Aide-Mémoire

Meeting with Foetal Anti-Convulsant Syndrome New Zealand (FACSNZ)

Date due to MO:	12 November 2025	**Date of Meeting:**	13 November 2025
Security level:	IN CONFIDENCE	**Reference:**	H2025074727
To:	Hon Simeon Brown, Minister of Health		
Copy to:			
Consulted:	Health New Zealand: ☐		
Proactive release:	This **title** is proposed by the Ministry of Health for proactive release: ☒		

Contact for telephone discussion

Name	Position	Telephone
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Rosie Moore	Acting Group Manager, Clinical, Quality and Safety, Strategy and Policy	

Author: Rosie Moore, Acting Group Manager, Clinical, Quality and Safety, Strategy and Policy

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Meeting with FACSNZ

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About the Meeting

Purpose of Meeting: FACSNZ requested the meeting to discuss their request of a public inquiry for all people affected by antiseizure medicines during pregnancy in New Zealand.

Details of Meeting:
Date: Thursday 13 November
Time: 9.00am – 9.20am
Venue: EW 6.6

Attendees

Denise Astill ONZM (for services to the prevention of foetal anticonvulsant syndromes), Executive Officer FACSNZ: Denise has lived experience of FACS, with twin daughters diagnosed at 4½ years old. FACS NZ aims to provide support, education, and awareness, leading to prevention of Foetal Anti-Convulsant Syndrome.

Jacki Morris, Chairperson FACSNZ: Jacki was diagnosed with epilepsy at the age of 7. Jacki is extremely passionate about all those of childbearing potential being given informed consent and informed choice around antiepileptic medicines in pregnancy.

Organisation

The organisation FACSNZ was formed to help families affected by foetal anticonvulsant syndrome. Their vision is for:

> Every person of childbearing potential who is on seizure controlling medicine(s) to have the necessary information to give informed consent and make an informed choice.

People who have been exposed to antiseizure medicine(s) during pregnancy and adversely affected can lead a life where they can reach their own potential.

Ministry representatives

Dr Joe Bourne, Chief Medical Officer
Billy Allan, Clinical Chief Advisor, Medicines

Background and context

1. FACSNZ have requested this meeting to explore with you the possibility of holding a public inquiry for all people affected by antiseizure medicines during pregnancy in New Zealand.

2. Foetal Anti-Convulsant Syndrome (FACS) can occur when antiseizure medicine (previously referred to as anticonvulsant medicines) is taken by women during pregnancy resulting in physical malformations and/or neurodevelopmental or cognitive impairment in the child. FACSNZ is an organisation that supports and advocates for children, parents and whānau whose lives have been impacted by FACS.

3. There have been several system changes in recent years to mitigate and inform about the risk of FACS **(see Appendix 1)** in response to the recognition of harm. Based on national pharmaceutical and maternity collections data, the risk of exposure to sodium valproate (the highest risk antiseizure medicine) in pregnancy has decreased over the past 18 years (124 pregnancies exposed in 2007 compared to 7 in 2024). Of the 7 pregnancy exposures in 2024, 2 children have been diagnosed with a congenital condition.

4. Uncontrolled epilepsy during pregnancy also presents a significant risk to the mother and the unborn child. Clinicians must balance the potential risks of antiseizure medicines to the unborn child against the risks of uncontrolled epilepsy and consider ways to reduce risk, including adjustments to medicines. It is important that women taking antiseizure medicines are provided information from their health professional to understand that the nature of these risks and for informed consent. Stopping antiseizure medicine without prior discussion with a health professional poses a significant risk to the mother and unborn child due to the risk of seizures and is not advised.

5. You met with FACSNZ previously on:

    a. 3 April 2025 [H2025064177 refers] at their request and the outcome was to progress three actions:

        i. Packaging and labelling options for antiseizure medicines

        b. Advice on restorative approaches for FACS NZ

        i. Publication of the Systems Thinking Analysis to Prevent Foetal Anticonvulsant Syndrome report

    c. Monday 14 July 2025 (WR item 5.2.1 week commencing 7 July 2025) to confirm the requirements for the publication of the report.

6. Following your meeting with FACSNZ in April, further briefings were provided to you on packaging and labelling options [H20250605021 refers] and restorative approaches [H2025065029 refers].

7. The Ministry of Health (the Ministry), the Accident Compensation Commission (ACC) and the Health Quality and Safety Commission (HQSC) are actively working with FACSNZ to

continue to reduce the risk of harm. Updates on the actions underway are provided in **Appendix 2**.

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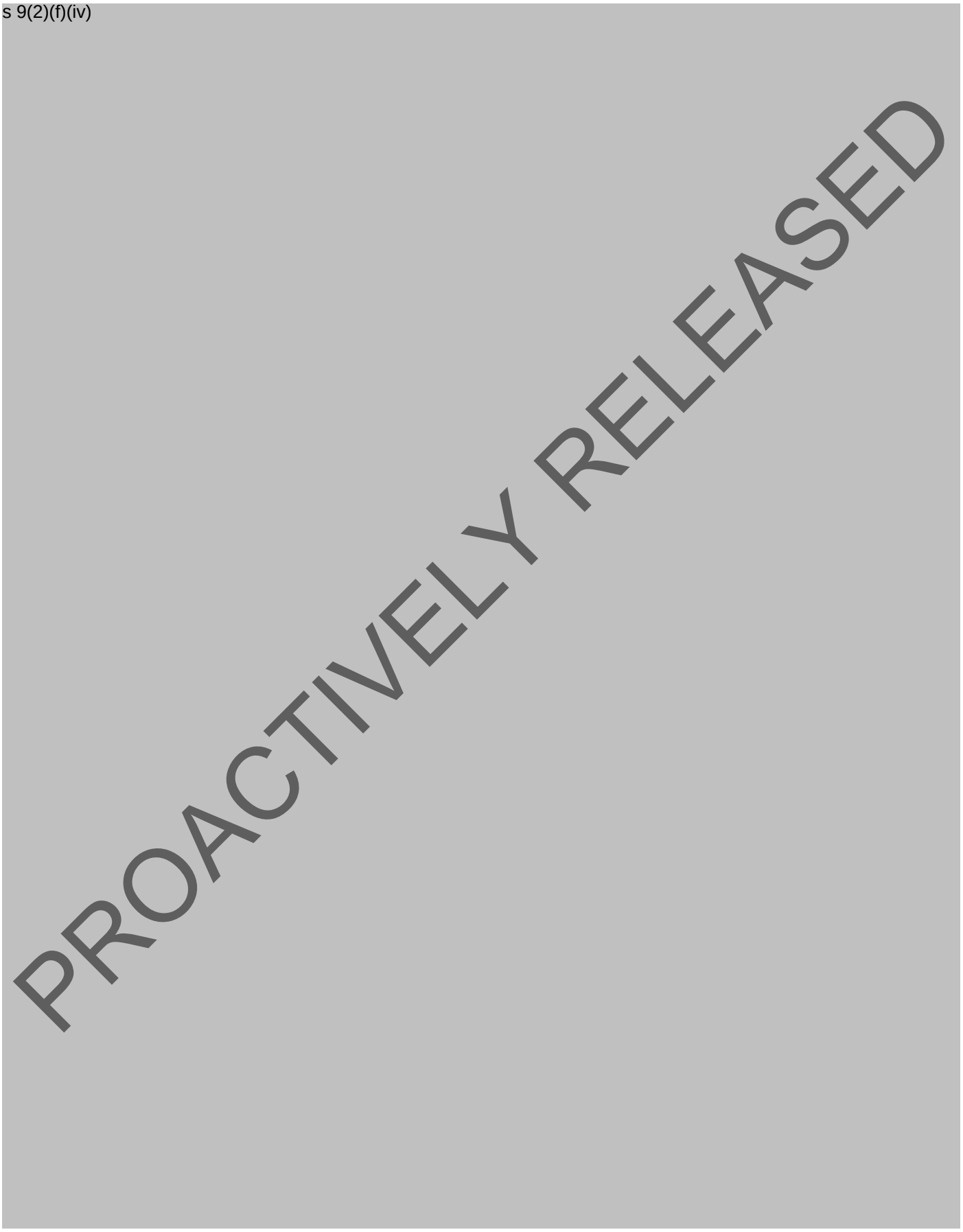

Risk of harm from antiseizure medicines is reducing due to collective effort across the health system

13. Risk of harm from antiseizure medicines has been reducing over the past 18 years because of actions taken across the health system.

14. Table 2 below outlines the pregnancies exposed to the red list[2] antiseizure medicines. It shows that there has been a reduction in the number of pregnancies exposed to the red list antiseizure medicines in most cases.

Table 2: Pregnancies exposed to red list' antiseizure medicines, from the Pharmaceutical Collection

Red Listed Medicine (Anticonvulsant)	Pregnancies exposed to the medicine		Total Pregnancies exposed to the medicine (2007 – 2023)	Total known congenital conditions for live births (since 2009)
	2007	2023		
carbamazepine	130	30	1,170	58
sodium valproate	124	9	903	59
phenytoin	18	0	103	5
topiramate	7	37	425	39
ethosuximide	0	0	0	0
phenobarbitone	1	0	9	1
oxycarbazepine	Not funded in New Zealand – data not available			
primidone	No pregnancies exposed			

15. There has been a small increase in exposures for topiramate. This will continue to be monitored by the Ministry and Medsafe. On 1 April 2025, Johnson & Johnson the sponsor for Topamax (topiramate) issued a 'Dear Healthcare Professional' letter announcing new restrictions to prevent exposure during pregnancy.[3]

16. As you are aware, there are three main initiatives in train to continue to reduce the risk of harm from antiseizure medicines:

    a. Development of a Cautionary Advisory Label (CAL) for the red list antiseizure medicines

    b. FACS communications campaign to raise awareness of FACS among health professionals and the public in partnership with FACSNZ

    c. Publication of the FACS Human Factors report

[2] Red coded antiseizure medicines are antiseizure medicines with an increased risk of birth defects, highlighted in red in the Medsafe publication 'Epilepsy medicines and pregnancy', January 2025. These are carbamazepine, ethosuximide, oxcarbazepine, phenobarbitone, phenytoin, primidone, sodium valproate and topiramate.

URL: medsafe.govt.nz/Consumers/educational-material/Epilepsy-medicines-and-pregnancy.pdf

[3] https://www.medsafe.govt.nz/safety/DHCPLetters/TopamaxApril2025.pdf.

17. An update on progress for each of these initiatives can be found in **Appendix 2**.

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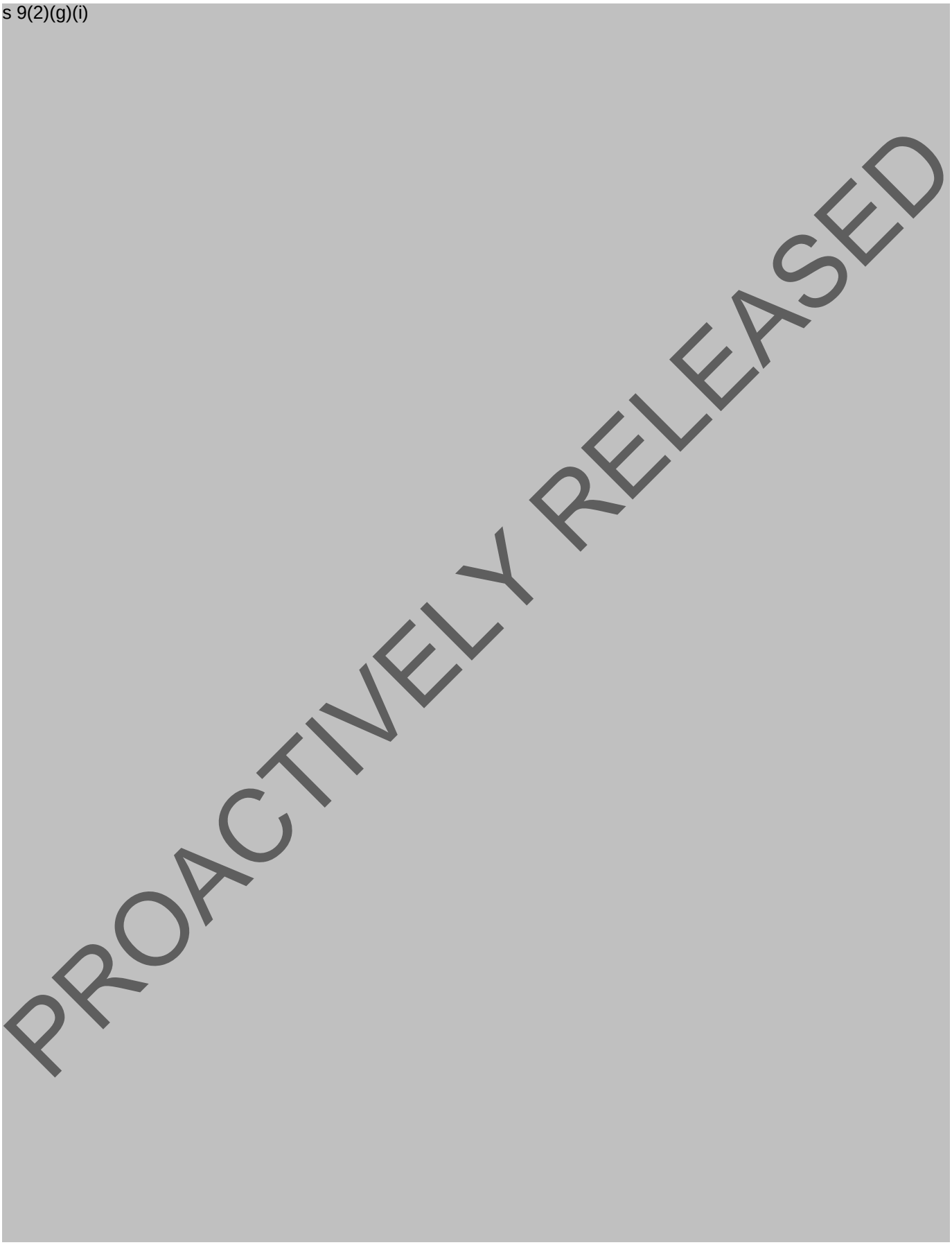

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[redacted]

Dr Joe Bourne
Chief Medical Officer
Strategy and Policy

Appendix 1

System changes in recent years (up to 2024) to mitigate and inform about the risk of Foetal Anti-Convulsant Syndrome (FACS)

Agency	Action
Cross-Agency	• The National Medicines Steering Group has been convened by Manatū Hauora since March 2023. The group now oversees the FACS action plan (actions following the Human Factors report). • A cross-sector Safer Prescribing and Dispensing Programme was established following the independent report into Pharmac, Health Select Committee and coronial inquiry • Cross-sector work to identify how to improve the consistency of informed consent.
HQSC	• Commissioned the systemic analysis of teratogenic medicines. • Have held cross-sector hui to understand the problem and identify solutions. • Worked across the sector to reduce harm.
Starship Guidelines Group	• A clinical guideline to support clinicians' paediatric assessment of FACS published on the Starship Hospital's website October 2023.
Medsafe	• Epilim was contraindicated in pregnancy in a data sheet update in 2005 and has had subsequent updates over time. • Warnings on packaging and blister packs were added for Epilim (sodium valproate). • *Prescriber Update* articles in 2009, 2013, 2014, 2021. • Safety communications in 2015, 2019, 2023. • A 2-page information sheet for consumers with risk comparison table on medicines. • Ongoing safety alerts as required
Digital tools	• A range of tools have been developed to support clinicians. For example, reCare have an Event Detection and Mitigation tool within the electronic health record system Conporto, which is used by a majority of primary care practices and most pharmacies (917 of approximately 1,000 pharmacies). This tool flags sodium valproate prescription for females aged 10-59 years to the prescriber and the dispenser, resulting in the interception of 500-600 events per day with close to 100% addressed before dispensing.
ACC	• A cross-agency group convened by ACC resulted in the publication of two brochures: 1. For patients and their whānau: 'Medicines for epilepsy, mental health, and pain can harm your unborn baby'[4] 2. For healthcare professionals: 'Benefits and risks of taking antiseizure medicines for epilepsy, mental health, or pain',[5] for healthcare professionals to discuss with anyone who could get pregnant. This brochure is available on Health Pathways. • ACC has created guidance for injuries related to FACS (2019).[6]

[4] https://www.acc.co.nz/assets/provider/medicines-epilepsy-mental-health-pain-harm-unborn-baby-acc7810.pdf
[5] https://www.acc.co.nz/assets/provider/benefits-risks-anti-seizure-medicines-epilepsy-mental-health-pain-acc7809.pdf
[6] https://www.acc.co.nz/assets/im-injured/acc8204-guide-facs-info-clients.pdf

Appendix 2

Progress on 2025 initiatives

Progress on development of the Cautionary Advisory Label (CAL)

The CAL is to highlight antiseizure medicines at a high risk of causing harm to the unborn child and during breast feeding. Key points are:

- To operationalise the CAL a notification, or prompt, needs to be enabled through the pharmacy practice management systems. This is enabled through the NZ Formulary (NZF).
- Digital systems need to be updated to enable the CAL and it is estimated that this ordinarily take 12 months to resolve. The CAL will initially be used on the eight 'red' high-risk antiseizure medicines (based on known highest risk of foetal harm), and extended to other medicines that can cause foetal harm, once the operational issues within NZF and vendor systems are resolved.
- Working with the dominant private pharmacy management system vendor who are already progressing existing development commitments (including enablement of 12-month prescriptions and the attention-deficit hyperactivity disorder medicine changes from 1 February 2026) they have indicated that they can implement the FACS CAL by April 2026.
- The CAL will be available in two formats:
    - A paper CAL label attached to the dispensed medicines.

    - An electronic version with the text printed on the dispensing label (without the infographic).
- Development and distribution of the paper label will be funded in part by ACC.

CAL development timeline

Activity	Completion date
Confirmation of the identification and wording for the electronic CAL	31 October 2025
Development of communications and frequently asked questions	30 November 2025
Confirm the distribution plan for the paper CAL	30 November 2025
NZF test data API to enable pharmacy management system integration testing	1 February 2026
Communications to pharmacies, prescribers, and consumers	March 2026
Distribution of the paper CAL to pharmacies	March 2026
Go live with the new FACS CAL paper and electronic	April 2026

FACS Communication Campaign

Within a funding agreement with ACC, the Ministry has also developed communication materials to raise awareness of FACS among health professionals and the public in partnership with FACSNZ. A series of videos and educational products will be launched in November 2025.

Activity	Active	Comment
Goodfellow Unit – Clinical Gem: Topiramate, and other 'red list'/high risk antiseizure medicines and foetal harm	2 July 2025	Over 30,000 opened the email
Goodfellow Unit – Podcast: Foetal Anti-Convulsant Syndrome	3 September 2025	with over 1,400 views
Healthify.nz - updates to the Foetal Anti-Convulsant information on Healthify website	September 2025	
Communication project. Three videos and an animation codesigned with FACSNZ and people with lived experience.	November 2025	Date to be confirmed
Pharmacy Today – The Ministry will use its regular column to communicate its work on FACS to the sector, including progress on the development of the CAL	November 2025	

FACS Human Factors Report

The Health Quality and Safety Commission (HQSC) have been working with FACSNZ to review the existing Human Factors Report considering the reformed health system and the actions that have already been progressed. Engagement with key stakeholders on the report has been completed and the revised report is being drafted. HQSC will provide a more detailed update in their weekly report next week.