Independent review of the *Systems Thinking Analysis Report on Fetal Anticonvulsant Syndrome*Final report for publication

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ALLEN + CLARKE CONSULTING

Contents

1 Introduction

Some medicines have teratogenic side-effects, which increase the risk that a baby will be born with physical malformations or experience developmental delays. This includes sodium valproate and other anti-seizure medicines which increase the risk of fetal anticonvulsant syndrome (FACS). Safe prescribing of medicines in pregnancy provides benefits to the child, the family, and the community and recognises duties of care towards patients. There is consensus that preventing any medicine-related harm in pregnancy is important, that a systems approach is valuable, and that agencies have a role to play in continuing to reduce harm from medicines with teratogenic properties.

In 2021, the Health Quality & Safety Commission Te Tāhū Hauora (HQSC) commissioned HFEx to prepare an independent systems thinking analysis on the prevention of FACS in New Zealand Aotearoa (the *Systems Thinking Analysis* report). Work to prepare the *System Thinking Analysis* report (and subsequent amendments to drafts made in 2022 and 2023) occurred when the health sector and community were responding to the Covid-19 virus and while the health sector transformation was in design and early-stage implementation. *Allen + Clarke* would like to acknowledge the independence of work completed by HFEx.

Since 2023, much has changed in the health sector including structures and operational priorities, with new activities to address potential harm from medicines used in pregnancy are underway. Some activities mentioned in the *Systems Thinking Analysis* have been completed or discontinued.

Key stakeholders continue to disagree about whether there is one *Systems Thinking Analysis* report (with a draft and a final version) or two distinct reports. Different views are also held about the allocated agency Responsibilities and the translation of the report's recommendations to actions. Supporting a report that accurately allocated Responsibilities was the focus of agency feedback to 2023, rather than altering the recommendations or other parts of the draft *Systems Thinking Analysis* report. In addition, not every agency contributed to a review process, with Health NZ not existing in at that time.

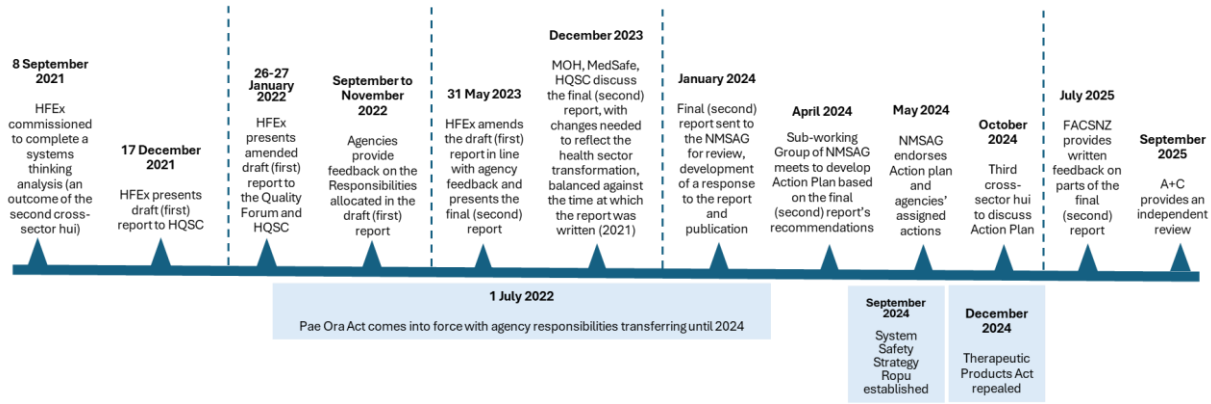
HQSC engaged *Allen + Clarke* to undertake an independent review of both *Systems Thinking Analysis* reports and to assess the feasibility of the Responsibilities and recommendations presented. This process should support future-focused action to continue to actively address opportunities to reduce harm from teratogenic medicines.

2 Method

The HFEx used a Systems Theoretic Process Analysis (STPA) to assess the management of medicines with teratogenic effects with a view to identifying opportunities for improvement and potential threats to safe medication administration. This involved interviewing 19 stakeholders during late 2021 (when the health sector was responding to the COVID-19 pandemic), completing the STPA analysis, allocating responsibilities for government agencies, and making recommendations to improve the overall management of teratogenic medicines.

The timeline in Graphic 1 summarises the key steps in the development of the *Systems Thinking Analysis* report and the consideration of its recommendations and allocated Responsibilities. This image also includes other influential sector-wide events, most of which occurred after the presentation of the final report.

Graphic 1: Timeline of activities



Allen + Clarke's methodology is summarised in Graphic 2. We reviewed both iterations of the *Systems Thinking Analysis* report and consider it reasonable to expect that commissioned reports are presented in draft and final. As such, our assessment and findings are focused on the final *Systems Thinking Analysis* report only.

Graphic 2: *Allen + Clarke*'s methodology

3 Findings

The *Systems Thinking Report* describes 11 systems constraints. Most constraints relate to supporting informed decision-making and consent for health care professionals, consumers, or both, or they are non-specific. Other constraints relate to data creation or sharing, and a few relate to individual and systems-level tracking of medicine use or adverse reactions monitoring. The systems constraints are used to allocate Responsibilities to government agencies. Often, agencies do not have jurisdiction for implementation of the allocated Responsibility, especially when the constraint to be addressed focused on informed decision-making occurring within the patient – health practitioner relationship. Agencies may play a role in creating environments and systems that support education and decision-making, but they do not provide personalised clinical advice. This means some of the Responsibilities as allocated in the *Systems Thinking Analysis* report are not possible for an agency to deliver, if the intention is to address the system constraint in a meaningful manner.

The *Systems Thinking Analysis* report allocates Responsibilities to a single agency, even when other agencies may also have a leadership role or when leadership by a single agency is unclear. In some instances, wording may place unachievable expectations on agencies. This approach does not reflect the health system's complexity and could introduce instances of agency over-reach especially in relation to the provision of health consumer advice and informed decision-making. A single agency approach also misses opportunities to embed the cross-agency approaches needed to deliver high-quality health care.

To be achievable, meaningful actions to reduce medicine-related harm in pregnancy need to align accountability (rather than Responsibility) to agency mandate, with agencies deciding on work programmes in line with Government priorities and direction. Some allocated Responsibilities are simply not feasible or place unrealistic expectations on agencies; other Responsibilities have been superseded. To support future action to prevent harm, context for each Responsibility is described in Table 1.

Table 1: Assessment of *Systems Thinking Analysis* Responsibilities

Responsibility (HFEx final report)	Context to support understanding	Summary
The Ministry of Health, Medsafe and the Centre for Adverse Reactions Monitoring The Ministry of Health is steward of the health system. Medsafe is New Zealand's medicines regulator and it is a business unit of the Ministry. CARM services are managed under contract to Medsafe. The *Systems Thinking Analysis* presents these as separate entities (R2, R7 and R10 series), which does not reflect the agency's functions.		
R2.1: Provide coherent policy and practice guidelines to other entities (SC1, SC2, SC7). *System constraints relate to informed decision-making or data sharing*	This Responsibility is vague. Responsibility is system-wide and likely belongs to more than one agency (including those outside of government). Allocation of leadership depends on the information being supplied, to whom it is delivered, and the mechanism by which it is provided. Examples include the National Quality Forum, HealthPathways, professional colleges, and NZ Formulary.	No single agency has the mandate for delivering this Responsibility.

Responsibility (HFEx final report)	Context to support understanding	Summary
R2.2: Identify and set achievable targets relevant to the management of teratogenic medicines. (SC8, SC10) *System constraints relate to tracking medication use or adverse reactions monitoring and informed consent*	Many medicines have teratogenic properties. It is unclear what targets would be appropriate as the *Systems Analysis Thinking* report did not canvas the wide range of medicine management aspects that could contribute to harm (beyond informed consent, data, and reporting). Aggregated data on community prescribing, some hospital dispensing data, and some unfunded (private) prescriptions is available, but there is no nationwide electronic prescribing record available. The accuracy of available data depends on accurate medical coding. There are no systems-level mechanisms to collect "without consent" data. There are mechanisms for reporting harm (CARM reports and, in some cases, ACC if an injury claim is accepted), but this is not 'real-time' (due to delay between fetal exposure and a diagnosis related to a medicine with teratogenic properties). Rather than developing targets, it may be valuable to build reporting improvements on fetal harm following medicine use into an updated Action Plan.	To make this Responsibility feasible, consider whether activities to improve tracking of medications use can be progressed through an updated Action Plan, including allocation of Responsibility.
R2.3: Provide adequate funding to agencies to achieve targets relevant to the management of teratogenic medicines. (SC1) *System constraint relates to data sharing*	Funding decisions about health care are not made by the Ministry of Health alone. It is unclear if there is a funding gap related to the management of medicine use and harm reduction in pregnancy or to having sufficient funding to achieve outcomes. Allocation of leadership depends on the funding decisions to be made. The system constraint relates to the provision of alerts and guidance. Alerts and guidance are provided by a range of agencies and providers.	No single agency has the mandate for delivering this Responsibility.
R2.4: Ensure reporting (such as agency reports or data analysis from relevant IT systems) enables the Ministry to operate in a manner that meets the needs of the consumer. (SC8, SC9, SC10) *System constraints relate to data sharing, tracking medication use, or adverse reactions monitoring, and informed consent*	The health system should ensure consumer care remains a core purpose of reporting. Efforts to modernise and develop data and digital standards and systems are underway at Health NZ, but some functionality is not yet in place. The timeframe to completion is uncertain. Championing reporting improvements could be built into an updated Action Plan with clarity provided on the activities most likely to support harm reduction, which agencies should participate, and agreement from those agencies regarding priority and implementation.	Consider whether activities to improve reporting can be progressed through an updated Action Plan, noting that feasibility and Responsibility will be determined by agency priorities.

Responsibility (HFEx final report)	Context to support understanding	Summary
R2.5: Drive legislative change in accordance with consumers' personal and cultural needs. (SC3, SC6) *System constraints relate to informed decision-making or data sharing*	Overall, responsibility for legislative change sits with the Government (not agencies). Developing policy advice on medicines regulation is a function of the Ministry. Medsafe can provide technical advice to inform this policy. Existing mechanisms support inclusion of consumer views in policy and legislative processes. The scope of anticipated legislative changes is not clear. The systems constraints relate to consumer knowledge about their medicines and data sharing between layers of the health sector. A national individual health record is not available to support data sharing. People can already access information about pregnancy and medicines via a range of sources, including personalised advice from the prescriber, Healthify, via datasheets, consumer medicines information, or through the NZ Formulary. Provision of general consumer information belongs to more than one agency.	It is not feasible for the Ministry of Health to lead this Responsibility; however, it has a role in providing policy advice to the Government should additional legislative changes be required.
R2.6: Respond to requests on pressing issues associated with consumer risk and safety. (SC9, SC10) *System constraints relate to data sharing, tracking medication use, or adverse reactions monitoring, and informed consent*	Responsibility for identifying and addressing consumer risk and safety issues belongs to different agencies or providers depending on the underlying problem to be addressed.	This is feasible as a cross-agency Responsibility (rather than being a Responsibility for the Ministry of Health alone).
R2.7: Make relevant information concerning teratogenic medicines and FACS prevention accessible by ensuring all relevant agencies are providing the same messages. (SC1, SC3, SC4, SC7) *System constraints relate to informed decision-making or data sharing*	This Responsibility belongs to more than one agency. Allocation of leadership depends on the information needed and being supplied, to whom it is delivered, and the mechanism by which it is provided. Ongoing cross-sector collaboration should continue to consider if there are inconsistent messages on fetal harm following medicine use and address any inconsistencies if identified.	This is feasible as a cross-agency Responsibility (rather than being a Responsibility for the Ministry of Health alone).
R2.8: Openly share information to all other entities concerning FACS prevention to support collaboration across all groups – both professional and consumer. (SC1, SC2, SC3, SC4, SC7, SC8, SC9, SC10) *System constraints relate to informed decision-making, data sharing, tracking use, or adverse reactions monitoring*	Responsibility for cross-agency collaboration to prevent medicine harm involves multiple agencies and providers. A single responsibility for agencies to collaborate and share information could be appropriate but it is not clear exactly where there are issues compared with identifying collaboration as a good practice for a health system.	This is feasible as a cross-agency Responsibility.

Responsibility (HFEx final report)	Context to support understanding	Summary
R2.9: Review current reports from IT systems to they meet the needs of the Ministry and provide the ability to report on consumer-driven OIA requests associated with FACS prevention. (SC3, SC8, SC10, SC11) *System constraints relate to informed decision-making, tracking medication use, or adverse reactions monitoring*	This Responsibility belongs to multiple agencies. Allocation depends on the information requested and the IT system. Reframing to reflect that information about FACS prevention should be easily available across the systems may help to progress efforts (rather than relying on OIA requests). Efforts to modernise data and digital standards and systems are underway at Health NZ but fundamental digital systems (including a national electronic patient record) are not yet in place. This may affect short-term implementation and championing reporting improvements could be built into an updated Action Plan.	Consider whether activities to improve reporting can be progressed through an updated Action Plan, noting that feasibility will be determined by agency priorities and areas of responsibility.
R2.10: All dispensing point-of-sale systems (two in existence at the time of this report) should have an API28 that feeds relevant information to the Ministry about dispensing teratogenic medicines. (SC3, SC8) *System constraints relate to informed decision-making, tracking medication use, or adverse reactions monitoring*	Available point-of-sales systems are provided by two private companies. Many medicines have teratogenic properties. Health NZ provides aggregated dispensing data via the National Pharmaceutical Collection. Information about dispensed funded and unfunded prescriptions is publicly available through the pharmaceutical data web tool or the medicines data repository. Health NZ has access to hospital dispensing data from its facilities (but not for trust-owned or private hospitals).	It is not feasible for the Ministry of Health to lead this Responsibility.
R2.11: The dispensing point-of-sale systems (two in existence at the time of writing this report) should provide data that meet or exceed the Ministry's reporting needs. (SC3, SC8) *System constraints relate to informed decision-making, tracking medication use, or adverse reactions monitoring*	Available point-of-sales systems are provided by two private companies. Health NZ provides aggregated dispensing data via the National Pharmaceutical Collection. Information about dispensed funded and unfunded prescriptions is publicly available through the pharmaceutical data web tool or the medicines data repository. Health NZ has access to hospital dispensing data from its facilities (but not for trust-owned or private hospitals).	It is not feasible for the Ministry of Health to lead this Responsibility. At an agency level, it makes more sense for this Responsibility to sit with Health NZ.
R7.1: Provide input into new legislation designed to strengthen the regulation of therapeutic products in NZ. (SC4, SC9) *System constraints relate to informed decision-making and data sharing*	Legislative change is led by the Government, but the Responsibility is appropriate for the Ministry of Health because developing policy advice on medicines regulation is a key function. Medsafe can contribute technical advice. There is opportunity to contribute to legislative change through new therapeutic products legislation	This Responsibility is appropriate for the Ministry of Health. Legislative amendment analysis could be built into a new published Action Plan (to be agreed by all parties).

Responsibility (HFEx final report)	Context to support understanding	Summary
R7.2: Proactively work with consumer groups to develop innovative safety messaging for teratogenic properties of medication. (SC3) *System constraint relates to informed decision-making*	Medsafe is a product regulator. While consumers input into a range of processes under the Medicines Act, Medsafe as the administrator of the Act and associated regulations is not a consumer-facing entity. The Medicines Act does not require pharmaceutical companies to provide consumer medicines information. Any requests for NZ market specific information must be negotiated with the company. The system constraint is about informed decision-making and the prescriber is the main party responsible for supporting that process with the consumer and balancing individual benefit and risk. General consumer information about health conditions and medicines is the remit of Healthify, a trust-based charitable organisation.	It is not feasible for the Ministry of Health to lead this Responsibility, but its activities are limited by the Medicines Act 1981 and associated regulations.
R7.3: Ensure close communications with CARM continues and identify opportunities to continuously improve communications which may (if appropriate) include responding to any enquiries. (SC9, SC11) *System constraints relate to informed decision-making and data sharing*	CARM reports are supplied directly to Medsafe, and Medsafe and CARM work closely together. Responsibility for collaborating and supporting cross-agency work sits across the involved agencies. Informed decision-making sits within the practitioner – patient relationship.	This Responsibility is appropriate for the Ministry of Health.
R7.4: Enable healthcare professionals to subscribe to MedSafe communications to receive important updates. (SC10) *System constraint relates to tracking medication use, or adverse reactions monitoring and informed decision-making*	Health practitioners can subscribe to a range of publications and updates that advise on medicine safety issues, including from the Ministry. The Ministry of Health cannot compel health practitioners to subscribe to or read these alerts.	This Responsibility is appropriate for the Ministry of Health, but health practitioner regulatory bodies and providers also have a role.
R7.5: Given Medsafe is a regulator of the therapeutic products industry, ensure the datasheets continuously meet the needs of healthcare professionals. (SC4) *System constraint relates to informed decision-making*	A datasheet provides comprehensive technical specifications, features, and performance data for a medicine. Health practitioners and consumers can use this to inform decisions. Datasheets are supplied by the manufacturer. Medsafe, as the product regulator, can provide guidance on the information that it thinks is necessary, but pharmaceutical companies cannot be compelled to deliver bespoke information (the Medicines Act does not allow for this to happen). To ensure that datasheets are accurate and comprehensive, New Zealand follows European market template rules.	This Responsibility is appropriate for the Ministry of Health, but its activities are limited by the Medicines Act 1981.

Responsibility (HFEx final report)	Context to support understanding	Summary
R7.6: Share data on adverse reactions with other agencies and consumers as appropriate. (SC8, SC10) *System constraints relate tracking medication use, or adverse reactions monitoring and informed decision-making*	Reporting of adverse reactions and monitoring involves different parties depending on when and where an adverse reaction occurs or where in the system an individual makes a complaint. An adverse reaction could be identified at the point of care and reported through primary care or Health NZ systems; a person could make a complaint through the CARM system, to the Health and Disability Commissioner or it could be identified through an ACC claim (if informed consent had not been provided at the time of prescription/administration). Data on adverse reactions is available through some of these mechanisms. Informed consent is most likely to be reported in individual patient or case notes and there is no national system that consistently and comprehensively captures information about informed consent. There is no national patient record, meaning there is limited opportunity to review data at an individual or systems level. Championing reporting improvements could be built into an updated Action Plan with clarity provided on the activities most likely to support harm reduction, which agencies should participate, and agreement from those agencies regarding priority and implementation.	Consider whether activities to improve reporting can be progressed through an updated Action Plan, noting that feasibility will be determined by agency priorities.
R10.1: Ensure it is easy for a consumer to submit an adverse reaction report. (SC11) *System constraint relates to informed decision-making*	Adverse reactions are now reported through the Medsafe website (or via email). It is easy to locate this information and to complete a form, but adverse reactions generally cover the pregnant person not a fetus.	This Responsibility is appropriate for the Ministry of Health.
R10.2: Change CARM's website URL to something more consumer friendly instead of nzphvc.otago.ac.nz/carm/. (SC11) *System constraint relates to informed decision-making*	The University of Otago URL is no longer active as the service is now hosted on the Medsafe website. It is easy to locate reporting how-to information and to complete a form.	This Responsibility is now redundant.
R10.3: Provide publications focusing on the medication and not just the service. (SC9) *System constraint relates to data sharing*	Deidentified information from the NZ Pharmacovigilance database is available on Medsafe's website. Reports are retrospective and do not focus on fetal harm (that is, the adverse reaction relates to the person taking the medicine).	Consider whether activities to improve reporting can be progressed through an updated Action Plan, noting that feasibility will be determined by agency priorities.

Responsibility (HFEx final report)	Context to support understanding	Summary
HQSC		
R3.1: Bring together agencies to focus on specific issues around FACS prevention and the prescribing of teratogenic medicine. (SC2) *System constraint relates to informed decision-making*	This Responsibility reflects completed and ongoing activities including cross-sector hui, engaging with the National Medicines Steering Group, the National Medicines Safety Advisory Group, and funding the New Zealand College of Midwives to develop an e-learning module. Consumer representation is included, but this is not specific to FACS.	This Responsibility is appropriate for the HQSC and is underway.
R3.2: Become the safety and quality centre of messaging associated with teratogenic medicines and FACS prevention. (SC3) *System constraint relates to informed decision-making*	This Responsibility now aligns to the role of the National Medicines Steering Group, which is convened by the Ministry of Health. Health NZ also plays a role via the Medicines Global Governance Group. Consumer representation is included, but this is not specific to FACS.	This Responsibility is appropriate for the Ministry of Health.
R3.3: Conduct a gaps analysis of opportunities to make better use of soft intelligence (the provision of information across agencies that raises awareness) of ongoing issues, helping the healthcare system to become more responsive. (SC4, SC6, SC8) *System constraints relate to informed decision-making, tracking medication use, or adverse reactions monitoring*	This Responsibility is allocated accurately but the text could reference the role of the National Quality Forum for greater accuracy.	This Responsibility is appropriate for the HQSC.
R3.4: Regularly review events where a lack of knowledge about teratogenic medicines was a factor for either prescribing health specialists or consumers. (SC2, SC4, SC7) *System constraints relate to informed decision-making*	Overall responsibility is related to where the child comes into contact with the system. For example, the Severity Assessment Code (SAC) rating and triage tool requires reporting of SAC 1 and SAC 2 events to the HQSC, but it receives few direct notifications of harm. ACC may have better oversight of individual events and of overall incidence of SAC 1/2 events, but its data only covers claims lodged with ACC and reviewed. Informed consent is a claim criterion, meaning that some anticipated harm may not be covered (therefore reviewed and counted). On average, a child is nine years old before an injury claim for FACS is made. This Responsibility could stay with HQSC but engagement with ACC is also of value.	This is a feasible Responsibility, but no single agency has the mandate for delivering this Responsibility.
ACC		
R8.1: Ensure the requirements for future Conporto projects are user-centric (meet the needs of healthcare practitioners). (SC2, SC4) *System constraints relate to informed decision-making*	Conporto was a pilot program, and funding has not been continued.	This Responsibility is redundant.

Responsibility (HFEx final report)	Context to support understanding	Summary
R8.2: Work closely with HQSC to identify synergies and areas where overlaps may occur to make best use of each agency's time, capabilities and skillsets. (SC9) *System constraint relates to data sharing*	This Responsibility belongs to more than one agency and is generally vague. Allocation of leadership depends on which agencies are collaborating and agreed cross-sector work programmes.	This is feasible as a cross-agency Responsibility.
R8.3: Proactively reach out to healthcare professionals about their consumers who are on teratogenic medicines with a view to encouraging transferring those consumers to safer alternatives. (SC1, SC2, SC6, SC7) *System constraints relate to informed decision-making and data sharing*	Determining which medication an individual should take (or when or for how long) falls within the scope of the health practitioner – patient relationship. Detailed prescribing information is most likely to be held in an individual's health records (of which there could be several as there is no single national patient record).	This is not a feasible Responsibility for ACC.
R8.4: Proactively reach out to healthcare professionals concerning their consumers to ensure a discussion occurs around ensuring informed consent has taken place and what that discussion looked like. (SC2) *System constraint relates to informed decision-making*	This is not a feasible Responsibility. Informed decision-making occurs between health practitioners and patients. Care is governed by training and advice from organisations like the Medical Council, the Health and Disability Commissioner, the code of rights, etc. Health NZ is developing a policy on informed consent (ongoing). Privacy needs to be considered (who holds a conversation if not the health practitioner?).	This is not a feasible Responsibility for ACC.
Responsibilities allocated to district health boards District health boards have been disestablished with services now offered by Health NZ. Health NZ did not comment on the *Systems Thinking Analysis* report.		
R12.1: Proactively support consistent messaging about FACS prevention across all health practitioner groups. (SC2, SC3, SC6) *System constraints relate to informed decision-making and data sharing*	The National Quality Forum provides a place for senior health agency leaders to discuss safety issues (which may include education). Responsibility for developing and implementing guidelines can sit with Health NZ, ACC, providers, and/or professional colleges. Health practitioners access information via tools such as HealthPathways. Data on specific medications can be accessed through the NZ Formulary.	No single agency has the mandate for delivering this Responsibility.
R12.2: Proactively engage with consumer groups to identify opportunities for improvements in healthcare. (SC11) *System constraint relates to informed decision-making*	This is a very broad recommendation and is part of Health NZ's way of ongoing ways of working. Work plans to engage with consumers are not specific to FACS or medicine harm alone (for example, the HQSC's Consumer Code of Expectations).	This Responsibility is appropriate for Health NZ.
R12.3: Proactively follow up on complaints received by the HDC, HQSC, the Ministry or ACC by conducting systems-thinking-based adverse event reviews. (SC8, SC9) *System constraints relate to data sharing, tracking medication use, or adverse reactions monitoring*	This Responsibility belongs to more than one agency as Health NZ is not the only provider of health care in New Zealand. Regardless, Health NZ has a range of methodologies to investigate adverse events reports and complaints and is developing a national policy for complaints management.	No single agency has the mandate for delivering this Responsibility.

Responsibility (HFEx final report)	Context to support understanding	Summary
R12.4: Avoid punitive responses to adverse events, focus on the system and focus on learning opportunities for the whole organisation. (SC2, SC9) *System constraints relate to informed decision-making and data sharing*	Health NZ does not use a punitive approach to investigating or mitigating against adverse events reported. The focus on addressing adverse events is educational.	This Responsibility is redundant.
R12.5: Proactively support healthcare staff to ensure that health policy focusing on FACS prevention is user friendly. (SC2, SC7) *System constraints relate to informed decision-making*	This Responsibility belongs to more than one agency. Allocation of leadership depends on the information being supplied, to whom it is delivered, and the mechanism by which it is provided.	No single agency has the mandate for delivering this Responsibility.

Allocated Responsibilities for the following agencies could be adjusted based on the analysis in the tables above.

- Government/ministers
- the Health and Disability Commissioner
- PHARMAC
- pharmaceutical companies
- advisory bodies systems
- schools, colleges and councils
- primary and secondary health practitioners including pharmacists.

4 Recommendations

Safe prescribing is a shared goal for all stakeholders involved in this work, and it is important that a future-focused document be published to support continued progress and ensure that accountability for progressing activities is clearly and accurately applied to all those who have a responsibility to support informed decision-making and consent. Publishing either *Systems Thinking Analysis* report releases inaccurate information about agency responsibilities and may not materially influence medicines safety in pregnancy.

In early 2024, an Action Plan based on the *Systems Thinking Analysis* recommendations was endorsed by the National Medicines Steering Group. *Allen + Clarke* recommends that this Action Plan be reviewed, considering the cross-agency nature of responsibility for medicines safety and the complexity of mandates across the New Zealand health sector. This provides an opportunity for stakeholders to review the Responsibilities listed in the *Systems Thinking Analysis* report and consider whether a) actions are feasible to further advance safer use of medicines in pregnancy and b) which of the Responsibilities (once accurately allocated) are likely to advance ongoing prevention activities. In preparing to close the work on the *Systems Thinking Analysis* report with existing stakeholders, it would be also important to map engagement expectations between agencies with mandates. Mapping responsibilities could clarify individual roles and explain how the complex parts of the system operate together in relation to how health service users receive, use and contribute to information about their conditions and the medicines they use. While this activity may not bridge differences of opinion about what agencies should do in terms of protecting consumers (rather than the legislative or operational mandates set by government), it is an important step in moving toward understanding. Mapping can also ensure that agencies have clear lines of sight for the delivery of activities to reduce medicines-related harm in pregnancy.

Areas to cover in an updated Action Plan could include activities to:

- identify potential legislative changes that could contribute to strengthening pregnant people's use of medicines with teratogenic properties and the systems-level monitoring of this use
- consider how best to ensure accountability is in place for Responsibilities that do not have a single agency 'owner' or where cross-agency accountability is required
- identify ways to strengthen health practitioner access to information so that they can support informed decision-making by patients, including advocating for consumer medicine information sheets supplied from pharmaceutical companies
- enable greater real-time reporting of harm events and monitoring systems in the absence of an electronic national patient health record and tin the context of potentially long latency periods between exposure to a teratogenic medicine and a diagnosis attributed to medicines-related harm that occurred during pregnancy.

Any review process should involve FACSNZ. This will also ensure that one of the biggest challenges identified by FACSNZ (ensuring it can contribute to solutions) is addressed. Ideally this process would provide a way forward and clear responsibilities for all stakeholders interested in supporting safe medicines use in pregnancy.

Appendix A: Systems constraints from the *Systems Thinking Analysis* report

The following systems constraints were identified by HFEx and are key to understanding the allocated Responsibilities.

- **SC1** Alerts and guidance around the use of teratogenic medications must be consistently delivered to the healthcare system
- **SC2** Healthcare specialists must conduct a discussion and take a standard approach, taking into consideration what the consumer wants and needs to know, when facilitating the process of informed consent
- **SC3** The consumer must understand the teratogenic effects of their medicine
- **SC4** Prescribing healthcare workers in New Zealand must know about all medicines that have teratogenic effects
- **SC5** Puberty MUST trigger a discussion with consumers of childbearing potential about pregnancy while on teratogenic medicines. (H5)
- **SC6** All relevant consumer circumstances must be included and supported as the consumer transfers between primary, secondary and tertiary health care services
- **SC7** All healthcare practitioners must have robust knowledge of the teratogenic effects of different medications
- **SC8** Data concerning medicines usage must be complete by including community and hospital data
- **SC9** Agencies should readily share information pertinent to FACS prevention
- **SC10** Data on complaints and adverse reactions provides must provide a complete view of the true numbers of people of childbearing potential using teratogenic medication without informed consent
- **SC11** Ensure the consumer feels they have been heard in terms of their concerns or any questions they may have and they must be fully cognisant of any decisions they are asked to make