New Zealand House of Representatives
Te Whare Māngai o Aotearoa

Petitions Committee
Komiti Whiriwhiri Take Petihana

54th Parliament
April 2025

Petition of Catrina McGregor: Inquire into Essure contraceptive device recall and compensate NZ women harmed

Presented to the House of Representatives
by Greg O'Connor, Chairperson

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Petition of Catrina McGregor

Recommendation

The Petitions Committee has considered the petition of Catrina McGregor—Inquire into Essure contraceptive device recall and compensate NZ women harmed—and recommends to the Government that it:

- amend the Medicines Act to require an application, assessment, and approval process for medical devices before they are supplied in New Zealand
- create a legislative mandate for reporting harm or injury caused by medical devices.

Request for an inquiry into Essure contraceptive devices

The petition was presented to the House on 25 June 2024. It requests:

> That the House 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.

About the Essure contraceptive device

Essure is a permanent female contraceptive. It consists of a flexible metal coil wrapped in synthetic fibres and enclosed in another, larger coil. It was implanted into the fallopian tubes in the same way as a standard intrauterine device. Essure was approved for use in several countries, including Australia, the United States of America, and the United Kingdom.

Essure was recalled from the New Zealand market in 2017. Prior to the withdrawal, Medsafe requested that Essure recipients be monitored.

Comments from the petitioner

The petitioner told us that Essure's New Zealand recipients were neither told about the device's recall nor monitored. Because the device was not widely used, it is hard for device recipients to find specialists and gynaecologists who are willing to review their care and treatment.

Further, the petitioner said that not all gynaecologists report patient harm caused by Essure or device damage to Medsafe. In some cases, she said, they failed to record harm or damage. The petitioner told us that, as a result, ACC has denied patient claims relating to Essure.

Comments from Medsafe

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority, a business unit of the Ministry of Health. It is responsible for regulating therapeutic products, including medical devices, under the Medicines Act 1981 (the Act).

Medical devices

The Act does not require an application, assessment, or approval process for medical devices before they are supplied in New Zealand. An importing company supplying any device is required to notify it to the Web-Assisted Notification of Devices (WAND) database within 30 days of supply. Medsafe is unable to edit information on WAND and does not assess or verify it. Essure was notified to WAND in 2007 by its distributor, NZ Medical and Scientific Limited (NZMS).

There is no legislative mandate for reporting harm or damage caused by devices, but Medsafe publishes information to facilitate reporting. Medsafe enters adverse events into a database, which it reviews to determine trends or whether to take action. When an issue is identified, Medsafe initiates an investigation and may seek further information to determine whether a recall is needed. Under the Act, Medsafe informs consumers and healthcare professionals about known and newly discovered risks associated with medicines and medical devices. It can also remove or recall devices proven to be unsafe.

Medsafe said that it undertakes around 350 actions on medical devices each year. These may be recalls or communicating important information about a device, such as software updates and updated instructions.

Adverse events and the recall of Essure

Medsafe said that 651 Essure devices were supplied in New Zealand, not all of which have necessarily been implanted. It is not known how many Essure devices were implanted, because there is no register of implanted devices that have been used. Medsafe has received 12 confirmed reports of adverse events related to Essure. These events included pain, heavy menstruation, perforation of the fallopian tubes, open fallopian tubes, dislocation of the device, and one instance where a pregnancy that had started prior to the device's insertion was not detected during the insertion.

In May 2017 representatives of Bayer and NZMS told Medsafe that they intended to discontinue supply of the device because of low sales. At the time, Bayer provided risk/benefit and clinical evaluation reports from ANSM, the French national agency for medicine safety. The reports did not question Essure's risk profile. However, in August 2017 NZMS told Medsafe that the product's European Union certificate of compliance had been temporarily withdrawn.

Consequently, Medsafe asked Bayer and NZMS to issue a letter recalling all un-implanted stock. In the letter, surgeons were advised that patients who received the device may not have been fully informed of its risks. It also included information about the adverse events that had been reported. The clinicians were asked to consider whether further action or advice to patients was needed. Medsafe said that having been advised, the decision on how to deal with patients was "a clinical matter" for surgeons.

Comments from the Accident Compensation Corporation

The Accident Compensation Corporation (ACC) provides compensation for treatment injuries under the Accident Compensation Act 2001 (the AC Act). It described the petitioner's request for "full ACC coverage for any Essure-related care" as "very broad". It said that ACC

assistance depends on the availability of cover. Further, the nature of the assistance depends on the injury and on the outcome of entitlement tests in the AC Act.

ACC told us that when clients enter a treatment event relating to a medical device on the ACC claim form, the name of the medical device is not recorded. Therefore, ACC was unable to use its treatment event data to identify claims involving Essure devices. Instead, it extracted data from the form's free text field. ACC determined that it received 11 treatment injury claims that mentioned Essure between 2018 and 2024 but some relevant claims may have been missed because of the method it used to find them.

ACC accepted five of the eleven claims. The injuries in the five claims included perforation of the fallopian tubes and technical failure of the device's placement and/or deployment. We were told that the declined claims failed to establish personal injury. Clients who are unhappy with ACC's decisions can raise concerns with ACC, which will seek to resolve the concerns. If still dissatisfied, clients can request an independent review, and ultimately, appeal to the District Court.

Reporting risk of harm

Under section 284 of the AC Act, ACC is required to report monthly to Medsafe if it believes that treatment injury and related claims demonstrate risks of harm to the public. The requirement to report exists whether a claim is accepted or denied. ACC also reports on findings about treatment issues relating to devices.

ACC told us that at least one report issued shortly before October 2024 referenced an Essure device. However, it said that at the time of writing its submission on this petition, it could not access its historical reports because its recording systems had recently changed.

Our response to the petition

We thank the petitioner for drawing this matter to our attention. We recognise the suffering caused by the recalled Essure device. We accept Medsafe's explanation of the process by which Essure was imported into, and then withdrawn from, sale in New Zealand. Therefore, we do not think it is appropriate to ask the House to investigate Essure's distribution. Neither do we think it is appropriate to change ACC's processes to ensure the approval of all claims relating to Essure.

We encourage Medsafe and Health New Zealand to consider how best to advise clinicians to include all harm and injury, and their causes, in patient records. We encourage ACC to consider updating the claim form for treatment injuries to include the device used in the treatment.

We are concerned that there is no current process for medical devices to be approved before they are supplied in New Zealand. We are also concerned that there is no mandate to report harm from medical devices. We note that the Government is developing new legislation to modernise regulation of medicines and medical devices.[1] We recommend that the Government amend the Medicines Act to require an application, assessment, and approval process for medical devices before they are supplied in New Zealand. We also

[1] Ministry of Health: Regulating medicines, medical devices and natural health products.

recommend that the Government create a legislative mandate for reporting harm or injury caused by medical devices.

Appendix

Committee procedure

The petition was referred to us on 25 June 2024. We met between 22 August 2024 and 10 April 2025 to consider it. We received written submissions from the petitioner, Medsafe, and ACC.

Committee members

Greg O'Connor (Chairperson)
Carl Bates (until 29 January 2025)
Kahurangi Carter (from 29 January 2025)
Greg Fleming
Paulo Garcia (from 29 January 2025)
Francisco Hernandez (until 29 January 2025)

Dr Hamish Campbell participated in some of our work on this petition.

Related resources

The documents we received as evidence in relation to this petition are available on the Parliament website.