Cancer Treatments Subcommittee of PTAC meeting held 9 April 2010

(minutes for web publishing)

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Note that this document is not necessarily a complete record of the Cancer Treatments Subcommittee meeting; only the relevant portions of the minutes relating to Cancer Treatments Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Cancer Treatments Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 5 & 6 August 2010, the record of which is available on the PHARMAC website.

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1 Alemtuzumab CaEC applications

1.1 The Subcommittee noted that there was some confusion around its March 2008 and February 2009 recommendations for alemtuzumab in patients with chronic lymphocytic leukaemia (CLL). Members considered that their February 2009 minute was misleading. Members clarified that the intent of their recommendation was that alemtuzumab should be funded for CLL patients with 17p53 deletion who are refractory (rather than intolerant) to fludarabine and where an allogeneic transplant is planned.

1.2 The Subcommittee noted that since a specific population could be identified, albeit small, the funding of alemtuzumab for these patients should be through a Pharmaceutical Schedule listing, rather than CaEC. The Subcommittee therefore **recommended** that alemtuzumab be listed on the Pharmaceutical Schedule under the following Special Authority.

Alemtuzumab – PCT only – Specialist – Special Authority

Special Authority for Subsidy
Initial Application only from a relevant specialist or medical practioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 The patient has B-cell Chronic Lymphocytic Leukemia (CLL); and
2 The patient is planned to have an allogeneic stem cell transplant following alemtuzumab treatment; and
3 The patient has CLL with 17p31.1 deletion by FISH (or lack of p53 function);and
4 The patient's disease is refractory to fludarabine treatment

Renewal Application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 The patient has had a treatment free interval of 6 months or more; and
2 The patient has relapsed and requires retreatment

1.3 The Subcommittee gave this recommendation a medium priority

1.4 The Subcommittee considered that there may be other rare groups of patients who may benefit from treatment with alemtuzumab, for example patients with T-prolymphocytic leukemia or other lymphoproliferative disorders but noted that it was not possible to identify and define specific populations at this time, therefore, members recommended that applications for funding of such patients should be considered on a case by case basis by the Exceptional Circumstances Panel.

2 Trastuzumab

2.1 The Subcommittee considered a paper from PHARMAC staff regarding the current funding of trastuzumab. Members noted that funding for trastuzumab for metastatic breast cancer and a 9 week course of trastuzumab for early breast cancer is listed in the Pharmaceutical Schedule with reimbursement provided for patients with a Special Authority approval, whereas reimbursement for 12 month courses of trastuzumab for early breast cancer occurs through a separate manual process; via submission of an invoice to the MOH.

2.2 The Subcommittee noted that the current manual claiming process for 12 month courses of trastuzumab is administratively cumbersome and confusing. Members considered that it would be preferable to have 12 month courses of trastuzumab listed in the Pharmaceutical Schedule, to reduce the administrative burden for hospital staff. Members also noted that all, except one, private insurance companies were refusing to fund 12 month courses of trastuzumab because it was not listed in the Pharmaceutical Schedule.

2.3 The Subcommittee noted that PHARMAC and the MOH are currently in discussions regarding the possibility of transferring all trastuzumab funding (including 12 month course funding) to DHBs and amending the Special Authority criteria applying to trastuzumab on the Pharmaceutical Schedule. This would allow 12 month treatment claims to be processed, and data collected, in the same way as 9 week and metastatic trastuzumab claims and other pharmaceutical cancer treatments listed in the Schedule.

2.4 The Subcommittee considered that it was important for any Special Authority criteria for trastuzumab to allow the full 12 month treatment courses to be approved under one initial application (rather than having to do an initial and renewal applications).

2.5 The Subcommittee noted that PHARMAC staff had recently received a query regarding the funding of trastuzumab for a patient who had received trastuzumab for early breast cancer who then subsequently relapsed, i.e. trastuzumab re-treatment. The Subcommittee were aware that some patients had been re-treated with trastuzumab under these circumstances. Members also noted that some international treatment guidelines were recommending treatment beyond disease progression in patients with metastatic breast cancer.

2.6 The Subcommittee noted that funding of trastuzumab for metastatic breast cancer was implemented as part of the Ministerially-directed “Cancer Basket” several years prior to any consideration of funding of trastuzumab in early breast cancer. Therefore, at that time there were obviously no metastatic breast cancer patients who had previously received trastuzumab. Members further noted that when the funding of 9 weeks treatment for early breast cancer was listed in the Pharmaceutical Schedule, the funding of patients with metastatic breast cancer was not reconsidered.

2.7 The Subcommittee considered that it was not clear from the current Special Authority criteria for trastuzumab if funding includes patients whose disease has relapsed following previous trastuzumab treatment for early breast cancer. Members noted that it was not possible to have an Initial-Metastatic Special Authority application for trastuzumab approved for a patient who already had an Initial-Early Breast cancer Special Authority

approval. Members considered that the application process was not very clear in this circumstance.

2.8 The Subcommittee considered that the funding of trastuzumab for HER 2 metastatic breast cancer should be reviewed so that it can be clarified if necessary.

2.9 The Subcommittee **recommended** that PHARMAC staff request funding applications for retreatment with trastuzumab after adjuvant therapy and treatment beyond disease progression in metastatic disease in HER 2 positive metastatic breast cancer from the Association of New Zealand Cancer Specialists - Breast Special Interest Group. Members recommended that the submission should include, at minimum, relevant available evidence, definition of the patient group and estimate of potential patient numbers. Members requested that the application should address separately the need for trastuzumab funding in both populations identified, namely:

- Trastuzumab treatment in patients with metastatic HER 2 positive breast cancer whose disease has relapsed following previous trastuzumab treatment for early breast cancer (i.e. trastuzumab re-treatment); and

- Trastuzumab treatment beyond disease progression in patients with HER 2 positive metastatic breast cancer.

2.10 The Subcommittee considered that it would be reasonable to request that such an application be received with urgency, such that it could be reviewed at the next Subcommittee meeting, planned for August 2010.

3 Bortezomib for the first line treatment of patients with multiple myeloma

3.1 The Subcommittee reviewed an application from Janssen-Cilag Pty Limited for the funding of bortezomib, in combination with melphalan and prednisone, as first-line treatment for patients with multiple myeloma (MM) who are unable to be treated with high dose chemotherapy. The Subcommittee noted that the application had been reviewed by PTAC at its February 2010 meeting and that PTAC recommended bortezomib should be listed for these patients with a low priority. Members further noted that PTAC further recommended that the application be reviewed by CaTSoP for advice regarding appropriate Special Authority criteria, including initial number of treatment cycles, and cost-utility analysis inputs.

3.2 The Subcommittee noted that it had previously considered applications for the funding of bortezomib as second and third line treatment for patients with MM.

3.3 The Subcommittee considered that the application was for the same population that it had recently recommended for funding with thalidomide i.e. stem cell transplant ineligible patients. Members noted that it gave this thalidomide recommendation a high priority.

3.4 The Subcommittee considered that effective, curative, treatment of MM was an area of high unmet need. Members noted that with current treatments, including bortezomib, multiple myeloma was not curable and, therefore, treatment goals were principally to extend and/or improve quality of life. The Subcommittee considered that multiple myeloma predominantly affected older people and that approximately half of all multiple myeloma patients would be ineligible for a stem cell transplant, mainly due to their age and associated comorbidities. Members noted that the incidence of multiple myeloma and risk of death from multiple myeloma is higher in Maori compared with non-Maori.

3.5 The Subcommittee reviewed evidence provided by the supplier from one open-label randomised phase III study comparing bortezomib in combination with melphalan and prednisone (BMP) with MP alone in patients with previously untreated MM ineligible for high dose chemotherapy or transplant (VISTA study - San Miguel et al. NEJM 2008; 359: 906-917 and Dimopoulos et al J Clin Oncol. 2009 Dec 20;27(36):6086-93). The Committee noted that the VISTA study enrolled 682 patients randomised 1:1 to receive MP given once daily on Days 1 to 4 for 9 six-week cycles with or without bortezomib dosed at 1.3 mg/m2 IV on days 1, 4, 8, 11, 22, 25, 29 and 32 for 4 cycles and days 1, 8, 22 and 29 for 5 cycles.

3.6 The Subcommittee considered that the quality of evidence from the VISTA study was good and demonstrated that BMP improved outcome in patients compared with MP treatment across all study endpoints including time to disease progression (24 months in the BMP group compared with 16.6 months in the MP group), median duration of response (19.9 months BMP compared with 13.1 months MP), time to response (1.4 months BMP compared with 4.2 months MP) group, and overall survival (72% BMP compared with 59% MP). Members also noted that outcomes remained favourable for bortezomib treated patients with renal impairment and those with other poor prognostic indicators.

3.7 The Subcommittee noted that bortezomib treated patients reported a higher incidence of peripheral neuropathy, gastrointestinal symptoms and herpes zoster infection.

3.8 The Subcommittee considered that the appropriate comparator for BMP in the first line setting is treatment with thalidomide-MP. However, members noted that thalidomide was not currently funded in this setting (although it has been recommended with high priority) and there are no studies directly comparing bortezomib with thalidomide in this patient population. Members considered that an indirect comparison of bortezomib with thalidomide based on evidence from VISTA and a number of studies comparing thalidomide plus MP with MP alone provided by the supplier was difficult to interpret given the differences in study designs and patient populations. Overall, members considered that the efficacy of bortezomib was likely to be similar, or possibly better, when compared with thalidomide. However, members noted that there was no clear evidence that either treatment was better than the other.

3.9 The Subcommittee considered that factors other than relative efficacy should be taken into account when comparing the relative priority of funding thalidomide and/or bortezomib. Members noted that the toxicity profiles and administration route of the two treatments differed. Members also noted that the cost of bortezomib was significantly higher than that of thalidomide, even though thalidomide itself was a relatively expensive treatment for such an old medicine. In addition members considered that the single use

vials containing either 3.5 mg or 1 mg bortezomib would result in significant wastage of this expensive drug.

3.10 The Subcommittee noted that PTAC had considered that based on the median time to first response for bortezomib treated patients in the VISTA study (1.4 months for BMP), it may be possible to reduce bortezomib treatment costs by patients stopping treatment if they had not responded after 2 or 3 cycles. Members considered that this timeframe was too short but considered that 4 cycles would be sufficient to demonstrate a treatment response in the vast majority of patients. Therefore, members considered that it would be reasonable to only fund additional cycles of treatment for those patients who have a demonstrated response to treatment after 4 cycles.

3.11 The Subcommittee considered that the estimated bortezomib market share, and number of patients treated provided by the supplier were far too low. Members considered that if both bortezomib and thalidomide were funded in the first line setting, most clinicians would likely use bortezomib first line and reserve thalidomide for second line treatment, such that most patients diagnosed with MM and ineligible for transplant would be treated with both treatments at some point. Members considered that in the third line setting, after bortezomib and thalidomide, patients would receive single agent dexamethasone.

3.12 The Subcommittee considered that a cost-utility analysis comparing bortezomib, and thalidomide treatment for MM should be completed. Members considered that 100% of patients diagnosed with MM would receive first line treatment, 90% second line and 80% third line.

3.13 The Subcommittee **recommended** that bortezomib should be listed in the Pharmaceutical Schedule subject to the following Special Authority criteria

Bortezomib – PCT only – Specialist – Special Authority

Special Authority for Subsidy
Initial Application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 7 months for applications meeting the following criteria:
All of the following:

1 The patient has newly diagnosed multiple myeloma; and
2 The patient is not eligible for high dose chemotherapy and transplant; and
3 Maximum of 4 treatment cycles of bortezomib

Renewal Application only from a relevant specialist or medical practioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
The patient has had at least a partial response to treatment, as per EBMT criteria.

3.14 The Committee gave this recommendation a medium priority.

3.15 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (v) the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded*

health and disability support services; and (vi): the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.

4 Bevacizumab for liver-only metastatic colorectal cancer

4.1 The Subcommittee considered an application from Roche Products (NZ) Ltd for the funding of bevacizumab (100mg and 400mg vial, Avastin) for the first line treatment of patients with metastatic colorectal cancer in whom metastases are confined to the liver only.

4.2 The Subcommittee noted that the application had been reviewed by PTAC at its February 2010 meeting. The Subcommittee further noted that it had previously reviewed bevacizumab for the first-line treatment of patients with metastatic colorectal cancer (mCRC) in 2005 where it recommended that the application be declined, the main issue being its high cost relative to benefit. The Subcommittee noted that in this application the supplier has attempted to limits costs by requesting that funding to be limited to a subset of mCRC patients; namely, those where metastases are confined to the liver.

4.3 The Subcommittee considered that complete resection of liver metastases was a potentially curative treatment for some patients with mCRC. Members noted that the goal of pre-surgical chemotherapy treatment in patients with mCRC confined to the liver was essentially to convert unresectable liver metastases into resectable metastases, thus improving complete surgical resection rates, which in turn potentially improves progression free survival (PFS) and overall survival (OS).

4.4 The Subcommittee reviewed evidence provided by the supplier from a large number of studies. Members considered that overall the addition of bevacizumab to other chemotherapy for mCRC resulted in modest OS gains, however, it was enormously costly and, in a small group of patients, it was very toxic.

4.5 The Subcommittee considered that the supplier's application was not sufficiently focussed on the relevant evidence and that despite a very large amount of material being provided, there was only limited evidence on use of bevacizumab in those patients most likely to benefit, i.e. as neoadjuvant (pre-surgical) treatment in mCRC patients with metastases confined to the liver in whom complete resection, with curative intent, was potentially possible.

4.6 The Subcommittee noted that the only relevant randomised comparative evidence was from a retrospective analysis of those patients enrolled in the NO16966 study (Okines et al British Journal of Cancer (2009) 101, 1033 – 1038) in whom complete resection was achieved following treatment with oxaliplatin (XELOX), with 5-fluorouacil plus oxaliplatin (FOLFOX4) chemotherapy with, or without, bevacizumab. Members noted that overall the number of patients achieving complete resection in this study was small (n=78, approx 18%), however, complete resection rates appeared to be slightly improved for bevacizumab treated patients (6.3%), compared with the control chemotherapy groups (4.9%) and that in these patients 2-year OS was slightly improved with bevacizumab (90.9%) compared with the control chemotherapy groups (82.3%). However, members

noted that the numerical improvements seen with bevacizumab were not statistically significant.

4.7 The Subcommittee considered that ideally bevacizumab funding should be limited to those mCRC patients who present with unresectable liver metastases but for whom treatment with bevacizumab plus chemotherapy could convert (downstage) them to completely resectable liver metastases. However, members considered that it would be very difficult to define and limit funding to these patients with 'potentially resectable' disease and in reality, if funded, the majority of patients with liver only disease, who were reasonably fit, i.e. those eligible for neoadjuvant chemotherapy treatment, would be treated.

4.8 The Subcommittee considered that the supplier's estimates for the number of patients who would be treated in the neoadjuvant setting was too low; members considered that most mCRC patients with liver only metastases eligible for neoadjuvant chemotherapy would be treated, Members noted that using the suppliers estimates this could be approximately 270-280 patients per year. Members considered that based on the average duration of neoadjuvant treatment from the studies provided, it would be reasonable to limit treatment in these patients to 4 cycles.

4.9 The Subcommittee **recommended** that bevacizumab should be listed in the Pharmaceutical Schedule subject to the following Special Authority criteria

> Bevacizumab – PCT only – Specialist – Special Authority
>
> Special Authority for Subsidy
> **Initial** Application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:
> All of the following:
> 1 the patient has metastatic colorectal cancer; and
> 2 metastases are confined to the liver only; and
> 3 neoadjuvant chemotherapy treatment prior to surgical resection of liver metastases is planned; and
> 4 bevacizumab to be used in addition to combination neoadjuvant chemotherapy for a maximum of 4 treatment cycles.

4.10 The Subcommittee gave this recommendation a medium priority.

4.11 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (v) the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services; and (vi): the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

5 Sorafenib for the Treatment of Hepatocellular Carcinoma

5.1 The Subcommittee reviewed an application from Bayer New Zealand Ltd for the listing of Sorafenib tosylate (200 mg tablet, Nevaxar) on the Pharmaceutical Schedule for the treatment of patients with advanced hepatocellular carcinoma (HCC). Members noted that PTAC had reviewed the application at its August 2009 meeting where it recommended the application be declined. The Subcommittee had requested it review the application at its November 2009 meeting.

5.2 The Subcommittee reviewed the supplier's original submission, including a letter from the supplier clarifying the patient population, previously reviewed by PTAC, plus some additional information subsequently provided by the supplier and a supporting submission from a clinician.

5.3 The Subcommittee considered that there was a high unmet clinical need for new effective treatments for patients with advanced HCC. Members noted that to date no systemic treatment had demonstrated any survival advantage in this patient population. Members noted that the incidence of HCC in New Zealand is higher than in other Western countries, with increased incidence in Maori,, Pacific Islanders and Chinese New Zealanders consistent with the higher incidences of hepatitis B and C infection in these populations compared with NZ Europeans. Members also considered that death rates from HCC were also higher in Maori, Pacific Islanders and Chinese New Zealanders compared with NZ Europeans.

5.4 The Subcommittee noted that the key evidence comprised data from two randomised, phase III studies comparing sorafenib with placebo: the SHARP study conducted in the USA, Europe, South America and Australia (Sorafenib Hepatocellular Carcinoma Assessment Randomised Protocol, study 100554, Llovet et al NEJM 2008, 359:378-90) and a study conducted in the Asian region (China, South Korea and Taiwan) (Chen et al Lancet Oncology 2009, 10:25-34).

5.5 The Subcommittee considered that both studies were of good quality and the standard of evidence high.

5.6 The Subcommittee noted that in the SHARP study sorafenib treatment improved overall median survival by approximately 3 months compared with placebo (10.7 months compared with 7.9 months). Members considered that although this benefit was statistically significant (Hazard ratio 0.69, 95% CI 0.55-0.87, p=<0.001), the magnitude of benefit was small. Members further noted that there was no difference in quality of life endpoints between the two patient groups, but considered that this was likely due to the fact that QOL data were taken early in the study.

5.7 The Subcommittee noted that no patient had a complete response to treatment and partial responses were observed in only very few patients. However the majority of patients (71% sorafenib and 67% placebo respectively) had stable disease.

5.8 The Subcommittee considered that in this disease setting stable disease was a clinically relevant endpoint. Members considered that based on the pre-clinical and early clinical trials sorafenib was more likely to result in stable disease rather than a reduction in tumour size and that ideally clinicians should use this treatment only in the sub-

population of patients who would derive this benefit. However, despite advances in imaging and pharmacodynamic information, it was not possible at this time to identify such patients prior to, or early in, treatment.

5.9 The Subcommittee considered that sorafenib was a very expensive treatment given the limited benefit demonstrated; therefore, members recommended that the application be declined. However, members supported a reapplication from the supplier should it become possible to effectively identify and target those patients most likely to benefit, or if the cost was reduced significantly.

5.10 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (ii) The particular health needs of Maori and Pacific peoples; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule*

6 Gemcitabine for locally advanced or metastatic cholangiocarcinoma

6.1 The Subcommittee reviewed an application from the Gastrointestinal Cancer Special Interest Group of the New Zealand Association of Cancer Specialists requesting that funding of gemcitabine for the treatment of patients with locally advanced or metastatic cholangiocarcinoma.

6.2 The Subcommittee noted that cholangiocarcinoma was a relatively rare cancer, fewer than 120 patients diagnosed each year, and the prognosis for patients was generally very poor. Members noted that cholangiocarcinoma was more common in men and in those aged greater than 65 years. Members further noted that the majority of patients, approximately 70%, presented with inoperable disease, and that in these patients expected survival was generally less than 1 year. Finally, members noted that even if patients presented with operable disease, recurrence rates were high, around 60-90%.

6.3 The Subcommittee noted that the goal of chemotherapy treatment for patients with advanced cholangiocarcinoma was palliative; to improve quality of life and extend disease free survival. Members considered that currently there was no standard treatment in New Zealand but considered that some oncologists would be using 6 cycles of epirubicin and cisplatin in combination with a fluoropyrimidine, most likely oral capecitabine (ECX). Members considered that other oncologists may be using capecitabine alone in this patient population. However, members considered that the evidence of benefit of these treatments was limited.

6.4 The Subcommittee reviewed unpublished evidence from the ABC-02 study, a randomised phase II/III study of gemcitabine with or without cisplatin in patients with advanced or metastatic biliary tract cancer (Valle et al 2009). Members noted that in this

study patients were randomised to receive either cisplatin (25 mg/m2) followed by gemcitabine (1000 mg/m2) on days 1 and 8 every 21 days for 8 cycles, or gemcitabine alone (1000 mg/m2) on days 1, 8 and 15 every 28 days for 6 cycles.

6.5 The Subcommittee noted that median overall survival (OS), the primary endpoint of the study, was improved by approximately 3.4 months in patients receiving cisplatin plus gemcitabine compared with gemcitabine alone. Members considered that the evidence demonstrated that cisplatin plus gemcitabine was well tolerated and provided some benefit in these patients in whom prognosis was generally poor.

6.6 The Subcommittee noted that there was no evidence comparing gemcitabine plus cisplatin with fluoropyrimidine-based treatments, e.g 5FU – cisplatin. However, members noted that in a pooled analysis of a large number of trials (Eckel and Schmid British Journal of Cancer (2007) 96, 896-902) there was a trend towards higher response rate and tumour control rate in studies using gemcitabine-platinum regimens compared with fluoropyrimidine-platinum regimens, albeit the data were not statistically significant.

6.7 The Subcommittee discussed the role of photodynamic therapy (PDT) for locally advanced unresectable cholangiocarcinoma. Members considered that PDT was an interesting, potentially effective treatment but that more studies were needed to confirm its role in the management of this disease. Members considered that the use of PDT should be confined to research trials at this time.

6.8 The Subcommittee considered that, if funded, gemcitabine plus cisplatin would be used for 8 cycles, as per the ABC-02 study. Members considered that cisplatin would not be appropriate in some patients, and in such patients gemcitabine would be given in combination with carboplatin.

6.9 Members considered that up to 50% of patients would go on to receive additional treatments after gemcitabine plus cisplatin for relapsed disease, most likely ECX or capecitabine alone.

6.10 The Subcommittee **recommended** that access to gemcitabine should be widened in the Pharmaceutical Schedule to include funding for patients with locally advanced or metastatic, cholangiocarcinoma.

6.11 The Subcommittee gave this recommendation a High priority.

6.12 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (ii) The particular health needs of Maori and Pacific peoples; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; and (v) the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services.*