**Submission to Senate re TGA Regulations**

**Background**

The Honourable Christopher Pyne, Parliamentary Secretary to the Minster for Health and Aging, has presented a Second Reading of the Therapeutic Goods Amendment Bill 2005, to the House of Representatives on August 17th, 2005.

The Bill aims to add additional sanctions to the already onerous requirements of the Therapeutic Goods Act which, it claims, will " ... better secure compliance with Australia's high standards for therapeutic goods." The proposed amendment will, according to the reading, " ... ensure ... timely and effective action" against manufacturers and sponsors. It is difficult to see how these proposed sanctions will have any great impact on Sponsors, as the legislation is aimed quite directly at Australian Manufacturers.

The need for these amendments, according the Secretary, arises as a result of the Pan Pharmaceuticals Ltd incident of April 2003, and the stated inability of the regulator (the TGA) to 'control' the industry. This failing is clearly indicated in the reading speech "... further amendments to the act are required to more effectively address continuing failure by other manufacturers to adequately comply with the regulatory requirements." With the exception of the Pan and API events, both of which were widely publicized, there has been no public indication of " ... continuing failure by other manufacturers to adequately comply with the regulatory requirements." Is this because there has been none, which negates the key plank underpinning this legislation, or is it indicative of a regulator who does not wish to have its continuing failure recognized or subject to public scrutiny?

It would seem to me, and most within the Complementary Healthcare Industry, that more could be achieved by working in a constructive and consultative (true consultation) manner rather than raining significant threats and additional, excessive regulation on the industry. **The Complementary Healthcare Industry needs appropriate regulation, not more draconian regulation.**

**Comments**

As indicated above, the existing Therapeutic Goods Act is an onerous Act as it is, without the additional draconian threats the proposed amendments bring to it.

It is apparent that much of the recent, and proposed, legislative changes to the Therapeutic Goods Act are aimed squarely at the Complementary Healthcare industry, and that most of this change is being undertaken under the guise of reaction to the Pan incident in 2003.

The regulators actions in response to the Pan event caused significant damage to Australia's reputation as a quality source country. In major Asian markets, Australian products dominated the shelves. In the post-Pan world, Australian products are generally now held in great suspicion and less regulated source countries, like the US, have elevated to the position of trust that Australian products previously held. This is significant given the relatively cursory regulatory oversight that US products are exposed to in their own market.

The Australian Complementary Healthcare Industry is a very safe industry, and the level of adverse events and deaths related to Complementary Healthcare Products (CHP's) is exceptionally low. Even in the much heralded Pan event, there were no deaths or serious adverse events directly related to CHP's. Recent regulatory changes, and those proposed in the current Amendment, are akin to taking a 15 ton road roller to crack a non-existent walnut.

The extreme reaction taken over the Pan event has not improved the safety of CHP's. Most reasonable people would consider, based on the number of adverse events or deaths relating to CHP's and reported before and after April 2003, that little has changed. An upsurge in the time immediately post-Pan would be expected, given the extensive and sensationalist nature of the coverage at the time. Post-Pan, compliance costs have increased dramatically, imports have increased dramatically, but there has been no tangible change in adverse events.

CHP's are, according to the TGA's own definition, Low Risk products, yet the existing, and these proposed amendments are, by any reasonable standards, excessive given this safety profile. It is clear that the regulator has adopted, and continues to apply, a **no-risk** approach to CHP's.

The regulatory environment as it has evolved over the last couple of years is driving manufacturers out of Australia, as the regulatory environment is totally out of step with what most people would consider the risk profile of the Industry. The local CHP industry has changed, post-Pan, from a largely self-supplied market to an Import supplied industry, at the expense of local manufacturers and Australian jobs. Not only did these events change the local market, but they killed off a thriving Export industry.

In the last 12 months, we have seen indications where one of the country's **largest manufacturers** is considering moving its sourcing of CHP's to India. Another example is the comment by one of Australia's largest marketers of CHP products that recent regulatory changes have added over A$2 million in compliance costs, with no tangible change in product quality. To even the most short sighted person, this is a clear indictment that it is easier, and more cost effective, to manufacture off shore than to do so locally.

The declining number of local manufacturers are having great difficulty competing in our own market against imported products manufactured to, it is apparent, lower standards. Clearly the TGA lacks the power to control **foreign** manufacturers with a fraction of the vigour that it applies to local manufacturers. The TGA cannot, understandably, conduct unannounced audits on off-shore manufacturers, yet that is what local manufacturers must live with. As such, the very reasons used for the implementation of unannounced audits in Australia, to "catch industry doing wrong and not give them time to cover their sins", provides off-shore manufacturers with ample notice to prepare for an audit.

As Australia represents less than 1.5% of the global pharmaceutical industry, off shore manufacturers have little to lose by failure to comply with Australian requirements, no matter how vigorously the TGA may advance its argument on quality manufacture. In the CHP sector, most off-shore manufacturers are highly unlikely to incur the significant compliance costs needed to meet the Australian market requirements, when they can compete elsewhere more profitably and with less regulatory scrutiny.

If the regulator aims to enhance the quality of products offered on the Australian market, then clearly greater control and evaluation of imported products is a must. It should be obvious to even the most casual observer that driving manufacture out of Australia, as this and recent regulatory changes have done and will continue to do, leaves the Australian consumer with no recourse but to use imported product. **Measures aimed at a non-existent local manufacturing sector will do nothing to ensure product quality**.

At a CHP Industry organized Sponsors Obligations Conference in March 2005, the Secretary, and other TGA personnel, went to great pains to paint themselves as a **"Light Touch Regulator"** (their term, not the authors). I would suggest that the search for anyone in industry who agrees with such a position would result in a long, lonely journey. The existing Legislation and Regulations belie this definition, and the amendments proposed in the current submission takes the TGA even further from this stated position.

I have grave concerns that the TGA overstepped their authority in relation to the Pan event in the way that it communicated with overseas regulators. This is reinforced by the proposed Therapeutic Goods Amendment Bill 2005, wherein the Secretary states that the Amendment "... authorises the release of information relating to a breach or an alleged breach of the act or regulations involving therapeutic goods to Australian and overseas regulatory agencies." If the Secretary is now seeking such powers, does this imply that their actions in regard to the Pan event, and communications that they had with overseas regulators relating to that event, were outside the powers they enjoyed at the time?

The proposed amendments further discourage local manufacture and at the same time, inhibit the ability of Australians to work off-shore, as they will still be subject to attack by a potentially over zealous regulator. It is apparent that these proposed regulatory changes are very personal, with no other practical aim but to inhibit the actions of anyone with a contrary view to industry than that portrayed by the TGA.

In industry today, it is very difficult to find candidates willing to accept the position of QA Manager in the Australian industry, and the personal liabilities that attach to such a position now. Should the proposed amendments and their **extended** personal liability be gazetted, it would, I suggest, become almost impossible to find individuals willing to expose themselves to the extreme personal liability that such a position entails. The net result of this will be a significant further contraction of a local industry, or an industry where no real decisions can be taken for fear of breaching (no matter how insignificantly) the draconian Act that is the Therapeutic Goods Act.

The recent Auditor Generals report clearly indicated that the regulator itself was far from perfect, yet it expects absolute perfection from those it regulates, and is now seeking extended powers to reinforce its view of perfection.

The TGA rules by creating a climate of fear throughout much of the surviving local manufacturing industry. It regulates to suit its purposes with no apparent regard for the consequences it creates within the industry. Few people within the Complementary Healthcare Industry are willing to stand up and speak publicly, for fear of retribution. Few wish to expose their businesses, or themselves, to a regulator that has no tolerance for any view that is in any way contrary to its own, or that would require the regulator to justify in the court of public opinion, its seemingly unchallengeable authority.

This submission is marked **Presented with the wish of Anonymity** for these very reasons.