

In Confidence

Office of the Associate Minister of Health, Hon Casey Costello
Cabinet Legislation Committee

**Government response to the Petitions Committee report on the Petition of
Catrina McGregor: Inquire into Essure contraceptive device recall and
compensate NZ women harmed**

Proposal

- 1 This paper seeks approval of the Government's response to the Petitions Committee's referral of the Petition of Catrina McGregor.

Background

- 2 In a petition to Parliament, Catrina McGregor requested: 'that the House of Representatives initiate a full investigation into the promotion, funding, distribution and prescription of all Essure devices for NZ women; find, contact, and advise women who received these devices that they have been recalled; and offer full ACC coverage for any Essure-related care they may require.'
- 3 The basis of the petitioners' claims in the petition were: 'Essure devices are permanent contraceptive implants, recalled worldwide after women internationally suffered complications that I believe were catastrophic, life-threatening, and life-altering and included hysterectomies, agonising pain, bleeding, hair & tooth loss, and crippling immune system disorders, among other ill effects. While Essure has been recalled in NZ, women who received it have not been notified of the updated risks and ACC deny coverage for most Essure-related care.'
- 4 The petition was presented to the House of Representatives on 25 June 2024 and referred to the Petitions Committee. The Petitions Committee received evidence from the petitioner, Medsafe and ACC.
- 5 On 11 April 2025, the Petitions Committee referred the petition to me for response, as the Associate Minister of Health with responsibility for the Medical Products Bill and women's health. The Petitions Committee's report made two recommendations on the regulation of medical devices: an approval process for medical devices and mandatory reporting of injuries and harm arising from medical devices.

Comment on petition's request and Ministerial response

Recommendation 1: an approval process for medical devices

- 6 The Petitions Committee recommends that the Government amend the Medicines Act 1981 to require an application, assessment, and approval process for medical devices before they are supplied in New Zealand.
- 7 Cabinet has previously noted the importance of establishing modern regulation for medical devices and agreed to replace the Medicines Act 1981 with a new Medical Products Bill [SOU-24-MIN-0115]. The Medical Products Bill will establish a regulatory framework, and work is already underway on the development of a Medical Products Bill.
- 8 The new Bill will also address other shortcomings with the Medicines Act, making it a more efficient mechanism to implement the Committee's recommendation. As such, the Government response does not support the recommendation to amend the Medicines Act 1981.
- 9 The Government response also does not support the Committee's recommendation to implement a uniform approval process for medical devices. The recommendation in the Committee's report does not reflect that medical devices have differing risks, which justify different degrees of regulation.
- 10 In contrast, the Medical Products Bill will enable efficient and risk-proportionate approval processes, including approvals based on decisions and assessments undertaken by trusted overseas regulators. Relevantly, while the Bill will enable a self-declaration pathway for low-risk devices [SOU-24-MIN-0115], higher risk devices, such as implantable contraceptive devices, will require evidence of their safety, performance, and quality.

Recommendation 2: Mandatory adverse event reporting

- 11 The Petitions Committee recommends a legislative mandate for reporting harm or injury caused by medical devices. The Government response does not support this recommendation.
- 12 As with recommendation 1, the Medical Products Bill provides the most appropriate vehicle to implement risk-proportionate adverse event reporting requirements. Any reporting requirements will require consultation with practitioners, industry, the public and government agencies such as ACC.
- 13 There are also existing systems for reporting harms, including via claims data collected by ACC, reports made by health practitioners and the Health Quality & Safety Commission national adverse events reporting policy. While there may be improvements that could be made to these existing systems, I do not want to duplicate processes that are already in place, or reviews underway.
- 14 I am also cognisant that harms arising from medical devices can be due to inappropriate use of a product, as opposed to a defect with the product itself.

Where harms arise from the inappropriate use of products, action can be taken by Responsible Authorities established under the Healthcare Practitioner Competence and Assurance Act 2003 or the Health and Disability Commissioner.

- 15 Given the complexity of implementing the solution, I believe any change to reporting requirements be considered as part of developing and implementing the Medical Products Bill, giving due consideration to existing reporting mechanisms and the views of stakeholders through public consultation. Public consultation will enable proper consideration of the views of women, clinicians and others interested in the regulation of implantable contraceptive devices.
- 16 Along with other Health Ministers, I am committed to ensuring the health system (including health legislation) take account of the views of patients and responds to their needs and interests.

Timing of the response

- 17 The Ministerial response must be presented to the House by 11 July 2025, in accordance with Standing Order 256.

Consultation

- 18 The following agencies were consulted: the Ministry for Women, ACC, Health New Zealand | Te Whatu Ora, the Health & Disability Commissioner, the Health Quality & Safety Commission and the Office of the Privacy Commissioner. The Department of the Prime Minister and Cabinet was informed.
- 19 Agencies support the Government response and provided information on adverse event reporting mechanisms.

Financial implications

- 20 There are no financial implications associated with the response. The response notes that the Committee did not think it appropriate to change ACC's processes to ensure the approval of all claims relating to Essure.

Publicity

- 21 I do not intend to publish a media release on the Government's response. The response will be published under the Standing Orders.

Proactive Release

- 22 This paper will be proactively released within 30 days of being considered by Cabinet, with redactions as appropriate under the Official Information Act 1982.

Recommendations

The Associate Minister of Health recommends that the Committee:

- 1 note that on 11 April 2025 the Petitions Committee referred the Petition of Catrina McGregor: 'Inquire into Essure contraceptive device recall and compensate NZ women harmed' to me for a response;
- 2 note that the Petitions Committee recommended that the Government:
 - 2.1 amend the Medicines Act to require an application, assessment, and approval process for medical devices before they are supplied in New Zealand
 - 2.2 create a legislative mandate for reporting harm or injury caused by medical devices;
- 3 approve the Government response, attached to this submission, to the report of the Petitions Committee: Petition of Catrina McGregor—to inquire into Essure contraceptive device recall and compensate NZ women harmed;
- 4 note that the Ministerial response must be presented to the House by 11 July 2025;
- 5 invite the Associate Minister of Health (Hon Casey Costello) to present the Government response to the House in accordance with Standing Order 256;
- 6 invite the Associate Minister of Health (Hon Casey Costello) to write to the petitioner enclosing a copy of the Government response to the petition, after the response has been presented to the House.

Authorised for lodgement

Hon Casey Costello

Associate Minister of Health