that such a process would lengthen the classification cycle considerably.

It was agreed that the Therapeutics Section would investigate whether or not a workable proposition could be developed.

**ii Guidelines on the Classification of Medicines**

Dr Martindale explained that the draft version was now being sent out to companies on request and would be incorportated into the *New Zealand Regulatory Guidelines for Medicines*. The *Regulatory Guidelines* were due to be sent to companies for consultation in the near future. Dr Martindale suggested that if members wished to comment on the classification guidelines they should do so by the end of December.

**iii Comparison of NZ and Australian Scheduling**

Dr Martindale outlined the situation to date in relation to trans-Tasman mutual recognition and the problem of how best to deal with classification differences. She asked members to consider whether or not they found any New Zealand classifications which were clearly out of line when compared to those of Australia. It was agreed that safety should be the first consideration, followed by consideration of harmonisation to facilitate trade. Members agreed to return their comments by the end of December.

**iv Canadian Drug Advisory Committee Report on harmonised schedules in Canada**

Dr Martindale told the committee that she had been impressed with the first part of this document which scheduled medicines on a cascading principle. She pointed out that Canada had the same classification categories as New Zealand but that the Canadian method more clearly defined the factors determining the different OTC categories. She suggested that the committee review its classification criteria to see if it could incorporate any of the Canadian ideas. It was noted that it would be easier to move medicines to a more restricted category using the Canadian system.

It was agreed that the Ministry should work on a revised statement of factors for the classification of medicines. These would be brought to the committee at the next meeting.

**v Nurofen Cold and Flu Tablet**

Dr Wilcox expressed his concern that this combination product containing ibuprofen and pseudoephedrine had been allowed to be marketed as a pharmacy-only medicine. He reported a gastro-intestinal bleed from a patient who did not realise he was taking a non-steroidal anti-inflammatory medicine.

Ms Egan suggested that Dr Wilcox write to the Pharmaceutical Society informing them of the problem so that pharmacists could be warned to take care with the sale of this product.

LATE AGENDA ITEM

**Recommendation on paracetamol from the *Report for the Director-General of Health concerning Deaths by Suicide, Healthlink South Mental Heath Services.***

One of the recommendations from this report, which had been forwarded to the Medicines Classification Committee, was that there be restrictions on the sale of paracetamol and adequate warnings on the packs.

It was noted that the Pharmaceutical Society submission for the reclassification of general sale paracetamol was on the agenda for the next meeting. Ms Egan pointed out that the recommendation in the report supported the Society submission.

Members noted that there was already a restriction on the quantity of paracetamol which could be purchased without a prescription. They acknowledged that the question of whether or not outlets for sale be restricted to pharmacies would be dealt with at the next meeting. It was agreed that whether or not pharmacists monitor their sales of paracetamol was a matter for pharmacists rather that the Medicines Classification Committee. There was unanimous agreement that more explicit

warnings on the packs about the dangers of paracetamol would be counter-productive. Dr Jessamine said that the warning statements, dose instructions and patient information for therapeutic use of paracetamol were currently under review.

***Recommendations***

That there be no change to the current classification before the Pharmaceutical Society submission has been considered at the next meeting.

That explicit warnings on packs would be counter-productive and the Therapeutics Section review will ensure appropriate package information for the therapeutic use of paracetamol.

The meeting closed at 3:15pm.