MINUTES OF THE TWENTY-FIRST MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE HELD IN THE MEDSAFE CONFERENCE ROOM ON THE EIGHTEENTH FLOOR OF GRAND PLIMMER TOWER, 4-6 GILMER TERRACE, WELLINGTON ON THURSDAY 25 MARCH 1999

PRESENT

Dr Stewart Jessamine (Chair)
Mrs Marilyn Anderson
Dr Tim Bevin
Dr Graham Wardrope
Mr David Thompson
Mrs Carol Smith (Secretary)

IN ATTENDANCE

Dr Susan Martindale (for item on Fees)

1 APOLOGIES

Mr Bernard McKone.

2 WELCOME

Dr Jessamine declared the meeting open at 9:30 am. He welcomed members to the meeting and introduced Dr Martindale who was to address the committee on the matter of fees paid to committee members.

It was noted that Mr McKone had submitted written comments on agenda items. Copies were distributed to members. Mr Thompson had received an earlier copy of these comments and agreed to speak on Mr McKone's behalf if necessary.

3 CONFIRMATION OF THE MINUTES OF THE TWENTIETH MEETING

The minutes of the twentieth meeting were confirmed as an accurate record of that meeting and were signed by the chairman.

4 DECLARATION OF CONFLICT OF INTERESTS

None of the members had interests which could be considered prejudicial to recommendations about any of the issues to be discussed at the meeting.

5 INTRODUCTORY COMMENTS

Fees for Committee Members

Dr Jessamine requested that the Committee should discuss the matter at this point rather than under General Business as Dr Martindale had attended in order to address the meeting on this subject.

Dr Martindale told the Committee that the way Medsafe had been reimbursing committee members was not totally in accordance with guidelines set by the State Services Commission (SSC). While the new SSC guidelines had been in effect for some time, Medsafe had not been aware of certain aspects of these. It had now been brought to Medsafe's attention that locum fees were not permissible and that the hourly rate for preparation time was below that which was currently being paid. As a result, the amount members would receive under the SSC guidelines was well below the current expectation. She explained that this was a Cabinet directive and that there was no flexibility within the guidelines to allow remuneration at the expected level.

Dr Martindale said that members should claim for the current meeting under the old system but informed the Committee that from the beginning of the 1999/2000 financial year they would be paid according to the SSC guidelines with respect to preparation time and locum expenses.

6 MATTERS ARISING

6.1 Sedating antihistamines.

Dr Jessamine told the Committee that Medsafe had completed the review of sedating antihistamines not in combination with other active ingredients. However, the review had not been brought back to the Committee at this stage. At the last meeting of the Trans-Tasman Working Party on Harmonisation of New Zealand and Australian schedules a joint review of sedating antihistamines had been requested. It was now the intention of Medsafe to submit an improved version of this initial review for joint consideration alongside a similar Australian review. Details of how this joint consideration would take place were still to be resolved.

Dr Jessamine said that a great deal of time and effort was being put into harmonising the schedules of Australia and New Zealand and that Medsafe did not wish to jeopardise this. He said that the aim of harmonisation was also to harmonise procedures. Consideration would also need to be given to how the reclassification process could be managed in both countries in order to maintain harmonisation. One solution might be that companies applying for reclassification would be required to make application in both countries. Traditionally, companies had applied first to New Zealand.

According to Dr Jessamine, the main difference between the Medicines Classification Committee (MCC) and the Australian National Drugs and Poisons Schedule Committee (NDPSC) lay in the way in which risk was interpreted. He said that there

were no general practitioners and only one pharmacist on the NDPSC. He said that the NDPSC did not currently report to the regulatory authority as did the MCC. However, this was about to change and there could be an opportunity to review the structure of the committee. Whereas the MCC policy was to classify downwards unless public harm could be illustrated, the NDPSC took a more toxicological approach.

It was agreed that the review of sedating antihistamines should be a joint New Zealand and Australian undertaking.

Some discussion followed about a letter sent to the Pharmaceutical Society by a Nelson pharmacist concerning the sale of sedating antihistamines marketed solely for sedation. It was agreed that although the pharmacist in question had been penalised for acting in a conscientious manner, the legislation was quite clear in that only those sedating antihistamines which were packaged and labelled expressly for sedation or anxiety were to be sold as restricted medicines. If consumers requested products other than these, pharmacists were obliged to make the sale

7 SUBMISSIONS FOR RECLASSIFICATION

7.1 Beclomethasone nasal spray (Beconase Hayfever, GlaxoWellcome)

This was a company submission for the reclassification of 50 micrograms per actuation of aqueous nasal spray indicated for seasonal allergic rhinitis, from restricted medicine to pharmacy-only medicine.

The Committee was concerned with the practicalities of enforcing a minimum age limit of 18 years on the use of a pharmacy-only medicine, especially when the minimum age limit was only 12 years on the same product when sold as a restricted medicine. They felt that one age limit for use of the product should apply whatever the classification. They were also unhappy about reclassifying beclomethasone alone without also considering the other nasal corticosteroids currently available over the counter for allergic rhinitis.

Dr Jessamine said that although the company had requested that the minimum age limit be raised to 18 years, it had produced very little evidence to support this. He said that earlier papers had suggested that there was very little effect on growth from the use of beclomethasone and that it was unclear whether any effects observed were due to the medicine or to asthma. Dr Jessamine said he had requested more information from the company but had not received a response. He was currently working through a transcript of a meeting on this subject which had been provided by the FDA in the hope that he would find some justification for raising the minimum age limit for OTC use of beclomethasone. He said that if justification were found it would be likely to apply across the whole therapeutic group. He was of the opinion that it was probably not wise to risk uncontrolled use for hayfever at this stage.

The Committee agreed to return to the matter at the next meeting when the three OTC nasal corticosteroids, beclomethasone, flunisolide and budesonide, should be

reviewed. The minimum age limit should be more thoroughly investigated for all three medicines and further consideration should be given as to whether the group was appropriately classified as restricted medicine or whether it should be changed to pharmacy-only medicine.

Recommendation

That the classification of the OTC nasal corticosteroids beclomethasone, flunisolide and budesonide should be reviewed to establish a suitable minimum age limit for their use and to consider whether or not they should be reclassified as pharmacy-only medicines.

7.2 Hyoscine butylbromide (Buscopan tablets, Boehringer Ingelheim)

This was a company submission for the reclassification of 10 milligram tablets from restricted medicine to pharmacy-only medicine.

There was unanimous agreement for the need for consultation over abdominal pain. Members agreed misdiagnosis was easy and there was danger, even with a 4-day pack, that the product could be used with acute appendicitis, renal stones or gastric ulcers and that bowel problems could be masked. There were also concerns associated with cardiac arrhythmia and glaucoma and with interactions with other medicines.

Mr Thompson pointed out that the product was rarely dispensed.

Mrs Anderson said that as hyoscine butylbromide had just been reclassified to the equivalent of pharmacy-only medicine in Australia for 10 milligram tablets in packs of not more than 20 tablets, justification would be needed on safety grounds for New Zealand not to harmonise with this.

Dr Jessamine said that the Australian reclassification was very recent and had been refused on a number of earlier occasions. The NDPSC now considered that their concerns had been adequately dealt with in the labelling of the product. They were happier to accept a more general indication of non-specific spasm of the gut rather than a series of specific indications including irritable bowel syndrome.

Members felt there was sufficient justification not to harmonise with the Australian classification.

Recommendation

That there be no change to the current classification of hyoscine butylbromide.

7.3 Phenylephrine 2.5% eye drops

This was a further submission from the New Zealand Association of Optometrists for

exemption from prescription status for phenylephrine 2.5% eye drops when used in practice by optometrists for diagnostic purposes.

The Committee noted that the Association had now requested an exemption for 2.5% drops only whereas on earlier occasions the submission had requested an exemption for preparations of up to 10%. Members queried whether there was a great deal of risk associated with concentrations as low as 2.5% as most of the data referred to 10% preparations. They felt that optometrists would be professionally competent to use such products, particularly in the light of modern training and that older members of the profession who had not received that training would be unlikely to want to use the product. They noted that the product was available to optometrists in most other countries and there appeared to be no reported problems.

As phenylephrine was a pharmacy-only medicine in Australia at concentrations of up to 2.5%, members realised that the matter would need to be addressed again in the near future for harmonisation purposes. They agreed that they would be happy to take their safety concerns to the NDPSC with regard to 2.5% concentrations being classified as pharmacy-only medicines and to see how they responded. Meanwhile, an exemption from prescription status could be granted for optometrists to use 2.5% concentrations in the course of their practice.

Recommendation

That there be an exemption from prescription status for phenylephrine in concentrations of 2.5% or less when used in practice by a registered optometrist.

7.4 Ranitidine 75 milligram tablets (Zantac, GlaxoWellcome)

This was a company submission for the reclassification of 75 milligram tablets from restricted medicine to pharmacy-only medicine. This strength was noted as half the strength which had qualified initially for sale as a restricted medicine.

Members were happy with the safety profile of the medicine and acknowledged that there appeared to be no evidence of increased problems associated with the use of any of the H_2 receptor antagonists since their reclassification to OTC status. They noted that sales of ranitidine were not large due to the relatively high cost of the product and that the cost of a half-strength ranitidine product was unlikely to be significantly less. They also noted that products were widely available world-wide as OTC medicines.

Any problems arising from misdiagnosis and the masking of gastric problems with 75 milligram products were seen as being no different from those which could occur with 150 milligram products.

The Committee felt that an overview would be beneficial. Rather that reclassify an individual product, the whole therapeutic group of OTC H_2 receptor antagonists should be reviewed to determine whether or not they should be reclassified as pharmacy-only medicines.

Recommendation

That all H_2 receptor antagonists currently sold as restricted medicines should be reviewed to determine whether they should be reclassified as pharmacy-only medicines.

7.5 Dextromethorphan (Late submission)

This submission requested that the pure active substance be reclassified from pharmacy-only to prescription medicine. It comprised evidence of abuse of the active substance provided by the Police, Customs and Mental Health Section of the Ministry of Health. Police and Customs had been seizing large quantities of dextromethorphan, particularly in the South Island. Most was sourced from South Africa either in bulk or in 250 milligram capsules. Classification of the pure active substance would give better control for Police and Customs and would be a move towards harmonisation with the Australian classification. The current New Zealand classification gave no upper limit for sale as a pharmacy-only medicine. No medicines containing dextromethorphan would be affected by the proposed change of classification.

Dr Jessamine described the substance as an opioid-like cough suppressant. He said that as doses were increased opioid-type side-effects such as confusion, paranoia and disassociation occurred although there was little analgesic effect.

The Committee agreed that there should be measures taken to help control abuse. Members felt that risk to pharmacists would not be increased by the proposed classification change as pure dextromethorphan was not stocked in pharmacies.

Members agreed to accept the proposed Medsafe wording for the classification of dextromethorphan. It was noted that no products currently marketed would be affected by this classification change. It was also noted that further adjustment could be necessary in the course of harmonisation with Australian scheduling.

Recommendation

- *That dextromethorphan should be classified as a general sale medicine when in liquid form containing 0.25% or less and when in solid dose form containing 15 milligrams or less per dose form.*

- *That dextromethorphan should be classified as a pharmacy-only medicine when in liquid form containing more than 0.25% and not more than 0.3% and when in solid dose form containing more than 15 milligrams and not more than 30 milligrams per dose form.*

- *That dextromethorphan should be classified as a prescription medicine except when fulfilling the above criteria for sale as general sale or pharmacy-only medicines.*

8 COMMITTEE PROPOSALS FOR POSSIBLE RECLASSIFICATION

Medsafe reports had been prepared for these items.

8.1 Mupirocin (Bactroban, SmithKline Beecham)

A letter was tabled from Dr Richard Meech in response to a request from Medsafe for his views on resistance issues associated with mupirocin.

The Committee noted that there had been no support for the continued sale of mupirocin as a restricted medicine and that the company who marketed the product had a global policy not to seek OTC status. It was observed that the New Zealand OTC classification was out of line with the prescription classification of most other regulatory bodies. Mrs Anderson said that the Committee had a choice either to reclassify immediately or to wait for a recommendation from the Antibiotic Working Party which might not eventuate for some considerable time.

The Secretary added that, in its most recent set of recommendations to the New Zealand Ministry of Health, the NDPSC had requested the addition of mupirocin to the prescription medicine schedule.

Dr Jessamine said that he had not been convinced of a need for change before reading the paper on methicillin-resistant staphylococcus aureus in Western Australia[1] but that he would now favour a change to prescription medicine. He said that Australia had asked for New Zealand to reclassify mupirocin and that New Zealand did not have safety ground on which to object to that request. The Committee agreed with this.

There was some concern about the lack of suitable alternative preparations available for self-medication and it was noted that these were mainly antiseptics. One member feared that consumers might use topical clindamycin as an alternative antibiotic but it was generally thought that most consumers would not recognise this potential use.

Dr Jessamine suggested that Medsafe should produce an article for *Prescriber Update* advising alternative courses of OTC treatment to mupirocin. The Committee supported this proposal.

Recommendations

- *That mupirocin be reclassified as a prescription medicine*
- *That Medsafe be asked to prepare a Prescriber Update article advising on alternative OTC courses of treatment to mupirocin.*

8.2 Domperidone

Methicillin-Resistant Staphylococcus Aureus in Western Australia, 1994-1997
Sirand Torvaldsen, Christine Roberts, Thomas Riley [1]

This medicine had been placed on the agenda because it was to be considered for reclassification to OTC status in Britain.

The Committee agreed with the conclusions in the Medsafe report and concurred that this was not a suitable medicine for OTC sale.

Recommendation

That there should be no change to the prescription medicine classification of domperidone.

9 NEW MEDICINES FOR CLASSIFICATION

The new medicines listed below had been recommended for classification as prescription medicines by the Medicines Assessment Advisory Committee. The MCC agreed that these should be prescription medicines. It was noted that, although pertussis vaccine was covered in the Schedule by the general entry for antigens, there was no individual entry for this particular antigen and that it should be added.

Recommendation

That the following medicines be classified as prescription medicines:

abacavir
mirtazapine
tolonium chloride
raloxifene hydrochloride
pertussis antigen

10 FOR THE NEXT MEETING

Topics arising from the current meeting for inclusion on the agenda of the twenty-second meeting were nasal steroids, H2 receptor antagonists and paracetamol suppositories (see below). There were no other suggestions at that stage for medicines or groups of medicines which might be suitable candidates for consideration for reclassification at the next meeting.

Dr Jessamine told members that there had been some dissatisfaction expressed by the pharmaceutical industry about the fact that the MCC met only twice a year and that not many classification changes were being made. He pointed out that the solution to this was obviously for industry to make more submissions as only small numbers were being received for consideration. He said that some extra work could be done out of session and that this would speed up processes and help satisfy the industry. While postal consultations had taken place on occasion, he said that the MCC had no formal out-of-session process. Dr Jessamine explained that the NDPSC had a system

whereby if, in the course of out-of-session consultation, there was a unanimous decision, the recommendation was carried forward. However, if only one member dissented, the matter was included on the agenda of the next meeting.

Some members remarked that they valued discussion and that they sometimes changed their opinion in the light of the discussion which took place in a meeting. However, it was agreed that some straightforward matters could be dealt with in this way. Urgent matters could possibly be handled by teleconference.

Dr Jessamine promised to explore this issue and report back to the next meeting.

11 GENERAL BUSINESS

11.1 Harmonisation of NZ and Australian Schedules

Dr Jessamine told the Committee that thyroid, one of the medicines agreed upon at the last meeting for inclusion in the New Zealand schedule as a prescription medicine in order to harmonise with the Australian schedule, had since had to be removed. He said that, in the course of processing the recommendations it had come to Medsafe's attention that dried animal thyroid was present in a number of dietary supplement-type products on the New Zealand market. These would become prescription medicines if thyroid were to be classified according to the recommendation. He said that this item would need to be returned to the NDPSC for further discussion.

The Secretary told the Committee that Medsafe had now looked at the second set of recommendations made by the NDPSC to the New Zealand Ministry of Health. Most of the recommendations were for the addition of prescription medicines which were not used in this country. These would be added to the Schedule as agreed. No decision was required from the MCC as no classification change or classification of a new medicine was involved.

However, a number of the recommendations required a change to the New Zealand classification. These had been summarised in table form and were circulated to members for discussion. (See Appendix) The Committee agreed to all the changes recommended by the NDPSC.

It was noted that the New Zealand schedule required an exemption for contact lens solutions for mercury (thiomersal). The Ministry also wished to enquire about the nature of 'a sealed device which prevents access to the mercury'. Such a device might not qualify as a medicine in New Zealand and would not therefore be entered into the Schedule.

Recommendations

That, in the interests of harmonisation with Australia, the following classification changes be implemented:

- *folinic acid: to become a prescription medicine*
- *edetic acid: an additional entry to be made to the prescription medicine*

schedule making an exception to general sale for dicobalt edetate in preparations for the treatment of cyanide poisoning

- *mebendazole: to become a pharmacy-only medicine for all pack sizes including those containing more than 600 milligrams which were currently prescription medicines*
- *oxetacaine: to remain a prescription medicine except for internal use which would become pharmacy-only medicine*
- *sodium cellulose phosphate: to become a prescription medicine*
- *tancetum vulgare: to become a prescription medicine in preparations containing more than 0.8% of oil of tansy and to remain general sale below this point*
- *diethylcarbamazine: to become a prescription medicine*
- *viprinium: to become a prescription medicine*
- *phenol: to become a prescription medicine in injections and a pharmacy-only medicine in medicines other than for injection containing more than 3%*
- *cresols: to become pharmacy-only medicines in preparations containing more than 3%*
- *xylenols: to become pharmacy-only medicines in preparations containing more than 3%*
- *tryptophan: to become a prescription medicine in preparations containing more than 100 milligrams per recommended daily dose and to remain general sale in medicines below this point*
- *chloral hydrate: to become a prescription medicine except in topical preparations containing 2% or less*
- *chloroform to become a prescription medicine for anaesthesia and a pharmacy-only medicine in other medicines containing more than 0.5%*
- *ether: to become a prescription medicine for anaesthesia. To become pharmacy-only medicine in other medicines containing more than 10%*
- *azelaic acid: to become a prescription medicine except for dermal use which should remain pharmacy-only medicine*
- *mercury; to become a pharmacy-only medicine in topical preparations containing 0.5% or less. To become a prescription medicine in all other preparations.*
- *mercurochrome; to be deleted from the Schedule - covered by the entry for mercury*
- *clotrimazole, econazole, isoconazole, tioconazole, nystatin: the limit to one course of treatment should be removed as a requirement for restricted medicine*

11.2 Fees

This item was discussed earlier in the meeting.

Downloading from the Medsafe Website

At the previous meeting, one of the members had enquired about whether or not it was possible to download the alphabetical listing of classified medicines from the Medsafe website. The Secretary was able to inform the Committee that this was not easy in its current form as a separate document had been created for each letter of the alphabet. However, it was possible that the list could be added as a single document at some stage. Dr Jessamine pointed out the dangers of downloading a document which was frequently updated.

Scheduling of paracetamol

The Secretary pointed out that a discrepancy had occurred in the classification of paracetamol since the last meeting when the general sale classification of powdered paracetamol in sachets containing not more than 1000 milligrams had been made consistent in pack size with tablets and capsules. Powdered paracetamol in sachets containing 1000 milligrams and in packs containing not more than 10 grams had previously been classified as pharmacy-only. This meant that 1000 milligram sachets in packs containing more than 10 grams had been prescription medicines. This pack size limit was not consistent with that for tablets and capsules and such pack sizes were now more appropriate as pharmacy-only medicines. The Committee agreed with this.

It was noted that the paracetamol entries could now be simplified and that it would no longer be necessary to distinguish between powders and other solid dose forms except for suppositories. While this simplification would technically make 1000 milligram tablets and capsules available as general sale or pharmacy-only medicines, the guidelines for paracetamol doses would ensure that tablets or capsules of this strength did not receive consent to market. Members agreed that there was no safety reason why suppositories should not align with other solid dose forms but saw that to do so could result in a classification change for some products. It was agreed therefore, that consultation would first be necessary and that the matter could be resolved at the next meeting.

Recommendation

- *That Medsafe should reword the schedule entries for paracetamol to ensure consistency of strength and pack size for tablets, capsules and powders containing paracetamol.*

- *That the classification of paracetamol suppositories be considered at the next meeting with a view to making their classification consistent with that of other solid dose forms.*

Date for the next meeting

Members agreed to meet again on Tuesday 12 October.

The meeting closed at 12:35pm

APPENDIX

HARMONISATION OF NEW ZEALAND AND AUSTRALIAN SCHEDULES

Changes recommended by the Australian National Drugs and Poisons Schedule Committee (NDPSC) to the NZ Ministry of Health at its meeting number 19 in November 1998

For each of the medicines below the NDPSC has recommended that NZ accept the Australian classification.
Consultation will be necessary if any change is to be made to current classifications.

Medicine	NZ Classification	Australian Classification	Comments
Folinic acid	P	RM	Approx 20 products to change. No risk envisaged from proposed relaxation of classification
Dicobalt edetate (Edetic Acid)	P over 0.25%	P over 0.25% but GS as an antidote for cyanide poisoning	NZ has 1 injection. Allow GS as antidote for cyanide poisoning.
Mebendazole	PO 600mg or less per pack P over 600mg per pack	PO	1 PM pack marketed. Good idea for family pack to be PO
Oxetacaine	P	P except for internal use PO for internal use	Mucaine oral suspension. Little absorption No other uses
Sodium cellulose phosphate	GS	P	Calcisorb sachets. Used only by specialists for acute renal failure. Change would not affect use.
Tanacetum vulgare (feverfew)	GS	P over 0.8% of oil of tansy	Consultation with health food sector necessary
Diethylcarbamazine	PO	P	Hetrazan tablets. Neurological side-effects.
Viprinium	PO	P	NZ has no products

Phenol	PO over 1%	P in injections PO over 3%	NZ has PO injectable products. May need to review shortly due to recent death from use as a facial peeling agent.
Cresols	PO over 1%	PO over 3%	
Xylenols	GS	PO over 3%	No products.
Tryptophan	GS	P over 100mg per recommended daily dose	NZ has about 130 infusions which are unlikely to be affected. Consultation necessary with the health food sector.
Chloral hydrate	RM up to 2g per day P	GS topical 2% or less P	
Chloroform	GS	P for anaesthesia PO over 0.5%	No products will be affected
Ether	RM except PO when used as a vehicle for a topical dose form	P for use in anaesthesia PO over 10%	No products
Azelaic acid	PO	P except for dermal use PO for dermal use	Skinoren. Has no use other than dermal.
Mercury	RM	PM PO topical use 0.5% or less	2 products which could change. NZ requires an exemption for contact lens solutions. (thiomersal)
Mercurochrome	PO	Delete	Covered by entry for mercury
Clotrimazole Econazole Isoconazole Tioconazole	RM for vaginal use for one course of treatment	RM for vaginal use	It would be consistent to relax the classification for vaginal use for nystatin at the same time.
Miconazole	RM for buccal use	RM for the treatment of oral candidiasis	Change to the wording only. No classification change involved.