Ombudsman
Fairness for all

Case note

Requests for information relating to the COVID-19 vaccination programme

Legislation	Official Information Act 1982, ss 9(2)(ba)(ii), 9(2)(g)(ii); Medicines Act section 23B
Agency	Ministry of Health
Ombudsman	Peter Boshier
Case number	544942
Date	June 2022

Request item one *for a broad range of clinical information provided to the Ministry of Health by the pharmaceutical companies developing the COVID-19 vaccine – clinical information subject to an obligation of confidence under section 9(2)(ba)(ii) of the Official Information Act 1982.* ***Request item two*** *for the names of the experts for the COVID-19 Vaccine Advisory Group and the Medicines Assessment Advisory Committee - withholding names necessary to maintain the effective conduct of public affairs (protection from improper pressure or harassment) in terms of section 9(2)(g)(ii) Official Information Act 1982.*

Background

A requester sought a broad range of clinical information provided to the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) by the pharmaceutical companies that were developing the COVID-19 vaccine, including safety trial data.[1] The information provided by these pharmaceutical companies shows the data, research and science behind their particular vaccines. The requester also sought names of the members of the COVID-19 Vaccine Advisory Group (VAG)[2] and the Medicines Assessment Advisory Committee (MAAC).[3]

[1] Medsafe is a business unit of the Ministry of Health. The pharmaceutical companies provided the information to Medsafe as part of an application for their vaccines to be approved for use in New Zealand.

[2] The COVID-19 Vaccine Advisory Group is comprised of experts in a range of relevant fields who advise Medsafe on specific questions raised during the COVID-19 vaccine application evaluations.

[3] The MAAC comprises of up to 12 members with specialised experience. It provides independent expert advice to the Minister on the risks-benefits of new medicines (not just for the COVID-19 vaccines).

The Ministry of Health refused the requests for clinical information on the basis that releasing the information would be likely to '*unreasonably prejudice*' the commercial position of the person who supplied the information, under section 9(2)(b)(ii) of the Official Information Act 1982 (OIA). The Ministry refused the request for members' names on the basis that withholding was necessary to maintain the effective conduct of public affairs (protection from improper pressure or harassment), under section 9(2)(g)(ii) of the OIA. The requester complained to the Chief Ombudsman.

Investigation

Vaccine data, research and science

After viewing the information at issue and the nature of the concerns raised by the Ministry, the Ombudsman considered that section 9(2)(ba)(ii) was the most relevant reason for refusal.[4] This section requires consideration of whether the information is subject to an obligation of confidence, either express or implied, and if so, whether making the information available would be likely to otherwise damage the public interest.

Information subject to an obligation of confidence

The companies involved were well-known pharmaceutical companies involved in the manufacturing and selling of medicines and medical products. The information included large volumes of scientific and research data, and a number of intellectual property rights (including established patents and trade secrets) were involved. The Ministry stated that, '*the vaccine information was given to Medsafe, to allow Medsafe to assess [the vaccines] for safety and efficacy under the Medicines Act, in the strictest confidence.* The Ministry stated that section 23B of the Medicines Act required the Minister to keep the information confidential.[5]

In the circumstances, the Ombudsman was satisfied that the clinical information, including safety trial data, was subject to an obligation of confidence. The Ombudsman accepted that release would be contrary to the Government's commitments to the suppliers.

Release would likely otherwise damage the public interest

The Ministry stated that if the information was released, other pharmaceutical companies would be in a position to take advantage of it. This would have a major effect on the suppliers' cost, profit margin and competitiveness in the industry. This was particularly the case given the

[4] Section 9(2)(ba)(ii) of the OIA applies where:

> *… the withholding of the information is necessary to protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information— would be likely otherwise to damage the public interest.*

[5] Section 23B of the Medicines Act requires the Minister to take reasonable steps to ensure that confidential information provided to support an application remains confidential, and is not used for other purposes.

substantial effort and money required to develop new medicines, including COVID-19 vaccines. The Ministry considered that the companies might choose not to sell or market their medicines in New Zealand if their commercial information, including patents and trade secrets, was released. This would likely compromise New Zealand's ability to secure vaccines in future. The Ministry noted the protections in section 23B of the Medicines Act reflected and highlighted the public interest in maintaining confidentiality. The release of the information would undermine the ability of Medsafe to perform its duties and responsibilities as the regulator under the Medicines Act 1981.

The Ombudsman accepted that there was a real risk that disclosure of the requested information would likely result in pharmaceutical companies not applying for their medicines to be approved for use in New Zealand. The COVID-19 pandemic poses an almost unprecedented threat to the health, safety and economy of New Zealand. New Zealand is reliant on the ability to acquire medicines developed by overseas pharmaceutical companies. Overall, the Ombudsman was satisfied that release of the information would be likely to '*otherwise damage the public interest'.*

Public interest in release

Section 9(2)(ba)(ii) only provides '*good reason'* for withholding a request for specified information if the need to withhold that information is not outweighed by other considerations which render it desirable in the public interest to make that information available.

The Ombudsman noted there is a public interest in transparency and holding Ministers, agencies and their staff accountable for their actions and decisions. This includes keeping people informed of the public health measures taken throughout the COVID-19 pandemic, including the vaccination programme.

The Ombudsman considered that there is a substantial amount of publicly available information about New Zealand's vaccination rollout. The Ministry (and other agencies) continues to regularly release updates, vaccine data and statistics. The Ministry's website contains volumes of information related to vaccine products, including information about clinical trials and testing. The Ombudsman considered that information on the Ministry's website met the required level of accountability and enabled informed public debate about vaccine clinical research. In the circumstances, the Ombudsman did not consider that the public interest in releasing the information outweighed the interest in withholding it, given the real risk that its release would dis-incentivise pharmaceutical companies participating in the Medsafe approval process.

Names of expert advisors

The Ombudsman's general position is that there is little basis for withholding officials' names as all that would be revealed is what they do in their official capacity. However, withholding

names may be justified where the withholding grounds relating to safety and improper pressure or harassment are properly engaged.[6]

The Ministry refused the request for the names of the experts for the COVID-19 VAG and MAAC under section 9(2)(g)(ii) of the OIA.[7] This section requires consideration of whether release of the particular information in question will lead to improper pressure or harassment of those employees, which will place the effective conduct of public affairs at risk.[8]

Improper pressure or harassment

The Ministry explained that Ministry/Medsafe staff have been the subject of abuse and threats via email, telephone calls and social media, from people who disagree with the position taken by Ministry staff and committees in relation to the approval of medicines, including vaccines.

The Ministry provided various emails to the Ombudsman demonstrating that communications about vaccines was often directed at particular staff members, targeting them personally and inappropriately. The emails were significantly more serious than what could be considered routine criticism or feedback. The Ministry included internal emails discussing abusive and threatening phone calls received by Ministry staff. These emails also outlined the effect the communications had on the Ministry staff members.

The Ombudsman noted that public sector agencies (and employees) will inevitably be subject to public criticism and comment. It was important that the public did not feel constrained in voicing their concerns. As such, there is a reasonably high threshold for the type of feedback or criticism that a public sector agency may reasonably expect to deal with. However, the evidence provided by the Ministry far exceeded the threshold of what would be considered reasonable. The nature of the email communication, including the language and the tone used, could readily be characterised as improper pressure or harassment.

Impact on the effective conduct of public affairs

The Ministry was concerned that releasing the names would impact the ability of members to carry out their role and potentially cause resignations. The Ministry noted that if released, the information was likely to be shared through social media and widely disseminated. The information could be obtained by people wanting to confront, target or abuse members. If the

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[6] See Names and contact details of public sector employees for Ombudsman guidance on how to deal with OIA and LGOIMA requests for the names and contact details of public sector employees.

[7] Section 9(2)(g)(ii) of the OIA applies where:

> *… the withholding of the information is necessary to … maintain the effective conduct of public affairs through- the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment*

[8] Successive Ombudsmen have stated that '*improper pressure or harassment*' is something more than ill-considered or irritating criticism or unwanted publicity. Nor is it sufficient to assert that there is a general risk that releasing the information at issue will cause employees to become exposed to improper pressure or harassment.

small group of experts in New Zealand were less inclined to participate, this would have significant repercussions for the committees. The Ministry emphasised that the MAAC is an integral part of the New Zealand regulatory regime. Again, with the pandemic continuing to pose an ongoing threat to New Zealand, the VAG performs an essential function.

Overall, the Ombudsman concluded that release of the requested information would result in staff being specifically targeted in a manner that would amount to improper pressure or harassment in terms of section 9(2)(g)(ii) of the OIA. The Ombudsman was satisfied that the committee members would become the target of abuse or harassment if their names became widely known. He accepted that such harassment would deter staff from taking up positions on these committees or working on particular approvals and that this would prejudice the effective conduct of public affairs, namely the ability of Medsafe to act effectively as a regulator of medicines.

Public interest in release

Section 9(1) of the OIA requires that the Ombudsman consider whether the public interest in release nevertheless outweighs the reasons for refusal in this particular case.

There is a clear public interest in the need for the Ministry/Medsafe to be accountable for its role in the decision to approve the various COVID-19 vaccines. All members contribute to this decision-making process although the overall responsibility for the approval rests with the Minister of Health. There is a public interest in transparency concerning the government's management of the COVID-19 response and the associated vaccine approvals. The Ombudsman acknowledged that disclosure of the members' names would allow the public to be sure of their credentials and experience. However, the Ombudsman noted that:

- There is substantial information relating to these committees on Medsafe's website notes, including the MAAC terms of reference and information relating to the work both committees do. There is also information available on the Ministry's website and the COVID-19 website, about the vaccines generally. There are regular updates from the Government and all information is readily accessible;
- Having reviewed the membership of the committees himself, the Ombudsman did not identify any particular concerns or red flags; and
- As discussed above, the Ombudsman was satisfied that disclosure of the committees' members' names would to lead to members being specifically targeted in a manner that would amount to improper pressure or harassment. It was important that the role of the committees was not compromised.

In all the circumstances, the Ombudsman was not satisfied that the public interest in releasing the members' identities was sufficiently strong to override the interest in protecting the members from improper harassment or pressure.

Outcome

The Ombudsman formed the final opinion that section 9(2)(ba)(ii) applied to the requests for clinical data and section 9(2)(g)(ii) applied to the request for names of the experts for the COVID-19 Vaccine Advisory Group and the Medicines Assessment Advisory Committee at the time the original decisions were made on these requests.

This case note is published under the authority of the Ombudsmen Rules 1989. It sets out an Ombudsman's view on the facts of a particular case. It should not be taken as establishing any legal precedent that would bind an Ombudsman in future.