Briefing

Advice on an active petition relating to Essure, a permanent contraceptive medical device

Date due to MO:	11 April 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024038651
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Advice on an active petition relating to Essure, a permanent contraceptive medical device

Security level:	IN CONFIDENCE	**Date:**	11 April 2024
To:	Hon. Casey Costello		

Purpose of report

1. This report responds to your request for advice on a petition about Essure, a permanent contraceptive medical device available in New Zealand until it was discontinued in 2017 and all un-implanted devices were recalled.

Summary

2. This report provides information on adverse events relating to Essure and its recall from markets including New Zealand's. Essure is a permanent contraceptive device designed to provide women with a non-surgical alternative to tubal ligation for permanent contraception (ie, sterilisation).

3. An active petition to the House of Parliament calls for an investigation into the handling of the Essure contraceptive device, its recall, and the subsequent handling of device related injuries to recipients in New Zealand.

4. As the petition calls for full ACC funding for injuries related to the use of Essure, you may wish to discuss this briefing with the Minister for ACC, the Hon Matt Doocey.

5. The petition closes on 31 May 2024, after which it will be presented to the House of Representatives and referred to the Petitions Committee of Parliament (the Petitions Committee). The Ministry may be asked to provide comment on Essure during this process.

Recommendations

We recommend you:

a)	**Note** that the Ministry may be asked to comment on Essure to the Petitions Committee	**Noted**
b)	**Indicate** if you wish for the Ministry to provide you further advice once the petition has progressed through the Petitions Committee.	**Yes/No**

c) **Agree** to meet with Ministry officials to discuss the broader challenges around medical device patient safety and well-being and how they relate to further work following the repeal to the Therapeutic Products Act **Yes/No**

d) **Agree** to share this briefing with the Minister for ACC, the Hon Matt Doocey **Yes/No**

Steve Waldegrave
Associate Deputy-Director General
Strategy, Policy and Legislation
Date:

Hon Casey Costello
Associate Minister of Health
Date:

Advice on an active petition relating to Essure, a permanent contraceptive medical device

Background

6. Essure is a permanent contraceptive device designed to provide women with a non-surgical alternative to tubal ligation ('tube tying'). The device, manufactured by Bayer, consists of small, flexible coils inserted in the fallopian tubes, leading to tissue growth that blocks the tubes, preventing conception (ie, sterilisation).

7. Essure has been linked to adverse events overseas and in New Zealand, leading to recalls in several countries, including New Zealand, Australia, the European Union and the United States. Bayer announced it ceased sales of Essure in all countries by 2018.

8. The underlying issues raised by Essure implanted women are multi-factorial and span: medical device regulation, clinical training and how doctors responded to patient concerns, the ability to identify patients implanted with devices, and compensation decisions for device-related harm. These issues are further compounded by gender biases that women experience in healthcare.

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

9. An active petition is being brought to the House of Representatives by Catrina McGregor requesting that:

   - the House of Representatives initiate a full investigation into the promotion, funding, distribution and prescription of all Essure devices for NZ women
   - women who received the device are found, contacted and advised, and
   - ACC offer full coverage for any Essure-related care they receive.

10. The petitioner has requested that Hon Louise Upston present the petition to the House of Representatives when it closes on 31 May 2024.

11. The petition, once received, will be referred to the Petitions Committee. The Petitions Committee either publishes a report to Parliament about every petition that it considers, or it asks a specialist subject committee or a Minister to do so. In its report, the Committee can make recommendations to the Government about law or policy changes it wishes to see, or actions it believes the Government should take, in response to the matters raised by the petition.

12. The Petitions Committee may inquire into how medical devices are currently regulated in New Zealand and what steps could or should be taken to avoid similar harms arising in the future. As part of any inquiry, the Petitions Committee can invite comment from the Ministry of Health (the Ministry), as has occurred in the past for similar petitions.

Regulation of medical devices in New Zealand

13. Medical devices are regulated in New Zealand by Medsafe. Current legislation does not enable or resource Medsafe to assess medical devices for safety, quality or performance prior to supply. Devices are required, with some specified exemptions, to be notified to the Web-Assisted Notification of Devices (WAND) database.

14. The Medicines Act 1981 permits some post-market activities including management of recalls and other post-market quality or safety actions and the removal of devices proven to be unsafe. Medsafe record and review adverse events reported and initiate post-market actions such as recalls.

15. Implementing a comparable regime of pre-market assessment of medical devices would not, on its own, prevent the harms that arose in relation to Essure. Adverse events related to Essure were identified first in jurisdictions with more robust regulatory regimes for medical devices.

16. Effective management of adverse events requires a collaborative approach involving healthcare professionals, regulatory authorities, manufacturers, product suppliers, and patients support groups.

Adverse events experienced by women

17. According to the US Food and Drug Administration, the most common adverse events reported internationally after implantation with Essure include changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation of tissues, migration of the device, and allergy/hypersensitivity or immune-type reactions.

18. Three patient testimonies obtained from the Auckland Women's Health Council website from women harmed by Essure are attached in **Appendix 1**.

19. Between 2002 and 2022, Medsafe received 11 confirmed adverse event reports related to Essure. In New Zealand the adverse events reported include pain, heavy menstrual bleeding, perforation of the fallopian tubes, dislocation of the device, patent (open) fallopian tubes and one instance where a pregnancy commenced prior to the insertion of the device but was not detected at the time of insertion.

20. In Australia, the Therapeutic Goods Administration (TGA) received 59 adverse event reports relating to women implanted with the Essure device.

21. In the United States the Food and Drug Administration (FDA) received 69,249 medical device reports related to Essure between 4 November 2002 (Essure's approval date) and 31 December 2022.

22. Surgery, including hysterectomy, is the most common procedure performed for the removal of Essure.

Removal of Essure from the market

New Zealand

23. Medsafe was contacted in May 2017 by representatives from Bayer and the New Zealand distributor of Essure, NZ Medical & Scientific Ltd (NZMS), to advise of their intention to discontinue supply.

24. On 31 May 2017, Medsafe was notified that Essure would be discontinued in New Zealand from 1 August 2017. The reason given was low volume sales. At that stage it was not the intention of the supplier to recall any un-implanted product.

25. Following a request from Medsafe, all un-implanted devices were recalled on 13 September 2017.

26. Medsafe required a commitment from Bayer to provide ongoing support to patients that had Essure implanted, that un-implanted stock be recalled, and that implanting surgeons be contacted and asked to monitor their patients. It is unclear whether Bayer met the conditions of the commitment.

27. The number of New Zealand women implanted with Essure is unknown as there is no register of implanted devices in New Zealand. Supply numbers may be used as a proxy but is an imperfect measure to understand how many devices were implanted in patients.

28. s 9(2)(ba)(i) [redacted]

29. Medsafe has not been notified of any other company importing Essure since the device was discontinued by NMZS. However, under current legislation, there is nothing to prevent a surgeon from importing an Essure device for a patient under their care, if it were available.

Overseas

30. In response to reports of adverse events, the FDA required Bayer to conduct additional clinical trials in February 2016, and a "black box" warning of potential complications was placed on the product in November 2016. The FDA restricted sales of Essure in April 2018, and in July 2018, Bayer announced the voluntary discontinuation of Essure in the US due to commercial reasons.

31. The TGA suspended the device from the Australian Register of Therapeutic Goods in 2017 due to safety concerns, and the device was withdrawn from the market in 2018.

32. The European Union suspended the marketing authorisation of Essure in September 2017. Bayer voluntarily withdrew the device from the market in the EU shortly after the suspension decision.

What may need to be considered in response to the petition

Redress for affected women

33. In the United States, several lawsuits have been filed against Bayer. In August 2020, Bayer entered into a $1.6 billion settlement to resolve approximately 90% of the 39,000 Essure claims. This settlement applies to US-based individuals only.

34. In Australia, a class action lawsuit against Bayer and related companies has been brought to Victoria's Supreme Court by 1000 women. The lawsuit is currently ongoing.

35. In New Zealand, the Accident Compensation Corporation (ACC) provides no-fault personal injury coverage. Under the scheme, New Zealanders cannot sue medical device

manufacturers for personal injury, including those caused by medical devices, regardless of fault.

36. Current ACC data (1 July 2005 until 13 April 2024) indicates that ACC has received a total of nine claims for assessment of treatment injury related to the insertion of the Essure intra-fallopian device for sterilisation. s 9(2)(a) [redacted]

37. The petition calls for 'full coverage' by ACC for any Essure-related care they receive'. On 17 April 2024, ACC advised the Ministry that ACC investigates claims lodged for treatment injury on a case-by-case basis and may accept cover for personal injuries caused by treatment that are not a necessary part or ordinary consequence of the treatment. There must be evidence an injury has occurred that has resulted in bodily harm or damage to the patient. A claim cannot be accepted solely for symptoms (such as pain or menorrhagia) in the absence of a coverable physical injury.

38. As mentioned above, the Essure product was recalled in 2017 and ACC understands that the overall complications rate remains relatively low. As such, any potential impact on ACC would therefore be confined to a limited number of historic treatments as the device is no longer in use.

39. With respect to implications for ACC of accepting this petition, the request for "full ACC coverage for any Essure-related care" is very broad and is inconsistent with current Treatment Injury legislation where entitlements are only available for covered personal injuries.

40. In light of the Petition's reference to ACC, we recommend you discuss this briefing with the relevant Minister, Hon Matt Doocey.

Clinical obligations

41. The New Zealand health systems' patient safety framework is built around the Health and Disability Commission (HDC) and the Code of Rights; and the Health Practitioners Competence Assurance Act 2003 (HPCAA). The HDC and Code of Rights establishes the rights of consumers to be fully informed and to receive services of an appropriate standard. The HPCAA provides a framework for the regulation of health practitioners in order to protect the public.

42. Under the HPCAA, responsible authorities are responsible for ensuring health practitioners registered with them are competent in the practice of their profession. Professional colleges are responsible for practitioner training. In September 2017, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists released a statement about Essure.

43. The New Zealand Medicines and Medical Devices Recall Code (the Recall Code) sets out requirements for product sponsors, wholesalers, pharmacies and health practitioners involved in a product recall. While it is not legally binding, the Recall Code represents best practice. Under the Recall Code, there is an expectation that healthcare professionals are open in their advice to patients who are being treated with a medicine or medical device that is the subject of a recall action. Clear communication with patients is also a requirement of the Code of Health and Disability Services Consumers' Rights.

44. The Recall Code requests that when an issue is identified with an implanted medical device, and the clinician is asked to contact patients, then every reasonable attempt should be made to locate and contact the patients. In this instance the notice went to implanting surgeons and requested they monitor patients.

45. Medsafe has advised that in the case of actions relating to implanted devices, there must be a consideration as to whether explanting the device may be a poorer clinical decision for the patient than leaving it implanted, particularly in cases where the device is performing as expected. This decision is best made by a clinician on a case-by-case basis.

Equity

46. The impact of adverse events associated with Essure is compounded by issues of equity, particularly concerning women's health. In consultation on the Women's Health Strategy, a common theme reported was that women often experience gender biases in healthcare settings, leading to underestimation or dismissal of their symptoms by healthcare providers[1]. They reported facing unique challenges in accessing accurate information, receiving appropriate care, and having their concerns heard and addressed.

47. The Auckland Women's Health Council collected and published a series of vignettes of women harmed by Essure, in which they report struggling to have their voices heard and their concerns taken seriously by regulatory authorities and healthcare professionals (**Appendix 1**). If widespread, failure of medical professionals to listen and respond to women's concerns could perpetuate cycles of harm and undermine trust in the healthcare system, though the extent of this problem is difficult to quantify at present.

48. The equity issue in the context of medical device safety can be addressed with approaches that centre women's experience, such as using patient reported outcomes and experience to drive continuous quality improvement.

Next steps

49. The petition closes on 31 May 2024 after which it will be presented to the House of Representatives and referred to the Petitions Committee.

50. As with past petitions, the Ministry may be asked to provide information on Essure for the Petitions Committee.

51. The Ministry will provide you further information at your request after the consideration of the petition by the Petitions Committee, including steps that may be taken to improve patient care with respect to medical devices.

52. Ministry officials are available to discuss the broader challenges around medical device patient safety and well-being and how they relate to further work following the repeal to the Therapeutic Products Act

ENDS.

[1] Women's Health Strategy 2023

Appendix 1 – Stories of women's experience with Essure

[Attachments have been provided separately to maintain formatting]

Appendix 1 is publicly available here: *https://www.womenshealthcouncil.org.nz/wp-content/uploads/2023/11/AWHC-November-2023-Newsletter-website.pdf*

Minister's Notes