MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

SUBMISSION TO THE JOINT STANDING COMMITTEE ON TREATIES

Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products

Level 1, 16 Napier Close Deakin ACT 2600
Phone 02 6282 6888 Facsimile 02 6282 6299 www.medicinesaustralia.com.au

Medicines Australia is the representative body for Australia's prescription medicines industry. The broad industry has a turnover of approximately $12 billion, employs around 35,000 people and accounts for approximately 1 per cent of the global market. The industry "backs Australia's ability" and is an indispensable component of a high-tech, twenty-first century economy.

Over the last decade pharmaceutical exports have grown from $146 million to more than $2 billion and the pharmaceutical industry is now one of the largest exporters of elaborately transformed manufactured goods in Australia - neck and neck with the wine industry. The industry invests $450 million in R&D in Australia.

Medicines Australia is broadly supportive of the formation of a Joint Therapeutic Agency for the regulation of therapeutic goods in Australia and New Zealand. The proposed agency will evaluate new medicines for safety, quality and efficacy. The formation of the joint agency provides an excellent opportunity for evaluation processes to be improved so that approval timelines meet or exceed international best practice (6-8 months).

Reimbursement and pricing harmonisation are not part of this treaty. Medicines Australia strongly endorses this approach as the two countries have different health structures and Government health priorities.

There are a number of key issues with the formation of a joint therapeutic agency that must be addressed prior to its implementation. These issues fall into 5 main areas:

- **Potential for weakening Australia's Intellectual Property Regime**
- **Parallel Importation**
- **Freedom of Information**
- **Approval to conduct Clinical Trials**
- **Merits Review**

1. Potential for weakening Australia's Intellectual Property regime

The formation of the Joint Therapeutic Agency must not weaken, directly or indirectly, Australia's Intellectual Property regime for prescription medicines.

There is a difference in patent terms between Australia and New Zealand. Under the Joint Therapeutic Agency it is proposed that there will be one licence to cover the two countries ("a dual country licence"). Medicines Australia is concerned that the granting of a dual country licence for a medicine that is off-patent in one country but still covered by a patent in the other country may re-open demands/opportunities for weakening of Australia's current Intellectual Property regime.

If a product patent expires in New Zealand prior to expiry in Australia, an Australian generic manufacturer could apply for a dual country licence to supply the product initially in New Zealand and, when the Australian patent expires, in Australia. An Australian generic manufacturer may argue that it should be permitted to manufacture the product in Australia to supply in New Zealand during the period of the Australian patent as it is otherwise legitimately allowed to supply the product to New Zealand under the joint agency legislation. Whilst this is currently prohibited by

the Australian patent legislation, the dual country licence may once again stimulate arguments to change the Australian legislation to permit manufacture in Australia for export of products that are protected by *a* current patent.

The dual country licence may also exacerbate patent infringements that some of our members have experienced with products protected by patent being supplied by a generic company in contravention of the Patents Act. A measure that could be taken by the Joint Agency to help prevent these patent infringements would be to notify the patented product's sponsor when an application to register a generic product is received. The recent US-Australia Free Trade Agreement has outlined a similar measure.

2. Parallel Importation

The current ban on parallel importation must be continued.

Medicines Australia is concerned that there is a potential for parallel importation of products between Australia and New Zealand, and particularly from New Zealand to Australia. With a clear pricing differential between Australia and NZ, a dual country licence must not be equated to access to one joint market with its free flow of goods. Without a ban on parallel importation there is the potential that cheaper New Zealand product will be imported by Australian pharmacists or wholesalers, thereby undermining the local industry and jeopardising Australian jobs. More importantly from the consumer perspective, the supply of product outside the regulated supply chain may expose consumers to product that has not been appropriately stored or transported. Further it may make it easier for counterfeit product to enter the Australian or New Zealand markets.

The current provisions whereby the authority to supply a product is solely vested in the product's sponsor must continue to apply under the joint agency regime, so that only authorised and regulated export can occur. Any other legislation, such as the New Zealand legislation relating to wholesalers, must be amended to similarly prohibit parallel importation.

In addition, we consider that sponsors must be permitted to have differently labelled product for supply in either country. The labelling would be required to comply with all regulatory requirements applicable under the joint agency, but additional elements that would differentiate product supplied in one country from the other should be permitted. We understand that such differential labelling is expressly prohibited in the European Union, which we do not support.

3. Freedom of Information (FOI)

How will FoI requests be handled by 2 separate governments?

Currently there is separate FOI legislation in Australia and New Zealand to allow a person to obtain access to a "document of an agency" unless the document is an "exempt document". However the level of disclosure of information between the two countries is very different, with more detailed information being disclosed under the NZ legislation. Medicines Australia would like to know how the Joint Agency is going

to deal with FOI requests concerning a single dossier but arising from different countries with different FOI legislation.

4. Approval to conduct clinical trials

The different mechanisms for approving clinical trials of new medicines must be retained.

Australia and NZ have 2 different mechanisms for approving the conduct of clinical trials. The industry in each country is strongly in favour of retaining their own current system as the investigators (doctors) and institutional human research ethics committees are very experienced in that system. The Australian industry believes that the adoption of the NZ system (which has been canvassed by the TGA and NHMRC) will lead to a significant decrease in clinical R&D activity as approval timelines may increase. This would lead to Australia being excluded from international studies for new medicines, which will seriously disadvantage sick Australians. We are proposing that the separate mechanisms be retained.

5. Merits Review

Merits review of decisions by the AAT and Federal Court must be retained, but operational questions must be resolved.

Currently in Australia, there are three successive mechanisms for reviewing a decision not to approve a new medicine for marketing. The first is an internal appeal mechanism within the Commonwealth Department of Health ("an appeal to the Minister"), the second is an application to the Administrative Appeals Tribunal, and finally an application can be made to the Federal Court. Very few appeals progress to the AAT and even fewer to the Federal Court.

It has been proposed that the AAT be retained in Australia, and a similar tribunal be established in New Zealand. It is unclear to us which tribunal would consider an appeal of a rejection of a "dual country licence". In addition, will the option of an appeal to the Federal court be retained, to which country's court, and will any decision be binding on both countries?