

Associate Minister of Health

Cabinet material: Government Response to the Petition of Sally Walker to Suspend the Implantation of Mesh Sling for Stress Urinary Incontinence

11 October 2023

These documents have been proactively released by the Ministry of Health on behalf of the Associate Minister of Health, Hon Willow-Jean Prime.

Title of Cabinet paper:

- Government Response to the Petition of Sally Walker to Suspend the Implantation of Mesh Sling for Stress Urinary Incontinence

Titles of minutes:

- Report of the Cabinet Legislation Committee: Period Ended 1 September 2023 (CAB-23-MIN-0418)
- Report of the Cabinet Legislation Committee Minute (LEG-23-MIN-0185).
- Report of the Cabinet Legislation Committee Minute (LEG-23-MIN-0169).

Some information has been redacted from the Cabinet minute as it out of scope of the subject of this proactive release.



Cabinet


Minute of Decision

This document contains information for the New Zealand Cabinet. It must be treated in confidence and handled in accordance with any security classification, or other endorsement. The information can only be released, including under the Official Information Act 1982, by persons with the appropriate authority.

Report of the Cabinet Legislation Committee: Period Ended 1 September 2023


On 4 September 2023, Cabinet made the following decisions on the work of the Cabinet Legislation Committee for the period ended 1 September 2023:

Out of scope



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Out of scope




LEG-23-MIN-0185

Government Response to the Petition of Sally Walker to Suspend the Implantation of Mesh Sling for Stress Urinary Incontinence
Portfolio: Associate Health

CONFIRMED

Out of scope



Rachel Hayward
Secretary of the Cabinet



Cabinet Legislation Committee

Minute of Decision

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Government Response to the Petition of Sally Walker to Suspend the Implantation of Mesh Sling for Stress Urinary Incontinence

Portfolio Health

On 31 August 2023, the Cabinet Legislation Committee:

- 1 **noted** that on 30 June 2023 the Health Committee presented its report to the House entitled “Petition of Sally Walker: Suspend the implantation of mesh sling for stress urinary incontinence”;
- 2 **noted** that the select committee recommended to the government that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause;
- 3 **noted** the announcement by the Director-General of Health on 23 August 2023 to support the Mesh Roundtable recommendation to immediately pause the use of mesh in stress urinary incontinence;
- 4 **noted** the decision to pause has been based on a collective agreement by the members of the Mesh Roundtable (which includes the relevant colleges) as a voluntary undertaking and was made in consultation with the Medical Council of New Zealand;
- 5 **approved** the government response, attached to the submission under LEG-23-SUB-0185, to the Report of the Health Committee entitled “Petition of Sally Walker: Suspend the implantation of mesh sling for stress urinary incontinence”;
- 6 **noted** that the government response must be presented to the House by 8 September 2023;
- 7 **invited** the Associate Minister of Health to present the government response to the House in accordance with Standing Order 256;
- 8 **invited** the Associate Minister of Health to write to the petitioner enclosing a copy of the government response to the report of the Health Committee on the petition, after the response has been presented to the House.

Sam Moffett
Committee Secretary

Attendance: see over

Present:

Hon Grant Robertson (Chair)
Hon Andrew Little
Hon David Parker
Hon Kieran McAnulty
Hon Barbara Edmonds
Hon Dr Duncan Webb
Hon Willow-Jean Prime
Hon Rachel Brooking
Tangi Utikere, MP (Chief Government Whip)

Officials present from:

Office of the Prime Minister
Officials Committee for LEG

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In Confidence

Office of the Associate Minister of Health
Chair, Cabinet Legislation Committee

Government Response to the Report of the Health Committee on Petition of Sally Walker - Suspend the implantation of mesh sling for stress urinary incontinence

Proposal

- 1 This paper seeks approval of the Government's response to the Health Committee Petition of Sally Walker to suspend the implantation of mesh sling for stress urinary incontinence.

Background

- 2 The Petition of Sally Walker to suspend the implantation of mesh sling for stress urinary incontinence was presented to the House 1 September 2022. The petition had over 1000 signatures of support.
- 3 Sally Walker is a mesh injured women and is an experienced consumer advocate for mesh injured women with the Health and Disability Commission (HDC). Her petition called for the suspension of mesh use, as has occurred in the United Kingdom, in light of ongoing harm, in the hope that no woman ever has to suffer from the procedure, as she has.
- 4 In the petitioner's view, the issue of mesh use is a result of surgeons implanting mesh incorrectly. Despite a directive from the then Director-General of Health in 2018 that clinicians be credentialled against Australian guidelines to implant mesh, Ms Walker believes that most clinicians are not meeting the guidelines' criteria.
- 5 While Ms Walker raised seven outcomes¹ she hoped to see to address the problems caused by mesh mid-urethral sling (MUS) implantation in New Zealand, the suspension of mesh MUS was her priority.
- 6 The petitioner's first priority would be to pause mesh implantation until surgeons are upskilled and have better knowledge of how to properly implant it. She said she does not want it banned and she wants it to be used in future. However, women's safety is paramount to her. The Committee heard that the petitioner wants to know that surgeons are willing to use a registry, be accountable, and put women first.

¹ Seven outcomes sought were: 1. Suspension of mesh MUS implantation, 2. Mandated credentialling, 3. Introduction of a mandatory register, 4. Proper informed consent, 5. ACC categorising of mesh injury as a sensitive claim, 6. Introduction of high -vigilance scrutiny for non-mesh pelvic floor surgery, 7. Protection of the title 'urogynaecologist'.

- 7 Ms Walker's petition has been presented in the context and awareness of a comprehensive work programme overseen and monitored by the Mesh Roundtable², aiming to address and reduce harm caused by mesh. Workstreams underway include the credentialling of surgeons, establishment of a mesh specialist service, scoping of a registry, and development of education resources.

The Health Committee findings

- 8 Alongside Ms Walker's comments, the Committee heard from the Ministry of Health, Royal Australasian College of Surgeons (RACS), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the Physiotherapy Board of New Zealand, an independent surgeon from Scotland, Dr Wael Agur, and from a mesh injured consumer and advocate, Charlotte Korte.
- 9 The Committee noted that submitters had differing views on whether a pause is necessary. They recognised that a pause could reduce access to a treatment that works for many women.
- 10 The Committee noted that the Ministry was already considering whether a pause should be implemented.
- 11 The Committee recommended to the Government that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause.
- 12 The Committee agreed that any pause should be time limited.

Comment on the Health Committee findings and recommendations

- 13 The Government responds to the recommendation in acknowledging that since May 2023 the Ministry of Health has been actively scoping a pause on the use of mesh in the treatment of stress urinary incontinence (SUI), at the request of the Mesh Roundtable.
- 14 The Mesh Roundtable's assessment is that the balance of benefit and harm from the procedure will be improved by a set of agreed measures, and it recommended an immediate time-limited pause be implemented until these measures are in place (see para 23)
- 15 On 23 August 2023, the Director-General of Health publicly announced her decision to support the recommendation of the Mesh Roundtable to immediately implement a time-limited pause on the use of surgical mesh in the treatment of SUI.

² The Mesh Roundtable provides oversight and monitoring of the surgical mesh work programme, including the actions and recommendations arising from the Health Committee and Restorative Justice reports. The group, chaired by the Manatū Hauora Chief Medical Officer, is made of members from across the sector (Health and Disability Commissioner (HDC), Health Quality and Safety Commission (HQSC), Te Whatu Ora, Te Aka Whai Ora, Accident Compensation Cooperation (ACC), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Royal Australasian College of Surgeons (RACS)), mesh injured consumers, clinicians, consumers, and Ministry representatives. The group meets eight weekly.

I N C O N F I D E N C E

- 16 The relevant colleges, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and Royal Australasian College of Surgeons (RACS) were part of the Mesh Roundtable subgroup who investigated how a pause could be effected. The Ministry separately engaged with the Medical Council of New Zealand as part of their consultation on scoping a pause.
- 17 Manatū Hauora Health Legal and Medsafe teams have explored relevant Acts (e.g., Health Act 1956, Medicines Act 1981, Health Competence Assurance Act 2003) to ascertain what legal mechanisms may be available to enact a pause. They have advised there are no appropriate legislative or regulatory levers available in New Zealand to do so.
- 18 The array of legal mechanisms available to specify and enforce a temporary prohibition on the usage of surgical mesh for SUI procedures are limited and would require demonstration that the device itself is at issue, rather than the use of the device.
- 19 The Director-General of Health does not hold any powers or authority to enforce a pause or to restrict the practice of clinicians but may make a recommendation to the sector and or endorse the position of established working groups, such as the Mesh Roundtable.
- 20 This is partly a result of the deliberate decision to codify (under Section 8 of the Health Practitioners Competence Assurance Act 2003) the requirement that all doctors operate under a 'scope of practice' (defined areas of medicine and specialities). This 'scope of practice' is set by Medical Council of New Zealand.
- 21 The Medical Council is independent in fulfilling this function, meaning it cannot be directed by the Government of the day regarding which medical procedures should or should not be included in such scopes of practice.
- 22 The decision to pause has been based on a collective agreement by the members of the mesh roundtable as a voluntary undertaking and is only enforceable through disciplinary actions from employers or responsible authorities (such as Medical Council of New Zealand). Manatū Hauora has confidence that the pause will be adhered to, as ongoing engagements with the relevant stakeholders has confirmed their position to either support or not oppose the pause.
- 23 The pause will remain in place until four predetermined conditions have been met, with progress monitored by the Mesh Roundtable. These conditions are:
- 23.1 mandatory credentialling of clinicians to the National Credentialling Framework Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures (2022),
 - 23.2 a mesh registry for female pelvic floor procedures including mesh,
 - 23.3 a structured informed consent process using a patient decision aid, and

23.4 patient case discussion at a multi-disciplinary meeting.

24 Manatū Hauora has advised that work is already underway across the sector to address each of the conditions. Notably already completed is the scoping of a register and functioning regional MDMs within the specialist service. Patient informed decision-making tools are under development, and the second round of national credentialling, is in the early development phase. The roundtable group will retain oversight on the progress and will provide advice to Manatū Hauora, at the point, the intended outcomes have been achieved.

Timing of the government response

25 The Government response must be presented to the House by 22 September 2023. However, it should be noted dissolution of the House is 8 September 2023

Consultation

26 The Ministry of Health has not consulted other agencies in the development of this paper.

Financial implications

27 There are no financial implications from the government's response.

Publicity

28 I do not intend to make any public statement about this paper.

Proactive Release

29 I intend to release this paper in accordance with the guidance in Cabinet Office Circular CO (18) 4.

Recommendations

The Associate Minister of Health recommends that the Cabinet Legislation Committee:

- 1 **note** that on 30 June 2023 the Health Committee presented its report to the House entitled "Petition of Sally Walker: Suspend the implantation of mesh sling for stress urinary incontinence";
- 2 **note** that the select committee recommended to the Government that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause;
- 3 **note** the announcement by the Director-General of Health on 23 August 2023 to support the Mesh Roundtable recommendation to immediately pause the use of mesh in SUI.

I N C O N F I D E N C E

- 4 **note** the decision to pause has been based on a collective agreement by the members of the Mesh Roundtable (which includes the relevant colleges) as a voluntary undertaking and was made in consultation with the Medical Council of New Zealand.
- 5 **approve** the government response, attached to this submission, to the Report of the Health Committee entitled “Petition of Sally Walker: Suspend the implantation of mesh sling for stress urinary incontinence”;
- 6 **note** that the government response must be presented to the House by 8 September 2023;
- 7 **invite** the Associate Minister of Health to present the government response to the House in accordance with Standing Order 252;
- 8 **invite** the Associate Minister of Health to write to the petitioner enclosing a copy of the government response to the report of the Health Committee on the petition, after the response has been presented to the House.

Authorised for lodgement

Hon Willow-Jean Prime

PROACTIVELY RELEASED

IN CONFIDENCE

**Government Response to
Report of the Health Select Committee
On the
Petition of Sally Walker – *suspend the implantation of mesh sling
for stress urinary incontinence***

PROACTIVELY RELEASED

Presented to the House of Representatives

In accordance with Standing Order 252

Government response to Report of the Health Committee on Petition of Sally Walker - Suspend the implantation of mesh sling for stress urinary incontinence

Introduction

- 1 The Government has carefully considered the Health Committee's report on the petition of Sally Walker, and the recommendation for the Government that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause on the use of mesh for stress urinary incontinence (SUI).
- 2 The Government welcomes the Committee's report and acknowledges the dedication and bravery of Ms Walker and many other mesh-injured women who supported the petition in sharing their insights and experience.
- 3 The Government responds to the report in accordance with Standing Order 252.
- 4 The Government has acted on all of the Committee's recommendations.

Recommendations and government response

- 5 **Recommendation 1:** That the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause.
- 6 Response: The Government responds to the recommendation in acknowledging that the Ministry of Health has been actively scoping a pause on the use of mesh in the treatment of stress urinary incontinence (SUI), at the request of the Mesh Roundtable¹ since May 2023.
- 7 The Mesh Roundtable's assessment is that the balance of benefit and harm from the procedure will be improved by a set of agreed measures, and it recommended an immediate time-limited pause be implemented.
- 8 On 23 August 2023, the Director-General of Health publicly announced her decision to support the recommendation of the Mesh Roundtable to immediately implement a time-limited pause on the use of surgical mesh in the treatment of SUI.

¹ The Mesh Roundtable provides oversight and monitoring of the surgical mesh work programme, including the actions and recommendations arising from the Health Committee and Restorative Justice reports. The group, chaired by the Manatū Hauora Chief Medical Officer, is made of members from across the sector (Health and Disability Commissioner (HDC), Health Quality and Safety Commission (HQSC), Te Whatu Ora, Te Aka Whai Ora, Accident Compensation Cooperation (ACC), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Royal Australasian College of Surgeons (RACS)), mesh injured consumers, clinicians, consumers, and Ministry representatives. The group meets eight weekly.

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- 9 The relevant colleges, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and Royal Australasian College of Surgeons (RACS) were part of the Mesh Roundtable subgroup who investigated how a pause could be effected. The Ministry separately engaged with the Medical Council of New Zealand as part of their consultation on scoping a pause.
- 10 Manatū Hauora Health Legal and Medsafe teams have explored relevant Acts (e.g., Health Act 1956, Medicines Act 1981, Health Competence Assurance Act 2003) to ascertain what legal mechanisms may be available to enact a pause. They have advised there are no appropriate legislative or regulatory levers available in New Zealand to do so.
- 11 The array of legal mechanisms available to specify and enforce a temporary prohibition on the usage of surgical mesh for SUI procedures are limited and would require demonstration that the device itself is at issue, rather than the use of the device.
- 12 The Director-General of Health does not hold any powers or authority to enforce a pause or to restrict the practice of clinicians but may make a recommendation to the sector and or endorse the position of established working groups, such as the Mesh Roundtable.
- 13 This is partly a result of the deliberate decision to codify (under Section 8 of the Health Practitioners Competence Assurance Act 2003) the requirement that all doctors operate under a 'scope of practice' (defined areas of medicine and specialities). This 'scope of practice' is set by Medical Council of New Zealand.
- 14 The Medical Council is independent in fulfilling this function, meaning it cannot be directed by the Government of the day regarding which medical procedures should or should not be included in such scopes of practice.
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- 16 The pause will remain in place until four predetermined conditions have been met, with progress monitored by the Mesh Roundtable. These conditions are:
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 - 16.3 a structured informed consent process using a patient decision aid and

- 16.4 patient case discussion at a multi-disciplinary meeting.
- 17 Manatū Hauora has advised that work is already underway across the sector to address each of the conditions. Notably already completed is the scoping of a register and functioning regional MDMs within the specialist service. Patient informed decision-making tools are under development, and the second round of national credentialling, is in the early development phase. The roundtable group will retain oversight on the progress and will provide advice to Manatū Hauora, at the point, the intended outcomes have been achieved.

Conclusion

- 18 Under the guidance of the Mesh Roundtable, the Ministry has investigated how a pause in the use of mesh for treatment of SUI could be effected.
- 19 Support for the Mesh Roundtable recommendation to implement a time-limited pause on the use of mesh in the treatment of SUI was announced 23 August 2023 by the Director-General of Health.
- 20 While there are no legislative or regulatory levers to enforce a pause, there is confidence from the sector stakeholders that the Director-General's recommendation to pause will be followed.
- 21 The Mesh Roundtable retain oversight of the progress to lift a pause and will provide advice to Manatū Hauora, at the point, the intended outcomes have been achieved.



Cabinet Legislation Committee

Minute of Decision

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Government Response to the Petition of Sally Walker to Suspend the implantation of Mesh Sling for Stress Urinary Incontinence

Portfolio Associate Health (Hon Willow-Jean Prime)

On 24 August 2023, the Cabinet Legislation Committee **deferred** consideration of the paper under LEG-23-SUB-0169 until its meeting on 31 August 2023.

Rebecca Davies
Committee Secretary

Present:

Hon Grant Robertson (Chair)
Hon Damien O'Connor
Hon Andrew Little
Hon David Parker
Hon Barbara Edmonds
Hon Willow-Jean Prime
Hon Rachel Brooking
Hon Jo Luxton

Officials present from:

Office of the Prime Minister
Officials Committee for LEG