PRODUCTIVITY COMMISSION DRAFT RESEARCH REPORT
REVIEW OF MUTUAL RECOGNITION SCHEMES

Department of Health and Ageing Submission

Hazardous Substances, Industrial Chemicals and Dangerous Goods

Draft Recommendation 7.1 - Following completion of the five year work plan for industrial chemicals in 2009, Australian and New Zealand Governments should consider converting the Trans Tasman Mutual Recognition Arrangement (TTMRA) special exemption for hazardous substances, industrial chemicals and dangerous goods into a permanent exemption. This should involve a cost–benefit analysis, based on a realistic assessment of the likelihood of achieving mutual recognition or harmonisation in the foreseeable future, given the slow progress to date.

The Department supports the draft Recommendation.

While noting that sectors of industry have a preference to strongly pursue mutual recognition, there are fundamental differences in the regulatory regimes of both countries which, at this point in time, preclude mutual recognition without a substantial shift in the direction of regulatory policy in both countries. In particular:

- Australia assesses all new chemicals and priority existing chemicals, both hazardous and nonhazardous;
- New Zealand assesses only hazardous chemical substances as identified by the manufacturer or importer;
- the definition of 'hazardous' is not the same for Australia and New Zealand, with New Zealand adopting the GHS (Globally Harmonised System for Classification and Labelling of Chemicals) definition which currently is more conservative than the Australian workplace classification (currently aligned with European Union definitions);
- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), like all other Organisation for Economic Cooperation and Development member countries, but unlike New Zealand, is a chemical entity based scheme (that is, not product registration). New Zealand assess products as well as chemical entities;
- differences between the New Zealand and Australian ecosystems may result in different risk assessment outcomes.

These differences do not, however, preclude continuing cooperation between Australia and New Zealand and with industry stakeholders, to pursue harmonisation and cooperation with the aim of minimising unnecessary duplication and undue regulatory burden.

The draft Report has recommended a national approach to overcome problems with existing arrangements including a new governance framework that will divide responsibilities between numerous agencies and jurisdictions according to task (such as standard setting) and area (such as workplace safety). The draft Report noted that, in contrast, New Zealand tended to regulate chemicals less intensively, had a single agency (Environmental Risk Management Authority) to deal with most assessment and standard-setting functions, and fewer regulators to administer and enforce the regulations thereby further acknowledging some of the basic differences between the two countries.

There was also comment to the Commission that a key step towards resolving the industrial chemicals special exemption would be for Australia to implement the Globally Harmonised

System for Classification and Labelling of Chemicals (GHS). While the GHS will help to bring about international harmonisation in regard to chemicals classification and some elements of labelling, it is not an objective of the GHS to bring about harmonisation in the overall approach to chemical regulation. The GHS is specifically not intended to harmonise risk assessment procedures or risk management decisions and therefore regulatory approaches between countries, given the varying national priorities and chemical use situations that may exist, will continue to differ.

Therapeutic Goods

Draft Recommendation 7.2 – The Special Exemption for therapeutic goods should continue until a joint regulatory regime can be achieved. The Australian and New Zealand Governments should resume negotiations to establish a joint regulatory scheme for therapeutic products, and a joint agency to oversee the scheme, as soon as feasible after the 2008 New Zealand national election.

The Department considers that a permanent exemption for therapeutic goods under the TTMRA is appropriate in the current circumstances.

The Department notes that the Australian position on harmonisation of therapeutic goods regulation is that the Government would only consider recommencing negotiations to establish a joint agency following advice from the New Zealand Government that successful passage of its legislation was likely.

Since the postponement of negotiations Australia and New Zealand have proceeded with domestic regulatory reforms. Health Ministers of the two countries have agreed that this work should proceed in a manner that would be consistent with minimising trade barriers as envisaged for the joint regulatory scheme.

In Australia, these reforms have essentially implemented the initiatives agreed during the ANZTPA negotiations. During consultations on these reforms, industry has emphasised that it expects the Australian domestic reforms to be implemented as quickly as possible and that it values certainty around the framework for future regulatory reform. The impact of uncertainty on industry would need to be considered if governments were to decide to resume negotiations.

Moreover, the Department is concerned that reopening negotiations with New Zealand could delay implementation of Australian reforms to streamline the Therapeutic Goods Administration's evaluation of the safety and quality of medicines and medical devices.

The Draft Research Report sets out four options for dealing with the special exemption for therapeutic goods in the future. These are discussed below:

Continue to roll over the special exemption

This option would maintain the status quo. Combined with draft Recommendation 7.5 this would result in a 3 yearly rollover of the special exemption which would reduce the administrative burden of the roll over process to some extent.

The Department agrees that the value of an annual rollover process is questionable and does not justify the administrative burden. It would seek as a minimum to extend the rollover period to a three yearly process.

Extend the special exemption without annual rollovers until negotiations can be resumed
This option would indefinitely extend the Special Exemption until such time as the political climate becomes more favourable for the establishment of a joint agency.

This option does not seem to have any advantages over a permanent exemption for therapeutic products from the TTMRA, but would require changes to the operation of the TTMRA.

Narrow the scope of the special exemption to complementary medicines
This option effectively excludes complementary medicines from the operation of the joint regulatory scheme.

Complementary medicines are fully integrated into the Australian system and their removal would put at risk the integrity of a joint therapeutic products regulatory scheme. "Complementary medicines" may be prescription medicines, over-the-counter medicines or listed medicines depending on the criteria set out in the Australian *Therapeutic Goods Act 1989*. In addition, Good Manufacturing Practice licensing applies to a manufacturer regardless of the specific medicine which it is producing at any point in time.

The Australia New Zealand Therapeutic Products Authority (ANZTPA) Treaty provides for the regulation of complementary medicines under the joint scheme. If either party to the Treaty sought to exclude complementary medicines, then renegotiation of the Treaty may be required.

This option would also increase the complexity of the joint scheme as the agency would be required to enforce different rules in each country and medicines would need to be carefully categorised for trade purposes.

The Department's view is that excluding complementary medicines is not consistent with the principles of harmonisation, and would greatly decrease the benefit of harmonisation to both countries.

Seek a permanent exemption for all therapeutic goods.
This option would seek to change the special exemption for therapeutic goods from the TTMRA to a permanent exemption.

A permanent exemption:

- would not require repeal of the ANZTPA Treaty, and negotiations to establish a joint agency could recommence at any time;
- may simplify the bilateral therapeutic goods regulatory relationship and may encourage cooperation efforts short of full harmonisation;
- would present the least administrative burden of the options identified, and does not require an alteration to the current operation of the TTMRA; and,
- would provide certainty for industry and allow domestic reforms to go ahead immediately in each country.

A permanent exemption does not imply that the Australian and New Zealand Governments have abandoned the goal of harmonised therapeutic products regulation. The TTMRA provides a framework for either country to seek removal of the exemption once current concerns have been addressed.

Risk Categorised Foods

Draft Recommendation 8.1 – Consideration should be given to narrowing the permanent exemption for risk-foods from the TTMRA to include only those for which harmonisation of risk-food lists and equivalence of import-control measures are not achievable in the long term. All other risk-foods should be reclassified as a special exemption. Efforts should be made to achieve equivalence of import-control systems and third-country arrangements through a cooperation program, undertaken by a trans-Tasman working group, consisting of regulatory body and policy officials.

The Department supports the draft recommendation, in principle.

The Department supports retaining the permanent exemption for risk-foods where equivalence of import-control measures has not been achieved. The Department would also support the removal of food from the exceptions list once equivalence is achieved. The Department supports the expansion of the trans-Tasman working group to include policy officials to advance the cooperation program to achieve equivalence of import control systems and third country arrangements for risk-foods where equivalence can be achieved.

Medical Practitioners

Draft Finding 9.1 – The permanent exemption for medical practitioners could become a special exemption. Harmonisation of competency standards for overseas-trained medical practitioners could then be pursued through a cooperation program.

The Department supports the draft finding.

The Department notes that at present there is fairly free movement of fully registered medical practitioners across the Tasman through two arrangements:

1. The Australian Medical Council (AMC) accredits all New Zealand and Australian Medical Schools, and AMC accredited medical school graduates who complete an appropriate intern year are eligible for general registration in Australia; and
2. The Competent Authority model for international medical graduates recognises the New Zealand Medical Council as a competent authority – this means that international medical graduates who have full registration in New Zealand are able to get advanced standing in Australia towards full registration.

While the Department has no objection to gradually moving towards mutual recognition with New Zealand for fully registered medical practitioners, any new system would need to accommodate the particular circumstances of partially regulated medical practitioners. Both Australia and New Zealand have specific provisions within their registration legislation to temporarily register international medical graduates who do not currently meet the requirements for full registration. As appropriate, these partial registrations are generally limited by location and supervision requirements. Any alteration to the current arrangements would have to exclude medical practitioners in these circumstances.

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