MINUTES OF THE TWENTIETH 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 19 NOVEMBER 1998

PRESENT

Dr Stewart Jessamine (Chair)
Dr Tim Bevin
Dr Graham Wardrope
Mr Bernard McKone
Mrs Carol Smith (Secretary)

IN ATTENDANCE

Ms Alison Cossar

1 APOLOGIES

Mrs Marilyn Anderson
Mr David Thompson

2 WELCOME

Dr Jessamine declared the meeting open at 9:40am. He welcomed members to the meeting and introduced Ms Alison Cossar who had prepared the Medsafe reports and who would be available to supply regulatory and other information in the absence of Mrs Anderson. It was noted that Mrs Anderson had made her views about the agenda items know to the Chair prior to the meeting. It was also noted that Mr Thompson had submitted written comments for each of the agenda items and that these would be referred to during the meeting.

3 CONFIRMATION OF THE MINUTES OF THE NINETEENTH MEETING

The minutes of the nineteenth 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

Dr Jessamine outlined to the Committee the changes of name and logo which had occurred to the former Therapeutics section since the last meeting. He explained that the functioning of Medsafe remained largely unchanged but that this was a step towards separation from the Ministry.

Dr Jessamine then explained that by far the most important development since the last meeting was the opening of the Medsafe website. Ms Cossar spent some time demonstrating the contents of the website. Members were invited to submit comments about information they would like to see included. One of the members thought it would be useful to be able to download the alphabetical list of classified medicines. The Chair agreed to find out whether or not this was possible.

6 MATTERS ARISING

6.1 Sedating antihistamines sold as sleeping aids

At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.

The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather that to 5 days' supply. This would bring the pack size limits into line with those of Australia.

Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of *The New Zealand Regulatory Guideline for Medicines, Volume 1* which was currently under preparation.

The *Gazette* notice to implement the classification changes was due for publication on 26 November.

6.2 Review of sedating antihistamines not in combination products.

The Chair informed the Committee that Medsafe had not yet undertaken the review and that he anticipated that it would be ready in time for the next meeting.

6.3 Review of the labelling of all NSAIAs

Dr Jessamine informed the Committee that, in the interests of Trans-Tasman harmonisation, work on this project had been postponed pending the outcome of a review of all analgesics currently under way in Australia. Copies of the Australian review document had been included with the Reckitt & Colman submission for the reclassification of paracetamol 1000 milligrams in powder form. The recommendations made in the document had not yet been accepted. It was suggested that members keep the document for later reference.

It was noted that the main differences to be resolved between New Zealand and Australia related to pack sizes. He said that the Australian report recommended that the reduction of general sale pack sizes of paracetamol to 6 grams in Britain be monitored before a decision were made about changing Australian pack sizes. Dr Jessamine pointed out that there had been attempts on several occasions to raise the New Zealand general sales pack size limits for paracetamol from 10 grams to 12.5 grams to match the Australian pack size limits. He felt that there should be no move to change the New Zealand general sale pack size limit at this point.

Meanwhile, Dr Jessamine said, there were no immediate concerns about New Zealand labelling for analgesics. He told the Committee that the USA wanted to include an alcohol warning on paracetamol packs but that there were, as yet, no hard data to justify such a warning.

He said that a paper was also expected on child deaths from use of paracetamol at normal levels. Members commented that there seemed to be a move away from standard child doses of paracetamol. It was also noted that prophylactic use of paracetamol was quite widespread, particularly for immunisation.

Dr Jessamine concluded by commenting that as the normal suicide attempt involved 1 to 2 packs regardless of pack size, this might be a good reason for New Zealand to reduce its general sale pack size limit for paracetamol at a later date.

6.4 Astemizole

The committee had indicated its wish for the reclassification of astemizole from restricted medicine to prescription medicine to take place as quickly as possible. The company position was verified as being in favour of the change. Consultation was undertaken and the classification change came into effect on 27 August 1998.

6.5 Levocabastine nasal spray

At the last meeting the Committee had requested that a sedation warning be added to the package information as a condition of reclassification from restricted to pharmacy-only medicine. The company had appealed against the requirement and had submitted papers in support of its appeal.

The Committee was not happy for there to be no sedation warning on the labels of these products even though the low dose would minimise the risk of sedation. It was noted that only oral forms of sedating antihistamines were required to carry sedation warnings. However, members felt that the reference in the package insert to possible sedating effects was less likely to be read than if it were on the pack.

Dr Jessamine pointed out that as far as the Medicines Regulations were concerned, information required on the consumer information panel (including warning statements) could be included on a separate information sheet supplied with the medicine when the label was too small to contain all the required information. Therefore, inclusion of a warning on the package insert would meet the requirements if a warning statement were necessary.

Members agreed to accept that the warning statement did not need to be on the actual label. Dr Jessamine suggested that, for consistency, the standard warning statement recommended in volume 1 of the *New Zealand Regulatory Guidelines* for inclusion on non-sedating antihistamine labels and data sheets might be acceptable. Members agreed to accept this statement.

Recommendation

That a sedation warning would be acceptable on the package insert rather than on the actual package of levocabastine nasal spray.

That, for the sake of conformity, the company should be asked to reword the proposed warning statement to the following:

> *Although this medicine is unlikely to affect the ability to drive or operate machinery, a few people may be impaired and care should be taken.*

7 SUBMISSIONS FOR RECLASSIFICATION

7.1 Clindamycin (Dalacin T range, Pharmacia & Upjohn)

This was a company submission for reclassification of 1% topical preparations from restricted medicine to pharmacy-only medicine.

Ms Cossar, who had prepared the Medsafe report, outlined her findings. She explained that clindamycin had been investigated by the Committee at an earlier date when it had been reclassified from prescription medicine to restricted medicine and that she had taken into account information from that exercise when preparing her report. Ms Cossar said that, in the course of outside consultation, she had come up with two completely opposing views with regard to resistance issues. The head of the Department of Microbiology at Otago University was strongly opposed to over-the-counter (OTC) sale of antibiotics on the grounds that antibiotic resistance was easy to acquire and almost impossible to reverse. However, Dr Meech of Napier Hospital maintained his earlier view that, as systemic use of clindamycin was not widespread in NZ, the problem of resistance was not likely to be an issue.

Ms Cossar said that the previous committee appeared to have regarded clindamycin as a second-line treatment although the product did not appear to be used in this way. She felt that the two matters the Committee needed to consider were whether or not clindamycin was being used as a second-line treatment and whether it felt that the issues surrounding antibiotic resistance were relevant. She concluded by mentioning the Antimicrobial Resistance Working Group to the Ministry of Health which had been established to review the use of antibiotics in New Zealand and to make recommendations on their use. The findings of this committee were not yet available.

Dr Jessamine said that, while there was a large number of microbiologists claiming that resistance was a big problem, there was only a small amount of information to show that this was actually happening. He said that in some countries only some bacteria appeared to develop resistance and that the reasons for this were not clear. He pointed out that salmonella resistance was almost unchanged in New Zealand over the past 20 years in spite of the increase in the use of antibiotics. He also pointed out that clindamycin use was not widespread in clinical practice. Nor was it used for the treatment of animals. Dr Jessamine concluded that he felt considerably more detailed information would be needed to justify a downward change of classification. This was particularly significant in view of the harmonisation project with Australia which would already involve a shift from prescription status in Australia. He felt that any further change should be postponed until either a New Zealand or an Australian panel of experts had made recommendations.

One of the members observed that pharmacists were seeing children as young as 9 or 10 seeking acne treatment. He said that he did not like to see clindamycin used extensively in such young children and that pharmacists would prefer to recommend home hygiene and other forms of treatment first, using clindamycin as a second-line treatment. As such he felt that restricted medicine was a suitable level of classification. It was generally agreed that teenagers were much more likely to listen to the advice of a health professional even if parents were to offer appropriate advice on hygiene.

Members agreed that until the results of the Antimicrobial Resistance Working Group to the Ministry of Health or a similar Australian body became available, they would prefer to take a conservative approach to issues relating to possible resistance and to treat clindamycin as a second-line treatment requiring pharmacist intervention in its sale.

Recommendation

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

7.2 Paracetamol 1000 milligram powdered form (Lemsip Max Strength Reckitt & Colman)

This was a company submission for the reclassification from pharmacy-only to general sale for 1000 milligram sachets of powdered paracetamol in packs of 5 sachets.

Ms Cossar told the Committee that this was a proposal only, and that the company had not yet submitted a product for evaluation. She said that her concerns with this product were firstly, that it would not be as effective for 'flu-type indications as the Lemsip which contained pseudoephedrine and, secondly, that those suffering from influenza would not be likely to be eating when taking the product. However, she pointed out that the total amount of paracetamol fell well within the 10 gram upper limit for general sale pack size.

Members expressed some concern that the product might be overused because it was palatable. They also thought it might not have the same impact as a tablet to cause consumers to regard the product as a medicine. They were concerned that there could be a tendency for consumers inadvertently to take tablets at the same time. However, they noted that the proposed packaging gave clear warning of the contents on each sachet and that there was a warning against taking other products containing paracetamol at the same time.

It was noted that, if the Committee were to agree to accept the company request for 5 sachets to become general sale medicine, it would be logical to increase the maximum pack size to 10 sachets to bring the upper pack size limit for powdered dose forms into line with that of tablets and capsules.

It was also noted that, while the general sale pack size had been reduced to 6 grams in Great Britain, it would be a while before data would become available to show whether or not the reduction of pack size had made any impact on the figures for poisonings and hospital admission rates.

With regard to harmonisation with Australia, Dr Jessamine said that the Australians did not wish to drop from 12.5 grams for general sale pack sizes and that, in order to retain the 10 gram limit, New Zealand would need to prove a lower rate of poisonings than Australia. He felt that the Committee should not recommend to move to the 12.5 gram general sale pack size limit at the current meeting.

Meanwhile, it was agreed that 1000 milligram sachets of powdered paracetamol should be available as general sale medicine in packs of 10 sachets and that Medsafe would work out suitable wording for the scheduling of the change.

Recommendation

That paracetamol in powder form should be classified as a general sale medicine when in sachets containing 1000 milligrams and in packs containing 10 sachets or less.

7.3 Tetrahydrozoline (Visine Eye Drops Pfizer)

This was company submission for the reclassification of 0.05% solutions of tetrahydrozoline from pharmacy-only to general sale medicine in eye preparations.

Ms Cossar said that it had been hard to find any information about the safety of the product.

There was some discussion about the treatment of red eye and the suitability of supermarket sales for products to treat this condition. It was generally agreed that some kind of advice should be available for eye conditions and that products for treating red eye should be sold from pharmacies. Consideration was given to whether or not products for eye comfort should all be available as general sale medicines while decongestants for the eye should be available from pharmacies. However, in view of the current classification of a number of other decongestant products and in view of the forthcoming harmonisation exercise with Australia, it was seen that grouping eye products into different classification categories in this way would not be feasible.

It was agreed that, in view of its indications, tetrahydrozoline should remain a pharmacy medicine in line with the Australian classification.

Recommendation

That tetrahydrozoline for use in the eye should retain its current pharmacy-only classification.

8 REAPPRAISAL OF EARLIER RECLASSIFICATIONS

These medicines had been agreed upon at the nineteenth meeting as possible candidates for reclassification to a less restrictive classification. The Ministry had prepared reports for each.

8.1 Aciclovir and penciclovir

Topical preparations for herpes labialis

Ms Cossar told the Committee that, as a result of her investigation into these two medicines, she was inclined towards the view that aciclovir would be suitable for general sale but that penciclovir should stay as a pharmacy-only medicine. She had been unable to find evidence of any problems with the use of topical aciclovir and pointed out that access was an important issue as treatment needed to be commenced as early as possible. Penciclovir was still a relatively new chemical entity and had been classified as a pharmacy-only medicine because its toxicity was no greater than that of aciclovir. It was still a prescription medicine in most other parts of the world. Therefore it would be prudent to observe the results of its use as a pharmacy-only medicine for at least 3 years before recommending a less restrictive classification.

However, the Committee was not generally in favour of general sale classification for either penciclovir or aciclovir.

Pharmacists felt that as the products were expensive, advice was necessary about whether or not the correct diagnosis had been made. Cases of impetigo infection were often observed by pharmacist as having been misdiagnosed by consumers. Such cases needed to be referred on. Pharmacists also observed cases where oral treatment would be needed and such cases also required referral to a doctor. Where the condition did appear to be herpes, the Committee felt that it was the duty of a pharmacist to point out that it could be too late for treatment to be effective for the current bout of infection but that the product should be on hand for immediate use for the next infection.

In addition, pharmacists had found that many consumers were not aware of the ease with which herpes infections could be transmitted. While this information could be provided in the package information, the Committee felt that a general sale classification for the medicine would not reinforce the message that the infection was highly contagious.

Some members thought that, as the products were so small, supermarkets would be reluctant to stock them because they could be easily shop-lifted.

There was general agreement that topical forms of both aciclovir and penciclovir for the treatment of herpes labialis should remain pharmacy-only medicines on the grounds that appropriate use is dependent on appropriate counselling.

Recommendation

That there be no change to the current pharmacy-only classification of topical aciclovir and penciclovir when indicated for herpes labialis.

8.2 Antifungals in topical preparations.

These products, with the exception of those indicated for infections of the nails, were currently classified as pharmacy-only medicines. The Ministry report prepared by Ms Cossar investigated whether or not they would be suitable for reclassification as general sale medicines.

The Committee agreed that toxicity was not an issue with these products. Nor was there any identified potential for abuse or misuse. The Chairman suggested that the Committee should consider whether topical antifungals should be made more readily available and, if so, whether this wider availability should be for general use or restricted to localised use and whether there should be any restriction on the indications.

It was agreed that preparations such as foaming solutions, intended for application to a large area of the body, were not suitable for general sale. Members felt that some types of fungal infections such as nappy rash were difficult to diagnose, even for doctors while others like athlete's foot were easily identified by the consumer. For that reason the committee agreed that it would be acceptable to limit the general sale indication to athlete's foot only, in order to provide for an element of advice in the sale of antifungals for other indications.

There was some discussion as to how the recommendation would affect products with a number of indications. Dr Jessamine thought that companies manufacturing these products would probably seek a new image for a general sale pack for use by sports people. Products with tinea pedis as only one of a number of indications would need to retain their pharmacy-only classification. It was thought that none of the products currently on the market was likely to qualify for reclassification to general sale in the current pack.

Recommendation

That topical antifungal preparations should be reclassified from pharmacy-only medicine to general sale medicine when indicated solely for tinea pedis.

8.3 Hydrocortisone

The Committee had requested that the Ministry investigate whether or not there should be an increase in volume limits for 1% lotions as restricted medicines. This had been proposed as the current limit of 15 millilitres, because of its viscosity, was impossible to dispense in quantities sufficient to be of any effect. Ms Cossar had prepared a Ministry Report and several outside comments had been received including a company submission for reclassification to pharmacy-only of 1% preparations.

Members agreed that they were not interested in reviewing the classification of either 1% or 0.5% concentrations at this point but were concentrating solely on whether or not the volume limit should be increased for the 1% preparations. They did not wish to increase the volume limit for 0.5% preparations. However, they recognised that, for the sake of consistency, they would also need to address the 15 gram limit for 1% cream preparations.

Dr Jessamine said that the classification of hydrocortisone would come under scrutiny shortly as part of the harmonisation exercise with Australia. He said that the current situation in Australia was that 1% hydrocortisone was a prescription medicine and 0.5% was restricted medicine but with a volume limit of 30 grams. He said that while the Australians might be happy to meet the New Zealand classification at 30 grams or 30 millilitres, they would be unlikely to accept 100 millilitres for over-the-counter sale.

None of the Committee was comfortable with 100 millilitre containers being available for OTC sale in New Zealand. Members agreed it would be reasonable to take on the 30 millilitres which was acceptable in Australia as a step towards harmonisation. However, they thought that 50 millilitres would be better because of the viscosity of the product. They agreed that the onus would then be on companies to produce appropriate packs if they wished to promote OTC products.

However, it was decided that there should be no recommendation for a volume increase until the matter had been addressed by the National Drugs and Poisons Schedule Committee Working Party on Harmonisation.

Recommendation

That there be no increase in the volume limit for 1% hydrocortisone lotions sold as restricted medicines.

8.4 Minoxidil in topical preparations

Ms Cossar summarised her report in which she concluded that 2% solutions would be suitable for sale as pharmacy-only medicines but that 5% solutions should remain restricted medicines.

The pharmacists on the committee remarked that most sales were of 5% strength products and very little of the 2% strength was marketed.

Dr Jessamine said that if there were to be any problem it would be one of chronic toxicity. He said that although there was some cutaneous absorption this was less than 1% and that the content of a whole bottle was only equivalent to one standard oral dose. He felt, therefore, that even overuse of a product would probably not result in a lowering of blood pressure. There appeared to be no evidence of increased adverse reactions during the period in which topical minoxidil had been available over the counter.

Some concern was expressed about Internet sales and the quality of the advice component in this kind of sale. However, members agreed that the products were expensive and that consumers would not continue to use them if they were unhappy with the result. They agreed that there was probably no need for extra pharmacist intervention for first-time use of the product.

In view of the fact that the main use was of the 5% solutions, the Committee did not feel there was any point in splitting the classification according to strength. Nor did they see any pressing need to reclassify. It was noted that there had been no company comment. Members agreed not to recommend a change of classification at this point but indicated that they would be willing to revisit the matter if companies requested this.

Recommendation

That there be no change to the restricted medicine classification of minoxidil for topical use.

9 NEW MEDICINES FOR CLASSIFICATION

Medicines classified by the MAAC

Members discussed briefly the list of new chemical entities provided by the Medicines Assessment Advisory Committee for which a prescription medicine classification had been recommended.

Recommendation

That the following new chemical entities be classified as prescription medicines:

alatrofloxacin mesylate
clopidrogel hydrogen sulphate
eprosartan mesylate
gemcitabine
piperazine oestrone sulphate
rizatriptan benzoate
rituximab
temozolomide
tolterodine L-tartrate
trovafloxacin mesylate

10 FOR THE NEXT MEETING (Suggested medicines for reclassification)

10.1 Mupirocin

This had arisen during the discussion about clindamycin and issues of increasing antibiotic resistance. Dr Jessamine said that there was now a considerable amount of New Zealand data available about resistance to mupirocin and the Committee should decide whether or not it wanted to pre-empt any recommendation of the National Working Party by reclassifying this medicine back to prescription status.

Members felt that, as mupirocin was of value in hospitals, it could be helpful to limit access. However, there was some doubt as to whether or not restricted access would improve the current situation.

One member remarked that there was considerable demand in pharmacies for the product and that the proposed use was not always appropriate. It was felt that reclassification could be a way of indicating to the public that there was a problem with the indiscriminate use of antibiotics.

The Committee agreed that a Medsafe report should be prepared and that mupirocin should be added to the agenda of the next meeting.

10.2 Domperidone

A recent *Scrip* article drew members' attention to the fact that domperidone had recently been made available over the counter in Britain and that it was already available OTC in eight other countries.

It was agreed that domperidone should also be added to the agenda of the next meeting.

11 GENERAL BUSINESS

11.1 Harmonisation of NZ and Australian Schedules

The Chairman outlined the proposal to harmonise the schedules of both countries. He told the Committee that the Australian National Drugs and Poisons Schedule Committee (NDPSC), of which he was a member, had set up a Working Party to make recommendations for changes necessary to harmonise the medicines schedules of both countries. He said that the recommendations of the first meeting of the Working Party had now been accepted by the NDPSC and that the paper which members had been sent contained the final minutes from their first meeting. The Committee would need to discuss these recommendations and make its own recommendations to accept, modify or decline to accept the recommendations of the NDPSC. Most of the recommendations at this stage were for action on the part of the NDPSC although some also required action from the MCC. The earlier recommendations were mainly of a policy nature. Those recommendations which were more specific were related to prescription medicines. Medicines with lower classifications would be dealt with at later meetings. Dr Jessamine said that the MCC would first need to decide whether it was happy to accept the general policies accepted by the NDPSC. It would then need to look at those more specific recommendations which required action on the part of the MCC and which were related to prescription medicines or groups of prescription medicines.

Policy Recommendations

The following recommendations which were made at the first meeting of the Trans-Tasman Harmonisation of Scheduling Working Party and accepted by the National Drugs and Poisons Schedule Committee on 18 August 1998 require no action on the part of the Medicines Classification Committee:

Recommendation 1
Recommendation 3
Recommendation 4
Recommendation 5
Recommendation 6
Recommendation 7
Recommendation 8
Recommendation 8a (second part)

Recommendation 2 from the Working Party to the NDPSC outlines the principles to be applied by the Working Party to the Trans-Tasman harmonisation of scheduling. The MCC agreed to accept these principles. It was noted that some of the points fell outside the terms of reference of the MCC but that the Ministry was in agreement with these general principles.

MCC Recommendation

That the MCC accept the following principles as recommended by the Working Party on the Trans-Tasman Harmonisation of the Schedules between Australia and New Zealand and accepted by the NDPSC:

1. *For both countries there should be:*

- *equivalent scheduling for drugs and poisons*
- *equivalent general exemptions from scheduling*
- *a common set of definitions and scheduling criteria and guidelines*
- *consistent interpretation of scheduling criteria*
- *common nomenclature for drugs and poisons*
- *within the schedules, common descriptions for generic drug and poison classes or any other general classification*
- *harmonisation of labelling and packaging*
- *harmonisation of safety directions, warning statements and first-aid instructions.*

2. *Where differences in scheduling of a drug or poison currently exist between New Zealand and Australia, the following principles should apply:*

- *the classification should be reassessed using the common set of definitions and scheduling criteria with a view to achieving a common outcome*
- *the underlying principle is to harmonise on the less restrictive schedule while giving due consideration to public health and safety issues and/or specific jurisdictional needs.*

3. *The process of harmonisation of drug and poisons scheduling should recognise the wider regulatory requirements of other agencies and any complexities should not be exacerbated by harmonisation of schedules.*

Recommendation 8a (first part only)
Although the first part of this recommendation was to the NDPSC, the recommendation was for the NDPSC to encourage the New Zealand Ministry of Health to adopt common nomenclature for drugs and poisons based on International Nonproprietary Names (INNs). The MCC recognised that New Zealand was already tending towards the use of INNs and agreed to recommend that the use of this common nomenclature be accepted.

MCC Recommendation

That, in the interests of harmonisation, New Zealand should adopt nomenclature for medicines based on their International Nonproprietary Names.

Specific recommendations

These recommendations relate to specific changes required to the schedules of either New Zealand or Australia in order to achieve harmonised schedules. The following recommendations are to the NDPSC only and do not require action on the part of the MCC.

Recommendation 9
Recommendation 11
Recommendation 12
Recommendation 14
Recommendation 15
Recommendation 16
Recommendation 17
Recommendation 18

Recommendation 10 was that each country should adopt into its prescription medicine schedule, all medicines in the corresponding schedule of the other country and not included in its own schedule whether or not there were registered products containing that medicine. The MCC agreed that there would be no regulatory impact from listing prescription medicines which were not available in New Zealand. However, it was noted that New Zealand medicines which were not scheduled were considered to be general sale medicines and that care would be needed to ensure that products considered to be general sale medicines in New Zealand were not inadvertently changed into prescription medicines by such a move.

MCC Recommendation

That New Zealand should accept into part 1 of the First Schedule to the Medicines Regulations 1984 and amendments, any medicines which are listed as prescription medicines in the Australian Schedule but which are not scheduled in New Zealand and are not deemed to be general sale medicines in New Zealand.

Recommendation 13 was concerned with common generic entries in the prescription medicine schedules of both countries. These were discussed separately by the Committee as follows.

The Committee was advised that as the schedules in the two countries worked differently, it seemed that harmonisation would be achieved if products containing scheduled ingredients were classified in the same way in both countries. Such harmonisation did not necessarily require identical wording to achieve the desired end result. For example, while the Australian schedule covered all poisons, the New Zealand one referred only to products which had already been identified as medicines for human therapeutic use. Therefore the words “for human therapeutic use” were redundant in the New Zealand schedule. In the same way, the words “except when separately specified in this schedule” in the Australian schedule were only valid in the New Zealand schedule when they related to a change of classification, that is, to S2, S3 or S4. Therefore, some of the recommended changes to the New Zealand wording were not relevant, as there was no inconsistency of classification and no change was

required. This applied to the following medicines in Table 11B appended to the Working Party minutes:

- Antigens
- Botulinum toxin
- Bromides
- Gonadotrophic hormones
- Heparins
- Immunoglobulins
- Lead
- Pancreatic enzymes
- Rauwolfia

Antimony

Organic compounds should be covered by the introductory statement to the Schedule. If not, this would be the place to amend the New Zealand schedule. No conflict of classification was seen to exist with this entry.

Anabolic steroids

Members noted that New Zealand also had an entry "steroid hormones" which the NDPSC recommendation appeared to have overlooked. Although no conflict of classification was apparent New Zealand would change the entry for anabolic steroids to "androgenic and anabolic steroidal agents" if this was considered necessary for harmonisation.

The Committee agreed to include the following generic entries for medicines which were already covered by individual entries in the New Zealand schedule. Members noted that monoclonal antibodies were contained in pregnancy test kits which were classed as medicines in New Zealand but were not considered to be medicines in Australia.

- Antibiotic substances; except when specified elsewhere in the Schedule
- Antisera; for parenteral use
- Hypothalamic releasing factors
- Ion exchange resins; except when specified elsewhere in the Schedule
- Monoclonal antibodies; except in pregnancy test kits
- Prostaglandins
- Sex hormones and all substances having sex hormone activity
- Toxoids; for parenteral use

Benzodiazepines

Dr Jessamine told the Committee that these were shortly to become controlled drugs in New Zealand following a World Health Organisation recommendation and international trends. As such they would be removed from the First Schedule to the New Zealand Medicines Regulations and added to the Misuse of Drugs Act which was not within the terms of reference of the MCC. The Committee was therefore unable to take action to harmonise the scheduling of benzodiazepines with Australia and any action in this area would need to be taken by other parties.

Barbiturates
Dr Jessamine said that all barbiturates appeared to be controlled drugs in New Zealand. There did not appear to be any individual listings for barbiturates in the Schedule although there was provision for them to be scheduled as prescription medicines if they were not already scheduled in the Misuse of Drugs Act. The MCC was therefore unable to harmonise the barbiturates entry in its Schedule with that of Australia.

The following medicines from Table 11b were not contained in any products registered in New Zealand. As they were not scheduled, Dr Jessamine pointed out that they would technically be general sale if contained in medicines. He said that a decision needed to be made about whether these should be added as prescription medicines or whether they should take the lower classification. Except for silicones there would be no need for any modifying statements. A number of internal and topical products contained silicone which was regarded as a general sale medicine when used in these ways. The Committee agreed that the following medicines should be added to part 1 of the First Schedule as prescription medicines.

- Arsenic
- Dinitrocresols
- Dinitronaphthols
- Dinitrothymols
- Silicones; for parenteral use
- Thyroid

Haloperidol
It was agreed that the proposed Australian wording was cumbersome and not particularly helpful in identifying other substances structurally derived from butyrophenone. It was suggested that any medicines should be listed separately for ease of identification and that a generic entry for butyrophenones could be an alternative way of scheduling these medicines. There should be further discussion with the Working Party about this matter.

MCC Recommendations

That the entry for anabolic steroids in part 1 of the First Schedule to the Medicines Regulations be amended to read:

Androgenic and anabolic steroidal agents

That the following generic entries be added to part 1 of the First Schedule to the Medicines Regulations:

Antibiotic substances; except when specified elsewhere in the Schedule
Antisera; *for parenteral use*
Hypothalamic releasing factors
Ion exchange resins; *except when specified elsewhere in the Schedule*
Monoclonal antibodies; except in pregnancy test kits
Prostaglandins
Sex hormones and all substances having sex hormone activity
Toxoids; *for parenteral use*
Arsenic

Dinitrocresols
Dinitronaphthols
Dinitrothymols
Silicones; for parenteral use
Thyroid

That further discussion should take place about the proposed wording for the harmonised scheduling of haloperidol.

11.2 Remuneration for Committee Members

Dr Bevin raised the matter of remuneration for attendance of members at meetings. He said he felt the cost to general practitioners for attendance at meetings was considerable. He stated that many patients would not come to a practice if a locum were in attendance or would attend a more competitive practice instead and that patients could be lost. He felt that the payment made to members was insufficient to cover this possible loss of business.

Dr Jessamine pointed out that the actual attendance fee was set by the State Services Commission and that a set scale of fees applied throughout the government sector. In order to compensate for this, Medsafe had taken upon itself to provide a fee for time spent preparing for meetings and for payment for a locum where a locum was necessary to keep a business operational. He said that it might be possible to reconsider the amount paid for preparation time as a means of increasing the amount received by members but that it would be unlikely that the attendance fee could be increased. Even if the Committee were to be upgraded on the State Services Commission scale, he pointed out that this would result in only some $40 or $50 dollars extra before tax for attendance at each meeting.

Other members commented that, while attendance at meetings might result in a certain amount of lost business opportunity, they felt it was probably fiscally neutral. They also felt that membership had positive aspects in that meetings were enjoyable and that the nature of the Committee business was interesting, providing a new dimension to their view of medicines.

Dr Jessamine pointed out that the Medicines Classification Committee was an important Ministerial Advisory Committee and that there was considerable professional kudos attached to membership of such committees. He agreed to investigate the possibility of increasing the amount paid to members for attendance at meetings.

11.3 Date for the next meeting

The Committee agreed on Thursday, 25 March 1999 as a suitable date for the next meeting.

The meeting closed at 2:50pm