THERAPEUTIC PRODUCTS AND MEDICINES BILL

SUMMARY OF KEY POINTS

NEW ZEALAND HEALTH TRUST
January 2007

OVERVIEW

The 494 page Therapeutic Products and Medicines Bill was tabled in Parliament in December last year, narrowly passed its first reading and has been referred to the Government Administration Select Committee for consideration.

Submissions can be made on the Bill by any person or organization until **7 February** 2007. Hearings will follow the closing of submissions and the Select Committee is due to release its report on the Bill on 30 April 2007.

After Select Committee reports back the bill will be read twice more in the House and needs to be approved by a majority of the Members of Parliament after both readings before it could become law.

If the Bill passed it would be divided into two new pieces of legislation; the Therapeutic Products Act 2006 and the Medicines Act 2006. The date that these Acts would take effect would be announced subsequently.

Parts 1 – 5 of the Bill relate to the creation of a Trans Tasman regulator for all "therapeutic products" including prescription medicines, over the counter medicines, dietary supplements and medical devices and seek to give effect to a treaty signed between the Governments of Australia and New Zealand in December 2003. Parts 6 & 7 of the Bill replace the existing Medicines Act.

This paper comments on Parts 1 – 5 of the Bill as being the parts that would become the Therapeutics Products Act.

Submissions on the Bill must include your name and a contact phone number and state whether or not you wish to be heard in person at the Select Committee hearings. Two copies should be sent to:

> The Secretariat
> Government Administration Select Committee
> Parliament Buildings
> Molesworth Street
> WELLINGTON

A discussion paper setting out the Government's intention to join with Australia in setting up such a regulator was considered by the Health Select Committee in 2003 who unanimously rejected the proposal. The Treaty was signed nonetheless and the treaty itself was again considered by the Health Select Committee in 2004 who once again re iterated their concerns.

The Government has this time not taken the logical step of sending the Bill back to the Health Committee for review, but instead, for reasons known only to them, have sent it to the Government Administration Committee.

Copies of the 2003 Treaty and the two previous select Committee reports can be viewed at www.nzhealthtrust.co.nz along with a link to an electronic copy of the Bill itself.

INITIAL COMMENTS

This document does not attempt to describe every provision of Parts 1 –5 of the Bill but instead to highlight some key elements as we see them to assist others in making submissions. For more detail we suggest you read the relevant sections of the Bill and the Treaty.

At the outset there are several general comments which must be made clear:

- This Bill gives effect the Treaty (Agreement) signed in December 2003 which has already been rejected by Select Committee. **In structure, scope and effect nothing material has changed**. Suggestions that concessions have been made which now satisfy the concerns of industry, consumers and previous select committees are groundless.

- The Government's only justification for this heavy handed system is that the current system is "outdated and unsustainable". However neither of these reasons justifies this proposal. A belief that the current system is outdated only supports a review of existing laws to bring them up to date. Industry has always supported this but this doesn't justify a trans Tasman pharmaceutical styled agency for natural health products. Insofar as Government claims regulation based in NZ to be "unsustainable, this claim is only made in respect of pharmaceutical regulation. **Nowhere is a valid reason provided as to why natural health products (dietary supplements) need to be regulated with drugs through an off shore agency**.

- Much of the media hype and Government spin has focused on how some natural products have allegedly been found with all sorts of undesirable ingredients in them. Don't be misled by that. The issue is not and has never been, is regulation of natural health products needed? The NZ Health Trust and industry has always accepted the need for regulation to prevent this sort of thing. Any good system of regulation would ensure products are manufactured to acceptable standards with only the stated ingredients in them. **The only issue here is what system of regulation is best for New Zealand and New Zealand consumers.**

- Because this system of regulation would cover both highly dangerous pharmaceuticals as well as what the Government acknowledges to be low risk natural health products, it is not an option to water down this system of regulation to make it more appropriate for natural products. The regulatory system proposed and the penalty regime are in fact still too light for the pharmaceutical industry given the potential for serious harm it poses and size of the companies operating in that sector and yet are enormously and unjustifiably excessive for the natural health industry. This simply highlights why the two industries cannot and should not be regulated through one agency.

- The Bill provides numerous examples of the way in which the New Zealand system of law generally is being forgone in favour of the existing Australian system to get harmonization. This evidences the very real fear that has been continually expressed that while the agency may be joint in name, it would in effect be nothing more than an Australian takeover.

In short, the concerns of industry, consumers and the health select committee have not been satisfied, the detail included in the Bill provides many further areas of serious concern and the inescapable conclusion is that the joint trans Tasman Therapeutic Products regulator (ANZTPA) would not be in the best interests of New Zealand.

KEY PROVISIONS OF THE BILL

Set out below are some of the key elements of the Bill to be aware of and our comments in respect of them in italics.

STRUCTURE OF THE AUTHORITY

As has always been the case the structure of the Authority is made up of three tiers of governance, the Ministerial Council, the Board and the Managing Director.

The Ministerial Council made up of the Ministers of Health of Australia and New Zealand. (clause 188)

> *Effect: The NZ Minister can doing nothing without getting the Australian Minister's consent. The relative bargaining strengths of the two countries must also be considered.*

Underneath the Ministerial Council is a Board made up of 5 members one of which is the managing director . The other members are appointed by the Ministers (clause 189) but only one member is solely appointed by the NZ Minister.

> *Effect: Potentially NZ could have only one representative out of 5 on this board.*

Even if this Board doesn't follow its own procedures its actions still stand (cl. 193).

The Board presents a statement of intent and annual report to Parliament every year (cl. 225 and 230) but the Authority is not a Crown entity and is not subject to the Crown Entities Act (cl.195). Only the Minister has the ability to review the operation of the agency under cl.200, not Parliament itself.

> *Effect: The power to regulate our health products goes to a body that is not even a Crown entity but an Australian corporation.*

The Board is responsible to the Ministerial Council only for financial and administrative matters relating to the Authority. It does not oversee the regulatory functions of the Authority.

The managing director is the key person in the authority and carries out all the authority's regulatory functions.

RULES AND ORDERS

Rules and orders are Australian terminology (like most of the provisions of the Bill) and have the force of law in the same way as what we know as regulations.

The Ministerial Council makes rules and the managing director makes orders – both have the same legal effect and will contain all the detail of the regulatory system that is as set unknown and that will determine things like what products may be sold, what advertisements will be allowed and what fees will apply.

> *Effect: In this way the important detail of the model is still unknown and won't be known until after the Bill is passed by which time the ability to take back control will have been lost.*

One set of rules and orders will bind both countries and if a rule or order is disallowed in one country then it ceases to apply in both countries.

Generally disallowance is an important tool in that it means our Parliament has the ultimate ability to reject any regulations that it doesn't agree with. The ANZTPA rules and orders however don't come under the NZ system of disallowance but have been given their own toothless version.

Under the existing system Parliament can amend as well as reject any regulation however under the ANZTPA system a package of rules and orders must either be passed as a whole or rejected as a whole. Therefore Parliament would have to throw out the proverbial baby with the bathwater if it objected to one or two particular rules, which it is unlikely to want to do.

In addition, if a member of Parliament does bring a motion to disallow some ANZTPA rules, that motion lapses if it isn't called in the house within 21 sitting days.

> *The existing NZ system of disallowance doesn't have much effect, in fact it has never to our knowledge, been used however at least it is there as a backstop. This watered down system is even worse and even less likely to provide any protection against bad regulations.*

ENFORCEMENT

This is one of the most concerning areas to us in the Bill for many reasons. Every system of regulation needs to have penalties and fines to enforce it however they need to be set so as to effective without being unjustifiable and most importantly there need to be arrangements to ensure they are applied fairly and even handedly.

In the Bill explanatory note the Government admits that the penalties imposed by the Bill are high by NZ standards and gives as the only justification for this that it is done to match Australia. Here like in many other places the possibility of Australia adapting to our system was apparently not considered.

The Bill provides for a number of offences based around not complying with the authority's rules. In each case there are several levels of the offence; civil penalty offences, summary offences, indictable offences and strict liability offences.

Strangely, supposed 'civil' penalty offences carry the highest potential penalty, are the easiest for the authority to prove (not including any need to prove any intention) and worst of all use a lower standard of prove that has never, to our knowledge been applied to prosecutions of this type. This runs contrary to all usual notions of prosecutions and procedural fairness.

Another serious concern is the ability of the authority to issue "non compliance notices". These can be issued up to 12 months after you are alleged to have committed an offence for up to $550,000 for the company plus $55,000 for each director. If you pay these amounts within 28 days nothing further comes of it. If you don't pay you get prosecuted. There is no recourse against the decision to issue such notices to the review tribunal.

> *We wonder how these can enhance consumer safety when they involve no admission of guilt and carry no record with them for future issues. Further it seems to us that these contain an enormous and uncontrollable amount of discretion that could allow agency staff to selectively use such notices and set varying fee levels depending on their relationship with different organizations. Further in many cases the prospect of the time and costs of full prosecutions may well mean that companies who may feel they have done nothing wrong are pressured to pay on such notices to remain viable. There is no accountability of the agency if it issues the same without a proper basis for doing so.*

Other concerns include

- The defendant having to provide evidence to the authority before the trial of certain defences but the authority not having to disclose its own evidence relating to that until during the trial. (cl.34)
- A ban on judges taking into account any efforts by the defendant to ensure harm was prevented in sentencing (cl.31)
- A certificate by the Managing Director being sufficient evidence of certain things in New Zealand but not in Australia (cl.35(1)(l))
- The authority having 6 years to lay charges instead of the usual 6 months that applies to summary offences in NZ (cl.30)
- As well as a company being liable for fines up to $5,500,000 each director and each member of a companies management team can also be liable for fines up to $550,000 and up to 5 years in jail. (cl.46 – 48)
- The agency staff have full search and seizure powers based on them holding a reasonable belief of wrongdoing. (cl.98 on)

ADVERTISING

cl.62 contains a detailed list of the types of advertisement it is an offence to publish and once again imposes fees of up to $5,500,000 for breach for a company and up to $50,000 for each director or manager.

In addition however the Bill provides in cl.63 that the rules may require pre-vetting of all advertisements if the rules decide to impose this obligation and further heavy penalties if this is not done.

Given the extensive restriction in cl.62 the additional obligation to have all ads pre approved at additional cost to business is a totally unnecessary layer of compliance costs with little discernable public safety benefit.

REVIEWS AND APPEALS

As anticipated the Bill provides for review tribunals in NZ and Australia to review certain decisions of the authority.

Our concerns include:

- The members of the review panel are all selected by the Ministerial Council and so are likely to be stacked with supporters of the authority.
- The review tribunals cannot therefore be viewed as wholly independent or objective and yet they exercise high level judicial functions
- The review tribunals are only able to review limited types of decisions of the authority relating to the granting, amendment, suspension or canceling of approvals. Many other important discretions fall outside their realm.
- Review tribunals may not be applied to until after any internal review measures the authority decides to set up have been worked through.
- Decisions of the authority stand until the tribunal reaches a decisions and yet there are no controls over how quickly they meet or how long they take to issue a decision. A wrong decision by the authority could potentially therefore apply for several years before being set aside.
- Appeals from the tribunals are limited to matters of law. If the tribunal makes a bad finding of fact there is no appeal right. (cl.147)
- Working firstly through internal reviews, tribunal reviews and finally high court hearings if allowed would present an enormously expensive and time consuming process that only the biggest businesses will be able to pursue. Small to medium businesses will often have no choice but to accept initial decision of the authority even if patently wrong.
- Judicial review is then the only recourse however this is the most expensive and hardest type of court action to succeed in and many applicants are likely to be put off for these reasons.
- The Australian Attorney-General can require NZ Tribunal matters to be transferred to Australia and can permit the tribunal to not give any reasons for a decision. There are no reciprocal rights for the NZ Attorney General.

- While the Official Information Act does apply to the authority, any information it has that had previously been held by the TGA is exempt, even if the new authority continues to use that information it will be outside the read of Official Information Act requests. (cl.170(2)(b))
- NZ privacy principles have been eroded so as to comply with Australian privacy laws (cl.162)

OTHER MATTERS

Dietary supplements will only have transitional approval if the companies making them provide various declarations and information to the authority at the start date. How long this transitional approval will last is as yet unknown.

The authority also has the right during any transitional approval period to impose additional rules on these products.

All fees and charges remain unknown and would only be finally set under rules and orders.

While there is provision for each country to exclude some products from the scheme this can only be where they can show "exceptional public health, safety, trade, environmental or cultural factors" that would justify exemption. This is likely to be very narrow in reality and presumably would create trade barriers for any exempted product with Australia.

CONCLUSION

This Bill would bring in exactly the sort of regime that industry and consumer groups have continually voiced strong opposition to since it was first suggested in 2002.

It is in all material ways the same proposal as has been twice rejected by the Health Select Committee. None of the keys concerns have been satisfactorily addressed.

The penalties regime is too heavy handed and discretionary and gives the authority unfair advantages in proving its case. Non compliance notices have an alarming potential for misuse and lack of transparency of application.

The review provisions taken collectively are so bad as to be worthless as a check and balance on unreasonable acts of the authority.

The Bill appears to demonstrates a mindset that wherever difference between NZ and Australia exist, the Australian way will be used.