Minutes of the PHARMAC Consumer Advisory Committee

8 May 2003

The meeting was held in the Myers Room, 12th floor, HP House, 171 Featherston St, Wellington from 10.30am.

Present

Sandra Coney	Chair
Vicki Burnett	CAC member
Sharron Cole	CAC member
Matiu Dickson	CAC member
Anna Dillon	CAC member
Deirdre Nehua	CAC member
Dennis Paget	CAC member
Paul Stanley	CAC member

Apologies

Kuresa Tiumalu-Faleseuga	CAC member

In attendance

Simon England	CAC Secretary

Helmut Modlik (PHARMAC Board member), Dr Peter Moodie, Rachel Wilson, Cristine Della Barca, Rachel Grocott (PHARMAC staff) attended for relevant items.

Helmut Modlik, Matiu Dickson, Deirdre Nehua, Paul Stanley held a meeting prior to the CAC meeting. Helmut Modlik attended the start of the full CAC meeting to introduce himself to members and answer questions.

Following a discussion on PHARMAC's decision making criteria, members requested that the agenda for the next CAC meeting contain an item to examine the framework PHARMAC uses to make decisions, in particular what analysis is done to assess the effects of decisions on Maori and Pacific Island people, and how these are consistent with obligations under the Treaty of Waitangi.

Members expressed a desire to have further such meetings with representatives of other PHARMAC bodies, in particular with the PHARMAC Board chairman and the Chairman of the Pharmacology and Therapeutics Advisory Committee (PTAC).

1. Record of previous CAC meeting

The minutes of the 14-15 November 2002 meeting of the Consumer Advisory Committee (CAC) were accepted as a true and accurate record.

Dickson/Stanley carried

Members agreed it would be preferable to have the minutes made available publicly as quickly as possible. Members agreed that once the draft minutes were circulated, there would be a 2-week period to provide comment, following which the minutes would be altered if necessary then signed by the chair, a report would be taken to the PHARMAC Board, then the minutes could be published on the PHARMAC website.

2. Chairperson's report

The chair reported on her attendance at the January meeting of the PHARMAC Board and the outcome of the issues raised at that meeting.

The chair's report noted that PHARMAC has issued a media release on Hormone Replacement Therapy that contained a reference to CAC, without first notifying CAC. The release had prompted some media to contact the chairperson for comment, in her capacity as a commentator on women's health issues and HRT. It was felt that a

protocol should be developed so that when PHARMAC was issuing a release that mentioned CAC, that members should first be notified.

Members noted that they were able to talk to the media as experts in their particular field. The CAC Terms of Reference (Paragraph 13.3) allowed members to be interviewed by the media as committee members provided this was done in consultation with the Chairperson of CAC and the PHARMAC Chief Executive.

The chairperson noted she had a paper on direct-to-consumer advertising (DTCA) published in the Journal of Public Policy and Marketing, a journal of the American Marketing Association. This was one of 5 papers canvassing various perspectives on DTCA in the US and NZ.

3. Matters arising

3.1. The committee noted the response from Medsafe to the committee's November 2002 recommendation on labelling of HRT.

3.2. Members felt the response from Medsafe did not sufficiently address the issues raised by the Committee. In particular, it was felt that if warning labels could be placed on the packaging of HRT products in other countries, this could also be done in New Zealand.

3.3. A motion was put that the Committee ask PHARMAC to write a further letter to Medsafe, reiterating the Committee's November 2002 recommendation, pointing out this was a step taken in the United States in January 2003, and providing suggested wording for a label.

Dickson/Dillon, carried

3.4. Members discussed the origin of funding for PHARMAC's Cardiovascular Risk Management campaign, which had resulted from a commercial agreement with a pharmaceutical company. Members felt this had the potential to raise a perceived conflict of interest.

3.5. The committee considered it would be useful to know if PHARMAC had developed a policy or guidelines on using funds received as part of commercial agreements with pharmaceutical companies for Demand Side or information programmes.

3.6. Members resolved to inform the PHARMAC Board of concerns raised about accepting funds received as part of commercial agreements with pharmaceutical companies, to pay for education or Demand Side campaigns. The committee also seeks a clarification on PHARMAC's policy on the use of funding which has resulted from commercial agreements with the pharmaceutical industry.

Nehua/Stanley, carried

3.7. The committee noted that the PHARMAC website's list of new funding applications did not appear to have been updated since November 2002. A device such as this can only be effective if it is kept up-to-date.

3.8. The paper provided to members on the assessment process for pharmaceutical cancer treatments contained no discussion of risks and benefits to consumers. The committee was told PHARMAC would be interested in a consumer viewpoint if they wanted to provide one.

3.9. The committee requested that it be provided with a report at a future date (for example six months), on the cancer drugs assessment process, on feedback received from patients and clinicians.

4. Update on Demand Side activities

4.1. Rachel Wilson briefed the committee on the development and launch of the pilot cardiovascular risk management campaign, now known as One Heart: Many Lives. The target audience is men aged 45 and over. The campaign pilot was launched in Porirua and Gisborne on 31 March 2003, and will run until the end of June, after which it will be evaluated. Local health provider networks, including Maori and Pacific Island health providers, are taking a leading role in the campaign.

4.2. Evaluation will take the form of qualitative research, patient focus groups and a health researcher looking at prescribing records. This part of the evaluation may require ethics committee approval. PHARMAC will also review Pharmhouse data to identify any changes in statin usage.

4.3. Following evaluation, recommendations will be taken to the PHARMAC Board.

4.4. The committee was able to view some of the resources developed for the campaign.

4.5. Members endorsed the messages and approach of the campaign, particularly the use of local, culturally-specific providers.

4.6. PHARMAC's Responsible Use of Inhaled Corticosteroids campaign began in December 2002 with packs being sent to clinicians, with a public and media launch being held in February 2003. More recently the campaign has extended to poster and mass media advertising. Further resources could include flip charts for use by clinicians, with a particular focus on Maori and Pacific Island people.

4.7. The central message of the campaign is for people to consult their health professional to see if they need to adjust their dosage of asthma preventer medication.

4.8. Independent evaluation of the campaign will be centred on health outcomes.

4.9. Demand Side activities in 2004 could include looking at mental health issues and dyspepsia management. These reflected areas of high pharmaceutical expenditure.

4.10. Members were keen to see some work done on diabetes and obesity. To date, PHARMAC's Demand Side activities in these areas had included sponsorship of Diabetes Week, an audiovisual display at Wellington Railway Station and Te Papa, the One Heart: Many Lives campaign which emphasised lifestyle change, and PHARMAC's funding of the Green Prescriptions initiative.

4.11. Members enquired whether progress had been made on developing a framework for consumer information. PHARMAC had received a copy of the Ministry of Health framework document and was working through it to determine its relevance to PHARMAC. A report on progress could be provided to the next CAC meeting.

5. Direct to consumer advertising

5.1. The committee expressed concern at the prevalence and nature of Direct to Consumer Advertising (DTCA) of prescription pharmaceuticals in New Zealand. This seemed to go further and be more pervasive than even the United States, where it is also permitted.

5.2.

5.3. PHARMAC had provided information to the Professors of General Practice for use in their report, Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or For Profit?

5.4. The promotion of the anti-impotence drug Cialis was raised as the latest example of a pervasive mass-media campaign.

5.5. The committee was told that PHARMAC has enquired whether it should use the Therapeutics Advertising Pre-vetting System (TAPS) for advertising developed for Demand Side campaigns, although these ads don't promote specific products and therefore don't necessarily have to be pre-approved by the industry.

5.6. Members felt the tone of DTCA was deteriorating and was becoming increasingly poor at describing risks of medicines to the public. `See your doctor' was being used as a catch-all to avoid having to fully explain risks.

5.7. The committee resolved to write to the PHARMAC Board indicating its support for a ban on DTCA and the reasons for it, and recommending to the PHARMAC Board that it also support a ban.

Paget/Cole, carried

6. Assessments of unregistered pharmaceuticals for use in hospitals

6.1. The committee was asked to provide a consumer perspective on PHARMAC assessing non-registered pharmaceuticals, or non-approved indications for pharmaceuticals, for use in hospitals.

6.2. PHARMAC staff informed the committee that there is widespread use of unregistered pharmaceuticals in hospitals, and that PHARMAC considered that in order to influence the use of these pharmaceuticals in hospitals, it is important that they are included in the assessment process. The concern with assessing these pharmaceuticals is that it could be seen as PHARMAC endorsing the use of pharmaceuticals with unproven effectiveness.

6.3. Members commented that their main concern from a consumer perspective was one of informed consent. The committee considered that clinicians and prescribers had a responsibility to inform patients that the pharmaceutical is unregistered, and to explain the implications of this and the strength of evidence for using the pharmaceutical for the particular indication. Informed consent could be underlined through the use of a written statement. The committee considered that it was also important that there were no exemptions for certain conditions.

6.4. The committee pointed out that clinicians who used an unregistered drug without fully informing the patient about the drug, risked breaching the Medicines Act, and Right Six of the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.

6.5. The committee noted that PHARMAC's primary role is to assess cost-effectiveness, and that assessing the safety of the pharmaceutical is one of the primary roles of Medsafe.

6.6. While the committee was supportive of including the assessment of unregistered pharmaceuticals and indications as part of the hospital assessment process, concern was expressed that the process might reduce the willingness of clinicians to use innovative therapies in individual cases, especially in the case of registered pharmaceuticals that are used for unregistered indications.

6.7. The committee considered that DHBs needed to introduce protocols for the use for unregistered pharmaceuticals and indications, and that these needed to be nationally consistent. The committee noted that there was a large

degree of variability across DHBs in the use of unregistered pharmaceuticals.

6.8. The committee requested that the legal disclaimer in the summary discussion documents should include a sentence stating

> *"Consumers should be informed that the pharmaceutical is not registered and the implications of this. Written consent should be obtained from the patient before beginning treatment".*

6.9. The committee considered that it should be mandatory for clinicians to notify Medsafe that they want to use an unregistered pharmaceutical. Members considered a letter should be sent to Medsafe raising the issue.

7. Assessment of certain pharmaceuticals for listing on the Pharmaceutical Schedule

7.1. Members asked for information on five medicines, Venlafaxine (for depression), Epilim (as a psychotropic medication), the removal of Special Authority on Olanzapine (short and long acting – when available), Cipramil dispersable 20mg tablet, Rosiglitazone for diabetes control.

7.2.

7.3. Members discussed whether it was the role of the committee to examine individual drugs. Members felt it would be preferable if they were to raise these issues with PHARMAC in writing directly. Members requested the CAC Secretary to write to members outlining what steps had been taken with the medicines specified.

7.4. Members agreed that the committee's role in regard to examining individual drugs could be to examine what priority the drugs receive.

7.5. The committee requested that it be provided with information on PHARMAC's funding priorities list.

8. Prescriptions for sleeping tablets

8.1. The committee was told that full subsidy for some sleeping tablets was only available on monthly prescriptions, and that if longer prescriptions were required, this incurred an additional dispensing charge for each repeat. There was concern about this, particularly for people on fixed incomes.

8.2. Members were told that some sedatives were only intended for short-term use and that there were a number of risks associated with long-term use, including pharmacodependence, cumulative effects such as the need for increasing dosage, and drowsiness which led to accidents.

8.3. The committee felt that access to sleeping pills was appropriately controlled, and that rather than relaxing access, it would be preferable to encourage long-term users to undergo a programme to help them discontinue use.

9. Listing of topical clindamycin for mild to moderate acne

9.1. Members were briefed on treatments for acne, available both over-the-counter and on prescription. Topical clindamycin (Dalacin T), an antibiotic cream, has been changed from an OTC product to prescription only, and PHARMAC is currently considering a funding application for it.

9.2. The antibiotics sub-committee of PTAC had recommended PHARMAC staff conduct a review of acne treatments and their availability, and that this review be submitted to PTAC for consideration.

9.3. The committee felt it would be useful to have a consumer perspective on any group examining the funding of acne treatments.

9.4. The committee agreed it would be desirable for a subsidised product to be available for the treatment of mild to moderate acne, as treatments for severe acne that are subsidised may be inappropriately prescribed in the absence of other subsidised products.

9.5. Such a listing should have a high priority as there were safety issues associated both with hormonal treatments for women, and with isotretinoin for severe acne.

9.6. Members noted that, while acne was not a life-threatening condition, it could have a devastating social and psychological impact on young people.

10. Teleconference on stat dispensing

10.1. Members were informed that some of the information requested at the 24 April teleconference on the proposed partial return to stat dispensing was not yet available.

10.2. Members discussed why information was being sought on some conditions, but not on others where people took medication for chronic conditions. The committee felt it would be useful to hear arguments about why some medicines for long-term conditions would still require monthly dispensing.

10.3. A further teleconference to discuss stat dispensing was scheduled for 22 May 2003

11. General

11.1. The committee was briefed on the meeting which took place between Maori members and PHARMAC Board member Helmut Modlik. This meeting was useful and constructive and would help people to be more effective and to support each other. Maori members felt it would be useful

to have further meetings with all Maori working at PHARMAC and with PHARMAC bodies, including PTAC, CAC, the Board and PHARMAC staff. This would help ensure the recommendations in PHARMAC's Maori Responsiveness Strategy were implemented.

11.2. CAC stated its support for a request to the PHARMAC Board for Maori members of PHARMAC staff and advisory committees to meet.

11.3. Members discussed the role and effectiveness of the committee. Members felt it was a little early to accurately judge the committee's effectiveness.

11.4. Members agreed it would be desirable to have at least two further meetings during 2003. One of these meetings could discuss the committee's progress and provide a report to the PHARMAC Board, and seek feedback.

11.5. Members agreed to invite the PHARMAC Board chairman to the opening of the next CAC meeting.

The meeting concluded at 3.20pm.

Action points/recommendations:

1. Agenda for the next CAC meeting to contain an item to examine the framework PHARMAC uses to make decisions, in particular what analysis is done to assess the effects of decisions on Maori and Pacific Island people, and how these are consistent with obligations under the Treaty of Waitangi.

2. A protocol to be developed so that when PHARMAC was issuing a media release that mentioned CAC, that members should first be notified.

3. CAC to ask PHARMAC to write a further letter to Medsafe about labelling of Hormone Replacement Therapies, reiterating the Committee's November 2002 recommendation, pointing out this was a step taken in the United States in January 2003, and providing suggested wording for a label.

4. CAC to inform the PHARMAC Board of concerns raised about accepting funds received as part of commercial agreements with pharmaceutical companies, to pay for education or Demand Side campaigns. CAC seeks a clarification on PHARMAC's policy on the use of funding which has resulted from commercial agreements with the pharmaceutical industry.

5. CAC to be provided with a report at a future date (for example six months), on the cancer drugs assessment process, on feedback received from patients and clinicians.

6. Report on progress toward developing a framework for consumer information to be provided to the next CAC meeting.

7. The committee requested that the legal disclaimer in the summary discussion documents for the assessment of non-registered pharmaceuticals should include a sentence stating:

    i. "Consumers should be informed that the pharmaceutical is not registered and the implications of this. Written consent should be obtained from the patient before beginning treatment".

8. A letter to be sent to Medsafe raising the issue of clinicians notifying Medsafe that they want to use an unregistered pharmaceutical.

9. CAC Secretary to write to members outlining what steps had been taken with the medicines specified in item 7.

10. CAC to be provided with information on PHARMAC's funding priorities list.

11. CAC recommended the listing of topical clindamycin should have a high priority as there were safety issues associated both with hormonal treatments for women, and with isotretinoin for severe acne.

12. Committee to hear arguments about why some medicines for long-term conditions would still require monthly dispensing.

13. Teleconference to discuss stat dispensing scheduled for 22 May 2003.

14. CAC stated its support for a request to the PHARMAC Board for Maori members of PHARMAC staff and advisory committees to meet.

15. CAC to have at least two further meetings during 2003. One of these meetings could discuss the committee's progress and provide a report to the PHARMAC Board, and seek feedback.

16. PHARMAC Board chairman to be invited to the opening of the next CAC meeting.

Signed

Chair

6/8/03

Date