

## August 2003 Meeting of the Pharmacology and Therapeutics Advisory Committee

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“**Minute**” means that part of the record of a PTAC or Sub-committee meeting (including meetings by teleconference and recommendations made by other means of communication) that contains a recommendation to accept or decline an application for a new investment or a clinical proposal to widen access and related discussion.”

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## August 2003 Meeting of the Pharmacology and Therapeutics Advisory Committee

### Review of Glivec section of record of PTAC meeting held 21 November 2002

The Committee received correspondence from Novartis who objected to the term “Phase I studies” being used in the record of the 21 November 2002 meeting. Novartis considered “Phase II study” reflected their submission more accurately. The Committee noted that the term “Phase II” was used in the published paper submitted by Novartis and although it considered that the study did not entirely reflect the usual features required of a Phase-II study, the Committee agreed to amend the record of the 21 November 2002 meeting with regard to Glivec to read “Phase II study”.

The Committee stood by its conclusion that “...no clear survival advantage had been established.” and noted, in response to the letter from Novartis, that editorial control over the record of the meeting is the responsibility of PTAC.

The corrected minute from November 2002 reads as follows:

#### Imatinib mesylate (Glivec)

PTAC noted the relevant minutes of the Cancer Treatments Subcommittee of PTAC (CaTSOP) September 2002 meeting concerning imatinib for gastrointestinal stromal tumours. The Committee noted that the PHARMAC Board had approved the listing of imatinib from 1 December 2002 as part of a multi-product agreement with Novartis and that a requirement for immunohistochemical documentation of c-kit (CD117) expression by the tumour had been added to the Special Authority access criteria in response to consultation. The Committee endorsed CaTSOP’s listing recommendation but expressed some reservations because the evidence for imatinib’s use in gastrointestinal stromal tumours was from Phase II studies and no clear survival advantage had been established.

The relevant section of the record of the CaTSOP meeting September 2002 is as follows:

#### *“GIST*

The subcommittee recommended the listing of imatinib for the treatment of patients with unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST) under the following Special Authority criteria:

- (a) Funded for patients with a diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumours.
- (b) Applications to be made and subsequent prescriptions can be written by an oncologist.
- (c) Initial and subsequent applications are valid for 1 year. The re-application criterion is an adequate clinical response to the treatment with imatinib (prescriber determined).

The subcommittee considered that the Special Authority applications should contain information on the degree of response to treatment a patient was getting.

The subcommittee considered that it would like to review the data provided in Special Authority forms (for both CML and GIST) on an annual basis. The subcommittee considered that a creation of a separate “Glivec panel” was not necessary at this stage.”

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### **Ezetimibe (Ezetrol)**

PTAC considered the July 2003 submission for the listing of ezetimibe on the Pharmaceutical Schedule, by the manufacturer Merck Sharpe and Dohme.

It noted that there are other effective treatments available, and that it was unlikely there would be a strong need for ezetimibe even if atorvastatin were not available.

Based on the available evidence, the Committee considered ezetimibe, in combination with a statin, to be suitable for the treatment of homozygous sitosterolemia. It considered that, given the small number of patients with this condition, funding could occur through the community exceptional circumstances process.

The Committee noted that cholesterol reduction may predict future clinical benefit. It considered that percentage rather than target cholesterol can be a useful measure. However, clinical endpoint data, including cardiovascular morbidity and mortality data, was not currently available for this drug. It also noted that it would require more long-term safety data before recommending the listing of ezetimibe, and would recommend post-marketing surveillance. If ezetimibe was listed on the Schedule, the maximum dose of co-prescribed statin would need to be specified in order to control treatment costs, given the potential for widespread prescribing.

The Committee restated its view, from the May 2003 meeting, recommending declining ezetimibe for listing on the Schedule at this time.

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### **Gliclazide 30mg modified release tablet (Diamicron MR 30mg)**

PTAC considered the June 2003 submission by the manufacturer Servier.

The Committee noted the importance of diabetes treatment in New Zealand. It also considered that the educational material that Servier provided to patients was useful.

The Committee considered that, where possible, metformin should be used in preference to sulfonylureas in the management of overweight people with diabetes, and the Committee noted that the data for the average daily dose of gliclazide 80 mg in New Zealand was significantly lower than that used in Australian patients, based on data provided by Servier.

The Committee considered that gliclazide 30 mg modified release has the same or similar therapeutic effect as gliclazide 80 mg. It considered that the once a day dose was unlikely to have a significant effect on compliance compared with the twice-daily dose of gliclazide 80 mg (particularly as many of the patients on gliclazide tablets would also be taking other medications).

The Committee considered that, although type 2 diabetes is a priority issue, gliclazide 30 mg modified release did not offer a significant health gain over the 80 mg tablet and recommended that the product be declined for listing on the Pharmaceutical Schedule. It recommended that, if gliclazide 30 mg modified release were listed in the future, it should be listed at the same average daily cost (or less) as gliclazide 80 mg.

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### **Verteporfin (Visudyne)**

The Committee considered an application from Novartis Ophthalmics for the listing of verteporfin (Visudyne) 30 ml infusion for the treatment of small subfoveal choroidal neovascularisation due to age-related macular degeneration.

The Committee considered the application to be of poor quality and did not provide any references. The Committee noted that the application claimed evidence of efficacy based on the post-hoc analysis of data from a subgroup of patients enrolled in three clinical trials. The Committee noted that the comparator used in these trials was placebo, and that Novartis was dismissive of the effectiveness of laser surgery for smaller lesions.

The Committee considered the cost of verteporfin to be extremely high and disproportionate to the benefits it would offer to patients. The Committee recommended that the application be declined.

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### Possible revisions to Discretionary Community Supply (DCS) List

Further to consideration of this issue in July 2003, the Committee considered the following issues and made the following recommendations:

Chloramphenicol 250mg caps	The Committee noted that, since consideration of this product by the antibiotic sub-committee, Pfizer notified discontinuation. Assuming it would still be available in NZ under an unregistered sponsor, the Committee considered that it should be listed on the DCS list. Up to 2 weeks supply for any appropriate indication.
Hypertonic saline – for CF patients	The Committee noted that hypertonic saline, in concentrations generally between 4% and 6%, is a relatively commonly used treatment in cystic fibrosis (CF). It is used in nebulised form to help improve sputum production, and may be an alternative to Pulmozyme. The Committee recommended adding it to the DCS list for CF only (indefinite supply).
Itraconazole (Sporanox) oral liquid	The Committee concurred with the view of the Antibiotic Sub-committee of PTAC that itraconazole oral liquid should be added to the DCS list restricted for use in liver transplant patients for up to 3 months.
Ivermectin	The Committee noted that this was another unregistered worm treatment for “creeping eruption.” It recommended inclusion on the DCS list restricted to the treatment of “creeping eruption” for an indefinite supply until EC funding is approved.
Lignocaine Viscous	The Committee noted that this product is sometimes used for patients receiving high dose radiation treatment to the oral cavity and neck region and also to the oesophagus to help in alleviating their symptoms. It recommended including the product on the DCS list for up to 6 weeks supply post radiotherapy.
Oxethazine, aluminium hydroxide and magnesium hydroxide (Mucaine)	The Committee noted that this product is sometimes used for patients receiving high dose radiation treatment to the oral cavity and neck region and also to the oesophagus to help in alleviating their symptoms. It recommended including the product on the DCS list for up to 6 weeks supply post radiotherapy.
Polyethylene glycol (Kleen prep) solution	The Committee considered that this should be added to the DCS list for use in patients 1-2 days pre-surgery, or in children for up to 5 days for catharsis.
Reteplase	The Committee noted that some DHBs fund this product to make thrombolysis available to rural patients immediately under the supervision of the local doctor. The Committee recommended that this product be added to the DCS list for thrombolysis pre-hospital admission (single administration).
Sodium bicarbonate caps	The Committee noted that there are no capsules registered in NZ so they would have to be prescribed under Section 29. The Committee recommended that they be included on the DCS list – indefinite supply for renal acidosis.
3,4 diaminopyridine (DAP) for Eton- Lambert Syndrome	The Committee noted that this product might not be registered. It considered that access to subsidies for this agent could be made available via Community EC.
Caffeine, oral liquid - for the treatment of apnoeas (neonates)	The Committee noted that this product might not be registered. It noted that this product was likely to require compounding in a hospital and recommended that it be made available via Hospital EC.

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Ciprofloxacin HC eardrops	The Committee noted that some mobile ear clinics are currently providing this in the community. However, it noted that the Antibiotic subcommittee of PTAC has considered listing this product on the Pharmaceutical Schedule and recommended not to do so. The Committee therefore considered that it would be inappropriate to list this product on the DCS list.
Cytotoxics - oral	The Committee noted that the majority of these agents are all included in Part V of Section H and are therefore able to be supplied by the DHB to outpatients. Therefore, no DCS listing was required.
Desferrioxamine mesylate injection 500mg	The Committee noted that Desferal brand (Novartis) has sole supply status in the community but clinicians claim that paediatrics have adverse reactions to this brand and need to have the alternative (Baxter) brand. The Committee did not consider this was a matter for the DCS list. It considered that Community EC might be a more appropriate mechanism to deal with this issue.
Devices such as infusor pumps	The Committee noted that the rules of Section H included devices in the definition of DCS Pharmaceutical. It recommended that this be amended if it was not PHARMAC's intention to enable DHBs to continue to supply devices under the new DCS provisions.
Imatinib mesylate	The Committee noted that one DHB had requested the inclusion of imatinib on the DCS list for indications other than those funded via the Pharmaceutical Schedule. It noted that there is an exceptional circumstances process to deal with rare indications for pharmaceutical cancer treatments currently under a 6-month trial. It noted that the process is due to be reviewed at the end of August 2003. It did not recommend a DCS listing.
Isotretinoin oral	The Committee noted that the oral formulation appears to have been discontinued by Roche but may be available under Section 29. It did not recommend inclusion on the DCS list. It considered that the product would most likely be used in patients with myelodysplasia and that access to funding via Hospital EC would be appropriate in this case.
Ketamine infusions- for terminal care patients.	The Committee noted that this was a similar issue to that considered under the initial DCS list in terms of bupivacaine and fentanyl infusions. It considered that this issue, like that associated with bupivacaine and fentanyl, should be referred to analgesic Sub-committee of PTAC.
Levamisole - treatment of nephrotic syndrome	The Committee noted that this was another unregistered worm treatment (for round worm). However, in this case it recommended that access to subsidies be provided via Community EC.
Levetiracetam	The Committee noted that this treatment is sometimes being used in paediatric patients refractory to other antiepileptic agents. However, the Committee did not consider that addition to the DCS list would be appropriate since this product is new and unapproved. It recommended that access to funding be sought via EC.
Mirena – an alternative to tubal ligation.	The Committee considered that this treatment should be funded via the Pharmaceutical Schedule.
Nifedipine 5mg non-SR caps - for severe hypertension	The Committee considered that this product should not be included on the DCS list. It noted the possible increase in mortality in patients with occult coronary disease, not on a beta-blocker, treated with short-acting nifedipine.. It considered that this presentation was sometimes used in paediatric patients with hypertensive encephalopathy but considered that Hospital EC access would be more appropriate in these cases.

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Omeprazole dispersible tablets (MUPS)	<p>The Committee noted that this product is registered but not marketed in NZ. It considered that it would be inappropriate to list it under DCS.</p> <p>The Committee noted that this product may be being used for paediatric patients and patients on PEG feeds in lieu of an oral liquid. It noted that practice in at least one hospital is to suspend Losec capsules in sodium bicarbonate for this purpose. The slightly alkaline nature of the solution creates a buffer to prevent the granules dissolving.</p>
Podophyllotoxin (Wartec) cream, 0.15% w/w	The Committee considered that this treatment for women with genital warts should be funded via the Pharmaceutical Schedule.
Risperidone Consta	The Committee noted that PHARMAC is considering an application to fund it in the community. The Committee considered that this treatment should not be funded via DCS in the interim.
Special Foods	The Committee noted that a number of DHBs had asked whether they could fund bridging supplies of Special Purpose Foods (and other Special Authority (SA) medicines) for patients discharged from hospitals prior to their SA numbers being granted. The Committee considered that this would be inappropriate. The Committee's main concern was that it is often difficult to withdraw a pharmaceutical once it has been started.
Stanozolol - for the treatment of angioedema	The Committee noted that this is an anabolic steroid that does not appear to be registered in NZ. It considered that it should not be added to the DCS list. It considered that Community EC would be a more appropriate funding mechanism.
Sulphadiazine and pyrimethamine	The Committee noted that neither of these products appears to be registered in NZ. It concurred with the view of the Antibiotic Sub-committee that at this stage both pyrimethamine and sulphadiazine for the treatment of toxoplasmosis should be excluded from the DCS list. The subcommittee considered that both pyrimethamine and sulphadiazine had a role in the treatment of opportunistic infections such as toxoplasma retinitis and cerebral toxoplasmosis. The Subcommittee considered that access to treatment could be achieved through HEC, but recommended that this be monitored and reviewed.
Topotecan	The Committee noted that this is a new pharmaceutical cancer treatment, which doesn't appear to be registered yet. It considered that it should be referred to the Cancer Treatments Sub-committee of PTAC (CaTSOP) when it is registered and should not be included on the DCS list in the meantime.
Vitamin A, oral caps/tabs	The Committee noted that there is no high dose supplement available on the Pharmaceutical Schedule because Roche discontinued Ro-Vit-A in 2000 and their agent requested a subsidy increase. The Committee recommended that PHARMAC consider sourcing a registered product and adding it to the Pharmaceutical Schedule. However, it considered that Community EC was an appropriate interim funding mechanism



## **August 2003 Meeting of the Pharmacology and Therapeutics Advisory Committee**

### **Effects of Alzheimer's disease agents on rest home placements relevant to cost-effectiveness and priority**

Further to earlier discussion of the issues at the May 2003 PTAC meeting, the Committee was asked to review the evidence relating to possible delays to rest home placement. These papers had been inadvertently missed from the previous agenda mail-out. Evidence comprised three abstracts/poster presentations relating to delays in rest home admission and hence savings to the health sector; a folder from Pfizer of material relating to Alzheimer's agents and three published studies directly relating Alzheimer's agents to delays in nursing home placement (one being a very recent formal publication of one of the above poster presentations/abstracts).

The Committee considered the quality of the three abstracts/poster presentations provided could not be adequately assessed. The Committee considered that all three of the published papers were grade 2 evidence (Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal). The Committee considered that the studies were variously limited by:

- last observation carried forward analysis with shorter follow-up in treated patients (due to increased dropouts with treatment);
- matching on too few variables, with significant difference between treated and matched controls in baseline ADLs, dementia rating scale measures, and antipsychotic use/extrapyramidal signs;
- open follow-up (non blinded); possible selection bias, with those patients able to tolerate higher doses being healthier (i.e. tolerance being a prognostic factor – conceded by the trial authors as a possible source of bias);
- use of telephone interviews two years following cessation of antecedent RCT; defining institutionalisation as placement for greater than two weeks (which in New Zealand would still include some respite care);
- reference group being patients who had dropped out of the antecedent RCT; and
- not accounting for all eligible patients, with incomplete ascertainment of follow-up.

Members noted that the three studies did show associations between Alzheimer's agent use and not living in rest homes. However, members noted that all three studies were retrospective cohort analyses showing simple association, and hence needed to show plausible evidence suggesting causality, which would be difficult, given inevitable confounding. Members noted there were many complex factors affecting the timing to rest home placement. Members noted that such confounding included the ability/inclination for caregivers to administer Alzheimer's agent medications, which may correlate with strong desire to keep ones loved one at home and hence greater reluctance to have a patient admitted to rest home care.

The Committee considered all three studies to have a relevance grading of 3 (Evidence of effect confined to intermediate or surrogate outcomes) and none of them to be applicable to the current New Zealand setting.

The Committee considered that there was no conclusive evidence that Alzheimer's agents delayed rest home placement and that its earlier view remained unchanged. Some members also expressed surprise that, given the importance of rest home delays and any cost savings to the cost effectiveness of Alzheimer's agents, a proper randomised control trial (RCT) has not yet been published despite such a study being quite feasible.

The Committee considered that in light of the available evidence the most likely of PHARMAC's previous rapid cost-effectiveness scenarios (and cost/QALYs) was still that of clinical benefits being limited in duration to a maximum of 6 months with no quantifiable savings in rest home care.

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Members considered the material submitted by Pfizer ('Aricept® (donepezil HCl) Compendium of outcomes research studies'), and noted there was no mention of either search strategy or selection criteria or whether any contrary evidence was identified. Members also noted the papers included on cost-effectiveness appeared not to be comprehensive; for instance there was no mention of the (detrimental) HTA review and the NICE guidance.

The Committee considered that in view of the most likely cost-effectiveness scenarios, its previous deliberations, and the outcomes research material provided by Pfizer, that acetylcholinesterase inhibitors for Alzheimer's disease should remain a low priority for pharmaceutical investment.

## **August 2003 Meeting of the Pharmacology and Therapeutics Advisory Committee**

### **Widening access to dornase alfa**

The Committee reconsidered the recommendation by the C.F. DN'ase Advisory Panel for the widening of access to dornase alfa.

The Committee noted that the Panel's recommendation was driven by the results of the Quan et al paper. The Committee noted that this paper, as well as the earlier Fuchs et al paper, was sponsored by Genentech – the manufacturer of dornase alfa. The Committee noted that the Quan study was much larger and of a longer duration than earlier trials for dornase alfa, particularly the Fuchs study, and was for a different patient group than those likely to gain access to treatment under the revised criteria.

The Committee noted that the results of the Quan study indicated that there was a 3.2% change in FEV<sub>1</sub> over two years compared with placebo, and that the authors had concluded that dornase alfa reduced the rate of respiratory tract infection exacerbations. In addition, the Quan study demonstrated that dornase alfa demonstrated efficacy and safety in a much younger age group. The questions of whether this small absolute gain in FEV<sub>1</sub> is clinically significant and sustainable and will translate into significant quality of life differences for those on treatment are still to be determined.

The Committee considered the argument that quality of life improvement from a 10% increase in FEV<sub>1</sub> may be independent of baseline lung function and therefore that all patients who meet the continuation criteria could be equally cost-effective to treat; however the Committee also noted international studies indicating the cost-effectiveness of dornase alfa therapy to be, at best, in the region of \$41,000 per quality-adjusted life year gained.

The Committee considered that the Quan study was tightly focused, with patients having an average baseline FEV<sub>1</sub> around 95% of predicted. The Committee felt that to interpolate between this trial and the results of the Fuchs trial (with an average baseline FEV<sub>1</sub> around 60% of expected) would not produce data of sufficient quality to make any recommendation to PHARMAC. In addition, the Committee considered that requiring a 10% improvement in FEV<sub>1</sub> for patients with such a high baseline FEV<sub>1</sub> would result in a large proportion of patients not continuing treatment following the initial one-month trial.

The Committee recommended declining the proposal on the basis of insufficient supporting evidence for effectiveness and cost-effectiveness, and invited the C.F. DN'ase Advisory Panel to submit further evidence on the effectiveness of dornase alfa for the intended patient population.

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### **Topical clindamycin phosphate 1%**

The Committee noted the recommendation of the Antibiotic Subcommittee of PTAC to list topical clindamycin with a low priority. The Committee noted the recommendation of CAC to list topical clindamycin with a high priority. The Committee considered that this was predominantly because there is currently no fully funded alternative for mild to moderate cases of acne.

The Committee recommended against the listing of topical clindamycin on the Pharmaceutical Schedule at this time. However, it considered that treatment options for mild to moderate acne were clinically important and noted that PHARMAC staff have been directed by the Board to undertake a review of acne treatments. The Committee recommended that there should be funded treatment options available for mild to moderate acne and that the listing of benzoyl peroxide and topical clindamycin and the availability of a fully funded tetracycline be investigated as part of that review.

The relevant section of the record of the relevant May 2003 Antibiotic Sub-committee meeting is as follows:

#### **“Clindamycin phosphate USP 1% - topical Dalacin T**

The sub-committee noted the information supplied by the supplier of topical clindamycin in its submission for a listing on the Pharmaceutical Schedule.

The sub-committee noted that other forms of clindamycin are indicated in hospital treatment of various infections. The committee noted that topical clindamycin and topical metronidazole can be effective in the treatment of mild to moderate acne.

The sub-committee noted that although there is limited resistance data on clindamycin in New Zealand, resistance is likely to have increased due to the availability of topical clindamycin, which was until recently available as a pharmacy medicine (without a prescription).

The committee noted that topical clindamycin is less expensive than minocycline and isotretinoin. It further noted that minocycline is not currently fully subsidised on the Pharmaceutical Schedule. The subcommittee noted that the treatment of acne with tetracycline is unwise in pre-pubescent adults as it can have an adverse side effect on developing teeth.

The sub-committee noted the evidence suggests that this can be an effective treatment but increased usage is likely to result in increased resistance.

The subcommittee considered that should topical clindamycin be listed on the Pharmaceutical Schedule it should be limited to a maximum of 6 months continuous treatment and should patients fail to show improvement then a dermatologist referral would be appropriate.

The sub-committee considered that fully subsidising topical clindamycin may reduce the number of patients using other pharmaceutical treatments such as minocycline, doxycycline and isotretinoin for acne.

The sub-committee noted its earlier recommendation that PHARMAC staff conduct a review of acne treatments and their availability and submit this review to PTAC for consideration.

The sub-committee recommended listing topical clindamycin on the Pharmaceutical Schedule with a low priority subject to outcome of the review of its place in therapy.”

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### Scopoderm: access criteria

The Committee was asked to consider amending the Special Authority criteria for Scopoderm TTS (hyoscine Scopolamine Patches, 1.5 mg) following a recommendation from the Analgesic Subcommittee. This would allow Scopoderm to be used in a wider range of conditions requiring control of nausea, vomiting and related symptoms (including excessive salivation). The Committee considered the number of additional patients would be small, but that they currently have an unmet need. It considered that the change recommended below should be given a high priority.

The Committee recommended that the Special Authority criteria for Scopoderm be amended as follows (changes in bold and strikethrough):

- Special Authority – Hospital pharmacy [HP3]
- a) Approvals can be granted for the control of **intractable** nausea, **vomiting, or inability to swallow saliva** in the treatment of ~~malignant~~ **malignancy or chronic** disease **where patients cannot tolerate or do not adequately respond to oral anti-nausea agents.**
  - b) **Applications and reapplications can be made by any medical practitioner.**
  - c) Approvals ~~only for 6 months~~ **are valid for one year.**
  - d) **The underlying malignancy or chronic disease must be specified.**

## **August 2003 Meeting of the Pharmacology and Therapeutics Advisory Committee**

### **Sub-committees**

#### **Record of the 29 April 2003 meeting of the Cancer Treatments Sub-committee of PTAC**

The Committee noted the record of the 29 April 2003 teleconference meeting of the Cancer Treatments Sub-committee of PTAC.

#### **Rituximab (Mabthera)**

The Committee endorsed the recommendation by CaTSOP to add “CD20 positive diffuse large B-cell NHL (stage II and above) in combination with CHOP chemotherapy” as a fourth indication for the listing of rituximab in Part V of Section H of the Pharmaceutical Schedule. The Committee recommended that a moderate-high priority be given to this recommendation.

The Committee noted that the application for extending the access criteria was supported by a single key study, and that that rituximab was expensive, with an estimated cost of \$31,000 to \$32,000/QALY. The Committee expressed concern over the use of a 15-year time horizon in the cost-utility analysis. The Committee considered r-CHOP with curative intent in new lymphoma patients may have greater value than rituximab alone in relapsed lymphoma.

The Committee noted that there had previously been inconsistency in funding cancer drugs across New Zealand DHBs. The Committee also noted that the adoption of recommendations for amendments to Part V of Section H of the Pharmaceutical Schedule would require agreement on funding arrangements between the 21 DHBs.

**Record of the Pharmacology and Therapeutics Advisory Committee Meeting  
Held on 21 August 2003**

**Riluzole (Rilutek)**

The Committee received a preliminary application from Aventis for a currently unregistered medication, Riluzole (Rilutek) for the treatment of Amyotrophic Lateral Sclerosis (AML). Aventis wished to establish whether a positive recommendation would be likely for this New Chemical Entity, if a full submission was made to the Committee. The Committee indicated that they would not routinely consider applications for unapproved medicines, but noted that in this case Aventis had received direction to make the submission from PHARMAC staff.

The Committee noted that there are approximately 200 patients in New Zealand with AML, that this disease has a three-year mortality rate of around 100%, and that there is a lack of alternative treatments for this condition.

The Committee considered the evidence provided by Aventis, which consisted of 4 key unpublished studies. The Committee considered that two of the studies did not provide sufficient evidence of efficacy. The remaining two placebo-controlled studies, and a subsequent meta-analysis, demonstrated a small benefit of riluzole on the combined endpoint of death or tracheostomy. The patients enrolled in the studies had early stage disease with continued arm function. The Committee considered that the benefit might amount to approximately 2-4 months of additional survival. The Committee noted the lack of evidence of benefit on quality of life. The Committee considered that riluzole provided a modest benefit at a disproportionately high cost and would be unlikely to be a cost-effective treatment in New Zealand.

The Committee considered that on the basis of the evidence provided and in consideration of the PHARMAC decision criteria, that a full application would be unlikely to receive support from PTAC.