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Dear Beth

### **RMI Submission – Draft National Safety & Quality Use of Medicines Strategy**

Thank you for the opportunity to provide comment on the draft strategy document.

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

Prescription medicines play a vital role in the prevention, amelioration and treatment of disease and the industry in New Zealand is committed to assisting New Zealanders in achieving these benefits through the safe and quality use of medicine. The RMI therefore supports the development of a National Strategy to provide a framework for achieving these objectives and wishes to be actively involved in the development of the strategy and its implementation.

#### **1. Safe & Quality Use of Medicines Partnerships**

In summary, the safe and quality use of medicine is about making sure that medicines are available when needed, prescribed correctly, correctly dispensed and taken in the right dose for the right amount of time. The medicines themselves must also be effective, safe and of good quality.

In order to achieve this all participants in the process must be involved and engaged:

- Those who take or consider taking medicines
- Those who prescribe, provide and monitor the use of medicines
- Those who develop, manufacture, market, distribute and sell the medicines
- Those who fund and determine access to funded medicines
- Those who evaluate, register and monitor medicines

It is therefore disappointing that the draft strategy does not acknowledge these partnership roles and synergies. While it is appropriate to have a focus on clinical and organisational (DHB) leadership and co-ordination, a broader and more inclusive approach would offer a greater opportunity to gain a community-wide awareness and commitment to the safe and quality use of medicines.

## 2. Strategy Goals and Objectives

The primary aim of the draft strategy, as stated in section 4, is **to achieve safer, more effective and more appropriate use of medicines so that health outcomes from the use of medicines are improved for the community as a whole**. Whilst the draft strategy is a move in the right direction, its scope and recommendations represent only a sub-set of what needs to be done, and who needs to be engaged, to achieve this outcome.

### 2.1 *Primary care*

Primary care is mentioned in a number of areas throughout the draft document. However, this appears to be primarily as a result of the interface with DHB hospitals and does not reflect the primary care perspective on priorities such as diabetes, cardiovascular disease and asthma. Government has identified primary care as a priority with the implementation and investment in the PHO environment and the issue of safety and quality use of medicines in primary care should therefore be developed further.

### 2.2 *Regulatory agencies and Pharmac*

Regulatory agencies play an integral part in the safe and quality use of medicines. Medsafe ensures that medicines approved for use in New Zealand are safe. The continued safety of all registered medicines is monitored in part by the New Zealand Pharmacovigilance Centre which maintains both the Intensive Medicines Monitoring Programme (IMMP) and the Centre for Adverse Reactions Monitoring (CARM). This group should be adequately resourced to stimulate and create an environment where health professionals understand the importance and benefits of adverse event reporting. The role of CARM should also be to provide timely reviews of data and information to support all bodies in the health sector. CARM currently links back to Medsafe through the Medicines Adverse Reactions Committee (MARC).

This list is not exhaustive and many other divisions of the Ministry of Health play an important role in maintaining the safety and quality of medicines.

Current Pharmac policies also directly affect the safety and quality of medicines as evidenced by reports of lack of effectiveness or increased side effects on switching

from branded to generic medicines. For example, recent issues such as enalapril, salbutamol and paracetamol are not indicative of a strategy for safe and quality medicines in the health sector. Frequent schedule changes also create an increased level of risk for administrator of the medicine, whether that is the health professional or the patient.

### 2.3 *Pharmaceutical Industry*

The pharmaceutical industry should be incorporated into any national policy on the safety and quality use of medicines in New Zealand. New Zealand pharmaceutical companies already interface on quality issues with both the primary and secondary care sectors and regulatory agencies.

Examples of some of these activities include:

- Technical product complaints related to product quality, packaging and labelling of manufactured products
- Spontaneous adverse event reporting in a post-marketing environment with appropriate cases forwarded to CARM, the company globally and international agencies.
- Drug safety information for assisting with the patient management of adverse events
- Provision of medicines information from independent experts and health professionals
- Updates to regulatory information (product Data Sheets) and correspondence with Medsafe on medical safety issues

Marketing activities can also support the quality use of medicines in the healthcare environment. Companies support the health workforce with information and materials to manage both common and serious adverse events while consumers benefit from patient support services and programmes. These can include website based information, 24-hour 0800 help-lines, and patient kits for some products which contain guidance on correct storage, administration and medication management. The advice of relevant members of the health sector is sought in producing these resources.

The RMI would also support the strategy providing further encouragement for all companies involved in the manufacture and/or supply of manufactured medicines (including complementary and generics) to comply with both global and local standards of quality.

### 2.4 *Beyond medication errors and adverse events*

The draft strategy paper in its current form is primarily targeted to address medication errors and the ensuing adverse drug events that might result from these errors in a DHB hospital environment. While this is a critical area for safety and quality use, equal attention must be given to other key areas involving the effective and appropriate use of medicines that have a significant impact on the improvement of health outcomes.

Some examples would include:

- Non compliance, waste or misuse
- Under-utilisation
- Utilisation beyond approved indications
- Delay in introduction and/or access to new medicines

### **3. Conclusion and recommendation**

The RMI congratulates DHBNZ and the SQM working group on their commitment to a national safety and quality use of medicines strategy and the progress made to date. We would however suggest that a strategy of this level of importance should be the responsibility of the Ministry of Health. A culture of safety and quality has to start at the top with adequate funding provided and collaboration with all relevant parties to meet the aims and objectives suggested by the SQM group.

With the move to a joint trans-Tasman regulatory agency environment, the RMI would also strongly recommend that New Zealand adopt a national quality strategy similar to the Australian National Strategy for the Quality Use of Medicines. The Australian strategy has a broad scope across all interfaces of the health sector and most importantly, is supported by the Australian government.

Quality Use of Medicines can mean different things to different people but, from a welfare and health outcomes perspective, it is important that it should be interpreted broadly rather than confining it to narrower interests. Any policy or strategy with the aim of improved health outcomes for the community as a whole from the use of medicines must reflect that broader view and the roles and responsibilities of all of the parties involved.

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RMI