Ombudsman
Fairness for all

Case note

Request for composition and active ingredients of veterinary medicine

Legislation	Official Information Act 1982, s 9(2)(b)(ii)
Agency	Environmental Risk Management Authority
Ombudsman	Beverley Wakem
Case number(s)	174687
Date	June 2007

Early release of product formulation would inform competitors of what will be brought to market, enabling them to impede the product's entry or bolster their own marketing—the likely degree of impact would be unreasonable—public interest in promoting public participation does not outweigh the need to withhold—s 9(2)(b)(ii) applies

Ancare New Zealand Ltd applied to the Environmental Risk Management Authority (the Authority), under the Hazardous Substances and New Organisms (HSNO) Act 1996, for approval to import or manufacture a veterinary medicine known as MEP600 (the product).

Wyeth (NZ) Ltd, a competitor and submitter on that application, requested the composition and active ingredients of MEP600. The Authority refused Wyeth's request on the basis that disclosure would unreasonably prejudice Ancare's commercial position (section 9(2)(b)(ii) of the OIA). Wyeth complained to the Ombudsman.

Ancare argued that releasing the information would inform its competitors, including Wyeth, of exactly what it intended to bring to the market. This would allow them to take steps to bolster the marketing of their products in the same sector, or to block the entry of Ancare's product in various ways, for example, by loading up distribution channels with special deals. They might also develop copycat products, and take other steps to impede Ancare's entry into the market.

In Ancare's view, it was highly likely its competitors would use the information in order to limit the impact of its product. It pointed out that normally competitors would not have information confirming formulation ingredients until after the product launch. That would allow Ancare a

reasonable timeframe to establish a market and brand. Early access to the information would cut the timeframe resulting in an unfair advantage to competitors and a concomitant prejudice to Ancare.

The Ombudsman agreed that release posed a real or significant risk of prejudice to Ancare's commercial position. Whether the prejudice was unreasonable was *'a question of degree'*. Ancare had spent significant time, money and effort to develop the product, in an industry where that process can cost hundreds of thousands of dollars. Ancare predicted that loss of its competitive advantage would have a significant impact (as much as 50 percent), on projected sales. This degree of prejudice was, in the Ombudsman's opinion, unreasonable.

Regarding the countervailing public interest in disclosure, Wyeth claimed to have expertise that would enable it to make submissions to the Authority, but it could not effectively do so without the information at issue. Wyeth effectively implied that the Authority could not safely determine Ancare's application without the benefit of its submissions.

The Ombudsman did not accept this argument. While the HSNO Act mandated public participation in the Authority's decision making, it also clearly envisaged the need to withhold some commercially prejudicial information (see section 57). That did not mean this information could not be considered by the Authority (see section 56), or that its processes would be unfair if it was.

The Ombudsman had no reason to doubt the qualifications and experience of the Authority's staff and statutory appointees. The Authority also had the ability to obtain independent expertise if necessary. The Authority had prepared an Evaluation and Review Report in respect of the application, which was available to Wyeth, and which seemed to be a very careful and thorough consideration of the relevant issues.

The Ombudsman did not want to appear to undervalue the importance of public participation. However, she was mindful of the commercial importance attached to the information at issue. She concluded that the public interest in disclosure did not outweigh the need to withhold.

The matter did not end there, as Wyeth appealed the Authority's decision to the courts. While the High Court initially found in its favour, the Court of Appeal and Supreme Court subsequently found against it. It is of note that the Court of Appeal agreed that:[1]

> *…the active ingredient of a formulation such as MEP600 is likely to be valuable commercial information and compelling release of it at this stage of the regulatory process is likely to cause significant prejudice to an applicant.*

It also concluded that there was sufficient information available to the public about the risks posed and the way in which those risks would be mitigated or managed to enable them to make meaningful submissions on the application.

[1] *Ancare New Zealand Ltd v Wyeth (NZ) Ltd* [2009] 3 NZLR 501 at paragraphs 60-67.

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