

25 November 2024

Chris Johnson
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Tēnā koe Chris

Your request for official information, reference: HN200067737

Thank you for your email on 7 October 2024, asking Health New Zealand | Te Whatu Ora for the information in relation to risk management under the Official Information Act 1982 (the Act). A copy of your clarified request of 14 October 2024 is set out in appendix one.

Response

The following paragraphs provide you with contextual information in relation to your request.

Health NZ along with other agencies, such as the Ministry of Health | Manatū Hauora, Pharmaceutical Management Agency (Pharmac), and the Health Quality and Safety Commission | Te Tāhū Hauora, are responsible for ensuring public funding and services protect, promote and improve the health of all New Zealanders (section 3 of the Pae Ora (Healthy Futures) Act 2022 (Pae Ora Act)).

These agencies along with others are also responsible for considering or implementing policies and procedures to ensure improved hauora outcomes for New Zealanders as well as identifying and managing risk.

For more information about the role of these organisations in the health sector please refer to the following web links:

- The Ministry of Health (the Ministry) is the government's lead advisor on health priorities and policies. The Ministry also regulate and monitor the health system.
 - www.health.govt.nz/
 - www.health.govt.nz/about-us/new-zealands-health-system/overview-and-statutory-framework
 - www.health.govt.nz/system/files/2024-01/briefing-to-the-incoming-minister-of-health-part-b-black-box-watermarked.pdf
- Health Quality and Safety Commission: www.hqsc.govt.nz/
- Pharmac: www.pharmac.govt.nz/
- New Zealand Medicines and Medical Devices Safety Authority: www.medsafe.govt.nz/

As you will be aware, there are a number of different types of risks that Health NZ identifies and if necessary, manages. The high level risks are presented on pages 53- 56 of Health NZ's annual report 'Pūrongo-ā-tau – Annual Report 2022 – 2023'.

The Annual report can be found here:

- www.tewhaturora.govt.nz/assets/Publications/Annual-Reports/Te-Whatu-Ora-HNZ-Purongo-a-tau-Annual-Report-22-23.pdf

Primary and Secondary Legislation

Risks can be managed through a number of different types of interventions such as primary or secondary legislation, for example the Public Finance Act 1989 (safeguarding and reporting on Public Finance expenditure) and an Order in Council (section 3 of the Health Act 1956).

Committees, Panels and Boards

Committees, Expert Groups, and Boards play an important role in New Zealand's health system providing specialised expertise and advice to support policy development and risk management. In addition, Health NZ has a number of expert groups who provide leadership in key health areas, and advise on and monitor complex health care services in New Zealand

Information on the committees and groups can be found at the following web locations:

- *Health Committees and Boards:* www.health.govt.nz/about-us/new-zealands-health-system/health-system-roles-and-organisations/health-committees-and-boards
- *Health New Zealand Expert Groups:* www.tewhaturora.govt.nz/corporate-information/about-us/expert-groups

Standards and Guidelines

Standards developed and published by Health NZ set the minimum requirements which must be met for health and wellbeing of patients, visitors, and staff. Guidelines set out the health sector best practice for employees, practitioners, or service providers in the sector. Some of our standards and guidelines are publicly available here:

- Standards: <https://www.tewhaturora.govt.nz/search?keywords=standards>
- Guidelines: <https://www.tewhaturora.govt.nz/search?keywords=guidelines>

As noted above there is a wide ambit of types of risks Health NZ needs to consider and types of interventions to manage risk.

Your request for information, even though it has been clarified is very broad, and substantial manual collation would be required to locate and prepare all documents within its scope. As such, providing all of the information requested would '*impair efficient administration*' under section 16(2)(a) of the Act.

However, in addition to the contextual information provided above, we provided examples in response to your request, under section 16(1)(e) of the Act. These are attached in **appendix two**.

How to get in touch

If you have any questions, you can contact us at hnzOIA@tewhaturora.govt.nz.

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at www.ombudsman.parliament.nz or by phoning 0800 802 602.

As this information may be of interest to other members of the public, Health NZ may proactively release a copy of this response on our website. All requester data, including your name and contact details, will be removed prior to release.

Nāku iti noa, nā

A handwritten signature in blue ink, appearing to read 'Danielle Coe', with a small 'pp' to its left.

pp

Danielle Coe

**Manager (OIAs) – Government Services
Office of the Chief Executive**

Appendix One: Clarified Request (14 October 2024)

OIA 1) Are there documented policies or procedures for assessing new information about a health policy or practice in Health NZ, that would lead to a formal review of the evidence, and a potential change in approach? Please provide the documents that describe this policy or procedure.

There may be many such documents - eg a procedure as a result of a decision by another regulatory body (eg MedSafe), or a request/warning from a professional body, a warning on a product (tool or certified technique/guideline), a Ministerial or Ministry of Health initiative (screening programme), or a set of findings in the medical literature that flag that a safety issue or unintended consequence of a practice needs attention, or surveillance/epidemiological/ACC reporting identifies an issue, or a concerned group from the public documents an issue.

OIA 2) Please identify all areas (including but not limited to the above) where Health NZ has an explicit risk management strategy in place to monitor and respond to feedback and requests from key stakeholders. For example, Health NZ may be able to provide a document from each of its senior leadership team that describes how they manage the risks and safety feedback from their stakeholders. There may also be a central dedicated Evaluation Unit that clinically assesses Health NZ initiatives for effectiveness, and focuses warnings and alarms generated internally and externally. The expected outcome of this is a list/table.

We asked: By "leadership team" did they mean Tier 2 Directors reporting to the Chief Executive?

You replied: Yes

We asked if they are interested in a copy of the current risk management policy and framework.

You replied: Yes. For this request I am also happy for only the Risk Management Policy/Framework/Registers in the Public Health part of Health NZ to be supplied - Eg screening programmes, immunisation, medication via consumer products/services etc. - and only entries related to community/clinical safety, and safety signals detected or raised with Health NZ and what rating/mitigating actions are being taken.

OIA 3) Please provide all Job Titles that deal with emerging warnings and risks and group them within the Health NZ organisational structure so that their role can be assessed in context and their leadership team executive identified. Eg Public Health/Hospital/Primary Health/Stakeholder Management/Executive. The expected outcome of this is a list/table.

We asked the requester to clarify what they mean by "emerging warnings and risks" as this request is very broad and to specify particular areas, projects or initiatives they are wanting information about.

You replied: I am interested in topics related to Health and Disability services purchased/funded by Health NZ. For example I am not interested in property management or supply chain logistics issues/risks etc. I have provided a suggested rewording below. Please let me know if this needs further refinement based on how Health NZ operates or is structured.

"OIA 3) Please provide all Job Titles that receive/detect/manage emerging warnings and risks that may indicate a safety issue with a health and disability product or service supplied, funded or mandated by Health NZ. Please group the Job Titles within the Health NZ organisational structure so that their role can be assessed in context and their leadership team executive identified. Eg Public Health/Hospital/Primary Health/Stakeholder Management/Executive. The expected outcome of this is a list/table - which may include job titles such as - Data Scientist, Epidemiologist, Contract Manager, Clinical Safety Officer, (Re)Evaluation Unit Manager, General Manager of Breast Screening, Clinical Audit, Rest Home Auditor, MedSafe Liaison Officer"

OIA 4) Please list the Criteria a suitably qualified Group from the Public would have to meet, in order for Health NZ to commence a formal review into a scientifically documented and quantified Issue of Concern. To be clear:

- This Group from the Public would not have any commercial or regulatory relationship with Health NZ - but might be entitled to use the services purchased or supplied by Health NZ or be self/privately funded.

- The Issue of Concern would be regarding a substantial initiative by Health NZ - such as a Public Health initiatives (eg a screening programme, vaccination - eg Thalidomide, forced medication of the population through consumer products), medical practice (Cervical Screening at Greenlane Hosptial), pharmaceuticals (eg ultimately leading to product recalls or severe limitation in the indication). Therefore substantial impact, liability and potential embarrassment.

Appendix Two: Response

Item 1: Are there documented policies or procedures for assessing new information about a health policy or practice in Health NZ, that would lead to a formal review of the evidence, and a potential change in approach? Please provide the documents that describe this policy or procedure.

As noted above the lead agency advising on health priorities and policies is the Ministry of Health. However, Health New Zealand, other agencies, organisations are consulted or provide advice to the Ministry for its consideration.

A review or assessment of information about health policies and procedures can be triggered in a number of different ways. Such as, a review of trends within the national health datasets, Coroners Reports, reviews of research papers and best practice guidelines issued overseas and in Aotearoa, reviews of current health legislation, or direction from the Ministry or Government. An example is the recent review of the Mental Health (Compulsory Assessment and Treatment) Act 1992 (Mental Health Act).

Information about the background to and the review process is available here: www.health.govt.nz/publications/transforming-our-mental-health-law-a-public-discussion-document. Members of the public have been essential to the process of both the preceding Government's Inquiry into Mental Health and Addiction and the public consultation (October 2019 – January 2022) on repealing and replacing the Mental Health Act as part of the democratic process.

It was also recognised that a review the Mental Health Act would take some time. So, to ensure that we improved peoples' experiences under the current Mental Health Act, new guidelines were released in the short to medium term.

The guidelines can be found here: www.health.govt.nz/regulation-legislation/mental-health-and-addiction/mental-health-act/guidelines-and-resources#mig

The guidelines and the review of the Mental Health Act have been supported by ongoing monitoring and reporting of access to services, as well as reaching out to those with lived experience. Links to the reports / data can be found here: www.tewhātuora.govt.nz/health-services-and-programmes/mental-health-and-addiction/mental-health-and-addiction-monitoring-reporting-and-data.

Item 2: Please identify all areas (including but not limited to the above) where Health NZ has an explicit risk management strategy in place to monitor and respond to feedback and requests from key stakeholders. For example, Health NZ may be able to provide a document from each of its senior leadership team that describes how they manage the risks and safety feedback from their stakeholders. There may also be a central dedicated Evaluation Unit that clinically assesses Health NZ initiatives for effectiveness, and focuses warnings and alarms generated internally and externally. The expected outcome of this is a list/table.

As noted above the number and types of risks are significant in an organisation of Health NZ's size and the work it does. Risk is managed depending on type, location and significance through various levels of Health NZ.

All employees (permanent, temporary and casual), medical officers, students, and other partners in care, volunteers, contractors and consultants working for and on behalf of Te Whatu Ora are required to manage risk.

Item 3: Please provide all Job Titles that receive/detect/manage emerging warnings and risks that may indicate a safety issue with a health and disability product or service supplied, funded or mandated by Health NZ. Please group the Job Titles within the Health NZ organisational structure so that their role can be assessed in context and their leadership team executive identified. Eg Public Health/Hospital/Primary Health/Stakeholder Management/Executive. The expected outcome of this is a list/table - which may include job titles such as - Data Scientist, Epidemiologist, Contract Manager, Clinical Safety Officer, (Re)Evaluation Unit Manager, General Manager of Breast Screening, Clinical Audit, Rest Home Auditor, MedSafe Liaison Officer"

Our overarching Risk Management Structure is set out below. The structure accounts for the risk management at a national, regional, and district level.

- The Te Whatu Ora Board / or its Commissioner/s are ultimately accountable for the organisation's risk management. The Board / Commissioner/s provides independent oversight and direction to the Chief Executive and Executive Leadership Team on organisational performance including risk management.
- Other Te Whatu Ora Board Sub-Committees that have oversight and provide specialist advice and support on specific subject area risks and risk management activities.
- Clinical Governance arrangements that oversee clinical activities and quality nationally and throughout the Te Whatu Ora regions and districts across the motu and, as part of this role, review clinical patient safety risks to ensure they are minimised and managed.
- The Te Whatu Ora Executive Leadership Team that manages the organisation's strategic, change, enterprise and operational risks.

Item 4 Please list the Criteria a suitably qualified Group from the Public would have to meet, in order for Health NZ to commence a formal review into a scientifically documented and quantified Issue of Concern. To be clear:

- This Group from the Public would not have any commercial or regulatory relationship with Health NZ - but might be entitled to use the services purchased or supplied by Health NZ or be self/privately funded.

There is no list of criteria that a group from the public would need to meet in order to request a Health NZ commence a review. However, this does not necessarily mean a review will be initiated following a request for a formal review. The information would need to be assessed for accuracy and considered in the context of New Zealand's population and health outcomes.

Please note a request for a review would need to go to the appropriate agency based on their responsibilities under the relevant legislation.