Level 1, 16 Napier Close
DEAKIN ACT 2600

12 June 2012

The Commissioner
Productivity Commission
GPO Box 1428
CANBERRA ACT 2601

RE: Strengthening Economic Relations Between Australia & New Zealand

Dear Commissioner

Thank you for the opportunity to contribute to this important review. The following submission covers two areas: firstly, the need to revitalise currently stalled negotiations between Australian and New Zealand to establish a joint regulatory body for therapeutic goods and secondly, the need to harmonise the rules and regulations for conducting clinical trials in these two countries.

About the PIC

Since 2006, the Pharmaceuticals Industry Council (PIC) has been a unique forum for developing, evaluating and providing expert advice to Government on issues affecting the Australian pharmaceuticals industry. It brings together senior executives from companies and peak bodies representing three industry sectors, including the research-based and generic medicines sectors and the biotechnology sector. Collectively, these sectors employ in excess of 40,000 highly-skilled Australians, and each year they export nearly $4 billion worth of goods and services (greater than the wine and automobile industries) and invest more than $1 billion in research and development. In addition, these sectors are among the Australian health system's most crucial components: they research, develop, manufacture and distribute products that Australians use to lead healthier and more productive lives.

1. Australia New Zealand Therapeutic Products Authority (ANZPTA)

During comprehensive negotiations between the Australian and New Zealand governments and the pharmaceuticals industry to establish a joint regulatory body (ANZPTA) prior to 2007, there were a number of reforms which were identified and agreed to that would improve the regulatory environment for therapeutics goods in both Australia and New Zealand. Not least among these was streamlining the submission and evaluation processes for new medicines. When those early negotiations were indefinitely postponed, the Australian Government gave the Therapeutic Goods Administration (TGA) the mandate to introduce many of the identified reforms in an Australia-only context. This ambitious reform program was initiated in 2007 under the leadership of the TGA's then National Manager, Dr Rohan Hammett. The streamlined submission process has since been implemented and is currently undergoing a process of review and refinement.

The New Zealand Medicines and Devices Safety Authority (MedSafe) will benefit from much of the work already completed in Australia, as well as the large body of reforms already committed to by the Australian Government for the future.

However, the most significant benefit from establishing ANZPTA would be the development of a single entry point for the submission and evaluation of products for marketing in both countries. Coupled with streamlined business processes, this has the potential to provide improvements in delivering timely access to medicines and other therapeutic goods for patients in both Australia and New Zealand. Furthermore, the capacity to evaluation the safety and efficacy of new medicines more efficiently should be enhanced by bringing together the combined resources of the TGA and MedSafe.

Additional benefits may be derived from enhanced reporting of adverse events associated with therapeutic goods (including medicines) and public access to a combined Australia New Zealand adverse event notifications database. Also, if a new joint regulatory body follows the same principles as the original scheme, in theory there should be the option of automatic registration of medicines that were not previously available in one market or the other.

In Australia, the TGA's "blueprint" for current and future reforms includes a number of improvements that will enhance the regulatory system for Australian patients: these improvements are being considered with input from authorities in New Zealand to ensure a more harmonised approach in the future. It is of course important that any new and improved systems that are harmonised between Australia and New Zealand are also harmonised with international best practice to maintain the TGA's position as a highly regarded regulatory agency around the world.

2. Clinical Trials

Research and development is another area of potentially significant collaboration between Australia and New Zealand, especially in the area of clinical trials. Both countries face fierce competition for global investment in clinical trials, especially from countries in Asia, South America and Eastern Europe. With their large populations and rapidly improving research infrastructures, these countries are among the fastest growing locations for international clinical trial activity.

As far as Australia is concerned, our declining competitiveness as a destination for global clinical trials investment is due to three main factors. Firstly the lack of a nationally harmonised system of ethics review for multi-centre clinical trials makes the process of initiating new clinical trials in Australia inefficient and costly. In fact, slow start up times are routinely identified by clinical trial sponsors in Australia as the most important reason why Australia is losing its competitive edge against other countries. Secondly, Australia is among the most expensive countries in the world in which to conduct clinical trials, and the situation is made worse due to the significant variability in what individual research sites in Australia charge for performing virtually identical tasks. Finally, low patient recruitment

rates mean that more than a third of clinical trials conducted in Australia, especially late phase clinical trials, fail to recruit the required number of participants.

Australia and New Zealand must maintain their capacity to conduct clinical trials. This is important not only from an investment perspective. Clinical trials also play a crucial role in improving a country's healthcare system; among other things, they provide early and free access to new healthcare technologies and allow healthcare providers to quickly translate latest research into everyday clinical practice.

Harmonising the rules and regulations for conducting clinical trials in Australia and New Zealand would allow faster, easier and ultimately cheaper access to research sites across the two jurisdictions. This would not only give researchers the ability to recruit more patients into clinical trials, but also give patients in both jurisdictions faster access to new healthcare technologies.

However, Australia and New Zealand must ensure that a more harmonised system builds on existing strengths of each jurisdiction and does not impose one's weaknesses on the other. For example, New Zealand is currently implementing substantial reforms aimed at significantly reducing the time needed to initiate new clinical trials. These include a single ethics approval for all national sites and concurrent ethics and research governance reviews for new clinical trials. Implementing similar systems in Australia would help greatly reduce the time it takes to initiate clinical trials in this country. Conversely, imposing current Australian standards in these areas on New Zealand would make their environment less efficient and therefore less competitive. That said, Australia has its own strengths as well. For example, for over two decades, Australia's "CTN/CTX" system has been a global benchmark for best practice in reducing the regulatory burden on clinical trial sponsors.

A harmonised system which builds on existing strengths of both Australia and New Zealand will enhance the competitiveness of both countries as a destination for clinical trials.

The PIC believes that a Trans Tasman Office of Clinical Trials could help provide structure and clear cross-jurisdictional leadership aimed at continually improving Australia's and New Zealand's global competitiveness in clinical trials across a complex regulatory and health environment. It would also play a key role in promoting these two countries as destinations for investment in clinical trials.

The PIC looks forward to ongoing engagement with the Productivity Commission in relation to its review of Trans Tasman economic relations.

Yours sincerely

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