IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

CIV 2007-485-1386

UNDER	JUDICATURE AMENDMENT ACT 1972
IN THE MATTER OF	THE NEW ZEALAND PUBLIC HEALTH & DISABILITY ACT 2000
BETWEEN	CHRISTINE MARY MIRIAM WALSH, AMANDA LEIGH RUDD, DIANE BARBARA MCCORMACK, DIANE ELLEN EDWARDS, JUDITH ANN RIDOUT, LOIS MARY BLAIR, WELARAMBAGE MANEL MANGALIKA MENDIS, AND ANNETTE ELIZABETH WIKEEPA Plaintiffs
AND	PHARMACEUTICAL MANAGEMENT AGENCY ("PHARMAC") First Defendant
AND	THE PHARMACOLOGY AND THERAPEUTICS ADVISORY COMMITTEE ("PTAC") Second Defendant

Hearing: 11 - 15,18 February 2008

Appearances: H A Cull QC and A Douglass for Plaintiffs
M G Colson and R E Brown for First and Second Defendants

Judgment: 3 April 2008

In accordance with r 540(4) I direct the Registrar to enclose this judgment with the delivery time of 9.30am on 3 April 2008.

JUDGMENT OF GENDALL J

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[1] In the course of this judgment, many descriptions and entities are abbreviated. Their meaning is contained in the following glossary:

Glossary

BCAC:	Breast Cancer Aotearoa Coalition Incorporated – a group representing breast cancer survivors and 19 breast cancer related organisations in New Zealand.
CaEC funding:	Cancer Exceptional Circumstances funding which may be provided by DHBs in respect of unlisted pharmaceuticals for cancer treatment, not listed on the Schedule, when certain criteria are met.
CaTSoP:	Cancer Treatment Sub-Committee of PTAC (one of many sub-committees).
CAC	Consumer Advisory Committee of PHARMAC
CUA:	Cost Utility Analysis, being a form of cost-effectiveness analysis.
DHBs:	District Health Boards which administer individual hospitals.
HER_2 positive breast cancer:	An aggressive form of breast cancer.
Herceptin:	Brand name for the drug Trastuzumab supplied by Roche Pharmaceuticals for treatment of HER_2 positive primary breast cancer
MedSafe:	A business unit of the Ministry of Health in charge with regulating therapeutic products in New Zealand.
metastatic:	Breast cancer where secondary spread has occurred.
NZPHD Act:	New Zealand Public Health & Disability Act 2000.
PTAC:	Pharmac's Pharmacology and Therapeutics Advisory Committee.
Roche	Roche Products (New Zealand) Limited – supplier of Herceptin.

TAR:	Technology Assessment Report on a pharmaceutical or medical treatment usually incorporating a Cost Utility Analysis.
Sequential treatment:	Herceptin being administered following completion of chemotherapy through the use of other drugs.
Concurrent treatment:	Herceptin administered concurrently with a particular group of chemotherapy drugs (but not all such drugs as some combinations are toxic).
Adjuvant treatment:	Treatment post surgery.
HERA:	A European study of Herceptin for HER_2 positive early breast cancer (3041 patients) involving sequential regiments of chemotherapy followed by either 12 or 24 months of Herceptin.
ROMOND (NCCTG N9831 NSABP B31):	US-based studies involving 1615 patients and 1736 patients of Herceptin for HER_2 positive breast cancer which studies were combined and published as ROMOND.
FinHer:	A Finnish study of Herceptin for HER_2 positive early breast cancer (234 patients) involved in a regiment of nine weeks Herceptin concurrent with other chemotherapy.

[2] Breast cancer is a dreadful disease afflicting women (and even occasionally men). An aggressive form of it is known as HER_2 positive which is associated with 15-25% of all breast cancers. It has a poor prognosis in relation to spread and overall survival. It may be treated by surgery, chemotherapy, radiation and other drug treatments.

[3] These proceedings challenge decisions made by Pharmac concerning the public funding of the drug, trastuzumab, commonly known as Herceptin, prescribed to treat HER_2 positive breast cancer.

[4] Herceptin has been registered in New Zealand for use since 2001, when it was listed by Pharmac on the Pharmaceutical Schedule. That Schedule is maintained

and managed by Pharmac pursuant to s 48 of the NZPHD Act 2000. Pharmaceuticals which are listed on the Schedule are subsidised by District Health Boards ("DHBs"), so that, for patients receiving treatment under a DHB, the whole or part of the cost of the pharmaceutical for a use which falls within the scope of the Schedule, will be met by the DHB.

[5] From 2001, the use of Herceptin has been subject to the requirement that there be a Special Authority for the subsidy as follows:

> "Initial application only from a relevant specialist. Approval is valid for 12 months where the patient has metastatic breast cancer expressing HER_2 3 + or FISH + Renewal only from a relevant specialist. Approvals valid for 12 months where the cancer has not progressed."

[6] That means the drug is public funded only where metastatic breast cancer exists. The approval authorised the use of the drug by DHBs, and accordingly the subsidisation of the cost to patients, only for the use in end stage metastatic breast cancer. Its use in adjuvant therapy following early surgery, in patients whose cancers had not advanced to the metastatic stage, was not approved. Herceptin could be prescribed by clinicians for treatment of patients not in that category, but the cost of treatment would not be met or subsidised by the DHB. The full cost had to be met by the patient. Herceptin is very expensive. Because of the price charged by the supplier (Roche) to DHBs (depending upon dosage, which in turn is dependent upon the patient's weight, and clinical circumstances), the cost of 12 months' therapy can vary from $68,000 to $70,000.

[7] The Plaintiffs are women who were diagnosed with HER_2 positive breast cancer, and were prescribed a 12 months course of Herceptin treatment following surgery in the early stage of the illness. They have had to fund it themselves.

[8] Pharmac is the Crown entity which approves State funding or subsidies for pharmaceuticals. It had approved the funding for Herceptin for metastatic (end stage) breast cancer, it had not approved or made any decision in respect of funding of Herceptin for early stage, immediately post-surgery treatment.

[9] The plaintiffs, along with many others, want full state funding for a 12 months course of Herceptin treatment at the early stage of the illness. Such has not been possible by reason of Pharmac's decisions.

[10] The case is not about the prescribing of the drug, or the entitlement of the plaintiffs to receive it for early stage treatment. If prescribed by the specialist it can be dispensed. The case is about Pharmac decisions which relate to the funding or subsidising of the cost of Herceptin. The plaintiffs say that decisions made by Pharmac, declining to approve funding of Herceptin for 12 months early treatment, and the advice it received from an advisory committee (PTAC), were unlawful, and that such decisions should be set aside.

[11] The plaintiffs' third claim relates to Pharmac declining to treat them as falling into an "exceptional' category so as to be entitled to individual funding, for 12 months Herceptin treatment, when they are not eligible to financial benefit from an approved 9 weeks regime. They also seek damages for what they allege were breach of their rights to "natural justice" under the New Zealand Bill of Rights Act 1990.

Background summary

[12] Pharmac is said to have made a "First Decision" on about 26 July 2006. Roche, the supplier of Herceptin, had applied for Pharmac approval for funding of 12 months Herceptin treatment for early stage HER_2 positive breast cancer. Pharmac received advice or recommendations from one of its committees, the Pharmacology and Therapeutics Advisory Committee ("PTAC") which in turn had advice from a sub-committee, the Cancer Treatment Sub-Committee ("CaTSoP"). I will discuss the process in detail later.

[13] The Board's decision on the Roche application was to not recommend funding or listing of Herceptin for early stage 12 months treatment on the Pharmaceutical Schedule (a necessary prerequisite for funding) "at this time". That is the first decision under challenge.

[14] Subsequently, the Board resolved on 24 April 2007 to amend the criteria for Herceptin on the Schedule to authorise funding of a particular nine-week early stage treatment regime for women with HER_2. It followed a consultation process involving meetings and communications with oncologists, interested groups, and feedback was sought from all pharmaceutical suppliers, hospital pharmacists, medical groups, the public and interested parties. The Board had reports and advice from PTAC, CaTSoP and its Consumer Advisory Committee (CAC). That is the challenged "Second Decision".

Plaintiffs' claims regarding the First and Second Decisions

[15] The lawfulness of these two decisions is challenged by the plaintiffs for multiple and overlapping reasons. In summary they contend that Pharmac:

a) failed to perform its statutory duty to consult;

b) acted ultra vires its statutory powers in creating operating policies and giving directions to its sub-committee PTAC (which in turn acted ultra vires in giving the advice it did);

c) required PTAC to act "under its direction" so that the committee's advice was unlawful;

d) itself acted under a direction, or at the dictation, of DHBs because it had sought their agreement to the recommendation not to fund 12 months Herceptin treatment;

e) failed to take into account relevant considerations;

f) took into account irrelevant considerations;

g) pursued a rigid pre-determined policy or plan so as to fetter its statutory discretion and function;

h) acted in breach of the plaintiffs' legitimate expectation;

i) acted unfairly and denied "natural justice" to the plaintiffs because they expected to be consulted – through groups to which they were aligned – before the decisions were made;

j) acted with procedural and substantive unfairness;

k) made decisions that were unreasonable and/or irrational;

l) breached the plaintiffs' rights to natural justice as contained in s 27(1) of the New Zealand Bill of Rights Act 1990.

The Third Decision

[16] This decision was the advice or recommendation by a Pharmac panel under its Cancer Exceptional Circumstances Policy ("CaEC"), that the plaintiffs were not eligible for individualised funding for their 12 months' treatment. That policy or scheme allows, in certain circumstances, for funding of pharmaceuticals for the treatment of cancer which are not covered under the provisions of the Pharmaceutical Schedule. It is designed to provide for exceptional cases where the funding of cancer drugs can be made, notwithstanding they fall outside the DHB budget for oncology drugs ("the oncology basket"). The circumstances must be exceptional. Certain criteria have been promulgated by Pharmac in consultation with clinicians and DHBs.

[17] The plaintiffs, through their solicitor sought 12 months Herceptin funding under the CaEC procedure, but were declined because they did not meet the required criteria in several respects.

[18] Under the policy adopted by Pharmac, applicants have the opportunity or "right" to appeal, for reconsideration by a panel of clinicians, against an adverse recommendation or decision. If dissatisfied, an applicant may proceed further and

seek review by the Medical Director of Pharmac. That was done, but the plaintiffs' application remained declined.

[19] The plaintiffs again allege multiple reasons why Pharmac's failure to recommend, or approve the applications, was unlawful and reviewable, as was the procedure for appeal and review. They contend that Pharmac:

a) failed to exercise its statutory function, through acting under the dictation, of DHBs;

b) acted ultra vires its powers;

c) failed to manage the Exceptional Circumstances policy for funding Herceptin;

d) imposed criteria it was not entitled to fix;

e) required DHBs to act outside their permitted functions;

f) fettered its statutory discretion or function in formulating the "exceptional circumstances" policy;

g) breached the legitimate expectation of the plaintiffs that their individual circumstances would be considered and acted unfairly in not considering individual merits;

h) adopted a closed mind by applying rigid criteria;

i) adopted a process tainted by "breaches of natural justice, errors of law, procedural and substantive unfairness";

j) reached a final decision tainted by bias because the review Panel and Medical Director were not, and could not be seen to be, independent of Pharmac;

k) reached an unreasonable and irrational decision;

l) made a decision in breach of the plaintiffs' rights under the New Zealand Bill of Rights.

Remedies sought

[20] The plaintiffs seek declarations that the first and second decisions were invalid and be quashed, and an order requiring Pharmac to reconsider the application (of Roche) to list Herceptin for 12 months.

[21] They seek a further declaration that the third decision was invalid and an order quashing it; and a further declaration that any appeal right and review authority in respect of the CaEC funding decision, be independent of Pharmac.

[22] The plaintiffs also seek compensation for the alleged breach of their rights under the New Zealand Bill of Rights Act 1990, on the basis that they lost financial capital through having to fund their 12 months Herceptin treatment when they are not able to benefit from the decision authorising nine weeks of funding (and I assume from 12 months early stage funding). They say that in the event that the decisions of Pharmac are quashed, they would have suffered loss, formulated as the cost of such treatment.

Preliminary comment

[23] It can be seen that the plaintiffs allege a total of 28 grounds of review, namely 10 in respect of each of the first and second decisions, and 8 in respect of the CaEC applications. Almost every cause of action or ground for review known under administrative law principles applicable to Judicial Review is thrown into the ring.

[24] The plaintiffs provided the Court with four bound volumes containing approximately 56 decided cases and authorities. They all deal with established Judicial Review principles. For the interim relief hearing, at least, Pharmac submitted 29 authorities although counsel's submissions largely focused on the facts

which he said (correctly) would provide most of the answers in many judicial review cases.

[25] A Judge has to be alive to the danger that elements which are truly relevant to the merits in a case in one area, do not become obscured by a barrage of allegations bombarded at the court. The "scatter gun" approach, too often adopted, in judicial review cases, is not usually helpful to the court.

[26] The parties must understand, what is well known to lawyers, namely that judicial review proceedings are process-oriented. They are not concerned with substantive merits except on questions of irrationality.

[27] The High Court's function is restricted to determining whether the public body acted lawfully; *Progressive Enterprises Ltd v North Shore City Council* [2006] NZRMA 72. In *Pring v Wanganui District Council* [1999] NZRMA 519 (CA), the Court of Appeal said at 523:

> "…in judicial review [proceedings], the Court does not substitute its own factual conclusions for that of the consent authority. It merely determines, as a matter of law, whether the proper procedures were followed, whether all relevant, and no irrelevant considerations were taken into account, and whether the decision was one which, upon the basis of the material available to it, a reasonable decision-maker could have made ….the weight to be given to particular relevant matters is one for [the decision-maker], not the Court to determine, but, of course, there must be *some* material capable of supporting the decision."

[28] Extensive opinion evidence and expert evidence has to be substantially helpful to enable the Court to determine a judicial review case based upon proper principles and not, as is often the case, designed to lead the Court into determining the questions of merits. As Asher J said in *Diagnostic Medlab Limited v Auckland District Health Board & Ors* [2007] 2 NZLR 832 at [314]:

> [314] It is inappropriate for a Court in inquire too closely into the reasonableness of a decision in a context where the Court can have no level of comfort as to its ability to understand and assess the medical and economic subtleties that arise.
>
> ……
>
> It would be arbitrary in the course of a judicial review hearing, where the evidence quite rightly has not been tested by cross-examination, to choose

> between conflicting sets of opinions presented by the parties. Indeed, a high requirement of unreasonableness is appropriate to the process of judicial review, were evidence generally takes the form of untested affidavits. Grave irrationality of the true *Wednesbury*-type described will normally be apparent on the papers and does not require detailed factual analysis.

[29] Expert evidence, and opinion evidence of witnesses (lay and expert) that goes into the merits of a challenged substantive decision will be of no help to the Court, and can be a hindrance because of the time that will be wasted on the topic.

[30] Because of the way the plaintiffs' case was presented, I set out the factual narrative in some detail, so that the procedure followed and process adopted at various stages, is seen and understood. But I cannot move into the realm of the merits – one way or the other – of "12 months versus 9 weeks" funding of Herceptin.

Pharmac structure

[31] Pharmac was established in 1993 as a Crown entity pursuant to the NZPHD Act 2000. Its statutory objectives are set out in s 47:

> "47 **Objectives of Pharmac**
>
> The objectives of Pharmac are-
>
> (a) to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided; and
>
> (b) any other objectives it is given by or under any enactment, or authorised to perform by the Minister by written notice to the board of Pharmac after consultation with it."

[32] Pharmac's statutory functions are set out in section 48:

> 48 **Functions of Pharmac**
>
> The functions of Pharmac are to perform the following within the amount of funding provided to it and in accordance with its statement of intent (including the statement of forecast service performance) and (subject to section 65) any directions given under the Crown Entities Act 2004:
>
> (a) to maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies:

(b) to manage incidental matters arising out of paragraph (a), including in exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the pharmaceutical schedule:

(c) to engage as it sees fit, but within its operational budget, in research to meet the objectives set out in section 47(a):

(d) to promote the responsible use of pharmaceuticals:

(e) any other functions it is for the time being given by or under any enactment, or authorised to perform by the Minister by written notice to the board of Pharmac after consultation with it."

[33] The Pharmaceutical Schedule contains a list of all pharmaceuticals subsidised by the DHBs. Pharmac makes decisions about which pharmaceuticals should be listed, what subsidies should be paid for each of them, and the eligibility and criteria for the provision of subsidies. In order to maintain and manage the Schedule, Pharmac manages a notional budget that is set by the Minister of Health each year following consultation between Pharmac and the DHBs.

[34] Pharmac must choose how to spend this notional budget across the vast number of potentially available pharmaceuticals. Obviously, any saving made on the subsidy paid for one pharmaceutical can be used to subsidise other, especially new, pharmaceuticals. The budget is notional because, but for $3 million, it is not in fact Pharmac that pays the subsidies.

[35] The notional budget is for pharmaceuticals dispensed by community pharmacies and is not for pharmaceuticals used in hospitals or dispensed by hospital pharmacies. These are paid for by DHBs out of their own budgets. Hospital cancer pharmaceuticals (including Herceptin) are funded directly by DHB hospitals (being dispensed by Hospital Pharmacies). Such cancer treatments that are administered in hospitals are funded by DHB hospitals from the funds provided to them by DHBs. That is, each DHB is allocated a set amount of funding by the Ministry of Health each year. From this set amount, the DHB must fund treatment within its area, by hospitals paying for such pharmaceutical cancer treatment from funds provided to them by DHBs.

[36] Pharmac and the DHBs had agreed to an arrangement for transitioning accountability to Pharmac for the funding of Pharmaceutical Cancer Treatments, so

that Pharmac managed the notional Pharmaceutical Cancer Treatment budget on DHBs behalf. It was anticipated that this would occur by 1 July 2007 - that had not happened. Nevertheless, for the year from 1 July 2007, Pharmac established a notional budget for Pharmaceutical Cancer Treatments of $48 to $53 million, and DHBs accepted that estimate.

[37] Pharmaceutical Cancer Treatments are currently listed in the Pharmaceutical Schedule and are subject to funding assessment by Pharmac, and the relevant rules in the Schedule. Decisions about whether DHBs should fund Pharmaceutical Cancer Treatments are made by DHBs collectively to ensure national consistency of access to these treatments.

[38] A "Pharmaceutical Cancer Treatment' is defined in the Schedule as:

> "…Pharmaceuticals for the treatment of cancer, listed in Sections A to G of the Schedule and identified therein as a "PCT" or "PCT only" Pharmaceutical that DHBs must fund, from their own budgets, for use in their hospitals, and/or in association with Outpatient services provided in their DHB Hospitals, in relation to the treatment of cancers."

[39] Rules regarding DHB's obligations in relation to Pharmaceutical Cancer Treatments are contained in the Schedule. They highlight different situations:

a) DHBs *must* provide access to Pharmaceutical Cancer Treatments for use in the treatment of cancers in their DHB hospitals and/or in association with outpatient services provided in their DHB hospitals;

b) DHBs *must not* fund pharmaceuticals for the treatment of cancer or Pharmaceutical Cancer Treatments for indications related to the treatment of cancer if they are not listed in Sections A to G of the Schedule unless the unlisted pharmaceutical meets certain criteria;

c) DHBs *may* provide access to unlisted pharmaceuticals for the treatment of cancer where the unlisted pharmaceutical:

    i) has Cancer Exceptional Circumstances (CaEC) approval;

ii) has Community Exceptional Circumstances or Hospital Exceptional Circumstances approval;

iii) is being used as part of a bona fide clinical trial which has Ethics Committee approval;

iv) is being used and funded as part of a paediatric oncology service; or

v) was being used to treat the patient in question prior to 1 July 2005.

[40] For the purpose of these proceedings, the distinction is:

a) If Pharmac lists a cancer treatment on the schedule DHBs *must* fund it.

b) If such treatment is not on the schedule, but CaEC approval is given by Pharmac, DHBs *may* fund it.

The Pharmac Board

[41] The eight members are appointed by the Minister of Health and at the relevant time included an accountant (the Chairman), an economist, members with corporate finance and iwi organisations experience, and a university professor of general practitioner medicine.

The Pharmacological and Therapeutics Advisory Committee (PTAC)

[42] Pharmac is required to establish this advisory committee "to provide objective advice to Pharmac on pharmaceuticals and their benefits" ((s 50(1)(a)) NZPHD Act 2000).

[43] Its membership comprises medical practitioners with expertise in clinical pharmacology, internal medicine and general practice. At the relevant time, its 11 members comprised four general practitioners, four physicians (with expertise in a rheumatology, and clinical pharmacology), a paediatrician, and a psychiatrist.

Consumer Advisory Committee (CAC)

[44] The Board is required to establish this Advisory Committee to "provide input from a consumer or patient point of view" (section 50(1)(b)) of the NZPHD Act 2000). It has nine members, five of whom are women. Members have interests in women's health issues, consumer health issues, Mäori health generally, mental health, young families and medical ethics, the health of the elderly, Mäori men and pacific people's health, Mäori women health and mental health, and isolated rural issues that are relevant to Mäori health.

Cancer Treatment Sub-Committee (CaTSoP)

[45] This is one of sixteen sub-committee of PTAC. It has 9 members and a PTAC member chairs it. Otherwise it comprises medical practitioners who are specialists in the treatment of cancer, including oncologists, haematologists, a consultant radiation oncologist, and experts in palliative care. It provides advice, when requested by PTAC, on specific issues relating to applications for inclusion of pharmaceuticals on the schedule.

Factual narrative and decision-making process between December 2005 and April 2007

December 2005

[46] Pharmac received an application from Roche requesting funding for 12 months sequential treatment of Herceptin for women with HER_2 positive primary breast cancer. Before then, and since 2001, Herceptin had been listed on the

Pharmaceutical Schedule authorising subsidisation only to patients for 12 months for metastatic ("later stage") breast cancer.

[47] Roche's lengthy submission comprised 83 pages. Roche provided data from European (the HERA) and American (ROMOND) trials to support of the submission that early stage 12 months treatment provided significant benefits to patients in terms of prevention of recurrence or spread of the cancer, and of increased longevity.

[48] The HERA European trial was a study of 3041 patients with HER_2 positive early breast cancer which involved sequential regimes of chemotherapy followed by 12 months sequential treatment. The ROMOND trials, known as NCCTG N9831 and NSABP B31, occurred in the USA and involved two groups (1615 patients and 1736 patients).

16 February 2006 PTAC meeting

[49] The Roche application, submission and other information, including papers prepared by Pharmac staff, were referred to PTAC for its consideration. PTAC and its members reviewed the studies or trials referred in the Roche submission. The Committee raised a question about cardiac side-effects of Herceptin when used in the studies. PTAC concluded that benefit and safety data was insufficient at that time, and it could not recommend that listing then. It recommended that Pharmac should obtain more research data from Roche, after which the application would be referred to CaTSoP.

[50] In March 2006, Roche provided further submissions regarding costs and benefits of Herceptin on the 12 months early stage regime. Its very detailed submission on those matters encompassed 174 pages.

Consideration by Consumer Advisory Committee (CAC), 17 March 2006

[51] The CAC had a paper from Pharmac which advised that it was considering the Herceptin funding issue but would not be making any recommendations until

Herceptin had been approved by MedSafe for use in HER_2 positive early breast cancer. But, in order to start the evaluation process, PTAC's advice had already been sought.

[52] The material before CAC included information of the clinical trials and that the likely cost might be about $30 million per year for payment for treatment of approximately 400-500 patients.

[53] The CAC was provided with Pharmac's decision criteria in its "Operating Policies and Procedures" ("OPP"). Ms Coney, the Chair of CAC, said that the committee noted that the possible benefits of Herceptin, the fact that results were fairly short term, and that potential harms had been signalled. The CAC recorded in its minutes:

> "The Committee noted the benefits of Herceptin may not be as great as stated by patient groups lobbying for funded access. The Committee also noted that at a total cost of about $30 million per annum, Herceptin had the potential to almost double the spending on hospital oncology drugs."

CaTSoP meeting of 19 April 2006

[54] That sub-committee had a Pharmac memorandum with questions for the sub-committee to consider, clinical trial evidence supplied by Roche, the minutes of PTAC's meeting of February 2006, and a summary of other data including cardiac safety issues and additional material.

[55] Members of the CaTSoP were aware at that time of other data reporting the effects of Herceptin, and that only two arms of the USA trials had been considered in the combined report by ROMOND. An unreported arm, relating to therapy provided in a sequential manner, apparently had not shown a benefit at that stage. The committee was aware of the small FinHer trial, where Herceptin had been given to patients in an abbreviated nine week course, together with chemotherapy. That had reported a benefit of a similar order as in the HERA trial.

[56] CaTSoP committee members felt the additional data raised questions as to the ultimate scheduling and duration of therapy with Herceptin. The CaTSoP committee

noted that sequential treatment might not perform as well as concurrent treatment, but that the data was premature to enable reliable conclusions to be drawn. The minutes referred to the members noting the resource burden of administration over a year would be significant and that:

> "the additional resource burden of the cardiovascular monitoring requirements would also be significant. Patients would be required to undergo 3-4 additional echocardiograms, with more required if any [symptoms] were detected. The Sub-Committee noted that this would have the effect of adding additional costs to cardiac departments.
>
> 3.2.1 The sub-committee noted that at present both infusion and echocardiograms services are working at, or near, capacity in DHB hospitals, and if trastuzumab were available for early breast cancer, then it may mean increased waiting times for existing cancer treatments and may adversely impact cardiac services.
>
> 3.2.2 The Sub-Committee considered that trastuzumab could be made available for the treatment of early breast cancer, and gave a low-to-medium priority to this recommendation.
>
> 3.2.3 The Sub-Committee considered that the relevant decision criteria in favour of the recommendation were:
>
> (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; and
>
> (vii) the Government's priorities for health funding. Members noted that other decision criteria were either neutral or against a positive recommendation.
>
> 3.2.4 Members noted that the priority rating could increase to high if the price of trastuzumab were to fall significantly, although such recommendation would be with caution, due to the lack of long-term safety and efficacy data and an absence of a proven increase in overall survival. Members noted that $30 million per year may be better spent in other areas of cancer control if such funding was available. One member noted that given the extent of the funding required, consideration may need to given as to whether such funding would be better directed towards other (non-cancer) health services."

PTAC meetings of 24 and 25 May 2006

[57] An additional lengthy supplementary submission by Roche was discussed. Two memoranda prepared by Pharmac staff contained a set of questions for the

committee's consideration, and its view on other matters. There was an updated cost utility analysis (CUA) paper, together with a CUA assessment supplied by Roche.

[58] PTAC was asked for its advice as to the reasonableness of Pharmac's CUA assumptions, its "quality of life" assessment in the CUA, the assessment costs in its CUA and Pharmac's staff review of Roche's CUA.

[59] The committee discussed the April 2006 CaTSoP minutes and the further clinical information supplied by Roche. Information contained in PowerPoint slides presented at a conference in relation to the USA study, together with the results of the FinHer study (which had not been provided by Roche), were also available.

[60] The minutes of the meeting record that PTAC agreed with the considerations of CaTSoP at its meeting of April 2006; made certain observations concerning the statistical significance of data contained in the trials; noted that the FinHer trial was relatively small and might not have been sensitive enough to detect cardiovascular toxicity and:

> "… the FinHer Study cast significant doubt over the optimal duration and timing of trastuzumab treatment. Members noted that funding of trastuzumab for the proposed indication would have a high budgetary impact, which would have significant consequences for future funding of other pharmaceuticals and services. The uncertainty surrounding the optimal duration and timing of treatment represented a large risk that should be addressed before any decision is made."

[61] As part of its general considerations, the committee considered that if Herceptin was available for early breast cancer it might result in increased waiting times for existing cancer treatments and adversely impact on cardiology services. Its recommendations, recorded in the minutes were:

> "The Committee concluded that, based on the interim trials published to date, trastuzumab may have a role in the treatment of primary breast cancer. However, the Committee considered that, with the data provided, they were unable to determine the optimum schedule and duration of trastuzumab treatment, the magnitude of treatment, benefit on the Overall Survival and, therefore, the cost-effectiveness of trastuzumab.
>
> Given the high cost of trastuzumab, the early nature of the clinical data, and the significant impact on other services and investments in health care, which may offer better health outcomes for the money invested, the Committee did not consider it appropriate to make a recommendation for

> funding this product at this time. It noted that although there was insufficient evidence to make a positive recommendation for funding this product at this time, it was likely that further data would enable the Committee to address it's [sic] questions regarding the long-term health benefits, optimal scheduling and cost-effectiveness of trastuzumab. The Committee noted that it would welcome any substantial body of evidence from the supplier for consideration at subsequent meetings."

26 June 2006 meeting of the Chief Executive Officers of DHBs

[62] Prior to this meeting, the DHB officers had received a lengthy paper from Pharmac regarding Herceptin. The treatment was then currently funded directly by DHBs rather than by Pharmac through its notional community pharmaceutical budget, but Pharmac was responsible for dealing with amendments to the Schedule.

[63] Pharmac considered the next step in the decision-making process was for it to discuss the issue with DHBs. Given PTAC's recommendations and Pharmac staff analysis, Pharmac was not in a position to make a recommendation for DHB funding at that time. But Pharmac wanted to determine whether DHBs would fund at any level, and if so, where. As a result, a memorandum to the DHB chief executives contained some recommendations and that the DHBs note that Pharmac did not recommend funding of Herceptin to DHBs at "this time"; that the DHBs support Pharmac's recommendation to the Board to decline Roche's application; that there be a joint approach taken of a public announcement of the recommendation; and that the DHB's indicate to Pharmac whether they would invest in the funding of Herceptin for early breast cancer treatment:

> "should PTAC ultimately make a positive recommendation during the 2006/2007 financial year; and if not, at what cost might the investment be acceptable."

[64] The memorandum concludes:

> "note that PHARMAC intends to continue to assess new clinical data as it becomes available, including data relating to the optimal dose and scheduling of trastuzumab. PHARMAC will return to the DHB CEO group with further updates as necessary should PHARMAC's view on funding change as a result of this ongoing review."

[65] Apart from that memorandum, the DHB chief executives had a number of documents including the minutes of PTAC and CaTSoP minutes, the TAR prepared by Pharmac, a summary of recent pharmaceutical investments, the NICE (United Kingdom) draft guidance on Herceptin for early breast cancer.

[66] Mr D W Meates', chief executive officer of a DHB, evidence refers to the conclusions of the meeting being:

> "We considered that the cost/benefit evidence was not clear and further advice is required based on the evidence. Having carefully considered the paper from PHARMAC, the DHB CEOs made the following resolutions to reflect our decision, as recorded in the minutes of the meeting:
>
> 6.2 **HERCEPTIN**
>
> Noted. process to date and PHARMAC recommendation that DHBs do not fund, as additional information has been sought which is expected to have a significant effect on choice of clinical regime and cost-benefit analysis.
>
> Agreed. that development of national guidelines for clinical use is supported by DHBs.
>
> Endorsed. PHARMAC recommendations in the paper, with the exception of recommendation 3, which was rejected as unnecessary given recommendation 4.
>
> Noted. that a Media conference is planned for Wednesday, 28th June to communicate CEO decision following meeting with the Minister on 27th June.
>
> Noted. PHARMAC would come back to CEOs with new recommendations if new information was available.
>
> ….
>
> We did not say at what point we would be willing to fund Herceptin for HER_2 positive early breast cancer as we felt that was a discussion for another day once further information had been received and raised. All DHB CEOs were very conscious of the amount of potential expenditure (approximately $20 million) and the effect this would have on the Pharmaceutical Cancer Treatment budget. This was a key concern and so the PHARMAC staff recommendation was readily accepted."

[67] A joint press release was issued which stated that funding had not yet been approved for Herceptin but would be kept under review by Pharmac as new information emerged.

Roche communications between 28 June and 6 July 2006

[68] Over this period, Roche, reviewed the minutes of PTAC and CaTSoP meetings, and wrote to Pharmac making representations. To support its application, it enclosed further material regarding the ROMOND, USA studies.

CAC meeting, 14 July 2006

[69] CAC had a memorandum from Pharmac staff reporting on the analysis undertaken by Pharmac, PTAC and its sub-committee and of the economic evaluation and various commercial discussions that had taken place with Roche. The CAC minutes record that the drug:

> "Continue[s] to be a high-profile issue and Pharmac was continuing to progress its assessment."

Pharmac Board meeting, 26 July 2006

[70] At this meeting the Board had a large volume of material as well as a memoranda prepared by Pharmac staff, including details of Roche's commercial proposal, assessments of clinical benefits, multiple memoranda containing background commentary on available clinical evidence and Cost Utility Analysis for the 12 months funding; PTAC and CaTSoP minutes from meetings of February, April and May 2006; assessments of clinical trials and risks; information concerning the Australian Pharmaceutical Benefits Scheme funding for Herceptin; and a New Zealand magazine article featuring one of the plaintiffs (Ms Walsh), discussing arguments surrounding the Herceptin funding issue.

[71] There was a lengthy discussion around the Herceptin decision. The evidence of Professor Coster, a Board member, was that:

> "The Board was aware of the high level of public interest as evidenced by the North and South article and was particularly conscious of the health care needs of individuals during its decision-making process. Nonetheless, PHARMAC is required to take an evidence-based approach to its decision-making, and it is required to be rigorous in its application of the decision

criteria during that process. The Board carefully considered all of the material before us and discussed the issues at length. We then:

(i) r**esolved** not to list trastuzumab (Herceptin) on the Pharmaceutical Schedule for the treatment of early breast cancer at this time;

(ii) **noted** that DHBs support this recommendation;

(iii) **noted t**hat PHARMAC intends to continue to assess new clinical data as it becomes available, including data relating to the optimal dosing schedule and duration of treatment with trastuzumab. PHARMAC staff will return to the Board with further updates as necessary should PHARMAC's view on the funding change as a result of this ongoing review;

(iv) **noted** the discussion between the Minister and the PHARMAC Chief Executive Officer;

(v) **directed** that the message be given to the media and public is that "PHARMAC is not funding at this present time" and "PHARMAC is still actively obtaining information and data, it is still under consideration, cost is high and the UK decision is being challenged.";

(vi) **directed** that the Demand Side consider adding to its work programme are to promote early detection of breast cancer, particularly for Mäori and Pacific Island women; and

(vii) **noted** the lengthy discussions around the Herceptin decision."

[72] Professor Coster's evidence was that the Board essentially concluded that the funding for early breast cancer Herceptin should not occur "at that time but the matter should remain subject to ongoing review as new information became available". He said that the Board was aware that DHB funding was unlikely but the decision of the Board at that time was based on the decision criteria, not the availability of funding from DHBs. He said:

> "At that time, we were satisfied that the funding of Herceptin for HER_2 positive early breast cancer was not in accordance with the decision criteria."

PTAC meeting, 17 August 2006

[73] Funding for Herceptin was again considered by the PTAC on 17 August 2006. There had been a suggestion that the FinHer trial results raised doubt as to the optimum schedule and duration of Herceptin treatment, and the committee received a memorandum from Pharmac staff seeking additional advice on that trial.

[74] It reviewed material including Roche's response to previous CaTSoP and PTAC minutes, items covering new information presented at the American Society of Clinical Oncology (ASCO) 2006 Conference, and the ScHARR Technology Appraisal (which had been commissioned by the National Institute of Clinical Excellence (NICE) in the United Kingdom).

[75] PTAC was asked by the Pharmac to consider whether it had sufficient information to make a recommendation on the use of Herceptin treatment for HER_2 positive cancer.

[76] Present at the meeting were three CaTSoP members. Professor Burgess, Chair of PTAC deposed:

> "Having analysed the evidence from the FinHer study we thought that it cast doubt over the optimal duration and timing of trastuzumab treatment. We recommended that the application for the funding of trastuzumab as per the HERA protocol (12 months treatment) be declined."

[77] The committee noted the FinHer protocol for nine weeks treatment, and funding of Herceptin on that basis could be considered. It referred the application to CaTSoP for further consideration of a nine week funding option.

[78] The PTAC minutes, in part, provide:

> "That the committee considered the number of patients treated in the FinHer study (232) was substantial compared to any other cancer treatment trials, and that although the HERA was a far larger trial, the number of patients treated in the FinHer was not insignificant and the data was valuable."

[79] The recommendations of the committee contained in the minutes were:

> "The committee recommended that the application for the funding of Trastuzumab as per the HER protocol (12 months treatment) be declined due to the uncertainty surrounding long term clinical benefits and risks; the uncertainty over optimal duration of treatment; and the high budgetary impact associated with treatment.
>
> The decision criteria relevant to PTAC's recommendation were:
>
> (i) The clinical benefits and risks for pharmaceuticals;

(iv) 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).

The Committee recommended:

That the application be referred back to the Cancer Treatment Sub-committee of PTAC to consider the clinical appropriateness of any funding regimen consistent with the FinHer protocol (nine weeks treatment)."

CaTSoP meetings, 26-27 October 2006

[80] This followed PTAC's recommendation that the application be referred to CaTSoP to consider the clinical appropriateness of funding based upon the FinHer study. The sub-committee had a vast amount of material before it including previous minutes of PTAC and CaTSoP; the slides from the ASCO presentation; data on the FinHer trial; an outline of progress on the application; information concerning cost of listing Herceptin under various treatment regimes and cost-effectiveness; an outline of the ScHARR report commissioned by NICE of the United Kingdom; a datasheet for Herceptin; a TAR prepared by Pharmac staff; a comparison of the FinHer trial and data against other key trastuzumab studies (i.e. HERA and ROMOND); and correspondence from Roche regarding PTAC's August 2006 minutes.

[81] The amount of material, commercially confidential and otherwise, considered by the sub-committee was very extensive, totalling 332 pages.

[82] The committee also had the proposals for a study arising from the Finnish group (the SOLD study) so that members could review the proposed study design, and consider its feasibility and interest for New Zealand participation in that study.

[83] Professor Harvey, a member of CaTSoP at the relevant time, said that the committee considered the material very carefully and produced a detailed minute outlining discussion and recommendations. He deposed:

> "… It was considered that the data from the FinHer study were valid and of good quality, though in a limited patient population. More scientific weight was attached to the data from the HERA study and the other US studies given the large number of patients involved in these studies."

[84] The minutes of the meeting record that the CaTSoP reconsidered the application from Roche for the user of Herceptin in early breast cancer, and its recommendations are recorded as follows:

> "The Sub-Committee **recommended** that:
>
> trastuzumab be listed on the Pharmaceutical Schedule for HER_2 positive early breast cancer. The sub-committee further **recommended** that, in the absence of availability of funding for 12 months treatment, 9 weeks treatment would be reasonable and gave this recommendation a high priority. However, the Sub-Committee noted, and wished to emphasise, that this recommendation was strongly based on financial considerations as the Sub-Committee had more confidence in the validity of the 12 month treatment results.
>
> ….
>
> The Sub-Committee considered that the relevant decision criteria in favour of the recommendation were (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 (viii) the Government's priorities for health funding."

[85] The minutes record that the sub-committee considered there was still uncertainty about the best way of administering Herceptin in terms of optimal treatment duration, dose and schedule and minimising cardiovascular toxicity and said more clinical search, research was needed to answer those questions. That is, it would be "ideal to do a comparative 12 months Trastuzumab versus a nine weeks Trastuzumab study".

[86] CaTSoP considered that cancer centres in New Zealand could be interested in participating in the proposed clinical study, and that the study design be presented at a meeting of the Association of New Zealand Cancer Specialists.

PTAC meetings 15-16 November 2007

[87] This meeting focused upon the CaTSoP minutes and recommendations of 26 and 27 October 2007. It reviewed a letter from Roche and relevant parts of an earlier PTAC meeting and reconsidered the CaTSoP minutes as to the proposal of pursuing funding for nine weeks treatment. It noted that more clinical research was needed to compare the efficacy of 12 months as against nine weeks treatment. It noted CaTSoP's view and recommended that subject to certain conditions, nine weeks treatment should be funded and gave the recommendation a high priority.

Pharmac Board meeting, 31 January 2007

[88] The Board had two separate memoranda, one setting out two proposals and the other analysing budget issues and implications.

[89] The first paper discussed funding of Herceptin under the FinHer nine weeks treatment protocol administered concurrently with some chemotherapy. Its efficacy had been demonstrated. The other proposal related to a funding of the clinical trial (the SOLD trial), comparing 12 months Herceptin with the nine weeks Herceptin. Detailed memoranda discussed the background to the proposals, their estimated effects, public acceptance of the proposal for a nine weeks funding, and Pharmac staff views and proposed timelines.

[90] The second memorandum analysed budget issues. The Board also considered material concerning Herceptin funding arising out of the Chief Executive's meeting with the Minister; the attendance by Pharmac staff at a breast cancer symposium in the USA; the proposed SOLD study, an editorial in the British medical journal *The Lancet* entitled "Questions About Adjuvant Trastuzumab Still Remain".

[91] Pharmac staff had prepared a table setting out advantages and disadvantages of various funding options, including funding for 12 months, funding for nine weeks, with a recommendation that DHBs fund studies to compare nine weeks versus 12 months subsidies.

[92] Professor Coster, Deputy Chairman of the Board deposed that after extensive discussion, review and consideration of the material, the Board directed Pharmac staff to progress a proposal for nine weeks funding, and for funding a comparative study of short versus long duration. It further recommended that subject to DHB's agreement, there being no material change to PTAC's recommendations, and consultation, Pharmac staff would return to the Board with a formal funding decision paper. It resolved to approve the Pharmac's budget increase for funding of nine weeks Herceptin and to approve Pharmac seeking additional operating funding from the Ministry and DHBs to fund New Zealand participation in the SOLD clinical trial. Other resolutions were made to approve the use of Pharmac's reserves towards operating the funding.

[93] Professor Coster said:

> "In making the resolutions … the Board was not committing PHARMAC to funding the 9 week treatment regimen. Before that could occur, PHARMAC needed to know whether the DHB CEOs would agree to fund Herceptin for HER_2 positive early breast cancer and that it was also necessary to consult on any proposal for funding. Rather, the Board was directing PHARMAC to continue to progress this proposal so the Board could then make a fully considered decision on this issue."

PTAC meeting, 22 February 2007

[94] That committee again reviewed a wealth of material regarding the funding of Herceptin for HER_2 positive early breast cancer. It was asked by Pharmac whether it wished to record comments on additional information provided and whether this changed the committee's previous recommendations.

[95] The committee reviewed the CaTSoP and PTAC minutes, a further submission from Roche dated 8 January 2007, academic articles, PowerPoint and presentations relating to studies and the efficacy analysis of them, Australian product information, New Zealand datasheet and USA prescribing information, a Belgian cost-effective analysis and particulars summarising key data and arguments in favour of supporting the SOLD clinical trial.

[96] The committee's conclusions or views are described by Professor Burgess as follows:

> "The Committee reiterated its view that there was still uncertainty about the best way of administering trastuzumab in terms of optimal duration, dose and schedule (sequential to, or concurrent with, chemotherapy), minimising cardiovascular toxicity, and long-term clinical outcomes.
>
> Specifically the Committee considered that data from Arm B of study N9831 [ROMOND] raised significant doubts about the efficacy of sequential 12 months trastuzumab. The Committee noted that it had requested in May 2006 that full data from N9831 trial be provided by the supplier [Roche], but thus far this had not been provided. The Committee considered that there was now likely to be longer-term follow-up of outcomes (disease free survival and mortality) in the study, and that all updated data from all three arms of the trial should be made available to the Committee ….
>
> The Committee reiterated its recommendation from its November 2006 meeting that nine weeks treatment with trastuzumab (concurrent with chemotherapy and before anthracycline) should be funded and gave this recommendation a high priority ….
>
> The Committee considered that more clinical research was needed to determine if long duration concurrent treatment (52 weeks) is any better than short duration concurrent treatment (9 weeks) and reiterated that a comparative study should be performed. The Committee noted CaTSoP's advice from its October 2006 meeting that the proposed SOLD study was well designed and would answer some of the questions relating to optimal dose, duration and scheduling of trastuzumab in early HER_2 positive breast cancer."

Meeting of DHB Chief Executive Officers, 26 and 27 February 2007

[97] There had been informal discussions between Pharmac and DHBs at earlier stages, but this was the first time the matter formally came before the Chief Executive Officers of the DHBs.

[98] The Pharmac Board in its February 2007 meeting had recommended that DHBs agree to fund a nine weeks treatment regiment.

[99] The DHB executives had a long memorandum of 34 pages containing a number of recommendations. These included that the DHBs "agree, in principle, that the preferred approach to funding trastuzumab, having had regard to all the options" was the nine weeks regiment. Further, that New Zealand participate in the

SOLD trial to further evaluate incremental costs and benefits (if any) of a 12 months treatment.

[100] It was recommended to the DHBs that they agree, subject to the Pharmac's Board decision, to fund a nine weeks treatment regimen, and to agree to fund costs associated with participation in the international clinical trial.

[101] It was recommended that the DHBs "note the desirability of Pharmac and the DHBs working together on public announcements related to the above decisions and those of the Pharmac Board". The meeting agreed to fund a nine weeks treatment of Herceptin (consistent with the Pharmac advice).

CAC meeting, 1 March 2007

[102] The committee had a Pharmac staff memorandum, a presentation was made, and questions asked by the committee. The Chair of the committee deposed that it was generally satisfied that Pharmac was considering the matter in a thorough way. It considered the key issue, was how the effectiveness of a 12 months sequential therapy compared to a 9 week concurrent regime. The committee noted that the efficacy of different treatments, and the balance with risks, was yet to be resolved.

[103] The committee recommended the development of a consumer/patient Herceptin resource, and the minutes record:

> "The committee was updated on issues around the best cancer drug Herceptin. The committee considered that, should PHARMAC proceed with funding for a 9-week concurrent course of Herceptin, women with breast cancer would need to have confidence in the medicine as funded. The committee considered there was a critical need for good information and that PHARMAC should investigate developing – within an appropriate consumer group – a patient-oriented resource."

Consultation following 20 March 2007

[104] As the Board had directed Pharmac staff to implement a plan to progress 9 weeks' funding, and the DHBs had agreed in principle, Pharmac then consulted on that proposal. A letter was circulated on 20 March 2007 seeking feedback on the

proposal to widen access to Herceptin, and another chemotherapy drug for Adjuvant treatment, for HER_2 positive early breast cancer. It was accompanied by a media release. This material was sent to all pharmaceutical suppliers, New Zealand oncologists, breast cancer community/patient groups, and international interested parties. The press release announced the start of consultation and referred to the Pharmac website where the consultation letter and other documentation could be viewed.

[105] Apart from those steps, Pharmac held several meetings with oncologists throughout New Zealand. On 8 March 2007 one meeting was attended by three CaTSoP members and seven oncologists from Auckland, Christchurch, Wellington and Palmerston North who represented four of the six cancer centres in New Zealand. The consensus from that meeting was although a majority preferred 12 months treatment to be funded, it was understood that it would not be a cost-effective use of health dollars or DHB resources, compared with other cancer treatments awaiting funding. The majority of the group agreed that funding for 9 weeks concurrent with Taxane (a chemotherapy drug) was reasonable.

[106] Some amendments to the funding proposal were made after feedback from those oncologists. There was a subsequent meeting with oncologists from two cancer centres (Waikato and Otago). The Waikato oncologists were opposed to the proposed for funding 9 weeks concurrent Herceptin for early breast cancer, and as a result of some submissions, Pharmac changed the proposal to reflect their concerns. Otago oncologists considered that funding should not proceed at all because the data at that time was premature.

[107] There were further meetings with interested groups during March 2007 and presentations were made to the New Zealand Breast Cancer Foundation, the Women's Health Action Trust and a representative of the Auckland Women's Health Council and the Breast Cancer Aotearoa Coalition (BCAC). The meeting with BCAC lasted more than three hours.

[108] A large number of public responses were received to the consultation letter. Nearly all wanted funding for a 12 months regime, rather than 9 weeks. As a result

of some representations received after consultation, proposed changes were recommended to the Board and a lengthy memorandum and consultation responses were provided by Pharmac staff for consideration by the Board at its meeting on 24 April 2007.

Pharmac Board meeting, 24 April 2007

[109] At this meeting that the Board resolved to implement the 9 weeks funding of Herceptin. The Board had before it a detailed memorandum prepared by Pharmac staff which considered:

a) the estimated effects of the 9 weeks proposal in terms of cost of testing for HER_2 and monitoring cardiac function, patient numbers, financial resources, and impact on DHBs;

b) the cost effectiveness of the 9 weeks proposal, and Pharmac staff support for it and their reasons;

c) risks of 9 weeks proposal and possible risk-mitigation;

d) background to the Herceptin funding issue and relating to the drug's uses;

e) the dynamics of the market for Herceptin;

f) PTAC's views;

g) comments from interested parties who had been consulted about the 9 weeks proposal.

[110] The Board was aware that DHB chief executive officers had agreed to fund a 9 weeks treatment regime; had copies of the consultation letter and all responses received; a further TAR regarding available clinical evidence and updated CUA;

minutes of PTAC and CaTSoP meetings from February 2006 to February 2007; and the Chief Executive's report and the CAC recommendations.

[111] Dr Coster, Deputy Chairman of the Board, deposed:

> "I wish to emphasis that it was clear to me that extensive consultation in relation to the Herceptin Funding Issue had been carried out by PHARMAC staff in accordance with PHARMAC policies. This was evidenced by the significant amount of discussion around the various consultation responses received in the April 2007 Board Memorandum (which was by far the most detailed and prominent part of the paper) and also the number of emails and letters included in the material that was placed before the Board at this meeting. The Board considered all of this material."

[112] Dr Coster said that the Board placed considerable weight on the advice provided by PTAC, as its expert advisory committee, but itself had considered a wide range of scientific material, competing views and trial data and that:

> "PTAC reiterated its view that there was still uncertainty about the best way of administering Herceptin in terms of the optimal duration dose and schedule (sequential to, or concurrent with, chemotherapy), minimising cardiovascular toxicity, and long-term clinical outcomes."

[113] The Board resolved to amend the special authority restriction in respect of Herceptin to enable funding for 9 weeks for HER_2 positive early breast cancer, Dr Coster said that:

> "… in resolving to fund trastuzumab for 9 weeks in accordance with the FinHer study, the Board carefully took into consideration the decision criteria set out in OPPS [Pharmac's Operating Policies and Procedures] and, in particular:
>
> (a) scientific evidence available to the Board;
>
> (b) advice provided to PTAC by CaTSoP;
>
> (c) recommendations from PTAC to the Board;
>
> (d) advice from PHARMAC staff;
>
> (e) results of the community consultation; and
>
> (f) available funding from DHBs.
>
> The decision to fund Herceptin for each HER_2 positive early breast cancer has been one of the most important decisions that PHARMAC has made over recent years, and possibly the most controversial. The Board was conscious that in the feedback from the extensive community consultation

> many were opposed to the proposal. These views were carefully taken into consideration by the Board and we were extremely cautious during the decision-making process. After much deliberation, the Board finally resolved to fund the 9 weeks concurrent Herceptin proposal based on the evidence before the Board and in accordance with PHARMAC's OPPS."

[114] It is apparent from Dr Coster's evidence that the Board was aware it was dealing with a significant, sensitive and high-profile issue. He said:

> "The Board acknowledges that some people, including the plaintiffs do not agree with the decision, but the Board is required to exercise its collective judgement and follow the processes as set out in the relevant legislation and operating policies.
>
> ….
>
> I appreciate that the plaintiffs disagree with the Board's decision. But I, and the Board, believe it was the right decision having regard to our expertise and obligations."

[115] The foregoing narrative has been set out, or summarised, at length so as to provide the factual foundation for the steps Pharmac, its committee and sub-committees took in considering initially the application by Roche; and thereafter the essentially alternative issue of 9 weeks early stage funding, rather than a 12 months funding.

The Cancer Exceptional Circumstances Scheme

[116] This Scheme is relevant to the challenged "third decision".

[117] It is one of three schemes established to allow medical practitioners to apply for funding access for medicines or pharmaceuticals not covered under the provisions of the Schedule. Hospital cancer pharmaceuticals are currently funded by DHB hospitals from funding provided to them by DHBs. Each DHB is entitled to make decisions about how to provide services for health care in its own region. With cancer treatments there was initially no consistency between DHBs as to which pharmaceuticals to fund. This led to inequities between patients and resulted in patients choosing to move between regions to receive funded treatment. So, the Ministry of Health, in consultation with relevant specialists, developed a national list

of cancer pharmaceuticals which all DHBs were required to fund. This has come to be known as the "Oncology Basket".

[118] It became apparent that an ability to update the list was needed (given the constant development of pharmaceuticals to treat cancer). Consideration had to be given to whether DHBs could fund other cancer pharmaceuticals that were not on the list. It was therefore decided that Pharmac should publish the list of cancer pharmaceuticals in the Schedule, and update it from time to time after analysing any proposed new addition, and confirming that DHBs would agree to fund it. Pharmac also made rules as to the use of these and other pharmaceuticals. It was empowered to do so.

[119] A rule provided that DHBs may fund cancer pharmaceuticals *not included on the list* provided that certain criteria were met, including peer review of the use of the pharmaceutical, and that it had not been previously considered and a decision made that it should not be included in the list.

[120] Pharmac and DHBs then agreed that the prescribing by clinicians of cancer pharmaceuticals in exceptional circumstances should be changed to require prospective approval from Pharmac, as part of the DHB's decision to fund. Criteria were developed in consultation with the DHBs and specialists. They are known as the CaEC criteria.

[121] The outcome was that DHBs must agree to make funding available for a cancer pharmaceutical before Pharmac will approve funding through CaEC. Payment for the pharmaceuticals under the CaEC scheme comes directly from DHBs. If Pharmac lists a treatment on the Schedule, DHBs must fund it, but if CaEC approval is given in exceptional circumstances, DHBs have the discretion, and the ultimate say, as to whether they will fund it.

[122] In order to qualify for CaEC the following criteria must be met:

a) confirmation that the proposed use was evaluated and approved using established DHB review mechanisms involving experienced clinicians;

b) confirmation that the DHB hospital providing treatment has agreed to fund the treatment;

c) confirmation that the condition is considered unusual (and therefore a decision to treat is unlikely to result in access inequities across DHBs);

d) the proposed use has not been considered or is not currently under consideration by Pharmac for funding;

e) specification of the:

    i) product to be used;

    ii) dose and treatment schedule;

    iii) duration of the treatment;

    iv) indication;

    v) total cost; and

f) the total cost is less than $30,000 over a 5 year period. If the application is for a treatment of $30,000 or over it will be referred for a Cost Utility Analysis (CUA) followed by a decision from Pharmac.

[123] The criteria are said to be based on the concepts of peer review within the DHB hospital, to ensure equity of access to pharmaceutical cancer treatments across DHBs. Applications are to be made by hospital physicians. The CaEC scheme is intended to be largely "self-assessed" by the hospital physician and the relevant

DHB hospital. Provided the patient meets the criteria as certified by the hospital physician, the provision of the cancer pharmaceutical is approved.

[124] A Pharmac staff member considers the application, and if the clinician certifies the criteria as having been met, approval is given. But the final decision to fund the drug remains in the hands of the DHB Hospital -–although in practise a DHB is unlikely to decide not to fund.

[125] If the staff member is unsure, the application is referred to a Panel of clinicians. If that Panel's decision is unfavourable, the applicant may "appeal" to the Panel for its reconsideration. It is described it as a "cross-check" rather than appeal. It is a revision by clinicians.

[126] If the application is still declined – or not approved – a request can be made to the Medical Director of Pharmac for a further "review". That was the process adopted in this case.

Evidence on behalf of the plaintiffs

[127] This comprised 26 affidavits. Much was directed at the merits of funding 12 months early stage Herceptin treatment.

[128] There was affidavit evidence of the eight plaintiffs, and the first plaintiff, Ms Walsh, filed three affidavits. The plaintiffs all describe their particular circumstances, having been diagnosed with HER_2 positive breast cancer, and having had Herceptin treatment, for which they have had to fund themselves. Some are members of a group known as "Herceptin HEROES", which provides support for each other, and as such, are members of BCAC.

[129] The plaintiffs generally describe how the application for CaEC funding was made by their solicitors. Ms Walsh, in a reply affidavit contested the information policies and process of the Panel considering the CaEC application. She further expressed views about the decision-making processes of Pharmac, and described how she became concerned about:

> "Pharmac's focus on funding the nine weeks treatment, and the possibility of a research trial which was not substantiated by the evidence."

[130] Her view was that the CAC did not consult with BCAC, nor with her, as an interested consumer. She does not believe her interests as a consumer were represented by CAC, or that her voice was heard as input into decisions of the Pharmac Board.

[131] Ms Burgess, in her capacity as Chairperson of BCAC, provided an extensive affidavit. It sets out in detail procedures that BCAC undertook in lobbying for 12 months funding for Herceptin. Much of the affidavit involves opinion and submission as to why that should occur. She sets out key points in the BCAC submission, which was received by Pharmac, along with over 200 other submissions, prior to the April 2007 decision. She has filed four affidavits. As Chair of BCAC, she is a driving force behind the campaign or movement advocating 12 months funding Herceptin treatment.

[132] She refers to consultations that occurred between BCAC and Pharmac and representations made to it and others. A large part of her detailed evidence, relates to the merits, given counsels' arguments on "irrationality and unreasonableness" on the part of Pharmac.

[133] She says that:

a) BCAC made a submission to Pharmac in February 2005 concerning the use of Herceptin in advanced breast cancer, being the only approved (more correctly "funded") use at the time;

b) after the public and professional attention focussed upon the results of the HERA trial and the ASCO conference (in America), BCAC issued a press release and a request to meet Pharmac representatives;

c) on 24 June 2005 the committee members of BCAC met with Pharmac representatives. Ms Burgess said it was in part to "foster consultation between Pharmac and BCAC" and:

> "To raise with Pharmac the need to fund Herceptin in early breast cancer, especially given New Zealand's high death rate from breast cancer in comparison to that of Australia."

Ms Burgess kept a record of that meeting and she said it was:

> "Generally positive and I anticipate an ongoing and consultative relationship between Pharmac and BCAC."

d) on 10 August 2005, BCAC wrote to Ms Coney as Chair of the CAC, to seek support for the "advancement of this initiative";

e) on 12 and 13 December, BCAC committee members met politicians, oncologists, MedSafe and Pharmac representatives in Wellington (at the request of BCAC). She said that:

> "In the area of access to drugs, Herceptin was obviously a key issue and we discussed the drug at every meeting."

Ms Burgess said she had read the Pharmac statement of intent and was concerned that Pharmac may have already decided not to fund Herceptin, notwithstanding that an application for funding by Roche was pending, and that Pharmac may have pre-judged the issue.

She said she raised the issue of funding at the meeting with Pharmac and understood that Pharmac had started its analysis of Herceptin prior to registration, that it would be treated speedily, and that Pharmac was confident funding would be put in place. She said she left the meeting optimistic of a positive outcome.

Thereafter, Roche made its application.

f) in January 2006, BCAC became aware that a former patient was collecting signatures for a petition calling on the Government to fund Herceptin immediately. The patient was paying for her own treatment, and had become a member of BCAC's committee;

g) in January 2006, Ms Burgess contacted Mr Crausaz, a senior manager at Pharmac. She said this was "to ascertain the way ahead for Herceptin". Her notes refer to her being told that Herceptin would be discussed by PTAC at its next scheduled meeting, thought to be 16 February, and PTAC was likely to refer some element of the issue to CaTSoP. Assuming advice raised by PTAC was not straightforward, CaTSoP would pass that advice directly to Pharmac which had already begun its research and processing of information on Herceptin. Her note records that once Pharmac received the PTAC and CaTSoP advice, it would advise the DHBs of the situation with Herceptin, the costs, cost effectiveness and other matters. As with every other cancer treatment intended for hospital administration, DHBs will be asked to pay for Herceptin and will be accountable and responsible for the money spent on this drug.

There is reference to Ms Burgess being advised that meetings would be held with DHBs around four times a year, and:

> "The DHBs will need to unanimously agree on the way forward with Herceptin as it is a hospital administrative infusion rather than a community pharmacy dispense drug."

h) on 16 March 2006, the petition of the patient who was to, or had, become a member of the committee of BCAC was presented outside Parliament;

i) on 17 March 2006, the CAC met and discussed Herceptin. Ms Burgess claims that it was not truly acting on behalf of consumers or their representatives but seeking information and advice from Pharmac, and she claims that there was no attempt made by the CAC to ascertain or represent the views of consumers or patients.

[134] The Health Select Committee met on 5 April 2006. Ms Burgess attended and made submissions about Herceptin on behalf of BCAC. Others present included the petitioners, oncologists from Palmerston North and (by phone) from Australia, and

supporting written submissions were presented by the New Zealand Association of Cancer Specialists.

[135] The Health Select Committee was asked to proceed urgently and it reported on 15 June 2006 recommending that all women newly diagnosed as having breast cancer be specifically tested for the HER positive feature.

[136] Before 26 July 2006, BCAC made inquiries of Roche as to how its negotiation or application with Pharmac was proceeding. Ms Burgess said that she was told that none were taking place. Her opinion is this was a "failure to attempt to negotiate a more favourable price for Herceptin [which] suggests that Pharmac had not attempted to reach agreement about pricing that would give a more favourable outcome". She draws the inference – or makes the assumption – that "this suggests that the decision not to fund 12 months of Herceptin treatment had been made at an early stage and was not revisited". Much of her affidavit comprises submission or opinion based upon her view of the facts.

[137] Her view is that had Pharmac consulted BCAC in June and July 2006, it would have been able to provide data from the ASCO conference, a review of Herceptin and its cost effectiveness under the ScHARR research, and other guidelines and information as to countries now funding Herceptin, together with views of patients, consumers and oncologists in New Zealand.

[138] The question is raised whether there was "consultation" before the first decision is made. Obviously, BCAC did not think so or that it was sufficient. It wished to have the opportunity to present further submissions, material and data to advance its argument.

[139] Ms Burgess says that there was not wider consultation with other groups, nor sufficiently detailed extensive consultation with it, and that it had been led to believe or understood that that might occur, given what was earlier thought to be a positive or optimistic view as to the ultimate outcome.

[140] Other affidavits on behalf of the plaintiffs were submitted by Dr R J Isaacs, an oncologist who is treating seven of the eight plaintiffs, and who has lent his support to them and BCAC in lobbying for 12 months funded treatment. He provides factual and opinion evidence as to Herceptin, and its efficacy, the clinical studies, and expresses the view that "a weight of evidence" supported the funding of a 12 months regime. Dr Isaacs was involved as the clinician treating seven of the eight plaintiffs in their application for CaEC funding. He was not, as is usually the case, the applying clinician for the CaEC application made by those plaintiffs' solicitors. Because he was the treating clinician he felt unable to complete the applications for the obvious reason that it did not appear to him that the applicants were eligible under the criteria. He advised however, that 12 months therapy was the optimal therapy for them, which he regarded as consistent with the current international standard of care. His view was that the plaintiffs had no access to the course of treatment because they fell outside the proposed nine weeks Herceptin treatment option, and not being at the end stage of cancer treatment, did not fall within the funding for Herceptin under the current criteria. Of course, the issue was not that the plaintiffs could not receive earlier stage Herceptin treatment, but whether such could be funded. He expressed a belief that Pharmac was putting him and other oncologists in an "invidious" position by funding Herceptin for use with limited safety data.

[141] I am not sure what to make of that submission because it is the specialist who prescribes the treatment – not Pharmac – and if the clinician does not regard it as appropriate or safe, he/she will not prescribe it. Funding, or not, only arises if it is prescribed.

[142] But it is obvious that Dr Isaacs is a strong supporter and advocate for the plaintiffs' position – as are many others.

[143] Two further affidavits of an English consultant clinical oncologist, Dr A D Brunt were filed. He was a lead investigator in the HERA Herceptin drug trial. He gave evidence for a claimant in the case of *R (on the application of Rogers) v Swindon NHS Primary Care Trust* [2006] EWCA 392. He supplied opinion on the evidence available for the best health outcomes reasonably achievable for

pharmaceutical treatment for HER_2 positive breast cancer; the FinHer treatment regimen and the statistical uncertainty of results; the significance of duration of treatment; developments in Herceptin in the United Kingdom since July 2006; and the decision to fund Herceptin confirmed by the National Institute for Health and Clinical Excellence ("NICE") in the United Kingdom. His opinion was that cost savings associated with providing Herceptin for early stage breast cancer was considerable, and that the majority of OECD countries now fund Herceptin for 12 months treatment.

[144] Three affidavits by an Auckland economist, Ms E A Davis expressed her opinion on Pharmac's CUA and challenging the expert analysis made by those advising Pharmac. As with Dr Brunt, Ms Davis' opinion and evidence was a challenge to Pharmac's factual conclusions and opinions.

[145] There are two affidavits by C M Frampton, a bio-statistician, which provide his summary of statistical interpretation of the evidence available to Pharmac of Herceptin treatment. He provided expert opinion to Roche and to BCAC.

[146] There are two affidavits from S Petersen, the Managing Director of Roche as to its application seeking 12 months early stage funding and confirming that Roche did not seek a 9 weeks funding regime.

[147] The eight plaintiffs other than Ms Walsh filed affidavits generally as to their personal circumstances, costs involved in funding their Herceptin treatment, the CAC application and that most of the women are members of the group which is allied with, or part of, the network represented by BCAC.

[148] Broadly speaking, the affidavit evidence of the plaintiffs, in summary, contained:

a) the personal circumstances of each plaintiff and the financial cost to them;

b) lengthy evidence as to investigations, actions, submissions, representations, and opinions of those involved with BCAC, with an oncologist who treated and supported eight of the nine plaintiffs, opinion from experts as to cost analysis, statistical interpretation of evidence, efficacy of Herceptin, whether on a 12 months or 9 weeks early stage regime, international funding decisions and opinions as to the preferable use of Herceptin;

c) challenges to the factual analysis opinions and views of Pharmac and its expert advisors (clinical and economic) – which even if valid seem to be directed squarely at the merits.

Pharmac evidence

[149] Pharmac also filed extensive evidence as to the process it followed, and the competing merits and considerations taken into account by it. Expert opinion evidence included an affidavit from a Professor of Health Economics at the University of Leeds. His opinion was that Pharmac's decision (to not fund a 12 month regime) was:

> "…based upon a comprehensive review of the evidence for it [sic] effectiveness and safety, and the incorporation of that evidence into an appropriate cost effectiveness model. These data were considered in the context of the potential budget impact of funding 12 months herceptin and alternative uses of those resources. Whilst any individual might attach different weights to the available evidence and make different assumptions where evidence is not available, there is nothing in the decision, as I understand it, that could be considered unreasonable in the light of the available evidence. PHARMAC's decision is coherent with the theoretical framework for health care resource allocation processes that utilise cost effectiveness analyses."

And that the decision to fund nine weeks Herceptin treatment regime:

> "…is based upon a reasonable, if at times in my judgement overly pessimistic assessment of the evidence. The different decision is legitimate given (a) the different cost effectiveness and (b) the different budget impact. The appropriateness of the decision is further strengthened by the parallel decision to support a randomised controlled trial to examine many of the uncertainties in the evidence base for the efficacy, safety and cost effectiveness of herceptin in early breast cancer."

[150] He concluded that Pharmac's decision was "economically rational and reasonable".

[151] Other defence expert evidence included affidavit evidence from the Assistance Director of Public Health in Derbyshire County, England, whose opinions were summarised:

> "…PHARMAC's decision to fund a 9 week regimen of Herceptin based on the FinHER study is entirely reasonable and rational having regard to:
>
> (a) the statistical significance of that study;
>
> (b) its own, the Belgium KCE and the ScHaRR health economic analyses of Herceptin;
>
> (c) the theoretically possible small gain in marginal benefit but very definite large marginal costs of a 12 month concurrent regimen compared to a 9 week concurrent regimen; and
>
> (d) the reduction of possible cardiotoxicity resulting from a much shorter regimen
>
> In my opinion, PHARMAC has been diligent in its assessment of the evidence and in pursuit of its duties to all parties."

[152] A specialist oncologist practising in Auckland provided opinion evidence that:

> "…PHARMAC's decision to fund a 9 week Herceptin regimen in New Zealand for the treatment of HER2 positive early breast cancer to be reasonable, in light of the constraints on public healthcare spending, and on pharmaceuticals in particular. I say this as a practising oncologist and doctor. I also draw on my doctoral studies in health economics.
>
> As a doctor it does not make me happy when funded access to an effective treatment is denied. However, currently there is no evidence demonstrating that any one treatment duration of Herceptin is better than another. Whilst there is greater statistical confidence in the results from the studies of 12 months Herceptin treatment, I do not see the current funded access to 9 weeks Herceptin treatment as a sign of unreasonableness on PHARMAC's part. In my opinion PHARMAC's decision was a direct result of its need to consider the cost of funding Herceptin and the potential impact funding 12 months Herceptin would have on the ability of the healthcare system to fund other health services and treatments. The constraint on the spending in healthcare, including pharmaceuticals, is politically determined through the size of New Zealand's Vote: Health budget, and is not a matter for PHARMAC to determine."

[153] This specialist attended the 8 march 2007 meeting of medical oncologists and Pharmac, at which the 9 week funding proposal was outlined. He said that:

> "… most oncologists at that meeting, while in an ideal world preferring 12 months treatment, accepted it would be reasonable for PHARMAC to fund nine weeks rather than having no funding at all. I agree with this view."

[154] It is abundantly clear that there was, and remains, room for more than one view. This Court cannot sit in its judicial review capacity as though it were entertaining an appeal. It is in no position to express a view as to which side of the factual argument is correct, or to be preferred. To a very large measure, that is what the plaintiffs' arguments were based upon. But there were also arguments as to the errors of process.

[155] Judicial review relief would only arise if the decision made on the facts was so unreasonable and perverse, ignoring relevant factors or being based on irrelevant factors, that there was a legal error to justify the Court's intervention.

[156] I propose to first discuss the First and Second Decisions, and my conclusions. The Third Decision involves different considerations and a separate analysis of its factual and legal foundation.

The First Decision

"*Ultra vires*"

[157] In its widest sense, any action undertaken, or decision made, by a statutory body beyond the powers entrusted to it is *ultra vires*. It can be because of all manner of errors of law beyond the statutory authorisation – bias, breach of natural justice, improper procedure, fettering of discretion, and the like. The body is entrusted with the duty to act lawfully. In that sense, if the body acts improperly it acts *ultra vires*. The plaintiffs' contention under this heading is directed more at the claim that Pharmac acted outside its statutory powers in seeking the advice it did from PTAC because it was not authorised to ask the questions it did. In addition, PTAC acted

ultra vires because of the advice that was given. Ms Cull contended that both acted outside the empowering legislation, and thus *ultra vires*.

[158] PTAC is an advisory committee of Pharmac established under s 50 of the NZPHD Act. It is to provide "objective advice to Pharmac on pharmaceuticals and their benefits." Ms Cull QC said that because the Committee's advice included funding considerations it acted *ultra vires* because it was not "objective advice" on the benefits of the drug.

[159] Yet what PTAC and its sub-committee CaTSoP recommended was:

a) CaTSoP regarded 12 months as preferable but in the absence of funding a nine weeks regime was reasonable and gave this high priority.

b) PTAC recommended that because of uncertainty around optimal duration for Herceptin treatment in terms of method, cardiovascular toxicity and long-term clinical outcomes, nine weeks treatment should be funded.

[160] I do not accept that reference to funding is outside the ambit of the Committee's proper considerations. The "benefits" (or otherwise) of a drug may be directly ascertained by, or relevant to, the duration of treatment – because of toxicity, side effects, and outcomes. Duration is a matter obviously related to its cost. Obviously it costs more to treat longer – which may produce more, or less, benefits. If funds are to be required to deal with possible side effects (e.g. cardiovascular monitoring) this is not irrelevant to advice the expert committees might give.

[161] But, in any event, it is the Pharmac Board which makes decisions and it must perform its functions "within the amount of funding provided" to Pharmac. To receive and seek advice on benefits and associated costs of drugs – and related monitoring – it is not acting *ultra vires* in its statutory functions. Nor does a committee which does not make a decision, but simply advises and assist. Even if it were to give advice which fell strictly outside its expertise, a later Board decision is

not flawed unless the advice is wrong and is relied upon by the Board so as to lead to its decision being unreasonable/irrational and reviewable for that reason.

[162] Pharmac was entitled to seek the advice it did from PTAC, which was entitled to give its views. I reject the argument that Pharmac and PTAC acted *ultra vires* the empowering legislation. The Board did what it was lawfully authorised, and required, to do.

Duty to consult

[163] As was observed by Tipping J in *Nicholls v Health & Disability Commissioner* [1997] NZAR 351, conventionally a duty to consult arises in two situations with possibly a third. The first is where the duty is provided expressly or impliedly by statute. The second is where the plaintiffs have a legitimate expectation of consultation deriving either from a promise of consultation or from past practice which may overlap and merge into each other because a promise can be implicit from past practice.

[164] Tipping J's view was possibly a third residual category, where the demands of fairness in the particular circumstances require the decision maker to consult either generally or with a particular person or persons before reaching the decision in question.

[165] In the present case, the Counsel for the plaintiffs contends that the duty to consult arises essentially because all three situations exist.

[166] The precise wording which imposes a duty to consult in certain circumstances, is in s 49 of the NZPHD Act 2000 which provides:

> "**Pharmac to consult in implementing objectives and carrying out functions**
>
> In carrying out its functions under section 48, Pharmac must, when it considers it appropriate to do so, -
>
> (a) consult on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups, or individuals

> that, in the view of Pharmac, may be affected by decisions on those matters; and
>
> (b) take measures to inform the public, groups, and individuals of Pharmac's decisions concerning the pharmaceutical schedule."

[167] Words such as "when it considers appropriate" and "in the view of Pharmac" do not confer unlimited freedom on Pharmac to decide to consult, or not, as it is inclined. As the Judicial Committee of the Privy Council said, in *Attorney-General for Canada v Hallet & Carey Ltd* [1952] AC 427 at 450, when considering acts which the executive deemed "necessary or desirable":

> "… the words that invest the Governor with power are neither vague nor ambiguous: Parliament has chosen to say explicitly that he shall do whatever things he may deem necessary or advisable. That does not allow him to do whatever he may feel inclined."

[168] The broad statutory framework within which the duty to consult "when it considers it appropriate to do so" is contained in ss 47 and 48 of the Act. The objectives are earlier set out in para [31]. They include securing/achieving the best health outcomes reasonably achievable from funds provided, and include other objectives given by the Minister to perform.

[169] The functions of Pharmac described in s 48 are also linked to the amount of funding provided. They are set out in para [32].

[170] The plaintiffs contend that Pharmac did not consult with BCAC, or oncologists specialising in the treatment of women's breast cancer, or any other group, organisation or body concerned with women's health and the treatment of cancer before determining not to approve funding of Herceptin for the 12 months regimen.

[171] The decision made by the Board on 26 July 2006 not to list Herceptin on the Pharmaceutical Schedule for the treatment of early breast cancer "at this time" followed upon consideration of Roche's application by PTAC and CaTSoP, and the extensive material submitted by Roche. Pharmac's CAC had a self-defined role as "ensuring the voice of the consumer is heard within Pharmac" are considered and the issue of Herceptin funding was discussed at meetings on 17 March 2006 and 4 July

2006 prior to the Board's resolution on 26 July 2006. The CAC was aware of the question being, as it says, "a high-profile" issue and "noted that the benefits of Herceptin may not be as great as stated by patient groups lobbying for funding access.

[172] At its July meeting, the CAC recorded that the application had been considered by PTAC and Pharmac staff had conducted an economic evaluation. It had commercial discussions with Roche and:

> "As funding of cancer drugs is decided by DHBs (not through the community pharmaceutical budget), Pharmac's "decision" is only in the form of a recommendation to DHBs on whether to fund the drug. At the time of writing, Pharmac and DHBs have not made an announcement on their position in relation to Trastuzumab."

[173] Pharmac acknowledged that there was no consultation of public groups in terms of s 49(a). But before that Board meeting, it contends that there was no obligation to do so, given the statutory requirement applies only when Pharmac considers it "appropriate" to consult. More particularly, it argues that the resolution of 26 July 2006 was not a final "decision" to decline the application, but simply a resolution not to list Herceptin for early breast cancer "at this time". That is, that consideration of that issue remained alive and open. In any event, it contends there was ample informal consultation with BCAC.

[174] Beyond doubt, the degree of consultation undertaken before the "second decision" was made to fund the nine weeks regime was extensive. On the acknowledged facts it was wide and comprehensive. It could not possibly be said that Pharmac failed to consult before the Board made that second decision. Pharmac contends that that decision, in fact was the decision to decline 12 months funding regime.

[175] But the plaintiffs argue that such later consultation was aimed at, and designed only to deal with, a proposal to fund the nine weeks' regime. That is, the 12 months' option had been put to one side and was not truly in contemplation, or was a matter upon which "meaningful consultation" was undertaken. Counsel for Pharmac said that the 12 months' option had not been rejected so as to be a

"decision" as all that had happened was a postponing of the decision for the time being.

[176] The question therefore is whether the Board's decision of 26 July 2006 was a decision or, as counsel for Pharmac submits, simply one step in a continuing process of assessing funding of Herceptin for early stage breast cancer, and was not a stand-alone decision to decline.

Was the resolution of Pharmac Board, 26 July 2006 a "decision"

[177] I am of the view that it was. It was a decision to decline Roche's application for funding at that time. In materials submitted to the Board, Pharmac refers to it as "this decision", and sets out "a decision criteria". Aspects of Pharmac taking measures to "inform the public, groups and individuals of that decision". But the Board's resolution provides that the public had to be advised that Pharmac were "still actively obtaining information and data, its [funding] is still under consideration ….".

[178] Roche regarded the Board's July resolution as a decision to decline its proposal. In a letter of 6 October 2006, it states that it wished "to express at the outset its extreme concern at the decision to decline funding of Herceptin for early HER_2 breast cancer". PTAC had reviewed additional information at its 17 August 2006 meeting recommending that funding as per the HER protocol (12 months treatment) be declined due to uncertainties of clinical benefits, optimal duration and budgetary impact, but recommended that PTAC consider the appropriateness of funding a 9 weeks treatment protocol.

[179] It is a fact that PTAC at its meetings of 26 and 27 October 2006 was asked by Pharmac for its recommendations or comments on funding of Herceptin, but the questions asked generally relate to whether funding was recommended "under a regime consistent with the FinHer protocol (9 weeks treatment)".

[180] As at 17 August 2006, PTAC was affirming its agreement or concurrence with the decisions that 12 months funding not be given, but that the FinHer protocol

be explored. Thereafter CaTSoP also reconsidered Roche's application, reviewed material recommending 9 weeks treatment, and said this would be "reasonable and gave this recommendation a high priority". It did so "in the absence of availability of funding for 12 months treatment" but that it had "more confidence in the validity of the 12 months treatment results".

[181] All this indicates that the 12 months funding application had been determined and declined. It was the alternative of the 9 weeks FinHer regimen that was under consideration. Viewed realistically, and in a practical sense, there was a decision to decline funding made by the Board at its July 2006 meeting.

[182] Pharmac contend that, in any event, the Second Decision of April 2007 dealt with the 12 months' funding issue implicitly, and full consultation clearly had occurred before then.

Was Pharmac required to formally consult before the First Decision was made?

[183] Pharmac's paper to the Board, before the First Decision, records:

> "**Comments from interested parties**
>
> Section 49(a) requires Pharmac to consult, when it considers it appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that, in the view of Pharmac, may be affected by decisions on these matters. Pharmac does not, however, consider it appropriate to consult on the recommendations contained in this paper because it has not been standard practice to consult on past decisions that were recommending a decline."

[184] It was apparent to Pharmac and the Board that the issue was "high-profile" perhaps controversial, upon which different views and opinions were held. Committee members of BCAC had met with Pharmac representatives in June and August 2005 over what they regarded as the need for Herceptin in early breast cancer to be funded.

[185] There had been further meetings with BCAC in December 2005 and on 16 March 2006 a petition calling on the Government to fund Herceptin for early

breast cancer was presented to Parliament. Ms Burgess on behalf of BCAC had attended the Health Select Committee in April 2006.

[186] It is difficult to accept that given that background, formal consultation with BCAC and other groups representing patients or concerned with women's health was not "appropriate". The reasons Pharmac staff gave for non-consultation – that it had not been standard practice in the past where there had been a recommendation to decline – are questionable in the context of what was being considered.

[187] The statute requires Pharmac to consult only if it considers it "appropriate" to do so, but its consideration of the appropriateness or otherwise has to viewed against the statutory objectives and functions. Any retreating from a mandatory requirement to consult must nevertheless be subject to a determination whether non-consultation was truly inappropriate.

[188] A practice of non-consultation where an application for funding is recommended as "decline", is not sufficient or proper grounds, of itself, to make it "appropriate" not to consult.

[189] It is the Board that makes decisions and groups or individuals clearly may be affected by decisions of the Board to decline to fund in certain circumstances. There cannot be an absolute requirement to consult in respect of every application. Pharmac has a discretion, but a practice or policy not to consult where an application is declined is not a proper exercise of that discretion. Where there is a known wide and continuing public interest by groups, organisations or individuals likely to be considerably affected by a decision, in my view it is not sufficient, nor within the statutory obligations, of Pharmac to choose not to consult simply because its recommendation to the Board is to decline the application.

[190] After all, it was considered "appropriate" to consult widely on the 9 weeks' funding proposal of Pharmac.

[191] I am satisfied that, as the Board's resolution was a decision on matters relating to the management of pharmaceutical expenditure, in this case it had a duty

to consult. The extent of such consultation was a matter for it. But to have no consultation at all, based upon its view that it did not do so when the recommendation to the Board was to decline an application, was erroneous, given the surrounding circumstances of the strongly held views about this drug's efficacy and the need to fund it.

Was the duty to consult met because of the wide consultation later undertaken?

[192] On behalf of Pharmac, counsel submitted that there was ample consultation thereafter on the 12 months issue, as well as the FinHer proposal, which enabled interested groups and individuals to be heard and make representations. The overwhelming number of the submissions received from members of the public opposing the 9 weeks proposal, indicated that the Pharmac had received and heard the views of the public and consumer. Yet that depends upon what it was actually considering in relation to the second decision – that is, was it a genuine reconsideration of Roche's application for one year funding, so as to remedy any earlier failure to consult prior to the July 2006 Board decision?

[193] The Board had earlier been presented with funding options, including the 12 months and 9 weeks comparative studies. On 31 January 2007 the Board's decision or recommendation was as follows:

> "Trastuzumab (Herceptin) – Recommendation to DHBs directed PHARMAC staff to implement the plan outlined in this paper for progressing a proposal for funding short duration (9 weeks) trastuzumab and funding a comparative study of short versus long duration (12 months) treatment."

[194] Thereafter the proposal being considered turned around funding for 9 weeks treatment and participation in the SOLD study. The chief executives of DHBs were so advised in recommendations to them of 20 February 2007 in which they were requested to agree in principle.

[195] There is evidence that Dr Harvey, a clinician member of CaTSoP communicated a view to the Pharmac Therapeutic Group Manager, after receiving

advice that Pharmac plans "…to consult on a proposal in the next couple of weeks…".

[196] Dr Harvey's email said:

> "…Why is Herceptin 9 weeks going to general public consultants? You must have received enough advocacy already. You will merely have everybody savaged before it gets to the Board. If there is no chance of 12 months what is the point?"

[197] The response was:

> "We do need to consult broadly on this given the high public interest…we are already getting media queries about when we are consulting so we do need to have some public statement around start of consultation…yes we will be swamped but it is important for us to gain all views…not just those we think will support our position…I know some members of the public who are supportive of our position!"

[198] "Our position" must refer to the Pharmac proposal of nine weeks' funding. It does not mean that it might not change its mind after hearing from others. But, it made the first decision without consultation and was on a path to confirm, or not, its nine week proposal with "no chance" of the first decision being revised. The consultation was comprehensive, valid and proper in the determination and making of the second decision. It was directed at Pharmac's 9 weeks proposal and it was more than sufficient to answer challenges to the Second Decision to approve 9 weeks' funding. But did it answer any non-consultation before the First Decision was made?

[199] The formal consultation which followed after 20 March 2007 through the circulation of a letter and media release, meetings with oncologists, BCAC and other groups resulted in many submissions or representations to support the proposition that funding should be for 12 months and not 9 weeks. But, the evidence all points to the consultation being aimed at receiving views as to the proposal that Pharmac staff had been directed to implement or progress, namely that what was being considered was the 9 weeks FinHer regime. It was a Pharmac proposal – not that of Roche – that was actually being consulted upon. I can understand the defence argument that this enabled many people and groups to make submissions to support a 12 months' funding regime, but the "consultation" was aimed, or directed at,

Pharmac's 9 week funding proposal. That is what the public and groups were told. The "consultation letter" dated 20 March 2007 to all "Pharmaceutical Supporters, Hospital Pharmacists, Medical Groups and Interested Parties" refers to "consultation on a proposal to widen access" to Herceptin and reads, in part:

> "**The funding proposal**
>
> PHARMAC is seeking feedback on a proposal to widen the access to trastuzumab and docetaxel to include adjuvant use for HER_2 positive early breast cancer.
>
> If this proposal is approved by the PHARMAC Board it would result in PHARMAC subsidising treatment with trastuzumab for HER_2 positive early breast cancer patients when it is administered for 9 weeks concurrently with taxane chemotherapy."

[200] The precise amendment to the schedule is set out in the notice, it being exactly as proposed by Pharmac. It is described as "this proposal" upon which feedback is sought.

[201] Although the position is finely balanced, I have concluded that reviewable error arose. I have reached that conclusion because consultation did not take place before the First Decision was made (and it should have), and the later extensive consultation was specifically directed at Pharmac's new proposal, and it did not cure the earlier deficiency – simply because the scope of the application (9 weeks or nothing) had changed.

[202] As I have concluded that the Board's resolution to decline "at this time" was a decision – which effectively led to consideration of Pharmac's new proposal of nine weeks funding – I am satisfied that there was a failure to consult before the First Decision was made. Pharmac acknowledges there was no consultation (apart from with Roche). The first decision is reviewable for that reason.

[203] What relief, if any, is appropriate? Counsel submitted that the Court should not intervene because of the exhaustive consideration of the issue by Pharmac staff, committees and the Board. It would be pointless as the decision not to approve 12 months' funding, but to fund for 9 weeks, has been properly made after intensive analysis and consideration, and any decision would be the same.

[204] That may be so, but the Court cannot enter into the realm of what might or might not have been the outcome had there been wide public consultation before the first decision. Where the process has been flawed through non-consultation before a decision was made, affected or interested parties are not to be deprived of the entitlement to proper process because the Court may consider it would made no difference. Naturally, there is some weight in the argument that those parties have already had ample opportunity to make submissions, and did so. But, the underlying facts are that what was being considered was the Pharmac proposition, and the Roche proposal for 12 months' funding had been shelved. Any consultation on that, was simply "going through the motions."

[205] The Second Decision did not cure earlier deficits in the process because it was not truly a consideration or review of the Roche application.

[206] I am persuaded that there had to be wide consultation before the First Decision was made and because that did not occur – as Pharmac acknowledges – the error in the process requires that decision to be set aside. It follows that the Roche application remains to be determined – it not having sought 9 weeks' funding. It does not follow that the application will be granted. What is required is that consultation should occur and the Board (with further advice of PTAC, CaTSoP and CAC) then make its decision. If it declines the application, the effect of the Second Decision (which as will be seen is not flawed nor subject to review) continues – as it will in the meantime.

[207] Consultation does not require ultimate agreement, nor does it involve negotiation. Consultation does not require or involve an ongoing dialogue over a protracted period; see *New Zealand Fishing Industry Association Inc v Minister of Agriculture and Fisheries* [1988] 1 NZLR 544 (CA). Consultation requires open-minded communication and hearing the voice of others who are given the opportunity, and right, to be listened to. What is meaningful (i.e. "true") consultation, its extent and how far it goes – and for how long – is a question of fact and degree. But it must be sufficient to satisfy the requirement to consult. It is a matter for Pharmac to consider, but I would have thought that the measures it took for consultation before the Second Decision were more than adequate. But there

may be additional material, submissions and opinions, and expressed in these proceedings which may form part of the consultation.

[208] The plaintiffs cannot expect as a matter of law that Pharmac must agree with their views or submissions, but they can expect consultation of such a degree that, they and their arguments are heard before the 12 months' funding issue is finally determined.

[209] The public consultation should not involve a lengthy period. I note the earlier public and professional consultation occurred over one month between March-April 2007.

[210] It is not necessary for me to deal with the other 11 separate grounds advanced by counsel, except to say that many overlap and all are without merit. Pharmac, and its sub-committees, did not act *ultra vires* their powers and functions in consideration of Roche's application. Nor did it, in the context of achieving DHB approval, act under the direction of DHBs. As is quite clear from the competing expert opinions referred to earlier, there was ample room for more than one view and allegations of unreasonableness (failing to take relevant considerations, and taking irrelevant considerations, into account) fail. They are a challenge to the merits which is outside this Court's functions.

[211] Allegations of breach of legitimate expectation, and of natural justice and rights under the Bill of Rights Act fall, simply, into the category of not being afforded "procedural fairness". Other than the plaintiffs' support groups not being initially consulted before the first decision was made, there was nothing in the decision-making process that was legally flawed so as to entitle a judicial review remedy.

The Second Decision

[212] Ms Cull contended that Pharmac had unlawfully fettered its discretion by a rigid application of pre-determined policy in making its decision of 24 April 2007 and also in formulating criteria for CaEC policies. She relied upon the well-known

authorities of *Westhaven Shellfish Ltd v Chief Executive of Ministry of Fisheries* [2002] 2 NZLR 158 (CA) and *British Oxygen Co Ltd v Minister of Technology* [1971] AC 610 in support of that argument.

[213] The Second Decision was not "tainted" by the First Decision, nor a wrongful application of a pre-determined policy. It was a decision made in the context of Pharmac's *new* proposal for 9 weeks' funding. If it had been declined, there would have been no listing of Herceptin for early stage treatment. It was not a case of funding for 9 weeks' or for 12 months'.

[214] That the Board has earlier made its first decision and decided not to approve funding then, could not have fettered its discretion to approve the proposal to fund for 9 weeks. There was wide consultation with clinicians, the public and interested groups who all were aware of the precise Pharmac proposal, though some (or many) wanted a 12 months' funding regime.

[215] The public was told, in clear terms, what Pharmac's proposal was. All who wanted to express a view were heard. No procedural unfairness occurred. The decision to fund the nine weeks' regime was not unreasonable or irrational in any legal sense. There was ample evidence to support it as being reasonable, though many may have disagreed. Naturally, the plaintiffs hoped the process to involve consideration of the 12 months' regime which they, and others, advocated, but in reality this had been decided against Roche by the first decision. It may have been open for reconsideration of that decision to have occurred, but the fact remained that it was Pharmac's nine weeks' regime, plus funding the SOLD study, that was the actual item for consideration thereafter. And the public was so advised.

[216] None of the grounds challenging the second decision have been made out. I accept that they were put forward on the basis that the plaintiffs and others were challenging the refusal to approve 12 months' funding which they say implicitly followed upon the 9 weeks' funding decision. But there was nothing that invalidates the second decision and it has not been shown that any basis exists to review it. Even if views are divided, there was expert opinion to support it; it was supported by

Pharmac's committees and sub-committee. The plaintiffs and others and groups supporting a view to an alternative funding were heard.

[217] The decision provides benefits to many patients – not as much as the plaintiffs allege, but nevertheless some respite from funding costs. Those patients are not parties to these proceedings. The evidence was that from the time of listing for 9 weeks' funding on 1 July 2007 until 18 October 2007, 150 New Zealand women had a Special Authority approval for the 9 weeks regimen of Herceptin. That was in line with Pharmac's estimates of 60 patients in the first month (July) and 30 patients each month thereafter. Even if some legal procedural flaw in the process had occurred – which I find on the facts did not arise – I would not exercise a discretion to set aside that decision, which would only serve to jeopardise funding of 9 weeks' treatment for those now eligible. The outcome I propose does not interfere with the validity, or implementation of, the second decision.

The Third Decision

[218] The functions of Pharmac set out in s 48 of the Act are directly linked to "the amount of funding provided to it" and include to maintain and manage a schedule that applies consistently, and to manage incidental matters including providing for subsidies in exceptional circumstances.

[219] Once Pharmac lists certain cancer treatments on the Pharmaceutical Schedule, District Health Boards must provide access to it. Where however, pharmaceutical treatments of cancer are unlisted, a District Health Board *may* provide access to it if the unlisted pharmaceutical meets certain criteria including CaEC approval.

[220] Authorisation of Pharmac to perform this additional function is given under s 48(e) of the Act:

> "Any other function it is for the time being given by or under any enactment, or authorised to perform by the Minister by written notice to the Board of Pharmac after consultation with it."

[221] This has occurred by a Gazette Notice of 4 September 2001. It was a ministerial authorisation enabling Pharmac to manage the purchase of all pharmaceuticals and the Gazette Notice provides:

> "Pharmac is authorised to manage the purchasing of any or all pharmaceuticals, whether used either in hospitals or outside it, on behalf of DHBs.
>
> In carrying out this function, Pharmac will need to address, at a minimum the following factors:
>
> (i) developing a management strategy;
>
> (ii) consulting and communicating with the DHBs and other interested parties as Pharmac considers it appropriate;
>
> (iii) …
>
> (iv) compiling and analysing information from DHBs on pharmaceutical volumes, expenditure and contractual arrangements;
>
> (v) adjusting the Pharmaceutical Schedule as necessary;
>
> (vi) carrying out purchasing on behalf of DHBs."

[222] The Ministry of Health developed a national list of cancer pharmaceuticals which all DHBs were required to fund, known as the "oncology basket". Inequities between patients were removed and a consistency within regions achieved. The rules and criteria promulgated by Pharmac evolved to include provisions permitting the prescribing and funding of cancer pharmaceuticals in exceptional circumstances, which required prospective approval from Pharmac, as part of a DHB's decision to fund.

[223] The criteria were developed by Pharmac in consultation with the DHBs and specialists. They are known as the CaEC criteria. Payment for pharmaceuticals under the CaEC scheme is made directly from DHBs and Pharmac's management of it comes within its statutory functions under ss 48(a), (b) or (e) of the Act.

[224] For a patient to qualify for CaEC funding, the following criteria must be met:

> "(i) Confirmation that the proposed use was evaluated and approved using established DHB review mechanisms involving experienced clinicians;

(ii) Confirmation that the DHB hospital providing treatment has agreed to fund the treatment;

(iii) Confirmation that the condition is considered unusual (and therefore a decision to treat is unlikely to result in access inequities across DHBs);

(iv) the proposed use has not been considered or is not currently under consideration by Pharmac for funding; …

(v) specification of the:

a. Product to be used;

b. Dose and treatment schedule;

c. Duration of the treatment;

d. Indication;

e. Total cost;

(vi) The total cost is less than $30,000 over a 5-year period… If the application is for treatment of $30,000 or over it will be referred for a CUA followed by a decision from PHARMAC."

[225] Those criteria are based on concepts of peer review within the DHB hospital system and are aimed at ensuring equity of access to pharmaceutical cancer treatments across the DHBs. The scheme was intended to be largely self-assessed by the hospital physician and the relevant DHB hospital. Provided all the criteria were met, approval was given by Pharmac.

[226] A DHB still has the final decision to fund the drug. But if the other criteria required are met and the application is then approved by Pharmac, it would be perverse for the DHB to decide not to fund at that stage. Of course if Pharmac declines approval under CaEC, the DHB cannot fund the treatment even if it had advised it was willing to do so.

[227] In the present instance, the applicants did not meet the criteria for CaEC funding, as their doctors advised. That being the case, it is not surprising that Pharmac did not approve the CaEC applications. Ms Cull Q.C. argued that the review panel, and later the Medical Director, could not be seen to be independent in their reassessment of the application, and accordingly the decisions to decline were

invalid on the grounds of bias. I do not accept that submission for the following reasons.

[228] The "managing" of the exceptional circumstances provisions has to be undertaken by Pharmac. Its task is to "manage" the process. It was entitled to set up a review or "appeal" mechanism in the way that it did. It was not required to do so. The process was not judicial or even quasi-judicial, so as to require a formal independent tribunal appeal structure set-up. That would have been unwieldy and unnecessary in the context of what was being assessed; namely eligibility for inclusion as an "exceptional circumstance".

[229] In reality, once the treating clinicians and the hospital certified that the criteria had been met, the recommendation of Pharmac would very likely be positive. If initially not given by Pharmac staff, but if criteria are met, it is hard to see how the review Panel would decline, although it may require more information or clarification of the application. I accept the defence submission that what occurs is really a cross check rather than a true "appeal". An applicant is further protected by, or has the benefit of, the review by the Medical Director who assess clinical matters, adherence to CaEC rules and correct procedures. This is a reasonable procedure to ensure that all exceptional circumstances applications are properly dealt with. It is not a case of Pharmac making a decision to support its own interests, or to support its decision. The Pharmac "decision" is to approve, or not recommend funding, but the ultimate decision rests with the DHB.

[230] The plaintiffs plead "bias". The test for apparent bias was recently dealt with by the Court of Appeal in *Muir v Commisison of Inland Revenue* [2007] 3 NZLR 495. A two-stage inquiry is required to establish the exact circumstances that had a direct bearing on the suggestion that a deciding authority was, or might be, seen to be biased. The second step was whether the circumstances established might lead a fair-minded lay observer reasonably to apprehend that the decision-maker might not bring an impartial mind to resolution of the case or matter in question.

[231] Before a Tribunal could be disqualified for bias, it has to be shown that it has formed a fixed opinion as to the ultimate merits of the matter pending, and does not

have an open mind. Judicial disqualification is not made on the basis of earlier adverse rulings or decisions. As Hammond J said in delivering the judgment of the Court of Appeal at para [98]:

> "It has to be accepted that there are occasions when a Judge's prior rulings might lead a reasonable person to question whether he would remain impartial on any subsequent proceedings. The reasons for this are straightforward. It is common sense that people generally hate to lose, and their perception of a Judge's perceived tendency to rule against him or her is inevitably suspect. As Kenneth Davis has said, "almost any intelligent person would initially assert that he wants objectivity, but by that he means biases that coincide with his own biases (*Administrative Law Treatise* 2nd Ed, Vol 3, 1978 (p 378)). A judicial ruling on an arguable point necessarily disfavours … someone, and every ruling issued during a proceeding may thus give rise to an appearance of partiality in a broad sense to whoever is disfavoured by the ruling …"

[232] The process of considering CaEC applications is neither judicial nor quasi-judicial, but Pharmac "managing" a process to grant permission to a DHB to fund, in special cases, which meet agreed criteria. The review appeal mechanism is not the sitting in judgement by Pharmac of its own decision, but rather an administrative review of the applicability of established criteria to an individual case.

[233] No fair-minded observed could reasonably apprehend that the review panel or medical director might, in those circumstances, be seen to be biased.

[234] The bias allegation is contrived to import a judicial review remedy into a factual circumstance which simply does not exist. Several of the criteria were not met and could not be met, so that the applications were bound to fail.

[235] I do not accept the argument that Pharmac acted ultra-vires its statutory functions in the managing the CaEC. It was required "to manage incidental matters … including in exceptional circumstances providing subsidies …." This is what it has done. It is not necessarily required to make the final decision itself, provided it properly manages the process it has set up. Its review and appeal process were simply a series of opportunities for specialists to confirm that an application meets the criteria for CaEC funding.

[236] Counsel argued that Pharmac acted under the "dictation" of DHBs and thereby failed to validly exercise its statutory function. As I have said, its function was to "manage" the process of such exceptional circumstances applications and I reject that argument. Within the scheme, it was necessary for criteria to be developed in consultation with clinicians and DHBs to ensure a consistency of approach and ensuring equity of access to pharmaceutical cancer treatments across all DHBs. Apart from s 48(a) and (b) delineating Pharmac's functions, subsection (e) also applies, given the Gazette authorisation by the Minister to Pharmac.

[237] It was contended that by requiring DHB approval a "Catch 22" situation, involving circular consideration, was created. That is, if Pharmac cannot approve a CaEC application when a DHB does not agree to fund it; and correspondingly if a DHB determines that it will not fund such non-scheduled pharmaceutical because approval will not be given by Pharmac, the exercise becomes pointless. I think that overlooks the true underlying nature of the procedure.

[238] The task of Pharmac is to recommend or approve the funding by DHB – not to decide that such funding *must* take place. It is not the decision making body for this purpose. If it was deciding the issue (i.e. to fund) it may be different. But there are not two decision making bodies, deciding a final issue. The true analysis of what occurs is that the approval or recommendation of Pharmac is simply a condition precedent to the DHB deciding to fund. The agreement to fund by the DHB is in reality the making of the ultimate decision and a "condition subsequent" to the implementation of the approval of Pharmac. Whether such agreement ought to come later – after approval or recommendation is given by Pharmac – rather than as one of qualifying the criteria (item (ii)) is perhaps arguable, given the final decision rests with the DHB. But signifying agreement to fund, and the granting of approval by Pharmac, would render a later refusal, challengeable as being perverse and irrational.

[239] It is the overall scheme which Pharmac must manage. As the oncologists for the applicants acknowledged, the patients did not meet criteria for CaEC funding, quite irrespective of any DHB approval to fund.

[240] Challenge was made on the basis that application of the criteria was flawed as a pre-determined policy. (It was an argument also directed at the First and Second Decisions which has failed). I do not accept it as rendering the Third Decision unlawful. The managing of CaEC applications, by definition involving exceptional circumstances. It requires some criteria, which are necessary to ensure flexibility to permit funding in exceptional cases, yet not providing for wide discrepancies and inequitable distinctions arising in many individual cases. The criteria were developed in consultation with DHBs and oncologists, being the treating physicians of patients. Applying criteria to individual case does not constitute a blind following of a pre-determined "policy".

[241] The criteria required of a patient seeking approval in exceptional circumstances, so as to be able to be funded outside the "oncology basket" of a DHB are clearly within the statutory scheme of being required to "manage incidental matters … including in exceptional circumstances …" providing for subsidies for non-schedule pharmaceuticals. The criteria, do not prevent applications being made, and reviewed by the Pharmac Panel or its medical directors. They are not policies, but factors aimed at determining eligibility where the patient's circumstances are exceptional. If qualifying, the patient is afforded the exceptional funding. There can be nothing wrong in Pharmac and DHBs providing qualifying criteria for funding outside that which would otherwise not be permitted or available.

[242] In *British Oxygen* (supra), Lord Reid said at p 624:

> "There are two general grounds on which the exercise of an unqualified discretion can be attacked. It must not be exercised in bad faith, and it must not be so unreasonably exercised as to show that there cannot have been any real or genuine exercise of the discretion. But, apart from that, if the Minister thinks that policy or good administration requires the operation of some limiting rule, I find nothing to stop him.
>
> ……

And at p 625:

> "…the circumstances in which discretions are exercised vary enormously and that passage cannot be applied literally in every case. The general rule is that anyone who has to exercise a statutory discretion must not "shut his ears to an application"… I do not think there is any great difference between a policy and a rule. There may be cases where an officer or authority ought to

> listen to a substantial argument reasonably presented urging a change of policy. What the authority must not do is to refuse to listen at all. But a Ministry or large authority may have had to deal already with a multitude of similar applications and then they will almost certainly have evolved a policy so precise that it could well be called a rule. There can be no objection to that, provided the authority is always willing to listen to anyone with something new to say – of course I do not mean to say that there need be an oral hearing. In the present case the respondent's officers have carefully considered all that the appellants have had to say and I have no doubt that they will continue to do so."

[243] Guidelines, or policies, may be specific, but decision-makers must bear in mind and conform with the purposes of the legislation under which they may decisions; *Westhaven Shellfish Ltd* (supra).

[244] Just as the plaintiffs were unable to show that the first two decisions were based upon rigid application of any pre-determined policy or principle, so as to remove from the Board any discretion in the exercise of its functions, so too with the criteria required of a patient seeking approval in exceptional circumstances. They have to be exceptional so as to be able to be funded outside the "oncology basket" by a DHB are clearly within the statutory scheme of managing such circumstances.

[245] There can be no objection to a policy of withholding assistance save in exceptional circumstances that will be rational in the legal sense provided that it is possible to envisage, and the decision-maker does envisage, what such exceptional circumstances may be; *R (on the application of Rogers) v Swindon NHS Primary Care Trust* (supra).

[246] If the plaintiffs' argument was to be accepted, there could be no criteria or pre-qualifying conditions for an exceptional circumstances application. In that even, what would there be to "manage"? Indeed, s 48(a) specifically authorises Pharmac to determine "criteria for the provision of subsidies".

[247] In the end, Pharmac, its review panel of clinicians as well as its Medical Director, had the experience and expertise to be able to assess whether an individual applicant properly came within the established criteria.

[248] The plaintiffs' argument, under this head, is rejected.

[249] Allegations of "breach of legitimate expectation" and "procedural and substantive unfairness" are not accepted. They fall under the claim for "breach of natural justice". The plaintiffs and their solicitors knew exactly what the procedure was for a CaEC application. Their treating oncologists advised them that they did not qualify – that is why the applications were made through solicitors rather than, as is usually the case, by the treating clinicians.

[250] The CaEC procedure adopted, and actions of, Pharmac were not flawed. Submissions were received from solicitors on behalf of the plaintiffs, with accompanying letters from the applicants' oncologists. The applications were considered as a group, and also individually. The solicitors were eventually advised that the panel declined the applications on the basis that at least three criteria were clearly not met (a DHB had not agreed to fund, the medical condition was not considered unusual, the proposed use had been considered for funding by Pharmac). Further submissions were made by the applicants' solicitors to Pharmac. The door remained opened. Review by the panel of clinicians and by the Medical Director was sought. Those steps occurred. Consideration by the panel (separate to Pharmac staff0 and the Medical Director were not tainted by legal bias.

[251] Within the mechanism developed for considering exceptional circumstances applications, it has not been shown there was any procedural unfairness, or absence of "fair play" so as to be a breach of natural justice. The individual situations of the applicants were heard, submissions received from counsel and considered; and the applications declined because, as the treating oncologists agreed, the applicants did not meet the established criteria were not met.

[252] The applicants were entitled to expect to have their applications considered fairly. As a matter of fact I am satisfied that that occurred. The general allegation of breach of natural justice under the New Zealand Bill of Rights Act falls under that heading, and fails. The procedure by which the plaintiffs' CaEC applications was determined was not unfair, nor procedurally improper or tainted by legal bias.

[253] The generalised pleading that the decisions were "unreasonable and irrational", likewise fails. It goes to the merits of the recommendation to decline the

applications, and the Court will not enter into such an inquiry. The criteria were clearly not met and, apart from the issue of DHBs' agreement of fund, other essential requirements did not exist. Based upon the criteria the applicants could not have succeeded and I do not accept that the criteria themselves were legally flawed. It may well be that some persons will disagree with them, and naturally the plaintiffs fall into that category. So too, other criteria could have been promulgated, or some deleted. But the legal responsibility of Pharmac, which is the subject of the challenge, is to manage the Pharmaceutical Schedule which defines cancer exceptional circumstances.

[254] In managing the Schedule and overseeing the "oncology basket", Pharmac had to develop criteria and mechanisms to deal with the "exceptional" situation – outside the "oncology basket" and whatever may be the arguments for and against the criteria, it cannot be said that they are, in the context to which they are approved, unreasonable or irrational.

[255] I do not accept Pharmac acted *ultra vires* its powers, or that it abdicated its responsibilities to the DHBs and acted under their dictation. It managed a process which it was required to do and had lawfully promulgated. It afforded every opportunity for the applicants to put forward their cases. No breach of "natural justice", or other reviewable error of law, existed.

[256] The plaintiffs have failed to establish that they are entitled to judicial review orders in respect of the "third decision". All grounds for review fail.

The claim for compensation

[257] There has been no breach of natural justice or of the plaintiffs' rights under the New Zealand Bill of Rights Act 1990, or in relation to their CaEC applications so as to entitle them to damages or compensation.

[258] If Pharmac's decision is to decline the Roche application for 12 months' funding the plaintiffs will remain in the same position.

[259] If the decision is to approve such funding (and it is not retrospective so as to provide funding for the plaintiffs), the question of Bill of Rights compensation (upon which the Court does not express a view) may remain for consideration. So, that pleaded cause of action is adjourned sine die.

Some concluding remarks

[260] Before concluding, and for completeness, I make observations on three matters.

First

[261] This relates to the plaintiffs' reliance upon the case of *R (on the application of Rogers) v Swindon NHS Primary Care Trust* (supra) where the English Court of Appeal dealt with a challenge to a refusal by the Primary Care Trust to fund Herceptin treatment for Ms Rogers. The Trust had a policy for funding Herceptin (notwithstanding it was not licensed nor approved by NICE). That policy was to fund the drug without regard to financial considerations, in cases where Herceptin was prescribed by a clinician and where it was decided that there were exceptional clinical or personal circumstances.

[262] The Court observed that there was nothing arbitrary or irrational in a general policy:

> "… not to fund … unlicensed drugs subject to the exception that, 'where a patient has a special healthcare problem that presents an exceptional need for treatment; it will consider that case on its merits but in doing so, it will have regard to the funds available." (para [24])

[263] But that was not the policy adopted in that case and the policy adopted was not capable of being rationally explained, and therefore was unlawful.

[264] The Court said there can be no objection to a policy of not funding save in exceptional circumstances which will be rational in a legal sense provided that it is

possible to envisage, and the decision-maker does envisage, what such exceptional circumstances may be.

[265] Even though superficially attractive to the plaintiffs, because of the reference to Herceptin, that case does not assist. The exceptional circumstances criteria to be managed by Pharmac within its statutory functions cannot be said to be arbitrary or irrational. That some may take issue with them is not the test. The applications are made, by treating clinicians who were involved, along with DHBs and Pharmac, in formulating the criteria.

[266] In *Rogers*, the policy was arbitrary because it referred to unidentified exceptional circumstances. In the present case, the criteria themselves identify what are exceptional circumstances. That decision did not assist counsel for the plaintiffs' argument.

Secondly

[267] Ms Cull QC argued that as MedSafe had not given approval to the use of Herceptin for a 9 weeks' early stage treatment, this affected the validity, or lawfulness, of the Second Decision. MedSafe had earlier given approval for 12 months' metastatic stage treatment. That was known to the Board. But in any event, it is the specialist or clinician who prescribes the drug and if he/she chooses to do so because of a clinical decision, the patient receives it. That is what happens now. Doctors can prescribe it if they wish. The funding of a drug or treatment, consequent upon Pharmac's decision, is something separate. Dr Isaac's opinion that "oncologists are now being asked to prescribe Herceptin for an unapproved use" is emotive but not accurate. The true position is as stated by Dr Laking (a practising medical oncologist at Auckland Hospital):

> "I agree that Herceptin given concurrently with a taxane is not approved by Medsafe and ideally this should be remedied by MedSafe and Roche. However, I note that dosing Herceptin as per the FinHER regimen is permitted under the Australian Therapeutic Goods Administration approved license for Herceptin. In fact the Australian product information for Herceptin specifically notes that 'The optimal dosage regimen and treatment duration have not been defined. A favourable risk/benefit ration has been demonstrated with the following regimens … HERA, NSABP B31/NCCTG

> N9831 and FinHER'. The issue of MedSafe approval falls outside the scope of PHARMAC's decision-making process. It is an issue for doctors and patients to consider but I cannot see that it imposes any particular obligation on PHARMAC. In oncology the practice of 'off-label' dosing (i.e. administering a treatment regimen that does not have licensing approval from MedSafe) is not uncommon It is permitted both ethically and legally."

[268] The MedSafe issue does not alter the lawfulness, or (legal) "rationality" of the Second Decision.

Thirdly

[269] I observe that it may not have been appropriate for Pharmac (before the Board made the First Decision) to seek the "support" or approval of DHBs to a decision by Pharmac not to list Herceptin for early stage treatment. That is because if a decision was made by Pharmac to do so, then DHBs had to fund it.

[270] But I did not accept the argument of Ms Cull QC that, by doing so, Pharmac abdicated its function and "acted under the dictate of DHBs". It clearly was bound to consult with DHBs as vitally interested parties. It sought their views, and support for the approach it was intending to take. When the Board came to make its decision not to list "at this time" it "noted" the DHB support. There is no evidence to support counsel's claim that it had allowed the DHB to dictate that decision.

[271] Clearly, the views of DHBs may be relevant to any future decision. But I think that the asking for "support" of a recommendation, might not appear to be entirely consonant with Pharmac, then, having an open mind. It may present to interested parties a proposal that it wishes to advance, and seek views and even support for it. But it is problematical for Pharmac to reach a preliminary view to decline an application, and then seek support for that view from the entity that would but for such a decision, have to meet the cost of funding.

Conclusions

[272] The first decision, namely the Board's resolution dated 26 July 2006 to decline the Roche application is set aside.

[273] Pharmac is to reconsider that decision. It is directed, under s 4(5) of the Judicature Amendment Act 1973, to consult with the public, clinicians, and others likely to be affected by any further decision on the Roche application for 12 months' early stage Herceptin funding, and to determine that afresh. The extent of the consultation process is for Pharmac to determine. It may consider all the material, submissions, opinions and reports already before it, and any subsequently submitted and/or filed in this Court, when making its final decision. It does not have to recommence the entire process, but simply to consult properly. The extent to which PTAC, CaTSoP and CAC further advice is obtained, is a matter for the Board to determine. But Pharmac is required to fulfil its obligation to consult openly and fairly with those who have a legitimate interest in the ultimate decision. The consultation process may not require extensive time, given all that has gone before, and should be undertaken with speed.

[274] For completeness, I add that the outcome may, or may not, be precisely the same, but true consultation is required. The fact that there is in place a decision for 9 weeks' funding cannot pre-determine any outcome, but is not required to be ignored as irrelevant given that if the final decision is to decline 12 months' funding, the present funding regime continues in place.

[275] All challenges to the second decision of the Board by its resolution dated 28 April 2007 are dismissed.

[276] All challenges to the third decision, and the actions of Pharmac in dealing with the plaintiffs' CaEC applications, are dismissed.

[277] The claim for compensation is adjourned sine die.

Costs

[278] Costs are reserved. If any issue should arise counsel may submit memoranda.

“J W Gendall J”

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