In Confidence

Office of the Minister of Health
Chair, Cabinet Legislation Committee

Government Response to the Report of the Health Committee on Denise Astill and Sarah Teare Petitions

Proposal

1 This paper seeks approval of the government's response to the Health Committee petitions on:

1.1 Denise Astill Petition for an "Inquiry into the numbers harmed by antiepileptic medicines during pregnancy" (**Attachment 1**)

1.2 Sarah Teare Petition for Patient Voice Aotearoa to "Publicly continue to fund Lamictal for epilepsy and mental health patients" (**Attachment 2**).

Background

Petition of Denise Astill

2 The petition by Denise Astill, Executive Officer of Foetal Anti-Convulsant Syndrome New Zealand (FACSNZ), was presented to the House on 8 May 2018. It requested the House of Representatives conduct an inquiry into the number of babies harmed since 1966 due to exposure to antiepileptic medicines during pregnancy, why it has occurred, is still occurring, and how to ensure informed consent.

3 Foetal Anti-Convulsant Syndrome (FACS) can occur through the exposure of antiepileptic drugs in the womb. The effects of FACS on the child can include structural abnormalities such as neural tube defects and congenital heart disorders, specific facial features, as well as developmental delays and learning or behavioural disabilities.

4 The antiepileptic medicine that was highlighted was sodium valproate, brand name Epilim. Epilim was contraindicated in pregnancy in New Zealand in 2005 and the data sheet updated to reflect this. A contraindication is where a medicine should not be used for treatment in a specific situation because it may be harmful to the patient. The guidelines for the regulation of therapeutic products now require a 'Dear Healthcare Professional' letter to be distributed if a contraindication is added to a data sheet for a medication. However, this did not occur with Epilim because it was not required at that time.

5 Epilim was the second most prescribed epilepsy medication in 2017. The use of Epilim during pregnancy is considered "off-label" use, and prescribers must seek informed consent of any pregnant person using the medication.

Petition of Sarah Teare

6 The petition by Sarah Teare for Patient Voice Aotearoa was presented to the House on 18 September 2019. It requested the House of Representatives urge Pharmac to continue funding the antiepileptic medicine Lamictal for epilepsy and mental health patients.

7 Lamictal contains the medicine lamotrigine. Three brands of lamotrigine were previously available and publicly funded in New Zealand: Lamictal, Arrow-Lamotrigine, and Logem. In April 2019, Pharmac published its decision to approve a sole supply agreement of lamotrigine and only continued to fund Logem. From 1 October 2019, patients taking 25mg, 50mg, or 100mg strength Lamictal or Arrow-Lamotrigine were prescribed Logem (except for child-strength 2mg and 5mg doses of lamotrigine, for which Lamictal and Arrow-Lamotrigine, respectively, would continue to be funded).

8 This decision has been the subject of three other reviews:

8.1 in June 2020, Pharmac contracted Claro Law to conduct an independent review of their lamotrigine brand-change process

8.2 in November 2020, the Chief Coroner began an inquest into the deaths of six patients with epilepsy

8.3 in March 2021, the Health and Disability Commissioner conducted a review of Pharmac's decisions and how the brand change was implemented and communicated to consumers.

9 The actions from this petition addresses the issues raised by the Health and Disability Commissioner and recommendations from the Chief Coroner's inquest regarding the lamotrigine sole supply decision.

The Health Committee findings

Petition of Denise Astill

10 The Health Committee responded to the petition of Denise Astill in August 2020. The Committee highlighted the concern raised by Denise Astill on the difficulty in ensuring warnings in relation to contraindications for antiepileptic medicines are passed on to the consumer. It noted the importance of including pregnancy pictogram warnings on packaging. It also noted the complexities associated with having warnings on the original packaging being carried through to the plain packaging when repackaged by pharmacists while noting the importance of this practice.

11 The Committee recommended to the government that:

11.1 it ensure any warnings on original packaging be transferred to generic packaging when medication is dispensed

11.2 the review of the Medicines Act explore appropriate mechanisms for ensuring that contraindications for pregnancy are clearly displayed on packaging in a way that consumers understand.

Petition of Sarah Teare

12 The Health Committee responded to the petition of Sarah Teare in July 2021. The Committee findings highlighted the need for requiring high levels of communication between a patient and their health professionals when there is a brand switch for epilepsy medication. It was noted that patients should only have their medication switched if the patient was willing, and under close supervision.

13 For medications where expert advice recommends that brand switches only occur under close clinical supervision, the Committee recommended to the government that it ask Pharmac to:

13.1 develop more in-depth protocols for consultation prior to a brand switch occurring

13.2 develop clear guidance on the responsibilities of Pharmac, prescribers, and pharmacists in communicating any proposed changes

13.3 ensure that sufficient time is allowed so that prescribers can discuss changes with individual patients and develop appropriate treatment and monitoring plans before the brand switch occurs

13.4 ensure that information on any proposed changes is communicated not only to prescribers and pharmacists, but also to patients. This should be in a manner that they can clearly understand, including information on the reasons for the change, any possible side effects, and the availability of any funding to assist them to discuss the change with their health practitioner

13.5 ensure that the application process for exceptional circumstances funding is clearly communicated from the outset, not only to prescribers and pharmacists but also to patients; and the criteria are sufficiently broad to allow patients to continue on their current brand, if the patient and their health practitioner believe this is the best clinical option.

Comments on the Health Committee findings and recommendations for both petitions

14 I am conscious that people have been harmed and I take these matters very seriously. I will personally write to both petitioners.

15 I have identified common themes between the Denise Astill and Sarah Teare petitions, particularly for high-risk medicines. There is the need to:

15.1 strengthen communication and consumer information

15.2 clarify the roles and responsibilities for communication between prescribers and pharmacists.

16 The matters raised in the petitions are important and will inform the future of labelling and consumer information. The issues around the lamotrigine brand changes and communication of contraindications for antiepileptic medicines are systemic across the health sector.

17 The Ministry of Health convened a hui on safer person-centred prescribing and dispensing on 6 October 2021 led by the Office of the Chief Clinical Officers. Attendees included, responsible authorities, professional associations and colleges with key prescribing and dispensing roles, Medsafe, ACC, Health and Disability Commissioner, Health Quality and Safety Commission and Pharmac. The hui identified system-level improvements for the next 12 months, including:

17.1 developing a dispensing and prescribing communications framework

17.2 scoping of support for equitable access to clinical pharmacists

17.3 defining processes for sharing risk of harm data

17.4 establishing a prescriber database.

18 A work programme is being progressed to improve communication practices with prescribers and dispensers regarding significant medicine brand changes which include addressing equity.

19 In addition to this work programme, in March 2021, the Ministry of Health met with the Pharmaceutical Society of New Zealand to discuss the impact of transferring warnings on the original packaging to generic packaging when medication is dispensed. It was highlighted that this is a wider issue than a label change alone and that prescribers, dispensers and consumers communication needed to be strengthened.

20 The Parliamentary Counsel Office is drafting the Therapeutic Products Bill (the Bill) and I intend to introduce it to Parliament later this year. The Bill will provide assurance of the safety, quality, and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare. The Bill allows for requirements for labelling and consumer information to be set in Regulations. The requirements set out will help communicate contraindications for medicines to consumers and safety information.

Timing of the government response

21 The government response must be presented to the House as soon as possible.

Consultation

22 The Ministry of Health has consulted with Pharmac on the development of this paper.

Financial implications

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

Publicity

24 I do not intend to make any public statement about this paper, but I do intend to write to the petitioners before tabling the government response in Parliament.

Proactive Release

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

Recommendations

The Minister of Health recommends that the Cabinet Legislation Committee:

1 **note** that on 6 August 2020 the Health Committee presented its report to the House entitled "Petition of Denise Astill—Inquiry into the numbers harmed by antiepileptic medicines during pregnancy"

2 **note** that the Health committee, for the petition of Denise Astill, recommended that the government:

2.1 ensure any warnings on original packaging be also transferred to generic packaging when medication is dispensed

2.2 in the review of the Medicines Act, explore appropriate mechanisms for ensuring that contraindications for pregnancy are clearly displayed on packaging in a way that consumers understand.

3 **note** that on 2 July 2021 the Health Select Committee presented its report to the House entitled "Petition of Sarah Teare for Patient Voice Aotearoa: Publicly continue to fund Lamictal for epilepsy and mental health patients"

4 **note** that the Health Committee, for the petition of Sarah Teare, recommended that the government:

4.1 develop more in-depth protocols for consultation prior to a brand switch occurring

4.2 develop clear guidance on the responsibilities of Pharmac, prescribers, and pharmacists in communicating any proposed changes

4.3 ensure that sufficient time is allowed so that prescribers can discuss changes with individual patients and develop appropriate treatment and monitoring plans before the brand switch occurs

4.4 ensure that information on any proposed changes is communicated not only to prescribers and pharmacists, but also to patients. This should

be in a manner that they can clearly understand, including information on the reasons for the change, any possible side effects, and the availability of any funding to assist them to discuss the change with their health practitioner

4.5 ensure that the application process for exceptional circumstances funding is clearly communicated from the outset, not only to prescribers and pharmacists but also to patients; and the criteria are sufficiently broad to allow patients to continue on their current brand, if the patient and their health practitioner believe this is the best clinical option.

5 **note** the submission of the Minister of Health and in particular his advice that:

5.1 communication of contraindications for antiepileptic medicines is a wider issue than a label change alone. To help ensure consumers are aware of the contraindications for antiepileptic medicines prescribers, dispensers and consumers communication needed to be strengthened

5.2 the Ministry of Health is progressing a work programme with health sector partners, including Pharmac, to improve communication practices with prescribers and pharmacists regarding significant medicine brand changes

5.3 the Ministry of Health is leading a cross-sector work programme for safer person-centred prescribing and dispensing

5.4 the Therapeutic Products Bill will provide assurance of the safety, quality, and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare. The Bill allows for requirements for labelling and consumer information to be set in Regulations.

6 **agree** that for both petitions:

6.1 the communication between prescribers, dispensers and consumers be strengthened to improve consumer knowledge of contraindications of high risk medicines

6.2 labelling and consumer information requirements for contraindications in relation to medicines be considered during development of the new therapeutic products regulatory regime.

7 **approve** the government response, attached to this submission, to the Report of the Health Committee entitled “Petition of Denise Astill—Inquiry into the numbers harmed by antiepileptic medicines during pregnancy” (**Attachment 1**)

8 **approve** the government response, attached to this submission, to the Report of the Health Committee entitled “Petition of Sarah Teare for Patient Voice Aotearoa: Publicly continue to fund Lamictal for epilepsy and mental health patients” (**Attachment 2**)

9 **note** that the government response must be presented to the House as soon as possible

10 **invite** the Minister of Health to present the government response to the House in accordance with Standing Order 252

11 **note** that the Minister of Health will write to the petitioners Denise Astill and Sarah Teare, enclosing a copy of the government response to the report of the Heath Committee on the petitions, before the response has been presented to the House.

Authorised for lodgement

Hon Andrew Little

Minister of Health

Attachments

Attachment 1: Denise Astill Petition for an "Inquiry into the numbers harmed by antiepileptic medicines during pregnancy"

Attachment 2: Sarah Teare Petition for Patient Voice Aotearoa to "Publicly continue to fund Lamictal for epilepsy and mental health patients"

Government Response to
Report of the Health Committee
on
Petition of Denise Astill—Inquiry into the numbers harmed by antiepileptic medicines during pregnancy

Presented to the House of Representatives

In accordance with Standing Order 380

Government response to Report of the Health Committee on Petition of Denise Astill—Inquiry into the numbers harmed by antiepileptic medicines during pregnancy

Introduction

1 The Government has carefully considered the Health Committee's report on the petition by Denise Astill entitled "Inquiry into the numbers harmed by antiepileptic medicines during pregnancy". The Committee recommends that the Government:

1.1 ensure that any warnings on original packaging be also transferred to generic packaging when medication is dispensed.

1.2 the review of the Medicines Act explore appropriate mechanisms for ensuring that contraindications for pregnancy are clearly displayed on packaging in a way that consumers understand.

2 The Government welcomes the Committee's report, which is influencing work the Ministry is undertaking to further improve safe prescribing and safe dispensing, including communications with patients.

3 The Government responds to the report in accordance with Standing Order 380.

4 The Government has taken action on the Committee's recommendations by convening a hui on safer prescribing and safer dispensing on 6 October 2021. However, the Committee's recommendations by nature are long term. The Government proposes to consider the Committee's recommendations throughout the drafting of the Therapeutic Products Bill and in the development of the regulations.

Recommendations and Government response

5 *Recommendation 1:* The Government ensure that any warnings on original packaging be also transferred to generic packaging when medication is dispensed.

6 *Response:* The mechanism that is available in the sector to support inclusion of warning statements on packaging when medicines are dispensed is the Cautionary Advisory Label (CAL) scheme. This scheme is overseen by the Pharmaceutical Society of New Zealand (PSNZ) and is utilised by national systems such as pharmacy dispensing systems.

7 In March 2021, the Ministry of Health (the Ministry) met with PSNZ to explore whether utilisation of the CAL scheme is a practical tool to meet the intent of the Committee's recommendation. Following discussion, it is our view that it would not be possible to achieve a meaningful outcome utilising this

mechanism alone as there is limited space on the label for inclusion of warnings and most medicines have cautions with respect to use in pregnancy.

8 It is our understanding that PSNZ has met with Denise Astill and communicated this limitation of the CAL system.

9 A more constructive approach would be to take steps to improve communication between prescribers, dispensers and consumers about the risks in general about use of medicines in women of childbearing age.

10 Improving risk communication between prescribers, dispensers and consumers on the use of medicines has also been highlighted through the *Petition of Sarah Teare for Patient Voice Aotearoa: Publicly continue to fund Lamictal for epilepsy and mental health patients*. The Ministry convened a hui on safer person-centred prescribing and dispensing on 6 October 2021, as noted in the Sarah Teare Government response. The hui included representative organisations of prescribers and dispensers, including responsible authorities, professional colleges and associations, as well as representatives from Pharmac, the Health Quality and Safety Commission, and Deputy Health and Disability Commissioner Dr Vanessa Caldwell.

11 The safer person-centred prescribing and dispensing hui identified system-level improvements for the next 12 months. System-level actions included developing prescribing and dispensing communications framework, scoping of support for equitable access to clinical pharmacists, defining processes for sharing risk of harm data, and establishing a prescriber database. Attendees agreed these actions were key to improve the quality and safety of prescribing and dispensing.

12 Workstreams for each of those system-level actions have been set up and will be reported quarterly within the Ministry of Health.

13 *Recommendation 2:* The Government in the review of the Medicines Act explore appropriate mechanisms for ensuring that contraindications for pregnancy are clearly displayed on packaging in a way that consumers understand.

14 *Response:* In 2015, Cabinet agreed to repeal and replace the Medicines Act with a new Therapeutic Products Bill [SOC-15-MIN-0049].The Medicines Act is no longer fit-for-purpose and needs to be updated to strengthen and modernise product labelling and consumer information.

15 The Therapeutic Products Bill ensures the safety, quality, and efficacy or performance of therapeutic products, such as medicines, across their lifecycle to protect public health and welfare. In 2018, a draft exposure of the Therapeutics Products Bill was consulted on. There is broad support among stakeholders and a desire for progress and increased certainty.

16 The Ministry acknowledges the importance of having mechanisms in place for the regulator to ensure that when medicine labels are the most appropriate place for communication of contraindications for medicines, it can be

enforced. The Ministry will continue to make patient safety a priority. It will ensure that appropriate regulatory tools have been explored for communication of contraindications in the progression of the Therapeutics Products Bill and later during the development of regulations.

Conclusion

17 This petition, along with the *Petition of Sarah Teare for Patient Voice Aotearoa: Publicly continue to fund Lamictal for epilepsy and mental health patients*, reinforces the need for the Governments role to influence system change to strengthen communication between prescribers, dispensers and consumers, and ensure appropriate mechanisms are in place for safer prescribing and dispensing, including for high-risk medicines.

18 The Government will continue to prioritise patient safety and explore all possible cross-sector mechanisms to ensure the patient is aware of any contraindications for pregnancy with therapeutic products. The Ministry has already taken action by hosting a hui on safer person-centred prescribing and dispensing with long-term workstreams to continuously improve communication processes, and replacing the Medicines Act to update and modernise product labelling and consumer information.

Government Response to
Report of the Health Committee
on
Petition of Sarah Teare for Patient Voice Aotearoa: Publicly continue to fund Lamictal for epilepsy and mental health patients

Presented to the House of Representatives

In accordance with Standing Order 380

Government response to Report of the Health Committee on Petition of Sarah Teare for Patient Voice Aotearoa: Publicly continue to fund Lamictal for epilepsy and mental health patients

Introduction

1 The Government has carefully considered the Health Committee's report on the petition of Sarah Teare for Patient Voice Aotearoa entitled "Publicly continue to fund Lamictal for epilepsy and mental health patients". The Health Committee recommends to the Government that it ask Pharmac to:

1.1 Develop more in-depth protocols for consultation prior to a brand switch occurring.

1.2 Develop clear guidance on the responsibilities of Pharmac, prescribers, and pharmacists in communicating any proposed changes.

1.3 Ensure that sufficient time is allowed so that prescribers can discuss changes with individual patients and develop appropriate treatment and monitoring plans before the brand switch occurs.

1.4 Ensure that information on any proposed changes is communicated not only to prescribers and pharmacists, but also to patients. This should be in a manner that they can clearly understand, including information on the reasons for the change, any possible side effects, and the availability of any funding to assist them to discuss the change with their health practitioner.

1.5 Ensure that the application process for exceptional circumstances funding is clearly communicated from the outset, not only to prescribers and pharmacists but also to patients; and the criteria are sufficiently broad to allow patients to continue on their current brand, if the patient and their health practitioner believe this is the best clinical option.

2 The Government welcomes the Committee's report, and notes that the Ministry of Health (the Ministry) is leading a programme of work to further improve safer person-centred prescribing and dispensing, including communications with consumers.

3 The government responds to the report in accordance with Standing Order 380.

4 The government has considered the concerns outlined in the petition and the recommendations made by the Committee. Work is currently underway at the Ministry and Pharmac, which will address issues and recommendations highlighted in this petition. These actions will also address the issues raised by the Health and Disability Commissioner and recommendations from the Chief Coroner's inquest regarding the lamotrigine sole supply decision.

Recommendations and Government response

5 *Recommendation 1*: Develop more in-depth protocols for consultation prior to a brand switch occurring.

6 *Response:* In June 2020, Pharmac contracted Claro Law to conduct an independent review of their lamotrigine brand change process. While Pharmac did have other interest group advice and engagement, the review identified that that the Consumer Advisory Committee (CAC) could have been consulted at the time of the lamotrigine request for proposal (RFP) to seek consumer input.

7 Pharmac has recently updated terms of reference for their Consumer Advisory Committee (CAC) following public consultation. The updated terms of reference now provide for the option of CAC engagement when considering funding proposals. Alongside other engagement and consultation, Pharmac has recently sought early feedback from the CAC about some proposals prior to the release of the competitive RFP.

8 *Recommendation 2:* Develop clear guidance on the responsibilities of Pharmac, prescribers, and pharmacists in communicating any proposed changes.

9 *Response:* Pharmac has an important role in communicating brand change decisions to prescribers, dispensers, and consumers. Prescribers, dispensers and pharmacists (including those involved in the dispensing of medicines) also have responsibilities in maintaining awareness of brand changes and communicating them when prescribing and dispensing medicines.

10 The Health and Disability Commissioner identified issues around lamotrigine brand changes and information delivery to patients in March 2021. Pharmac continues to improve how to communicate brand changes and how information can be delivered and accessed in timely, consistent and accurate ways.

11 The Ministry has identified these as important system-level issues and is progressing a work programme with health sector partners, including Pharmac, to improve patient communication practices with prescribers and dispensers about medicines, particularly regarding significant medicine brand changes. This aims to clarify the roles and responsibilities for communication between all parties, which is particularly important where changes may involve safety risks to patients.

12 The Ministry has taken steps to improve communication. On 6 October 2021 it convened a hui on safer person-centred prescribing and safer dispensing, which brought together responsible authorities, professional associations and colleges from key prescribing and dispensing roles, Pharmac, Medsafe, Accident Compensation Corporation (ACC), Health and Disability Commissioner (HDC) and Health Quality and Safety Commission (HQSC). This hui sought agreement on how progress can be made to support safer patient outcomes, and best practice communication across the prescribing and

dispensing continuum. These findings have informed an ongoing system-wide work programme led by the Ministry's Office of the Chief Clinical Officers.

13 The importance of the communication between prescribers, dispensers, pharmacists and consumers about the risks in general of medicine use has also been highlighted in the *"Petition of Denise Astill – Inquiry into the numbers harmed by antiepileptic medicines during pregnancy".*

14 *Recommendation 3:* Ensure that sufficient time is allowed so that prescribers can discuss changes with individual patients and develop appropriate treatment and monitoring plans before the brand switch occurs.

15 *Response:* Pharmac seeks advice from its advisory committees and during consultation on proposed transition timeframes to manage any proposed change. Pharmac notifies brand changes well in advance of these occurring, which allows sufficient time for prescribers to discuss changes with individual patients and implement plans before the brand switch occurs. For all brand changes, careful consideration is given to the range and type of initiatives to ensure there is enough time and information to support a change. Where necessary, extra controls and communication processes can be implemented high-risk medicine brand changes for safer prescribing and dispensing.

16 For example, Pharmac includes information on brand changes on the medicine information webpages in the New Zealand Formulary, a comprehensive medicine information source for healthcare professionals.

17 To ensure that information can be delivered and accessed in timely, consistent and accurate ways by prescribers and dispensers, the Data and Digital directorate in the Ministry is progressing a workstream to improve access to better real-time information across health IT systems for those involved with patients in primary care, including prescribers and dispensers.

18 Additionally, Pharmac is also placing more emphasis generally on its media communication as part of building strong public awareness and confidence in its work. This includes providing clinical experts as spokespeople on brand changes.

19 *Recommendation 4:* Ensure that information on any proposed changes is communicated not only to prescribers and pharmacists, but also to patients. This should be in a manner that they can clearly understand, including information on the reasons for the change, any possible side effects, and the availability of any funding to assist them to discuss the change with their health practitioner.

20 *Response:* Pharmac has focused on providing information to support prescribers and pharmacists to have conversations with their patients. This has included funding extra visits with prescribers and brand switch fees. This is to ensure that the consumers are well informed, their needs are being met and are assured of their safety.

21 Pharmac does not have contact details of all patients who may be affected by a brand change and relies on communications through healthcare professionals to support those conversations. Pharmac is part of a wider group of stakeholders who are looking to identify opportunities and improvements to how and when consumers receive information about changes.

22 Pharmac has been working with an IT service provider to run a pilot to support the adalimumab biosimilar introduction, including looking at ways the pharmacist and prescriber IT systems can directly inform patients about the change. Similar interventions worked well during COVID-19 lockdowns to help manage demand for medicines and healthcare services in primary care.

23 *Recommendation 5:* Ensure that the application process for exceptional circumstances funding is clearly communicated from the outset, not only to prescribers and pharmacists but also to patients; and the criteria are sufficiently broad to allow patients to continue on their current brand, if the patient and their health practitioner believe this is the best clinical option.

24 *Response:* Pharmac will ensure that patient information resources include relevant information about exceptional circumstances, and other funding, directly for patients. Other funding could include, for example, implementing a GP co-payment waiver for those who need an extra visit because of the change in brand. Recently Pharmac worked with Parkinsons New Zealand to share information about a GP co-payment waiver directly with patients through their newsletter (related to a discontinuation of the medicine selegiline). Pharmac is also including information about exceptional circumstances for the adalimumab biosimilar introduction.

Conclusion

25 This petition, along with the Denise Astill Petition, reinforces the need to strengthen communication between prescribers, pharmacists and consumers and ensure appropriate mechanisms are in place for safer prescribing and dispensing, including for high-risk medicines.

26 The Government will continue to prioritise patient safety and explore all possible cross-sector mechanisms to ensure the patient is aware of any brand changes with medicines and therapeutic products. The Ministry has already taken action by hosting a hui on safer person-centred prescribing and dispensing with long-term workstreams to continuously improve communication processes, and replacing the Medicines Act to update and modernise product labelling and consumer information.