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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*

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 Roundtable[1] 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.

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.

15 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.

16 The pause will remain in place until four predetermined conditions have been met, with progress monitored by the Mesh Roundtable. These conditions are:

16.1 mandatory credentialling of clinicians to the National Credentialling Framework Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures (2022),

16.2 a mesh registry for female pelvic floor procedures including mesh,

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.