

11 March 2009

Hon Peter Dunne
Associate Minister of Health
Parliament Buildings
WELLINGTON

Dear Minister

The classification of tramadol under the Misuse of Drugs Act 1975

The Expert Advisory Committee on Drugs (the Committee) is established under the Misuse of Drugs Act 1975 to provide you with expert advice on the classification of substances under the Act. The Committee last met on 13 November 2008 and discussed, *inter alia*, progress with the classification of tramadol under the Misuse of Drugs Act 1975.

Background

The Committee first discussed the medicine tramadol at its meeting on 19 February 2008 to assess whether or not there was an associated risk of diversion and misuse that would warrant a recommendation to classify tramadol as a controlled drug under the Misuse of Drugs Act (MODA).

The Committee considered the evidence that was available at the time and agreed that tramadol should be classified as a Class C2 controlled drug. I wrote to the former Associate Minister of Health with responsibility for drug policy, Hon Jim Anderton, setting out the Committee's advice. That letter is attached.

Hon Jim Anderton accepted the Committee's advice and directed the Ministry of Health to proceed with the classification of tramadol. As part of this process, the Ministry conducted a targeted consultation with the New Zealand manufacturers and distributors of tramadol, PHARMAC and MedSafe. The pharmaceutical industry raised concerns about the increased costs associated with the classification of tramadol and provided additional information about the risk of harm and adverse events associated with tramadol. PHARMAC also provided feedback to the Ministry advising its view that tramadol is less harmful than equivalent analgesics and that it is considering subsidising it. PHARMAC expressed concern that the classification of tramadol would increase its cost and make it too expensive to subsidise.

On 13 November 2008, the Committee further discussed tramadol and considered the concerns raised and additional information provided by pharmaceutical companies and health agencies. The minutes of this meeting are attached.

Discussion

In light of the additional information and further discussion on diversion and misuse of tramadol, the EACD decided that there is insufficient evidence to warrant progressing the classification at this time. The EACD advises that a decision regarding classification should be put on hold for two years in order to gather further evidence and to assess the impact of a potential PHARMAC subsidy on diversion and misuse.

Therefore the Committee's advice to you is that:

- **The classification process is put on hold for a two year period to allow further evidence to be collated of any misuse associated with the use of tramadol**

In addition, I have undertaken to

- write to PHARMAC regarding the Committee's concerns about increased diversion and non therapeutic use of tramadol should it be subsidised, noting that further data will be gathered in order to reassess the classification issue in two years.
- obtain PHARMAC data as part of the evidence that is collated over the next two years
- write to the Medicines Adverse Reactions Committee regarding the side effect profile of tramadol.

As this is the first EACD advice to you since you became Minister, I would be happy to meet with you to discuss both the advice and the role and work programme of the Committee, should you wish.

Yours sincerely

Ashley Bloomfield (Dr)
Chair
Expert Advisory Committee on Drugs

Enc: Extract from the draft minutes of the Expert Advisory Committee on Drugs meeting, 13 November 2008.
Letter from to Hon Jim Anderton providing advice regarding tramadol, 4 April 2008.