

**MINUTES OF THE NINETEENTH MEETING  
OF THE MEDICINES CLASSIFICATION COMMITTEE HELD  
IN THE THERAPEUTICS SECTION OF THE MINISTRY OF HEALTH  
ON THE EIGHTEENTH FLOOR OF GRAND PLIMMER TOWER,  
4-6 GILMER TERRACE, WELLINGTON  
ON WEDNESDAY 20 MAY 1998  
COMMENCING AT 9:30 AM**

**PRESENT**

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

**1 WELCOME**

Dr Jessamine welcomed members to the nineteenth meeting. He explained that he had recently been appointed to the position of chair of the Committee following the resignation of Dr Boyd. The reason for Dr Boyd's resignation was that the Therapeutics Section was moving towards becoming a business unit. This meant that a number of redelegations of authority were necessary. As Chief Advisor, Regulation and Safety, Dr Boyd was already the Ministry delegate for two other Ministerial Advisory committees serviced by the Therapeutics Section. It was, therefore, appropriate that he also be the delegate for Medicines Classification Committee (MCC) matters. However, it was not appropriate for him to continue as chair of the MCC in the new role as Ministry delegate for classification matters. As legislation required that the chair of the Committee be a Ministry of Health member, Dr Jessamine, who was also the New Zealand member for the Australian National Drugs and Poisons Schedule Committee (NDPSC), had been appointed. This had left a vacancy for a second Ministry member to fulfil the requirements of the legislation. Mrs Anderson had therefore been appointed to the second Ministry position.

Mrs Anderson spoke briefly about her qualifications and experience. Dr Jessamine added some examples of the types of projects with which Mrs Anderson had been involved in the Therapeutics Section during the five years since she had joined the Ministry.

**2 APOLOGIES**

There were no apologies.

### **3 CONFIRMATION OF THE MINUTES OF THE EIGHTEENTH MEETING**

The minutes of the eighteenth 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 declared as prejudicial to recommendations about any of the matters to be discussed during the meeting.

### **5 MATTERS ARISING**

Before moving on to discuss agenda items related to individual medicines Dr Jessamine told the committee a little about the NDPSC of which he was a member. He explained that as the MCC and NDPSC meetings coincided he was not able to attend the current Australian meeting. The latter covered three days and dealt not only with medicines but also with veterinary products and all agricultural and industrial chemicals. However, he had forwarded his written comments on relevant agenda items. Included were comments about the framework for non-steroidal anti-inflammatory agents (NSAIAAs) and how New Zealand had reached its position on the classification of these. He added that the views he expressed to the NDPSC were intended to be taken as his own rather than those of the MCC.

Dr Jessamine also explained to the committee that there were a number of agenda items which were common to the current agendas of both committees. He had hoped to be able to arrange for teleconferencing to allow discussion between the two committees. Unfortunately there had not been enough time to make the necessary arrangements but he saw this as being a potentially useful tool for future use in the interests of harmonisation of classification between the two countries.

#### **i Non-Steroidal Anti-Inflammatory Agents**

##### **a Ibuprofen 200mg tablets in packs of 96**

At the eighteenth meeting the committee had recommended that companies marketing packs of 96 200mg tablets should be asked to remove these from the market as members did not see such large packs as fitting into the OTC criterion for short-term use. The Boots Company had been asked to submit its views on this request and had responded accordingly.

Concern was expressed by some members that larger packs might encourage the use of higher doses for anti-inflammatory purposes and that a restricted medicine classification could take care of this potential shift in usage. However, others were of the opinion that the easy access to smaller pack sizes would not prevent this from

occurring. There was also concern about the trend towards the use of higher doses by sports people but it was agreed that this was an issue of abuse, was not relevant to the matter under discussion and would not be controlled by limiting pack sizes.

Some members felt that the Boots Company had made a good case for the 96 tablet pack as a multi-use, family pack and had demonstrated that it was not generally being used long-term. It was pointed out that ibuprofen was basically a safe product and there was no evidence of harm occurring from use of the larger pack size. There was, therefore, no justification for the reclassification of larger pack sizes. However, it was agreed that the committee would not like to see this pack size available as general sale medicine.

The committee accepted that the submission from the company had established that the pack was intended for multi-user purposes and had demonstrated satisfactorily that this use was predominantly short-term.

### ***Recommendation***

*That there be no further move taken to withdraw 96 packs of 200mg ibuprofen tablets from the market or to consider their reclassification to restricted medicine status.*

### **i (b) Review of Aspirin Labelling**

The Committee had requested that the labelling of all products containing aspirin be reviewed by the Therapeutics Section. The Chairman informed the Committee that while the request had been passed on to the leader of the Evaluation Team, the Team had not yet been able to undertake this project. Dr Jessamine explained that the Ministry resources were limited and that it was necessary to prioritise. He told the Committee that the Evaluation Team had been involved in a large project to revise the guidelines for all their operating procedures and that this project accounted for the lack of resources for other projects.

The Committee expressed regret that the review of aspirin labelling had not yet occurred and hoped that the project would now be given a higher priority.

The Committee also concluded that it would be appropriate for the labelling guidelines to be standard for all non-steroidal anti-inflammatory agents (NSAIAAs) and that the scope of the project should be enlarged to cover labelling requirements for all medicines in this class.

### ***Recommendations***

- *That the Committee convey to the Ministry its regret that the project to review the labelling of aspirin had not been undertaken*
- *That the Ministry be asked to give a higher priority to the project.*
- *That the scope of the project to review the labelling of aspirin products be broadened to cover the labelling of all NSAIAAs*

**c Ibuprofen 200mg tablets**

This Whitehall submission for reclassification to general sale of packs of up to 24 tablets had been made as part of the company comment on the proposed NSAIA framework but was received too late for inclusion on the agenda of the eighteenth meeting. The company wished to have this and the following submission for liquid ibuprofen considered at this meeting in spite of the recommendation made at the last meeting to retain the status quo for the classification of all NSAIAAs.

Although there was agreement about the general safety of the medicine there was a definite reluctance to see ibuprofen sold outside pharmacies. Prolonged discussion on various safety issues ensued. This included concern about use with asthma. Dr Jessamine pointed out that UK data showed that the incidence of allergy with asthma was low. He pointed out that aspirin was already available on general sale and that if that were the reason for limiting access to ibuprofen then the same limits should be applied to aspirin.

Dr Jessamine continued that he felt that, as aspirin was classified the way it was for historic reasons, he would prefer to see ibuprofen considered on its own merits. He suggested that members should consider whether they wished to classify a medicine for the majority of the population who would use it responsibly or for the small percentage who would misuse products.

The potential for a change in the use of the medicine, as already discussed earlier in the meeting, was revisited. There was concern that consumer perception of the product as a "safe" general sale item might lead to its being used in the higher doses required for anti-inflammatory purposes and there could be a move away from the predominantly analgesic doses for which the product had originally been reclassified.

A point made during discussion at the eighteenth meeting was that the introduction of general sale paracetamol had brought about a decline in the use of aspirin. Members thought that the introduction of ibuprofen at general sale level could have a similar effect on the use of paracetamol. Although ibuprofen was safer than aspirin, a shift in usage of this nature would result in exposing a far larger group of consumers to the likelihood of adverse effects.

The committee noted that data supplied by the company concentrated on studies which excluded high-risk patients. In addition, the post-marketing data was felt to be insufficiently sensitive to allow separation of over-the-counter use from prescribed use. While there had been limited evidence of increased adverse effects associated with the change to general sale availability of ibuprofen in both Britain and the USA, the committee acknowledged that it was widely recognised by adverse reaction reporting bodies that the currently used reporting systems were not sensitive enough to pick up small but significant increases in side-effects from over-the counter products. It was generally agreed that the data submitted did not meet the committee's normal requirements to justify a classification change which, in this case, would be a substantial body of new safety data in respect of actual short-term use by consumers on a self-medicating basis.

Members agreed that they had earlier considered the limiting of pack sizes to be an unsatisfactory reason to classify ibuprofen tablets as restricted medicine. They felt it would therefore be inconsistent to use pack size to support a recommendation for a general sale classification.

The committee summarised the reasons for its reluctance to see ibuprofen 200 mg tablets reclassified to general sale medicine as follows:

- there was a need for access to pharmacist advice if required
- moving outside a pharmacy environment might widen the use and indications
- the majority of data submitted excluded high-risk patients
- a need was seen for real-use data outside pharmacies. The post marketing data received, while reassuring, might not cover use outside pharmacies.

The chairman suggested that as committee had established that it was unhappy to see ibuprofen reclassified on the information already to hand, members should next consider what sort of information would be required in order for it to be reclassified to general sale. He said a clear statement should be made so that companies would know what was required.

It was agreed that the committee would require both utilisation data to show that ibuprofen was safe in a general sale environment, and also post-marketing surveillance data from use of ibuprofen in a general sale environment. Members agreed that this type of information would be required before any NSAIA could be considered for general sale availability. They recognised that this would prevent New Zealand from taking an initiative in making NSAIA's available as general sale medicines as this sort of information could only be obtained after a medicine had been marketed at that level over a number of years in another country.

### ***Recommendation***

*That there be no change to the pharmacy-only classification of 200 milligram ibuprofen tablets.*

### **d      Liquid Ibuprofen 100mg/5mL**

This was a Whitehall submission for reclassification from restricted medicine to pharmacy-only medicine. It was received at the same time as the above submission for ibuprofen 200mg tablets.

Most committee members had few problems with the product becoming available as a pharmacy-only medicine. There was some concern about gastric and kidney effects but it was agreed that these aspects could be covered by appropriate consumer information in the same way as was already done for the product as a restricted medicine.

There was also concern that liquid ibuprofen would be treated in a similar way to liquid paracetamol by consumers and particularly that it would be given without food.

This was also seen as an issue which could be addressed by the provision of suitable consumer information.

Members agreed that there were no concerns about Reye's Syndrome or necrotising fasciitis. Data showed that there were no significant differences from paracetamol in these respects.

The potential for poisoning was discussed. Paracetamol poisonings in children were acknowledged as usually being accidental. Ibuprofen was seen as being safer than paracetamol in this respect.

The chairman pointed out that liquid ibuprofen currently had a number of requirements which had to be fulfilled before products could be sold as restricted medicines. He said he would be comfortable if these same requirements were carried over as requirements for liquid ibuprofen as a pharmacy-only medicine. The rest of the committee accepted this suggestion.

### ***Recommendation***

*That ibuprofen should be a pharmacy-only medicine when in liquid form for oral use in medicines sold in the manufacturer's original pack containing 200 millilitres or less in volume and in strengths of 100 milligrams or less per 5 millilitres and when bearing the package information required in the New Zealand Regulatory Guidelines for this medicine to be sold over the counter.*

## **ii Objections to recommendations made at the 18<sup>th</sup> meeting**

### **a Cyclopentolate - Optometrist exemption from prescription status.**

Smith and Nephew had objected to the recommendation made at the last meeting that optometrists should have access to this medicine. The company had objected on the grounds that use in patients suffering from narrow-angle glaucoma might precipitate an acute attack of angle closure glaucoma. The Ministry had replied that this aspect had already been considered by the committee and that the risks had been considered acceptable. As there was no new evidence to cause the item to be reconsidered by the committee, the classification exemption had been implemented on 22 January.

### **b Sodium phosphate bowel preparations**

Baxter had objected to the recommendation for a prescription medicine classification. The Ministry was of the opinion that the matter should be returned to the committee only if there was evidence to prove that the adverse reactions which had occurred were not attributable to sodium phosphate bowel preparations. As such evidence was not forthcoming, the recommended classification change was implemented on 22 January.

### c Terfenadine

The Ministry had become aware of the intention of Hoechst Marion Roussel's intention to object to the recommendation to reclassify terfenadine as a prescription medicine only shortly before the change was due to be gazetted on 22 January. Notification of intention to object had not been received by the Ministry. However terfenadine had been removed from the *Gazette* notice pending resolution of the objection. The Ministry did not consider that the objection contained material to justify a reconsideration of the earlier recommendation. It therefore notified the company that the classification change would take place in either the next cumulative *Gazette* notice or the new amendment to update the First Schedule of the Medicines Regulations.

Dr Jessamine pointed out that part of the company objection was based on the fact that terfenadine had been treated in isolation whereas on previous occasions it had been considered alongside other non-sedating anti-histamines, particularly astemizole. He told the Committee that the company marketing astemizole had expressed the desire to have astemizole considered for classification to prescription status at the next meeting of MCC. So far this had been conveyed only by telephone and there was some doubt as to the company's definite position. However, he added that the classification of astemizole was on the agenda for reclassification to prescription medicine at the current meeting of the Australian scheduling committee and that the company had stated that they intended to market astemizole only as a prescription medicine world-wide.

Members agreed that they would be in favour of New Zealand following the same course of action as Australia in this matter. They would be happy to fall in with the company's wishes for astemizole to be reclassified to prescription status. It was agreed that, in order to minimise the delay in following Australian reclassification, a postal vote might be undertaken provided the requirements for consultation could be met.

#### ***Recommendation***

*That the secretary consult with the company in order to verify its position with regard to the classification of astemizole in New Zealand. Depending on the outcome, the Ministry should then proceed:*

- *either to implement the classification change as quickly as was feasible*
- *or to place astemizole on the agenda of the next meeting as a candidate for a change to prescription medicine.*

### iii Codeine

The committee had requested information on action to date on matters relating to the classification of codeine as a pharmacy-only medicine. There had been some concern

about the abuse of pharmacy-only products containing codeine and a desire for a possible more restrictive classification.

Dr Jessamine pointed out that codeine was a Class C (Part VI) controlled drug, scheduled under the Misuse of Drugs Act 1975. As such, it came under the jurisdiction of the Mental Health Section which was responsible for the Drugs Advisory Committee, a ministerial advisory committee set up under the Misuse of Drugs Act. He told members that the only way a change to the classification of codeine could be influenced by a change to the Medicines Regulations would be by reclassifying all medicines which are controlled drugs under Section C Part VI of the Misuse of Drugs Act. This would include pholcodine. The Committee agreed that such a move was undesirable.

The Committee debated whether or not they should ask the Drugs Advisory Committee to consider removing codeine from Part VI of Section C. It was noted that the availability of codeine over the counter had been an issue for many years. During that time efforts had been made to make the codeine less easily extractable from products. However, this had met with limited success. It was also noted that the MCC had consistently been of the opinion that it would be unfair to deny genuine users access to a useful product because of its misuse by a minority of the population. Dr Jessamine pointed out that restricting access to codeine could also increase the number of pharmacy break-ins and violence towards pharmacists from those seeking to obtain morphine.

The committee decided not to pursue the matter at that point but that a watching brief should be held on over-the-counter codeine.

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#### **iv Reappraisal of earlier reclassifications**

At the request of the committee, the secretary had prepared a list of all medicines which had previously been reclassified from prescription medicine to restricted medicine and which had been in that category for three years or more.

A suggestion to review the classification of vaginal antifungals was met with reserve. Members felt that the advice component should not be removed from the sale of these medicines and that self-medication was not appropriate as conditions other than fungal infections were often responsible for symptoms. Although some members doubted whether pharmacists were in any better position to diagnose than were customers provided with adequate package information, there was little enthusiasm for pursuing vaginal antifungals as candidates for reclassification.

However, topical antifungals which had been pharmacy-only medicines for many years, were seen as possible candidates for general sale status. There appeared to be no evidence of danger from the use of these products. Some members thought that there could be a resistance issue and that perhaps some antifungals should be reserved. It was decided that the Ministry should investigate this as part of the evaluation report.



Cold sores were seen as a suitable condition for self-medication and aciclovir which had already moved from restricted medicine to pharmacy-only medicine was suggested as another possible candidate for general sale. It was noted that penciclovir should also be considered. The Ministry should look at issues relating to transference, resistance and labelling.

The committee agreed that the volume limit of 100mL for 1% topical hydrocortisone should be considered and that the 15 gram limit on creams would therefore also need to be looked at.

Topical minoxidil was also agreed upon for consideration.

### ***Recommendation***

*That interested bodies be consulted and the Ministry be asked to report on the following medicines as candidates for possible reclassification to a less restrictive category:*

*aciclovir (topical for herpes labialis)*

*penciclovir (topical for herpes labialis)*

*antifungals (dermatological preparations)*

*hydrocortisone (topical 1% preparations - volume limit to be increased)*

*minoxidil (topical)*

## **6 SUBMISSIONS FOR RECLASSIFICATION**

### **i Amorolfine cream and nail lacquer (Loceryl, Roche)**

The company had made a submission for reclassification from prescription medicine to pharmacy-only medicine.

The secretary told the committee that the company had since informed the Ministry that it would be unlikely to continue marketing the cream due to low sales volumes but intended to continue marketing the nail lacquer.

Members agreed that, in spite of the fact that good package information was provided, there was a need for pharmacist intervention in the sale of the nail lacquer due to the need for persistence with long-term treatment and to the need to prevent cross-infection. They were happy for the cream preparation to be classified as a pharmacy-only medicine as this would be consistent with other topical antifungals. As both preparations were topical, a cut-off point could be used to distinguish between a cream and a nail lacquer. It was agreed that products containing 0.25% or less of amorolfine should become pharmacy-only medicines and concentrations greater than this should be restricted medicines.

### ***Recommendation***

*That topical medicines containing 0.25% or less of amorolfine be classified as pharmacy-only medicines and those containing more than 0.25% should be classified as restricted medicines.*

#### **ii Levocabastine nasal spray and eye drop (Livostin, Janssen-Cilag)**

This was a company submission for reclassification from restricted medicine to pharmacy-only medicine in response to a Ministry suggestion that these products would be suitable candidates for reclassification.

Overall, the committee agreed that this medicine was well-tolerated and members agreed with the Ministry recommendation to reclassify to pharmacy-only medicine. Some concern was expressed about possible effects on the QT interval and about use with renal impairment. However, it was agreed that doses were so small that any possible side-effects were unlikely.

Although this medicine was a non-sedating antihistamine, the committee agreed that, as all anti-histamines were capable of causing some degree of drowsiness, a sedation warning should be added to the pack for the nasal spray. This would be in keeping with other non-sedating anti-histamine products.

### ***Recommendations***

- *That levocabastine should be reclassified from restricted medicine to pharmacy-only medicine*
- *That the company be asked to add a sedation warning to the package information for the nasal spray*

#### **iii Sedating antihistamines sold as sleeping aids (National Toxicology Group)**

This was a submission from the National Toxicology Group for the reclassification from pharmacy-only to restricted medicine of sedating anti-histamines when sold as sleeping aids. The submission provided evidence of increasing intentional abuse of products marketed in this way.

The committee accepted that there was now a problem of increased intentional overdose associated with sedating anti-histamines and that this had emerged since the relatively recent marketing of products expressly for sedation. It acknowledged that there had been intensive advertising campaigns for some products and that little could be done under current legislation to control such advertising.

Members felt that if only those products marketed as sleeping aids were reclassified it would not take long for those who wished to abuse products to realise that the same effects could be obtained from products marketed for other indications. On the other

hand, members recognised that there was a large number of products on the market which had been widely used for a very long time with little evidence of significant harm. To restrict access to such products would penalise the majority of consumers who had no intention of misusing the products. More restrictive classification would also result in a considerable increase in workload for pharmacists. The committee questioned whether the benefits derived from such a move would justify the consequences of more limited access.

It was generally agreed that sedation was an area in which advice was required and that doctors were now prescribing sedatives with greater caution. It was also agreed that current pack sizes for sedation were too large and that a maximum of 5 days' treatment would be adequate for sale as restricted medicine. Quantities greater than this were seen as being suitable for availability only on prescription. The committee agreed that this should apply not only to sedating anti-histamines, but also to any OTC product marketed as a sedative. The Ministry should be asked to provide guidelines for OTC medicines for sedation.

Other areas of concern with regard to sedating anti-histamines were also noted. These included possible overuse when administered to children by parents and use to enhance the abuse of other drugs. Although only anecdotal evidence was available at this point, the committee felt that there was sufficient concern to warrant further investigation of all oral forms of sedating anti-histamines. This should apply only to those oral forms of sedating anti-histamines not in combination with other ingredients. The subject should be advertised for consultation in the normal way. A report should be prepared by the Ministry and the item would be put on the agenda for a later meeting.

### ***Recommendations***

- *That a sedating anti-histamine or any other OTC product indicated for sedation or anxiety should be classified as a restricted medicine when in packs sufficient for 5 days' supply or less; those containing more than 5 days' supply should be classified as prescription medicines.*
- *That the Ministry be asked to review the classification of all oral sedating anti-histamine products where the anti-histamine is not combined with another active ingredient.*
- *That the Ministry compose guidelines for all OTC products indicated for insomnia or anxiety.*

## **7 NEW MEDICINES FOR CLASSIFICATION**

### **i Flurbiprofen 8.75mg throat lozenge (Boots)**

The company had submitted a new medicine application for a throat lozenge in the Strepsils range containing 8.75mg of flurbiprofen. The submission sought a change to

the current classification of flurbiprofen from prescription medicine to general sale for the strength to be used in the product.

The committee showed immediate concern about the use of the name *Strepsils* for a product containing uncontrolled doses of a non-steroidal anti-inflammatory agent (NSAIA). Members felt that products already marketed under that name and containing mainly antiseptics, were often consumed continuously over a number of days. Uncontrolled use over that time would result in a steady state of flurbiprofen. Even as a restricted medicine, the committee agreed that, once it had left the pharmacy, the product would be regarded as just another in the *Strepsils* range, rather than as a potent NSAIA with its own side-effects. There was unanimous agreement that any product containing flurbiprofen should not be called *Strepsils*.

Members agreed that flurbiprofen would be appropriately classified as a restricted medicine when used in the manner and strength proposed for this product. A cut-off point of 10mg or less per dose unit was agreed to be a suitable upper limit for throat lozenges containing flurbiprofen.

### ***Recommendations***

- *That flurbiprofen should be reclassified from prescription medicine to restricted medicine when contained in throat lozenges containing 10mg or less of flurbiprofen per lozenge.*
- *That the name Strepsils not be permitted for use for throat lozenges containing non-steroidal anti-inflammatory agents.*

### **ii Medicines classified by the MAAC**

The committee was provided with a brief description of the new chemical entities for which the Medicines Assessment Advisory Committee had already recommended a prescription medicine classification.

### ***Recommendation***

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

<i>basiliximab</i>	<i>mibefradil</i>
<i>cerivastatin</i>	<i>montelukast</i>
<i>daclizumab</i>	<i>orlistat</i>
<i>desonide</i>	<i>topotecan</i>
<i>fluvoxamine</i>	<i>valsartan</i>
<i>grepafloxacin</i>	<i>vinorelbine</i>
<i>ibandronic acid</i>	<i>zolmitriptan</i>
<i>imiquimod</i>	<i>zolpidem</i>
<i>meloxicam</i>	

### iii Medicines of misuse or abuse

The Compliance team of the Therapeutics Section had requested that the committee should classify substances which did not have consent to market in NZ and which were therefore not scheduled, but which were potentially harmful or subject to misuse or abuse. The intention was that classification would provide an element of control over the importation of such substances.

The committee discussed the list of substances which they had been asked to classify and the information provided. They felt that insufficient information had been provided for them to make a recommendation. They were also unsure about the validity of the information provided. In at least one of the cases presented, it appeared to members that the doctor concerned was acting legally under Section 29 of the Medicines Act and they did not understand what advantage could be expected from classifying the substance.

It was agreed that before any recommendations could be made about the classification of substances which did not have consent to be marketed as medicines in New Zealand, a full report would be required. This report would need to contain an explanation of the benefits of the proposal. Documented evidence from acceptable sources would be required to support claims of harm or abuse. The evidence should also illustrate either problems already occurring in New Zealand or overseas evidence supporting the potential for harm or abuse in this country. Anecdotal evidence alone should be considered insufficient.

The committee was unsure about its legal ability to take any kind of action and whether or not there were other legal implications about which they were unaware. They agreed that legal aspects would need clarification with regard to both the Medicines Act and any other relevant legislation. This should be included in the report.

Reports would need to be peer reviewed at a meeting of the Compliance Team and signed off by the Manager of the Therapeutics Section in the same way as Ministry reports on submissions for changes to classification. This would ensure that the view presented was that of the Ministry rather than of a particular individual.

#### ***Recommendation***

*That before the Compliance Team request the classification of a substance which does not have consent to market as a medicine in New Zealand it should prepare a full report on each individual substance. The report should:*

- *provide a full explanation of the benefits of the proposal*
- *provide acceptable documented evidence of harm or abuse caused by the substance or the potential for these in New Zealand*
- *provide clarification of any legal implications of the proposal*
- *be peer reviewed by the Compliance Team and signed off by the Team Leader*
- *be signed off by the Manager, Therapeutics Section*

## 8 FOR THE NEXT MEETING

It was noted that **astemizole** should be considered at the next meeting for reclassification to prescription status only if this classification change was unable to be accomplished at an earlier date. ( See agenda item 5 ii c)

Oral **sedating anti-histamines** when not in combination with other active ingredients should be considered for possible change to a more restrictive classification category.

As decided earlier in the meeting, the following items should be investigated for possible change of classification to a less restrictive category. The committee recognised that Ministry resources were limited and that it might not be possible for them to deal with all these medicines in time for the next meeting. It was agreed that all the items should be advertised in the newsletter for initial consultation with interested bodies and that the Ministry should deal with those for which it had the resources. Outstanding items would be dealt with at a later meeting. This would also apply to oral sedating anti-histamines.

**aciclovir** (topical for herpes labialis)

**penciclovir** (topical for herpes labialis)

**antifungals** (dermatological preparations)

**hydrocortisone** (topical 1% preparations - volume limit to be increased)

**minoxidil** (topical)

## 9 GENERAL BUSINESS

### **Date for the next meeting**

Although the next meeting was due to take place in October, Dr Jessamine suggested that the date be changed to coincide with the next meeting of the NDPSC so that teleconferencing or some other means of communication could be employed if there were agenda items of mutual interest to both New Zealand and Australia. The date of the next meeting was therefore set for Wednesday 18 November.

The meeting closed at 2:35pm.