

SUPPLEMENTARY COMMENTS

Australian Labor Party

Therapeutic Goods Amendment Bill 2005

- Whilst the Labor Party supports the Bill in principle, we are concerned about some aspects of the Bill, particularly the lack of appeal rights and review.
- On the balance of the report, we agree with the recommendation that the Bill should be passed, but we also urge the Government to seriously consider the recommendations in the report. In particular, we would like to encourage the Government to publish more clear and detailed guidelines regarding the practical application of the Bill. We would like to see the Government publish a Regulatory Impact Statement to ensure the objectives of the Bill are observed by varying sectors across the health care industry, as well as giving the industry adequate knowledge to assist in their understanding of the implications of the Bill.
- Labor accepts the need of more stringent laws, but also believes that there needs to be a transparent and fair sanctions regime to ensure consumers have the adequate knowledge, and access to safe, efficacious, quality medications, and the interests of and impacts on the healthcare industries are also duly considered.
- We support the Bill in the interests of consumer protection; public health and safety. To ensure proper regulation, access and quality of therapeutic goods. However, the Bill should include more detailed legislative provisions to make it more clear as to how the tiered penalty regime is meant to operate.

The advantage of the new provisions is the high deterrence factor in relation to breaches under the Act, and important in attempting to avoid another Pan-like scandal. It is necessary to have a level playing field, and also crucial to protect the consumer.

Simultaneously, however, we are concerned about the unprecedented, and absolute discretionary power given to the TGA. Deciding whether a breach has been made, the severity of the breach, what penalty should be imposed and what action to take against a company/manufacturer or individual should be an objective test.

We agree with the Australian Self-Medication Industry (ASMI) in that “*elements of the Bill may be open to administrative abuse.*”

Labor has a number of concerns which are set out as follows:

1. Uncertainty of operational and procedural mechanisms

The TGA needs to publish adequate and detailed industry guidelines on when, how and why the different enforcement options will be exercised.

The Bill is unclear in relation to when the TGA will impose the range of alternative sanctions and penalties. There needs to be greater clarity in the practical application/operational mechanisms, and the procedures and processes involved in implementing the proposed provisions.

The TGA needs to publish clear and detailed guidelines as to when and how it proposes to invoke the civil or criminal penalty schemes, or other alternative sanctions such as enforceable undertakings or infringement notices.

The Bill is ambiguous in its practical application, and also fails to provide any justification for the TGA choosing one penalty option over another.

For example – if three or four companies commit the same breach under the Act, they may be handed different penalties.

Also, the submissions and the transcript of the inquiry mention the possibility of ‘double jeopardy’. The Bill is unclear whether in some instances there is the risk of being liable under both the civil and criminal penalty regime. The Bill seems to imply that a person might be subject to double jeopardy- that is, subject to both criminal and civil penalty proceedings over the same conduct.

2. Publicly naming offenders

The Bill allows the TGA to reveal the identity of drug companies and employees that flout its rules. Labor is concerned about the risk of publicly naming and damaging a person/company’s reputation before their guilt has been proven.

Labor feels that drug companies shouldn’t be publicly outed for misdemeanours particularly if the charge has not been tried or tested in court and the penalty has not been scrutinised by a court.

Our legal system is based on the notion of ‘innocent until proven guilty’. If a company or individual is named by the TGA, firstly the charge must be proven, and guilt must be attributed on the basis of sufficient evidence.

Further, the TGA has the power to invoke infringement notices. The danger in this is that innocent people may pay the amount specified in the notice simply to avoid expense of contesting proceedings.

There is total lack of court scrutiny, and further, the payment of infringement notices reflects presumption of guilt.

3. Lack of transparency and accountability

The Labor Party is concerned about the heightened degree of power granted to the TGA in this Bill, in so far as the TGA is able to enforce any of the alternative sanctions at its discretion.

Whilst Labor agrees that post-Pan, the regulatory regime needs to be tightened, with the need for stricter controls/enforcement mechanisms, we believe it should be done so in a proper, fair, clear and transparent manner.

Labor agrees with the ASMI's comments in its submission that "the tiered fine system would give enormous, unaccountable discretion to the TGA. We know of no precedent for it or anything like it."

We are concerned about what is going to happen step by step through the process in relation to how the TGA comes to a particular decision in imposing a particular penalty, and the justifications in doing so. Where is the accountability and transparency in the TGA's decision of what constitutes civil or criminal action, and how a matter may or may not go to court, and then what happens once the decision has been made to take it to court. What protection is there in the implications of decision made by the TGA?

4. Lack of right of appeal or review.

Labor believes that the need for appeal is not only mandatory, it is a right; and is crucial for this Bill to work fairly and effectively.

According to the transcript of the inquiry, even the Department believes there should be an appeals process.

There should be appeal rights at each part of the process. We feel very strongly about having a particular penalty imposed (at the discretion of the TGA) and not having a formal appeal process within that.

5. Effect of Joint Trans Tasman Agency

The Government is seeking to establish a Trans Tasman agency which would provide for a joint regulatory regime with New Zealand.

When enacted, it is important to note that the amended Act may only have effect for a short time because of the impending establishment of the Trans-Tasman agency on or about 1 July 2006. Labor is concerned about the implications of the Trans-Tasman agency in terms of how the legislation will fit into the new regime, and what effect it will have on this Bill if it is passed.

The major concern we have is, following the finalisation of negotiations between both governments, whether the enforcement regime created by this Bill will transfer into the new regulatory environment governing the Trans-Tasman arrangement. Alternatively, it could also be presumed that provisions of the Bill will only last until the proposed Trans-Tasman Agency is established under new and different legislation, with new and different legislation pertaining to the penalty regime.

Conclusion

The Labor Party believes that because the Bill confers greater, discretionary powers on the TGA in terms of who they think has breached the Act, and what penalties should then be imposed, that this carries a greater burden and responsibility on the TGA to demonstrate transparency in their process, and accountability in their procedures.

The decision making route by the TGA to impose particular penalties must be clearly mapped out in the Act or Regulations.

We strongly recommend that the necessity of the right to review and appeal be provided for explicitly in the Bill.

The Labor Party agrees with the Chairman's Draft Report that the Bill should be passed in principle, but we highly recommend that the Government take into consideration the abovementioned points. This will not only ensure that the health and safety of consumers are protected, but will also ensure that industry and public confidence in the TGA is restored, and maintained.

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