Walsh v. Pharmaceutical Management Agency

[2008] NZHC 441; [2010] NZAR 101

Country: New Zealand
Region: Oceania
Year: 2008
Court: High Court
Health Topics: Chronic and noncommunicable diseases, Health care and health services, Health systems and financing, Medicines
Human Rights: Right to due process/fair trial, Right to health, Right to participation

Facts

Herceptin was a drug used to treat an aggressive form of breast cancer called Her2, and it cost roughly $68000 to $70000 for a 12 month course.Â The first defendant, the Pharmaceutical Management Agency (Pharmac), was responsible for determining which pharmaceutical treatments would wholly or partially be subsidised by District Health Boards (DHBs). From 2001, Pharmac authorized public funding for Herceptin only for patients who suffered from end stage metastatic Her2 cancer. Later in 2007, Pharmac also authorized nine-weeks of funding for Herceptin to treat patients with early stages of the cancer.

The plaintiffs were a group of breast cancer patients who were prescribed a 12 month course of Herceptin, but were not eligible for funding for the drug as their cancers had not advanced to the metastatic stage. Â Â Â Therefore, the plaintiffs challenged Pharmacâ€™s decision to authorize funding for a 12 month course of Herceptin only in cases of end stage metastatic Her2 or for just 9 weeks in cases of early stage Her2. Specifically, the plaintiffs challenged the following three decisions made by Pharmac:

In July 2006, the manufacturer of Herceptin, Roche, applied to Pharmac to fund Herceptin for 12 months for patients with early stage Her2 cancer.Â Pharmac received advice from two sub-committees: the Pharmacology and Therapeutics Advisory Committee (â€œPTACâ€•) (the second defendant) and the Cancer Treatment Sub-Committee (â€œCaTSoPâ€•). In line with advice given by the sub-committees, Pharmac determined not to authorize Herceptin for funding for early stage 12 month treatment â€œat this timeâ€•;
In April 2007, Pharmac decided to review its position with regards to funding for Herceptin and determined the drug should be subsidized for a 9 week course for early stage Her2. This decision followed from Pharmacâ€™s consultation with oncologists, interested groups, pharmacists, medical groups, and other interested parties.

Pharmac advised under its Cancer Exceptional Circumstances Policy (CaEC) that plaintiffs were not eligible for individualized funding for their 12 month treatment. CaEC grants funding for drugs in exceptional circumstances where treatment is not authorized for a subsidy by Pharmac or for another DHB drug subsidy program.

The plaintiffs alleged that Pharmac failed to perform its statutory duties, acted ultra vires, failed to take into account of relevant considerations and took into account irrelevant considerations, pursued a pre-determined policy or planned to fetter its statutory discretion, breached the plaintiffsâ€™ legitimate expectations, acted with procedural and substantive unfairness, and made decisions which were unreasonable or irrational. The plaintiffs put particular emphasis on that fact that Pharmac should have consulted more widely with interested parties when making its decisions, acted ultra vires by relying funding advice from the second defendant when it should have only attended to advice about the objective benefits of the drug, and showed a predetermined bias against funding the drug when determining all three decisions. The plaintiffs sought damages under the New Zealand Bill of Rights Act 1990 for alleged infringement of their right to natural justice.

Pharmac responded that it had acted within its legislative decision-making capacity, it correctly exercised statutory discretion throughout its decision-making process and it was not biased against funding the drug.

Decision and Reasoning

With respect to the first decision, the Court set aside Pharmacâ€™s determination not to fund Herceptin for 12

months for early stage Her2 Â cancer. Â The Court reasoned that due to the controversial and high-profile nature of the decision Pharmac had a duty to consult widely on the issue, including with breast cancer groups and womenâ€™s health groups. Â Â However, the Court did not find that Pharmac acted ultra vires or unlawfully and so dismissed the other grounds of judicial review. The Court determined that Pharmac had acted with procedural fairness (with the exception of its failure to consult), it was entitled to receive and seek advice on benefits of drugs from PTAC, and its decision fell within the bounds of reasonableness.

With respect to the second decision, the Court held the plaintiffs had not established any ground for judicial review. The Court concluded that consultation between Pharmac and all relevant and interested parties was comprehensive and meaningful.Â There was no evidence Pharmac had unlawfully relied on pre-determined policy or that it was influenced by its first decision.

With respect to the third decision, the Court found no impropriety on Pharmacâ€™s behalf.Â The Court reasoned that the CaEC gave the DHB the final decision and Pharmacâ€™s duty was limited to managing the process of a CaEC application.Â In other words, the task of Pharmac was not to decide whether the DHB should fund a drug under CaEC but rather to approve or recommend the funding, and Pharmac had not acted unlawfully, ultra vires or unreasonably in managing the CaEC Herceptin application.

In light of the above, the Court also found there was no breach to the plaintiffsâ€™ rights under the New Zealand Bill of Rights that would entitle them to any damages or compensation.

Decision Excerpts

[208] â€œThe plaintiffs cannot expect as a matter of law that Pharmac must agree with their views or submission, but they can expect consultation of such degree that they and their arguments are heard before the 12 monthsâ€™ funding issue is finally determined.â€•

[210] â€œIt 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 Rocheâ€™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 Courtâ€™s functions.â€•

[216] â€œNone 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 monthsâ€™ funding which they say implicitly followed upon the 9 weeksâ€™ funding decision. But there was nothing that invalidates the second decision and it has not been shown that any basis exists to review it.Â Even if views are divided, there was expert opinion to support it; it was supported by Pharmacâ€™s committees and sub-committee. The plaintiffs and others and groups supporting a view to an alternative funding were heard.â€•

[235] â€œI do not accept the argument that Phamac acted ultra-vires its statutory functions in the managing the CaEC.Â It was required â€œto manage incidental mattersâ€¦including in exceptional circumstances providing subsidiesâ€¦â€•.Â This is what is has done.Â 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 to confirm that an application meets the criteria for CaEC funding.â€•