

Australian Therapeutic Goods Amendment Bill 2005

Comments by NZ Health Trust
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We have commented before on the extensive new penalties regime proposed by the Australian TGA however we thought it was timely to look at this issue once again.

The Amendment Bill is currently set to be introduced to the Australian Parliament and if passed would bring into force a regime of penalties and enforcement actions which would give the TGA unheralded and almost unbridled power.

What must be remembered is that this is a body that has been criticised by the Australian National Audit Office for its lack of transparency and accountability. The Australian Audit Office Report highlighted numerous instances of the TGA using its discretion in an inconsistent and arbitrary manner. Furthermore there has recently been public comment from Pharmaceutical companies, which are also regulated by the TGA, indicating that it already uses its powers in an intimidating way, punishing organisations who disagree or comment negatively on its management by delaying or refusing applications for registration.

The new penalties regime that is proposed is presented without any sound justification or apparent logical rationale as to how the penalties will be applied. The penalties themselves are excessive in nature and maximum penalties for some offences are increasing by as much as 50 times from current levels. Furthermore some substantial penalties under the Act could be imposed by way of simple infringement notice at the whim of the particular officer concerned. Bearing in mind the typically small to medium size of natural health products businesses, in most cases it will be simply impossible to mount any legal challenge if such penalties are imposed without sufficient justification and therefore the potential for these offences to effectively drive companies out of business without proper basis is considerable in a practical sense.

Furthermore the Bill allows the TGA to issue media releases about its actions and of course once such comments are made publicly then the damage is done whether or not the concerns are later shown to have any justification. This little trial by media is quite unacceptable.

In short the TGA have failed to provide any written justification for the level and extent of the new penalties or for the way in which they are entitled to be imposed. The penalties appear to be based on an inadequate assessment of risks and there does not seem to be any consideration of alternative management or enforcement options. When this level of power and lack of accountability is considered in the context of the already identified problems with the way the TGA operates the potential for the abuse of power and substantial unfairness is very high. Particularly in respect of manufacturers of natural health products who simply will not have the political influence or resources to protect themselves.

New Zealand must at this time stop and ask itself whether this is the sort of harsh, unaccountable and fear driven regulator that it wants controlling our own therapeutic goods.