Government Response to
Report of the Health Committee
on
Petition 2011/102 of Carmel Berry and Charlotte Korte

Presented to the House of Representatives

In accordance with Standing Order 248

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Introduction

The Government has carefully considered the Committee's report on Petition 2011/102 of Carmel Berry and Charlotte Korte, requesting that the House of Representatives inquire into the use of surgical mesh in New Zealand.

The Government responds to the report in accordance with Standing Order 248.

The Government supports all of the Committee's recommendations.

Recommendations and government response

Recommendation 1: That the Government work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry.

Response: The Government is working on a new and comprehensive regulatory regime to regulate therapeutic products in New Zealand, which will replace the Medicines Act 1981. This regime will modernise the regulatory framework for all therapeutic products, including medical devices, and will be flexible enough to ensure effective control over evolving technology. The regime will look to align with international standards where appropriate.

The Government has made a series of decisions about the new regulatory regime. These decisions confirm the government's intention that the new regulatory regime will be comprehensive and will cover all therapeutic products. This regime will enable controls that assess and manage the risks of therapeutic products used in New Zealand.

Post market monitoring of therapeutic products is an important aspect of ensuring the benefits of using these products continue to outweigh the risks. There currently exists an array of post-market mechanisms which are used to monitor the performance of therapeutic products and can be used to make ongoing decisions about continued use of products. These mechanisms include adverse reaction / event reporting by health care professionals, suppliers and patients; ongoing monitoring and testing by the regulator and through obligations placed on the product supplier to notify concerns. Actions taken can include recall of products, removal of product from the market and product correction. The new regime will require a continuation and further development of these provisions to ensure adequate and effective control of medical devices once they have been placed on the market. The use of registries can be seen as a further mechanism that may assist in deciding whether products continue to meet risk / benefit expectations.

Establishing medical device registries in New Zealand requires careful consideration and it will be important to balance the benefit likely to accrue against the cost to the health system. Important matters for consideration will include:

- The expected utility of information available from a registry. Information may, for instance, be useful for tracing patients, measuring health care outcomes and performance, providing information about products used and so on.
- The dataset that should be collected and how this could be achieved.
- The utility of the data in determining problems and trends. The small New Zealand population may mean that the trends may not be readily apparent.
- Whether a registry would be cost effective, how it would be funded, who should operate it and have access and whether it should be mandated in legislation.

The Ministry of Health will carefully consider the utility of a registry to record surgical mesh use and will consult with the relevant parties. This consultation may take place within a wider consideration of the need for medical device registries and also within the context of the development of new therapeutic products legislation. Consultation on the new regime will be wide-ranging and involve all relevant stakeholders including the medical colleges

Recommendation 2: That a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications.

Response: If a surgical mesh registry is established, consideration will be given to aligning terminology with recognised international standards and classification terms.

Recommendation 3: That the Government suggests that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures.

Response: The Ministry of Health will discuss the outcomes of the Health Committee report with the relevant colleges in the context of the expectations of the profession in terms of maintaining best practice and ensuring patients receive the information they need to make an informed decision about their care.

The Ministry of Health agrees that the professional colleges are the most appropriate organisations to take the lead on professional practice matters such as appropriate use of surgical mesh and ensuring patients are informed of the benefits and risks of any treatment. This is consistent with the requirements for health practitioners described in the Health Practitioners Competence Assurance Act 2003. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists' *Code of Ethical Practice* (available at: https://www.ranzcog.edu.au/the-ranzcog/policies-and-guidelines/code-of-ethical-practice.html) is an example of how this requirement is addressed.

Recommendation 4: That the Government encourages health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored.

Response: The Ministry of Health will work with DHBs and other health providers to ensure the consistency of coding of procedures in regard to the use of surgical mesh is improved.

Recommendation 5: That the Government encourages utilisation of the adverse events reporting system as applicable to medical devices.

Response: The Government strongly supports the reporting of suspected adverse events associated with the use of all medical devices and has in place mechanisms to facilitate this. Arrangements will be made to further encourage use of this system including reminding health care professionals about their responsibility to report adverse events.

Recommendation 6: That the Government endorses the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery.

Response: The Government supports ongoing education for all healthcare professionals in New Zealand. The Health Practitioners Competence Assurance Act 2003 requires healthcare professionals to operate within their scope of practice and maintain competence in this scope.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists has issued advice to its members about the use of surgical mesh. The College is expected to update advice as new information about the use of surgical mesh becomes available. The Ministry of Health's view is that it is appropriate for the profession to take the lead in ensuring surgical mesh is used appropriately and publishes links on the Medsafe website to guidance published by the College and by internationally recognised regulators.

Recommendation 7: That the Government considers expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in New Zealand.

Response: The Government is working on a new and comprehensive regulatory regime to regulate therapeutic products in New Zealand, which will replace the Medicines Act 1981. This regime will modernise the regulatory framework for all therapeutic products, including medical devices, and will be flexible enough to ensure effective control over evolving technology.

The new regime will also look to align with international standards where appropriate and put in place an upgraded domestic regime for the regulation of therapeutic products. This is necessary to address the legislative framework and gaps in policy settings, which increase the risks of adverse health outcomes, especially in relation to medical devices and cells and tissues therapies.

The new regime is seeking to implement a life cycle approach to regulation. This approach includes risk appropriate requirements for approvals to be issued before a medical device can be used in New Zealand, as well as strengthening post market controls to identify safety issues and take action in a timely manner.

Conclusion

The government has carefully considered the Committee's report on Petition 2011/102 of Carmel Berry and Charlotte Korte, requesting that the House of Representatives inquire into the use of surgical mesh in New Zealand.

The government supports all of the Committee's recommendations.

The government has initiated a project to develop a new and comprehensive regulatory regime to regulate therapeutic products in New Zealand, which will replace the Medicines Act 1981. This regime will modernise the regulatory framework for all therapeutic products, including medical devices, and will be flexible enough to ensure effective control over evolving technology. The regime will look to align with international standards where appropriate.

The recommendations of the Health Committee that are associated with the regulation of medical devices in New Zealand, adverse event reporting, and options for a registry will be carefully considered as part of the development of new legislation and the associated regulatory regime for therapeutic products.

The Ministry of Health has noted the recommendations associated with ensuring patients receive informed consent, and ensuring health care professionals who use surgical mesh maintain best practice and keep informed about the risks and benefits of using these products. These actions sit with the professional bodies such as the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Royal Australasian College of Surgeons. The Ministry will be discussing the outcome of the Health Committee report outlining its expectations to the Colleges with respect to professional practice.