MINUTES OF THE EIGHTEENTH 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 15 OCTOBER 1997 COMMENCING AT 9:30 AM

PRESENT

Dr Bob Boyd (Chair)
Dr Stewart Jessamine
Dr Tim Bevin (from 9:50am)
Dr Graham Wardrope
Mr Bernard McKone
Mr David Thompson
Mrs Carol Smith (Secretary)

IN ATTENDANCE

Dr Kathlyn Ronaldson (For agenda item no.10)

1 WELCOME

Dr Boyd declared the meeting open at 9:35am and welcomed members to the eighteenth meeting of the committee. A particular welcome was extended to Dr Wardrope attending his first meeting as a new member of the committee.

2 APOLOGIES

There were no apologies.

3 CONFIRMATION OF THE MINUTES OF THE SEVENTEENTH MEETING

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

5 CORRESPONDENCE

A letter from PSM Holdings was brought to the attention of the committee. This letter expressed the view that the committee had a medical bias and that there was a lack of suitable products flowing from pharmacy to general sale outlets. Members noted the secretary's reply. They expressed interest in the figures provided which illustrated that, between 1991 and 1996, more medicines had moved into general sale than into any of the other three levels of classification. Dr Boyd commented that while the proposed new Therapeutic Products Bill would allow for wider representation on the committee, there had been no progress made to advance the introduction of this bill.

6 MATTERS ARISING

(i) Non-steroidal anti-inflammatory agents
Finalisation of the framework for classification.

This item was discussed at the end of the agenda.

The committee had considered the responses to the consultation process which the Ministry had undertaken in respect of the proposed framework for the consistent classification of all NSAIAs. Members noted that, while there was some support for a framework per se, there was very little support for the inclusion of aspirin in such a framework. Reasons for the lack of support to include aspirin were mainly to do with its very long history of use with little restriction on its availability and with the increased cost of products which would be an inevitable outcome of reclassification.

Dr Boyd suggested that the committee should consider whether, in view of the lack of support, members felt they should persevere with the concept of a framework. While members agreed that consistency of classification was desirable, they were reluctant to see aspirin included in this framework in view of the lack of support from interested bodies. A substantial body of new safety data in respect of actual short-term use by consumers was normally required in order to justify a classification change. This was not in evidence for aspirin. It was felt that a move to reclassify without this justification would strain the credibility of committee recommendations. Members agreed that aspirin should not be included in a framework. However, this should not be seen to be downplaying the risks associated with aspirin and that, in order to minimise these risks, the Ministry should be asked to re-examine the labelling of products containing aspirin.

The committee discussed the possibility of reclassifying all those NSAIAs with a similar safety profile to the same level of availability as aspirin. This received little support from the committee because of the lack of information available on long-term usage of these. Members were of the opinion that wider availability of NSAIAs could change the way in which they were used and hence the volume of use. They agreed that aspirin use had declined over recent years in favour of paracetamol. The former was now used mainly as an analgesic rather than as an anti-inflammatory agent. On the other hand, those other NSAIAs available over the counter were used principally for

their anti-inflammatory properties for musculoskeletal problems, particularly sports injuries.

Considerable time was spent discussing possible new benchmarks in place of aspirin for the basis of a classification framework. Dr Jessamine pointed out that a benchmark should be based on data relating to use for self-medication in the community. Such studies had not been undertaken in order to enable this sort of data to be used as a benchmark. Those studies which had been done related to long-term use for chronic illness under medical supervision. Other suggestions including gastro-intestinal toxicity and half-life were seen not to be feasible. The committee was unable to establish a suitable alternative benchmark.

The pack size for NSAIAs was also considered but members could see no evidence to support changing the pack sizes currently available for most products. Pack size was generally not considered to be a contributing factor to any problems which might be experienced from short-term use of products. However, there was considerable concern about the availability of ibuprofen in packs of 96 tablets as a pharmacy-only medicine. This was considered an inappropriate number for short-term, over-the-counter use. Members agreed that the company should be asked to remove these packs from the market and that the Ministry should report back to the committee on the company response to this request.

The committee concluded that, with the removal of aspirin as a benchmark, the concept of a framework for the classification of NSAIAs did not appear to be feasible. Members wished, primarily on safety grounds, to keep NSAIAs other than aspirin within the pharmacy and to retain the restricted medicine status of those with a higher risk. For that reason they did not wish to recommend a change of classification for any medicines in this group. Mefanamic acid and 250 milligram tablets of naproxen in packs of not more than 20 tablets, both pharmacy-only medicines when indicated for dysmenorrhoea, had been seen to be inconsistently classified in the light of the proposed framework. However, the committee resolved not to recommend a change in classification for these products.

Recommendations

- *That the status quo be maintained for the classification of aspirin and all non-steroidal anti-inflammatory agents.*

- *That the Ministry of Health be asked to review the labelling required for all aspirin products.*

- *That companies marketing packs containing 96 tablets of ibuprofen be asked to remove these from the market.*

(i) Classification of outstanding NSAIA submissions

(a) Diclofenac tablets (Cataflam, Ciba)

This was a reapplication to the seventeenth meeting for reclassification of 25 milligram tablets in packs of up to 30 units from restricted medicine to pharmacy-only medicine. The Committee had recommended against the change in April 1996. A recommendation had been deferred at the last meeting pending the resolution of the proposed framework for the classification of all NSAIAs.

In view of the decision not to proceed with the proposed framework, the committee agreed that it would uphold the earlier recommendation that these remain restricted medicines.

Recommendation

That there be no change to the April 1996 recommendation for 25 milligram tablets of diclofenac in packs of not more than 30 tablets to remain classified as restricted medicines.

(b) Naproxen Sodium tablets (Aleve, Roche)

This was a reapplication to the seventeenth meeting for reclassification to either pharmacy-only or general sale medicine of a new 220 milligram tablet. The Committee had recommended against the change in April 1996. A recommendation had been deferred at the last meeting pending the resolution of a proposed framework for the classification of all NSAIAs .

In view of the decision not to proceed with the proposed framework, the committee agreed that it would uphold the earlier recommendation that these remain restricted medicines.

Recommendation

That there be no change to the April 1996 recommendation that 220 milligram tablets of naproxen should be classified as restricted medicines.

(c) Ibuprofen tablets (Nurofen Double Strength, Boots)

This was a company submission for reclassification of 400 milligram tablets from prescription medicine to pharmacy-only medicine. The product had subsequently been transferred to a new sponsor, Knoll. Knoll had notified the secretary that the company no longer wished to proceed with the Boots submission for reclassification. The committee was happy that ibuprofen 400 milligram tablets remain prescription medicine and no further discussion was considered necessary.

(d) Flurbiprofen tablets (Froben, Boots)

This was a company submission for reclassification of 50 milligram tablets from prescription medicine to pharmacy-only medicine. The product had subsequently been transferred to a new sponsor, Knoll. Knoll had notified the secretary that the company no longer wished to proceed with the Boots submission for reclassification. The committee was happy that flurbiprofen remain a prescription medicine and no further discussion was considered necessary.

(iii) Objections to recommendations made at the seventeenth meeting

(a) Sennosides

Reckitt & Colman had objected to the recommendation made at the seventeenth meeting that sennosides should remain pharmacy-only medicines rather than become general sale medicines as requested in the company submission.

The company had addressed the issue of abuse potential in its objection and had found little evidence to support the abuse of sennosides. However, the committee observed that abuse was often devious and therefore difficult to document. Members remarked that misuse or abuse of laxatives was often not considered to be an adverse reaction and was not reported as such. Nor were there comprehensive recording mechanisms for adverse reactions associated with over-the-counter medicines.

In addition to the above, members were also concerned about the possible masking of malignancies and other bowel disorders. They felt that general sale classification of stimulant laxatives would move customers one step further from access to advice which could lead to the early detection of problems requiring medical intervention. They also felt that the public was not generally aware of the implications of long-term use of laxatives.

While pharmacists were not required to intervene in the sale of pharmacy-only medicines, the committee agreed that advice was available if requested. It was noted that pharmacists tended to direct customers towards bulk laxatives and that the profession generally discouraged large sales of laxatives. Many pharmacies held laxatives behind the counter where customers were unable to select for themselves. It was noted that pharmacy staff were often directed to alert pharmacists to frequent purchasers.

The committee did not feel that the argument for international harmonisation was sufficiently strong for them to consider reversing their earlier recommendation for sennosides to become general sale medicines.

Members agreed that they would like to confirm the policy of the earlier committee that bulk laxatives should be general sale medicines but that stimulant laxatives should be pharmacy-only medicines.

Recommendation

That there be no change to the committee's earlier recommendation that sennosides remain pharmacy-only medicines.

(b) Nicotine for inhalation

Pharmacia & Upjohn had objected to the recommendation made at the seventeenth meeting that inhaled nicotine should remain a prescription medicine rather than become a pharmacy-only medicine as requested in the company submission.

The Ministry had reviewed the safety data supplied by the company in support of its objection and concluded that, in view of this new data, the Ministry would no longer have any objection to inhaled nicotine being available over the counter.

Committee members did not consider that the company had produced data to show that there was less evidence of transferred addiction and there was still concern amongst members about the nature of the device to deliver the nicotine. Some members had observed problems with consumers stopping use of nicotine products.

Dr Jessamine pointed out that the results of fairly substantial studies provided by the company showed that the ability of consumers to cease using the inhaled product was similar to figures provided for the cessation of gum usage. He felt that psychological dependence was a different issue and one which could not be resolved until products were under widespread use. He said that until it could be observed how these behaved in relation to nicotine gum, he would be happy to see inhaled products available either as restricted medicines or as pharmacy-only medicines with the same classification as the gum.

The potential for youth abuse of inhaled products was discussed but the committee was of the opinion that cost would probably be a prohibitive factor.

Issues relating to the need for counselling were also discussed. Members agreed that use was often initiated by medical practitioners or cardiologists but that continued medical supervision would be expensive and could prove a barrier to continuing treatment. Although members saw continuing medical supervision as desirable, they agreed that a restricted medicine classification would remove this added cost barrier.

Recommendation

That nicotine for inhalation should be reclassified from prescription medicine to restricted medicine.

The committee agreed that it would be beneficial to discuss the classification of the Pharmacia & Upjohn new medicine application for a nicotine sub-lingual tablet at this point on the agenda (see agenda item no. 8)

iv Further matter arising

Paracetamol pack size

Dr Jessamine suggested that as the committee was now aware of moves taken by the United Kingdom to limit pack sizes for aspirin and paracetamol, members should consider whether they wished to review the recommendation made at the seventeenth meeting that there should be no change to current pack sizes. It was noted that the United Kingdom situation differed from that in New Zealand in that there was a marked increase in intentional overdose in the United Kingdom. As most poisonings in this country were due to overdose of prescribed liquid paracetamol by children, reduction of pack size would have no relevance to this problem. However, the committee was pleased to note that all proprietary packs of liquid paracetamol had child-resistant closures and that the Transitional Health Authorities had recently approved funding for the provision of child-resistant closures on dispensed packs of liquid paracetamol.

Recommendation

That there be no change to the current pack sizes for solid-dose paracetamol available as general sale medicine.

7 SUBMISSIONS FOR RECLASSIFICATION

(i) Chlorbutol (Allergan)

This was a company submission for the reclassification of chlorbutol in concentrations of 0.5% or less from pharmacy-only medicine to general sale medicine when used as a preservative. Such a change would bring the classification into line with that of Australia and allow for the general sale classification of three Allergan ocular lubricants which were currently pharmacy-only medicines in New Zealand due to their chlorbutol content.

Both the Ministry and the committee were in favour of this reclassification. No safety reasons could be found to support retaining the pharmacy-only classification and a change was seen as being in the interest of harmonisation with Australian classification.

Recommendation

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

(ii) Cyclopentolate

This submission was made by the New Zealand Association of Optometrists seeking an exemption from prescription status for cyclopentolate when used by an optometrist.

The committee noted that, according to an earlier agreement, the Ophthalmological Society had been consulted with regard to this submission and the following submission for a similar exemption for the use of phenylephrine. The Ophthalmological Society did not support the use of cyclopentolate by optometrists. However, the Ministry paper pointed out that the risk of developing acute angle closure glaucoma, as cited by the Society as a reason against the use of cyclopentolate, was very similar to the risk associated with tropicamide which was already available to optometrists. The report concluded that, as optometrists currently performed vitreous pressure tests to diagnose glaucoma, they were in a position to minimise the risks of provoking acute glaucoma by the provision of advice to the patient on action to be taken should symptoms occur. It was also noted that the condition was quickly and effectively reversible.

The Ophthalmological Society also expressed concern that optometrists would use cyclopentolate to undertake the management of squint in young children, a practice which they considered inappropriate for optometrists. The Ministry paper considered this to be an issue relating to appropriate professional practice and therefore not within the terms of reference of the committee.

The committee agreed with the Ministry report. Given that cyclopentolate had a safety profile essentially similar to that of tropicamide and that there might be occasions when a longer acting cycloplegic would be useful, members could see no reason why optometrists should not have access to this medicine. As it was available to optometrists in both Australia and the United States of America, they had no objection to its use in New Zealand by optometrist acting within the requirements of their professional code.

Recommendation

That cyclopentolate be exempt from prescription medicine classification when used in practice by a registered optometrist.

(iii) Phenylephrine for ophthalmological use

This submission was made by the New Zealand Association of Optometrists seeking an exemption from prescription status for phenylephrine when used by an optometrist.

As for cyclopentolate, the Ophthalmological Society had been consulted with regard to this submission and did not support the exemption. The Society was of the opinion that tropicamide provided adequate dilation for detecting and diagnosing eye disease. Detecting diabetic retinopathy and diabetes, as claimed in the submission as the reason for wishing to use phenylephrine, was not a valid reason for requesting the use of this medicine. The Society stated that the degree of diabetic retinopathy was irrelevant to optometrists who should refer any suspected case immediately. Concern was also expressed about possible side-effects relating to blood pressure, particularly in the elderly and about the inability of optometrists to deal with any cardiac crisis which might occur.

The Ministry report was also against an exemption for the use of phenylephrine by optometrists on both safety grounds and on the basis of a need to use the product.

Members agreed that there were a number of factors which made this medicine unsuitable for use by optometrists. These included the high degree of absorption of even a single 10% dose, the nature and frequency of adverse reactions including fatalities, the range of conditions for which this medicine was contra-indicated and the possibility of interactions with several other medicines. It was agreed that a considerable amount of history-taking would be required for the use of the medicine and that this was not within the scope of an optometrist. The committee noted that tropicamide was used for screening for diabetes and that an adequate range of safer medicines was available for those eventualities where there was a need to dilate the pupil.

Recommendation

That there be no exemption from prescription medicine classification to allow phenylephrine to be used by optometrists.

(iv) Diclofenac for topical use (Voltaren Emulgel, Novartis)

This was a company submission for reclassification from pharmacy-only to general sale medicine.

The committee voiced some concern about use of topical products in conjunction with oral non-steroidal anti-inflammatory medicines. Dr Jessamine told the committee that plasma levels from the use of topical applications were so low that oral use would not significantly increase the risk to consumers.

There was also concern about use by asthmatics with aspirin allergy. However, no evidence had been found to suggest that problems had arisen from the use of topical diclofenac.

Members acknowledged that the pharmacy-only classification denied access to the product by sports bodies, gymnasiums, physiotherapists and other sources where these products would be useful.

A comparison was made with topical salicylates which were general sale medicines. The committee noted that topical diclofenac had a better safety profile and appeared to be more efficacious than the salicylates. There was also an exceptionally low risk of gastro-intestinal upsets. In addition members agreed that good consumer information was provided on the packs.

While the committee felt comfortable with a recommendation that topical diclofenac move to a general sale category, it did not wish to see this as a precedent for the whole

therapeutic group and agreed that any further submissions for reclassification of topical non-steroidal anti-inflammatory agents as general sale medicines should be considered individually.

Recommendation

That diclofenac for topical use should become a general sale medicine.

(v) Ketorolac tromethamine eye drops (Acular, Allergan)

This was a company submission for reclassification from prescription medicine to restricted medicine for treatment of allergic conjunctivitis.

There was general reserve about the proposal to make this medicine available over the counter. Members had had little experience with its use. All agreed that red eye was not easy to diagnose or treat with over-the-counter products. Members expressed concern about use of the product with eye infection. They felt that if the product were very effective it might mask other conditions. It was noted that pharmacists tended to be cautious with eye conditions and to refer customers to a medical practitioner. The committee agreed that there was already a good range of products available for the treatment of seasonal allergic rhinitis.

Dr Jessamine informed the committee that there were no other non-steroidal anti-inflammatory agents available over the counter for use in the eye. He told members that consent to market had also been granted for a tablet and an injection form of ketorolac tromethamine for post-operative pain. However, these had been used excessively by surgeons, resulting in large numbers of adverse reactions. Consequently the products had been withdrawn. Dr Jessamine pointed out that, as the other dose forms of the medicine had a history of side-effects, these could also prove likely for ocular use.

The committee concluded that it would like to see more information about long-term safety in the use of the product in the community before considering its reclassification. It agreed that the product was still too new for over-the-counter availability and that the three-year rule should apply.

Recommendation

That ketorolac tromethamine for ophthalmological use remain a prescription medicine.

(vi) Ketoconazole 1% shampoo (Nizoral, Janssen-Cilag)

This was a company submission for reclassification from pharmacy-only to general sale medicine. No product containing 1% concentration of ketoconazole had yet been given consent to market

The committee was in agreement with both the Ministry report and the data supplied in the company submission.

Recommendation

That ketoconazole should be a general sale medicine when contained in shampoos containing 1% or less of ketoconazole.

(vii) Sodium phosphate bowel preparations (Fleet Phospho-Soda Buffered Saline, Baxter)

This had been referred to the committee by the Ministry. The matter had earlier been addressed by the Medicines Adverse Reactions Committee. The problems associated with this medicine were identified as being primarily due to lack of proper information on the correct use of the product. A data sheet had since been requested and approved by the Ministry and a package insert had been submitted for approval. However, in view of the life-threatening nature of the adverse effects which could result if preparations were not used correctly, the Ministry wished to see further action by having the medicine removed from general sale availability. The report prepared by the Ministry proposed a restricted medicine classification.

Dr Jessamine informed the committee that the product should be regarded primarily as a bowel-cleansing preparation for use prior to surgery or diagnostic procedures. As a laxative, it should be regarded only as a third-line treatment, mainly for palliative care. Dr Jessamine felt that, given the side-effects if wrongly used, a medical practitioner should be involved in the use of the product.

Some concern was expressed about the possibility of the product being discovered and abused by anorexics if it were to remain available over the counter. Members also foresaw the possibility of the product being considered suitable for use in rest homes. As dehydration was viewed as a potential hazard in the elderly, the risks associated with this medicine would be greatly increased.

Because the safety concerns were so high, the committee felt it would prefer to see this medicine available only on prescription where its use could be monitored more carefully, rather than available over the counter as a restricted medicine. Members did not think that the more restrictive classification would prove a barrier to access to the product for either bowel cleansing or for palliative care.

Recommendation

That sodium phosphate should be classified as a prescription medicine when contained in oral bowel preparations.

(viii) Terfenadine

Although terfenadine had recently been reclassified from pharmacy-only medicine to restricted medicine, the Ministry had referred this back to the committee in case it wished to take further action. The reason for this was that a safer alternative, the active metabolite fexofenadine, was now available as a pharmacy-only medicine. Fexofenadine did not demonstrate the adverse cardiac effects of terfenadine. In addition, a number of other regulatory bodies had taken action to limit the availability of terfenadine which had been moved to prescription status in the United Kingdom and withdrawn from the market in France. The United States of America had announced the intention to have terfenadine withdrawn from the market and Australia was also considering a change to its classification status.

The committee discussed the Ministry report at some length. Rather than make a recommendation, the Ministry report had explained the consequences of both allowing terfenadine to remain a restricted medicine and of reclassifying it as a prescription medicine.

It was noted that although terfenadine was still widely prescribed and purchased, there had been no data to demonstrate that there had been problems with its use in New Zealand. The committee also noted that although fexofenadine was being aggressively marketed, the company had not indicated whether or not it wished to withdraw terfenadine from the market.

The committee concluded that it would prefer to see terfenadine reclassified as a prescription medicine. This was because, although rare, adverse cardio-vascular effects were known to be a risk and a safer alternative to terfenadine was available from the same company. Members felt that medical intervention might be more effective in reducing the likelihood of the use of terfenadine in the presence of contraindications.

Recommendation

That terfenadine be reclassified as a prescription medicine.

8 NEW MEDICINE FOR CLASSIFICATION

Nicotine sublingual tablet (Pharmacia Upjohn)

This item was discussed in conjunction with the item for inhaled nicotine.

The main concern of the committee with regard to the sublingual nicotine tablet was the possibility of irritation to the oral mucosa. Members noted that, while the gum was moved about the mouth in the process of chewing, the sublingual tablet was likely to remain in one place. They noted that there was, to date, no sublingual tablet of any kind marketed which was intended for daily use on a long-term basis. Although it was considered likely that consumers would cease to use the product if irritation were to

occur, they felt that they would like to see more information on this aspect of the product before recommending that the sublingual route of administration be classified in the same way as the gum.

As for the inhaler, there was concern about the potential to abuse the sublingual product, particularly by simultaneous use with other nicotine-containing products.

Recommendation

That nicotine in sublingual tablets should be classified as restricted medicine.

9 MEDICINES CLASSIFIED BY THE MAAC

The following new medicines had been assessed by the Medicines Assessment Advisory Committee. A classification had been recommended as part of the assessment process. A prescription medicine classification had been recommended for each of the medicines listed. Dr Boyd told the committee that the medicines listed did not necessarily have consent to market at this stage. A short explanation of the nature of each medicine was circulated for members' information.

Prescription Medicines
Alfuzosin
Brimonidine
Candesartan
Citalopram
Dolasetron
Donepezil
Gadoteric acid
Irbesartan
Latanoprost
Miglitol
Nelfinavir
Nevirapine
Quetiapine
Rivastigmine
Tazarotene
Tiagabine
Tolcapone
Tramadol

Recommendation

That the above medicines be classified as prescription medicines.

10 ROLE OF THE PHARMACIST

The secretary reported action taken following the recommendation made at the seventeenth meeting. The committee had recommended that the Ministry should work with the Pharmaceutical Society to produce a code of practice for the sale of restricted and pharmacy-only medicines. Members' attention was drawn to a Pharmaceutical Society draft protocol for the sale of restricted medicines. It was noted that a protocol for the sale of pharmacy-only medicines had not yet been drafted.

Members felt that in view of the fact that pharmacists were able to sell an increasing range of restricted medicines and that earlier agenda items had pointed to a lack of adverse reaction information about non-prescribed medicines, pharmacists should be encouraged to report adverse reactions. They agreed that they would like to see this added to the protocols for the sale of restricted and pharmacy-only medicines.

Dr Kathlyn Ronaldson, secretary of the Medicines Adverse Reactions Committee, was invited to tell the committee about adverse reactions reporting. She explained the system pointing out that although most reporting was done by medical practitioners and hospital pharmacists, retail pharmacists were encouraged to report adverse reactions. However, the reporting rate was fairly low with only about 30 adverse reaction reports per year made by retail pharmacists. There was provision on the prepaid adverse reactions reporting forms for pharmacists to report adverse reactions. Copies of these forms were provided with the New Ethicals Catalogue so were readily available to retail pharmacists.

Recommendations

- *That the Pharmaceutical Society be asked to incorporate the reporting of adverse reactions into its protocols for the sale of restricted and pharmacy-only medicines.*

- *That when the committee makes recommendations for classification of restricted and pharmacy-only medicines these recommendations are made on the understanding that sales will be made according to the protocols for the sale of restricted medicines and pharmacy-only medicines included in the code of practice manual for pharmacists.*

11 FOR THE NEXT MEETING

The Secretary provided a brief summary of the items already received for the nineteenth meeting. These included:

- A Whitehall submission for the reclassification of 200 milligram ibuprofen tablets to general sale medicine.
- A Whitehall submission for the reclassification of liquid ibuprofen 5 milligram per 100 millilitre suspension to pharmacy-only medicine.

- A Janssen-Cilag submission for the reclassification of levocabastine from restricted medicine to pharmacy-only medicine at the request of the Ministry. The submission, intended for discussion at the eighteenth meeting, had been postponed due to a company delay in supplying data requested by the Ministry.
- A new medicine application for a general sale throat lozenge containing 8.75 milligrams of flurbiprofen. Flurbiprofen is classified prescription medicine. 50 and 100 milligram tablets are marketed.

The classification of codeine in combination with other ingredients was identified as an area which some members would like to be investigated. The secretary undertook to report back on earlier action taken by the Medicines Classification Committee on this matter.

Vaginal antifungal preparations were also suggested as a possible area for classification reappraisal. These had been one of the earliest groups of medicines to be moved from prescription to restricted medicine status after the review of the classification of all medicines in 1989/90. The secretary agreed to prepare a list of these earlier classification changes for the committee to consider for possible further derestriction.

Members agreed to send any further suggestions to the secretary by the end of October.

Wednesday 22 April 1998 was set as the date for the next meeting.

12 GENERAL BUSINESS

There were no items of general business for discussion.

The meeting closed at 3:10pm