Australian Democrats Dissenting Report

Therapeutic Goods Amendment Bill 2005

The Australian Democrats share the many concerns raised by the majority of submissions made to the Committee in relation to this Bill.

In particular, we are concerned about:

- the degree of discretionary power afforded the TGA and lack of clarity regarding how this power will be applied;
- the unjustified and seemingly excessive level of the fines proposed in the civil penalties regime and the potential impact of these fines on the complementary medicines industry; and
- the failure to codify the right of appeal and review provisions and need for better and more transparent due process.

The Government's stated intention in introducing this Bill is to better secure compliance with Australia's high standards for therapeutic goods – presumably to ensure high standards of safety and quality in medicines. However the Government has failed to make a case for how the proposed regulatory provisions would improve public health and safety over and above current existing penalties and sanctions. Australia's current regulatory system is one of the strictest in the world and more than adequate for public safety.

Moreover given the TGA's handling of the Pan Pharmaceuticals debacle, questions must be raised about the ability of the TGA to appropriately administer the existing system in relation to complementary medicines, let alone oversee a more flexible and discretionary system. While it could be argued that the Pan incident demonstrated a system that in fact worked to protect consumers from an unsafe product, allegations have subsequently been made that the TGA's actions were mishandled in a manner that had a significant impact on other companies within the complementary medicines sector – that there was no evidence to suggest that such a huge number and quantity of products needed to be recalled and destroyed.

In response to the TGA's actions in reaction to the problems with Pan, it has been suggested by some sectors of the complementary medicines industry that the TGA staff are, if not actually hostile to natural health products, inadequately informed on their intrinsically low risk nature in comparison to pharmaceutical drugs. This lack of expertise and experience may have contributed to the TGA exercising its authority in an overly partisan manner in relation to the Pan Pharmaceuticals recall in 2003. In light of the Pan crisis it may be appropriate for the TGA to review the nature and frequency of its audits but there seems to be little justification for the introduction of what have been described as 'draconian' measures, particularly given the lack of a regulatory impact statement that would better inform the government and the industry of the impact of these new measures.

Concerns about the TGA's ability to regulate non-prescription medicinal products were raised in the Australian National Audit Office's audit report released in December 2004. This report was critical of the level of consistency, transparency and accountability in TGA systems and procedures. There is no evidence that these processes have been improved. The Australian Democrats believe that as much of the detail of this legislation is expressed in guidelines and will be implemented through regulations that have not yet been drafted, in combination with a seeming lack of procedural redress for any misapplication of the provisions, it would be inappropriate to support this legislation in its current form.

SENATOR LYN ALLISON (AUSTRALIAN DEMOCRATS, VICTORIA)