



26 June 2008

Hon Phil Goff
Minister of Trade
Parliament Buildings
Wellington

Dear Minister,

PHARMAC Proposals Impact on GATT and TRIPS Commitments

On 27 May PHARMAC publicly released a consultation document with a proposal to fund an anti-epileptic drug levetiracetam. (Copy of proposal attached).

The processes outlined in the PHARMAC proposal are unprecedented and may well constitute a breach of New Zealand's obligations and commitments under the Uruguay round of GATT and the WTO's Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).

We have expressed our concerns to PHARMAC who advise that they were "just keeping their options open" and have now agreed to amend the consultation document.

We draw this matter to your attention out of concern that the PHARMAC proposal, if implemented, may well have caused great embarrassment to Government and compromise this country's credibility in future trade negotiations. The very fact that this proposal was issued as a public document by a Crown Agency means that it could trigger concerns with our trading partners.

The issues are as follows. The pharmaceutical company UCB Pharma have been granted ministerial authority (through Medsafe) to distribute levetiracetam in the New Zealand market. As the innovator, who developed this pharmaceutical product, UCB Pharma enjoys five years of "data exclusivity" from the time that their authority to distribute was granted. This "data exclusivity" is due to expire on 24 December 2009.

Section 23(b) of the Medicines Act 1981, titled "protection of confidential information supporting information about innovative medicines" was an amendment inserted in that Act to specifically ensure compliance with the WTO TRIPS agreement which come into effect on 1 January 1995.

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It seems that PHARMAC was unable to agree on funding terms and conditions with UCB Pharma and subsequently reached a provisional agreement with a generic supplier, Rex Medical Limited, where the registration process cannot commence until the expiry of UCB Pharma's "data exclusivity" in December 2009.

To circumvent these obstacles and secure an immediate supply of publicly funded levetiracetam at a much lower cost the PHARMAC proposal provided for the funding of any brand of this medicine whether it is registered with Medsafe or not.

Section 29 of the Medicines Act 1981 makes provision for the use of non authorised medicines when they are required by medical practitioners to treat patients currently under their care.

There are obvious potential issues of clinical safety associated with the use of medicines that have not been authorised by Medsafe.

It is also clear that the intent and purpose of section 29 is to make provision for exceptional cases to address the specific clinical needs of particular patients. This section of the Act should not be abused by PHARMAC for the purposes of commercial leverage.

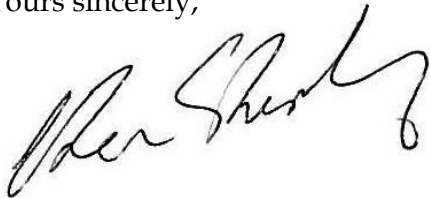
The situation is further compounded when the abuse of section 29 is applied to usurp the provisions of section 23(b) which underpins New Zealand's compliance with the WTO TRIPS agreement.

While UCB Pharma is not a member of the Researched Medicines Industry Association the principles at stake with this issue and the precedent that the PHARMAC proposal, if implemented, would establish are extremely alarming.

We are mindful of the preliminary negotiations that are occurring at several levels with potential FTA advances and appreciate the many sensitivities, including pharmaceuticals, that may be associated with some of these negotiations.

It is clear that the public consultation document issued by PHARMAC is potentially damaging to this country's reputation and no doubt Government will wish to ensure that its Pharmaceutical Management Agency does not continue to act in this manner.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Ken Shirley". The signature is fluid and cursive, with a large, stylized initial "K".

Ken Shirley
Chief Executive Officer