

Investigation of limited access to Ministry of Health influenza vaccine adverse reaction reports

Ombudsman's opinion

Legislation	Official Information Act 1982, ss 9(2)(a), 9(2)(ba)(i) and 18(f)
Requester	Mr Ron Law
Agency	Ministry of Health (Medsafe)
Request for	Information re 2010, 2011 influenza vaccine adverse reaction reports
Ombudsman	Professor Ron Paterson
Case number	330879
Date	May 2016

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Summary

The complainant, Mr Ron Law, requested information held by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), a Ministry of Health business unit, concerning adverse reactions to influenza vaccines in 2010 and 2011.

Health practitioners provide adverse reaction reports (ADR reports) on a voluntary and confidential basis to the Centre for Adverse Reactions Monitoring (CARM), University of Otago. The Ministry contracts CARM to collate and analyse the ADR reports.

Medsafe withheld information contained in the ADR reports and other information in reliance on sections 9(2)(a) (protection of privacy of natural persons), 9(2)(ba)(i) (protection of information subject to an obligation of confidence) and 18(f) (substantial collusion required) of the Official Information Act 1982 (OIA). The information withheld included the patients' doctors' names, the places where the patients lived, the patients' ages, the date of their doctors' attendances, and details of the patients' medical history.

Medsafe released 'listings' of some information in the ADR reports, including the following information: whether CARM considered the reaction described in the ADR reports was causally associated with the influenza vaccines, brief details of the adverse reactions, medicines prescribed to patients, the patients' age group and gender, the outcomes of the reported reactions, and whether the reported reactions were within the World Health Organisation definition of 'a serious reaction'.

There is a risk that disclosure of all of the requested information (even non-identifying information) would compromise the significant privacy interests of patients whose ADRs are reported. Full disclosure would risk undermining New Zealand's pharmacovigilance regime, and would be contrary to protection of public health and inconsistent with the practice of comparable international medicines regulators. Publication of all the requested information would also be likely to damage voluntary reporting by medical practitioners, which underpins New Zealand's system of pharmacovigilance. This would potentially be detrimental to public health.

In all the circumstances, Medsafe was entitled to withhold the information at issue.

Background

1. Medsafe is the New Zealand Authority responsible for ensuring medicines approved for use are of an acceptable efficacy, quality and safety. It contracts CARM (the Centre for Adverse Reactions Monitoring at the University of Otago) to collate and analyse ADR reports.

2. Although other persons are able to forward ADR reports to CARM, health practitioners submit virtually all the reports. The New Zealand Pharmacovigilance Centre website states:¹

Currently the CARM Database holds over 110,000 reports received largely from health professionals, although there has been a small but increasing proportion from patients in recent years. Pharmaceutical companies are also important contributors to the CARM Database.

...

CARM Database

...

Each report received by CARM is evaluated by a Medical Assessor to determine the extent of an association between the adverse reaction(s) described in the medicine/therapeutic product(s) involved which are entered into the database along with all the relevant details in the report. After each report has been assessed by one of CARM's Medical Assessors, letters providing relevant information about the ADR are sent in response to each report. These written responses may include information about causality, similar reactions and prescribing advice to assist with risk: benefit assessment of future treatment for the patient involved.

The database also serves to support enquiries from health professionals regarding clinical decision-making when unusual symptoms are thought to be therapy related.

Caveat

Reports received by CARM are submitted voluntarily and therefore the use or the interpretation of these data holdings is subject to significant limitations such as incomplete or biased reporting of adverse events and the extent to which the clinical detail provided in reports are complete. All data that is extracted for external use is provided in the context of a Caveat document explaining the limitations of the CARM dataset.

Data Privacy

Any data that is extracted from the Database is always anonymised both for the patient and reporter. Usually report data is provided in summary format, but where an individual report may be appropriate, special attention is devoted to ensuring that the identity of the patient is protected. Original reports are never released.

¹ <https://nzphvc.otago.ac.nz/carm> (accessed on 7 January 2016).

3. During 2010 and 2011 influenza vaccines were made available to the New Zealand public.

Request

4. In March 2012, Mr Law requested:

Copies of all adverse reaction reports received by Medsafe and/or CARM during 2010 and 2011 including causality assessments and reports and summaries from CARM submitted to the MARC meetings.

5. In context, Mr Law's request related to the 2010 and 2011 influenza vaccine ADR reports.
6. MARC is the acronym for the Medicines Adverse Reactions Committee, a government appointed committee providing expert advice to Medsafe. It also reviews local and international data on medicine safety, which is potentially relevant to New Zealand.²

Refusal

7. In response to Mr Law's request, Medsafe released copies of the following information:
 - a. listings of certain information in ADR reports prepared by CARM based on information provided by the patients' medical practitioners; and
 - b. reports presented to MARC in 2010 and 2011 with the ages of patients deleted. Medsafe released the age range of patients, eg 25 to 48 years.
8. The listings included the following information:
 - a. the ADR report numbers;
 - b. the dates of the ADR reports;
 - c. whether CARM considered the reaction described in the ADR reports was causally associated with the influenza vaccine;
 - d. brief details of the adverse reactions reported;
 - e. medicines prescribed to patients, the subject of the ADR reports;
 - f. the patients' age group and gender;
 - g. the outcomes of the reported reactions; and

² The New Zealand Pharmacovigilance website, footnote 1, states: "The MARC may recommend that Medsafe alert prescribers to an adverse reaction through an article in Prescriber Update or a 'Dear Doctor' letter. The MARC may also recommend that the pharmaceutical company update the datasheet [for the medicine] with advice to improve the safe use of the medicine."

- h. whether the reported reaction was within the World Health Organisation definition of 'a serious reaction'.
9. In reliance on section 9(2)(a) of the OIA, Medsafe withheld:
 - a. the ADR reports received by CARM;
 - b. the names of patients' doctors;
 - c. the situation of their doctors' surgeries;
 - d. the patients' addresses and ages;
 - e. and other information in certain ADR reports, including patients' medical history.
10. During this investigation, Medsafe advised that it also relied on sections 9(2)(ba)(i) (prejudice to the supply of similar information provided in confidence) and 18(f) (substantial collation required) to withhold the information not released.

Complaint

11. In April 2012, Mr Law complained to the Ombudsman about Medsafe's refusal. With reference to the information released to him, he commented:

This complaint related to the fact that incomplete information has been provided, including the deletion of important information needed for undertaking risk and policy assessment.

In particular the reports provided are summaries or redacted reports, and many less serious reports have been deleted.

The age of patients has been deleted on the grounds that including such detail could result in identification of individual patients ... of course this is a nonsense given the claim that over 1 million people have been vaccinated. Besides, all deaths in New Zealand are reported by age and individual death certificates and even Coroners reports are available with all details if requested.

Also, in a report on Medsafe's website, it states that 4 children died following influenza vaccination in New Zealand in 2011 ... no such reports appear to have been included in the papers supplied. The cover letter from the NZPhC on page 39 states that 2011 reports are included but they appear to be missing.

Causality assessments are also mostly missing.

I request that Medsafe be required to provide full reports as requested. Having received reports in earlier years I know that this is not an arduous exercise.

12. In response to the part of Mr Law's complaint relating to apparently missing information, Medsafe advised:

The causality assessment was provided as the summary tables include a column labelled causal with the indication Y or N. Medsafe considers this to be the assessment of causality. Interpretation of this column could have been included in the cover letter to Mr Law for clarity.

The Prescriber Update article published in March 2012 on seasonal flu vaccine appears to infer that there were four reports of death in children. This is because the sentence 'There were four reports of death coincident with influenza immunisation in 2011' was included under the subheading 'Use in children'. This is an editorial error and will be clarified in the online article on Medsafe's website. The sentence should have been placed elsewhere in the article as the reports in question refer to adults. These reports were included in the summary table provided.

13. In the light of the explanation provided by Medsafe concerning the apparently missing information and the deaths of the four children, I did not further investigate that part of Mr Law's complaint.
14. In its initial report to this Office, Medsafe advised that it did not hold copies of the ADR reports. At the time of Mr Law's request, CARM did not provide Medsafe with full copies of ADR reports.
15. In response to my advice to Medsafe that section 2(5) of the OIA deemed Medsafe to hold information held by CARM in respect of ADR reports – as it engaged CARM as an independent contractor to collate and analyse these reports – Medsafe accepted it held the influenza vaccine ADR reports.

Investigation

16. In March 2014, Medsafe was notified of my intention to investigate Mr Law's complaint, and asked for a report on its decision to withhold the information and a copy of the information at issue.
17. In April 2014, Medsafe provided its report and a copy of the information at issue it considered it held. After giving consideration to the effect of section 2(5), Medsafe provided further information.
18. During this investigation, Medsafe provided further information relating to the complaint, including information about the reporting of adverse reactions to medicines in other countries, and advice from Dr Nikki Turner, Director, Immunisation Advisory Centre (IMAC), University of Auckland.
19. In August 2015, under section 29(B) of the OIA, I consulted with the Privacy Commissioner concerning the privacy issues relating to this complaint.
20. In September 2015, the Privacy Commissioner provided advice on the privacy issues.

21. In January 2016, I advised the parties of my provisional opinion and sought comments.

Information at issue

22. Accepting Medsafe's explanation about the information Mr Law stated was 'missing', the following information remains at issue:

- a. the ADR reports;
- b. the names of the patients' doctors;
- c. the situation of their doctors' surgeries;
- d. the patients' addresses and ages; and
- e. other information contained in certain ADR reports, including the patients' medical history and medicines prescribed.

Analysis and findings

Sections 9(2)(a) and 9(2)(ba)(i)

23. Sections 9(2)(a) and 9(2)(ba)(i) provide:

(2) Subject to sections 6, 7, 10, and 18, this section applies if, and only if, the withholding of the information is necessary to –

(a) protect the privacy of natural persons, including that of deceased natural persons; or

...

(ba) 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 –

(i) would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied;

24. The interests protected by sections 9(2)(a) and 9(2)(ba)(i) are subject to section 9(1) of the OIA:

(1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5, unless, in the circumstances of the particular case, the withholding of that

information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.

Section 18(f)

25. Section 18(f) entitles an organisation to refuse a request where:

the information requested cannot be made available without substantial collation or research.

26. Section 18(f) is not subject to section 9(1).

Reliance on section 9(2)(a)

27. With regard to its reliance on section 9(2)(a) to withhold the information at issue, Medsafe submits:

Information having the ability to directly or indirectly identify the patient was redacted to protect their privacy interest in having personal health information such as diagnosis and treatment options kept private.

In balancing the public interest in releasing this information with the protection of the privacy of natural persons, Medsafe considers the public interest in being informed of [ADR reports] is met by the publication of a summary of the report in Prescriber Update. The public interest in the private information withheld would not outweigh the persons' expectation of privacy. Further, Medsafe also took into account the public interest in the continued provision of ADR reports from healthcare professionals.

28. Mr Law provided a number of examples where the Ministry and Medsafe had released the gender and age (or the age band) of patients suffering suspected adverse reactions to drugs, various viruses and diseases.
29. Some of the examples provided by Mr Law relate to 'notifiable diseases' and 'notifiable infectious diseases'.³ As Medsafe comments:

... there are material differences in the purpose for which this information is collected and this impacts what information may be disseminated to the general public.

Information on infectious and notifiable diseases (specific communicable diseases that are required to be reported)⁴ is collected for the purpose of

³ The expressions 'notifiable diseases' and 'notifiable infectious diseases' are defined in section 2, Health Act 1956.

⁴ Sections 74 and 74AA of the Health Act 1956 set out the obligations of medical practitioners and medical laboratories respectively to report 'notifiable diseases'.

preventing the outbreak or spread of any disease. This is a legislative requirement in the Health Act 1956. Communicable diseases⁵ are a significant risk to public health both in New Zealand and around the world and because of their inherent nature (ability to spread from one person to another) require different levels of detail in the reports. For example, as there is the potential for person-to-person transmission of a disease, it is important to define the area where this disease has occurred to prevent further transmission.

Reports of communicable disease contrasts significantly to an adverse drug reaction (ADR) report, as for one, the ADR is not transferable to another individual. Therefore, information such as the area where the ADR occurred has no bearing on how the report is analysed. The intention behind releasing information is to improve the safe use of medicines and thus protect patients. It should also be noted that differences in what is released by different Ministries is in part due to the different legislative requirements.

30. Section 3A of the Health Act 1956 states:

Without limiting any other enactment or rule of law, and without limiting any other functions of the Ministry or of any other person or body, the Ministry shall have the function of improving, promoting, and protecting public health.

31. The Ministry is performing its statutory function of ‘*improving, promoting and protecting public health*’ in publishing relatively detailed information about reports of actual or suspected ‘*notifiable diseases*’ and ‘*notifiable infectious diseases*’. The publication of information about patients’ age and gender and, on occasion, the area where they live, alerts the medical profession to the presence of disease in sub-groups of the population in specific localities.
32. Mr Law provided examples of occasions where Medsafe has published information of suspected adverse reactions derived from ADR reports, with details of the patients’ age and gender. The sheer number of adverse reactions in the examples provided makes it impossible to identify the patients.
33. Mr Law also provided examples where Medsafe had published the age and gender of a very few patients suffering suspected adverse reactions, to support his claim that Medsafe acts inconsistently.
34. Whether Medsafe acts inconsistently is not the issue I have to determine. Rather, I must determine is whether it is *necessary* to protect the patients’ privacy by withholding the information at issue.
35. I agree with the Privacy Commissioner’s advice that the release of information leading to the identification of the patients would breach the privacy of the individuals concerned:

⁵ The expression ‘*communicable disease*’ is defined in section 2, Health Act 1956.

There is a significant privacy interest in withholding, given that this information was provided either in a clinical relationship of confidentiality or in a context of a confidential adverse drug reaction report.

Section 9(1)

36. The question for determination is whether the patient's privacy interest is, under section 9(1), outweighed by other considerations rendering it desirable, in the public interest, to make that information available.
37. Medsafe accepts that the public health benefits of ADR reports lend weight to a public interest argument favouring their release. Medsafe provides the online 'Suspected Medicines Adverse Reactions Search' (SMARS) containing anonymised information from reports of suspected adverse reactions considered by CARM to be causally related to medicines.
38. Medsafe submits that the provision of information in SMARS satisfies the public interest in terms of section 9(1). It refers to the practice of three other countries – Canada, Australia, and the United Kingdom – in releasing information concerning ADRs. The Appendix contains information Medsafe provided concerning the practice in these countries, which appears very similar to the practice followed by Medsafe in response to Mr Law's request.
39. Medsafe submits:

Reporting of adverse reactions to medicines is the only method Medsafe has to monitor in a timely fashion, the safety of medicines used in New Zealand. ... Releasing full details of ADR reports has potential to reduce confidence in this system and reduce reporting. Any significant reduction in reporting affects CARM and Medsafe's ability to detect safety concerns. Weakening Medsafe's pharmacovigilance capability will impact negatively on public health in New Zealand.
40. The New Zealand Pharmacovigilance Centre website states:

New Zealand has had the highest rate of reporting adverse reactions to medicines per population in the world for at least the last two decades. However, since 2011 Singapore and in 2012 the USA now has a higher rate of reporting, but [New Zealand] is still the 3rd highest reporting country globally. This high rate does not reflect a bigger problem in New Zealand; rather that we are more diligent about reporting these events.
41. It is in the public interest that people intending to have influenza vaccines, and health practitioners, are aware of potential adverse reactions. However, there is a real risk that, if Medsafe released further information, the privacy of patients, the subjects of the ADR reports, would be compromised.
42. I agree with the Privacy Commissioner's advice:

There is no strong countervailing public interest in disclosure; indeed, there is a significant public interest in maintaining the integrity of the pharmacovigilance regime, and releasing all the information Mr Law is seeking would prejudice that.

43. In terms of section 9(1), I can see no compelling public interest reasons to make the information at issue available.

Opinion

44. For the reasons given above, I conclude that Medsafe was entitled to rely on section 9(2)(a) to withhold the information at issue.

Reliance on section 9(2)(ba)(i)

45. To justify its reliance on section 9(2)(ba)(i) to withhold the information at issue, Medsafe must show:

- a. the information was subject to an obligation of confidence;
- b. the making available of the information would be likely to prejudice the supply of similar information, or information from the same source;
- c. it is in the public interest that 'such information' should continue to be supplied; and
- d. the necessity to withhold the information to protect the confidentiality of the information under section 9(2)(ba)(i) is not outweighed by other considerations rendering it desirable, in the public interest, to make the information available.

46. Medsafe explains that the ADR reports are submitted voluntarily –

with the expectation [the reports] will be received in confidence and no information that can identify a patient or a reporter is disclosed. As the patient's consent is not required prior to submitting a report, confidence in health care professionals (eg, doctor-patient relationship) may be reduced if patient information has been submitted and the patient is then contacted.

.....

Reducing the provision of this information is likely to impact on Medsafe's ability to monitor the safety and efficacy of medicines in New Zealand if confidence is lost in the confidentiality of reports submitted.

There is high public interest in maintaining reporting of ADRs, with the expectation that information will be kept private. It is estimated that less than 10% of ADRs are reported, therefore a further reduction in ADR reporting will also have an impact on the amount of information that is then made available

to the public about their medicines (ie, from the public[ly]accessible SMARS database).

47. I am satisfied that the information at issue was provided in confidence to Medsafe. In reaching that conclusion, I take into account the confidential nature of a doctor-patient relationship, the fact that CARM receives the ADR reports largely from health practitioners concerning their patients, and the following statements on the New Zealand Pharmacovigilance Centre website:

Data Privacy

Any data that is extracted from the Database is always anonymised both for the patient and reporter. Usually report data is provided in summary format, but where an individual report may be appropriate, special attention is devoted to ensuring that the identity of the patient is protected. Original reports are never released. Following Stakeholder consultation from 01 November 2012, Medsafe has access to copies of original reports submitted to CARM (anonymised where possible) to facilitate the conduct of pharmacovigilance in New Zealand. This level of data access is limited to Medsafe only and is in keeping with international practice as Pharmacovigilance Centres are usually part of the Regulatory Agency.

48. The Court of Appeal interpreted the phrase ‘*would be likely*’ appearing elsewhere in the OIA⁶ to mean “*a serious or real and substantial risk to a protected interest, a risk that might well eventuate.*”⁷
49. Medsafe considers there is a substantial risk that the releasing of the information at issue will deter health practitioners from providing ADR reports to CARM. It sought Dr Nikki Turner’s opinion on whether providing the ADR reports submitted during influenza used immunisation programmes to external third parties may impact on their efficacy, and impact on the public’s and health practitioners’ willingness to submit information contained in ADR reports. I accept Medsafe’s submission that Dr Turner’s opinion applies to the information at issue in this complaint.
50. Dr Turner advised:

IMAC runs a range of National and Local Services which includes immunisation coordination, promotion, health professional education and training, development and implementation of National guidelines and quality standards for the NZ National Immunisation Programme. As part of this role, IMAC is involved in both promoting the importance of and supporting the actions of Healthcare professionals and the NZ public to notify Adverse Events Following Immunisation (AEFI).

⁶ Sections 6(c) and 27(1)(a).

⁷ *Commissioner of Police v Ombudsman* [1988] 1 NZLR 385, 391.

51. Dr Turner described the purpose of 'the CARM system':

This is not intended to be a collection of all events following immunisation. The purpose is to look for any unusual events or pattern of events that are not already well established and expected. Each event is reviewed in order to assess whether it contributes to any new or unexpected aspect that could be a signal generation for further review or research.

I can see the importance of making public[ly] available information such as the type of event, the temporal association with the vaccine in an age grouping. However, I am unclear why there is a need to release further data that potentially identifies either the Healthcare professional who submitted the data or the patient. For the intended purpose of the safety monitoring programme (i.e. signal generation), this extra and potentially identifiable data will not offer any additional beneficial information.

NZ Healthcare professionals in the public are very supportive of the CARM system. Even though it is a voluntary system, NZ has one of the highest reporting rates in the world. Doctors and [n]urses submit the data on the understanding that it will be anonymous and there will be no public[ly] identifying features of the provider or their patients. NZ is a small community and it is not difficult to uncover who a particular provider or patient is with just a few initial identifying details. If [d]octors or [n]urses felt there was any risk that their personal or patient details could be exposed in a public arena, their willingness to continue to participate in the pharmacovigilance of vaccines will likely be diminished. The voluntary notification to CARM is currently a strong and effective part of both the NZ immunisation programme and the medication monitoring system and any issue that will affect a Healthcare provider's desire to continue to support it is likely to have a detrimental effect.

There are examples both internationally and in NZ where this type of data has been used indiscriminately and publically, resulting in loss of confidence in vaccination programmes. I have been in public forums and received mail where the AEFI information from CARM has been presented inappropriately and inaccurately with, at times, personalized angry accusations. To date, the data behind this information has always been anonymous and not been tracked back to the provider or patient.

While I strongly agree with the importance of making vaccine safety data public[ly] available where at all possible, I can see there are sensible reasons for also having some anonymity in this situation. Identifiable data such as year of birth, locality or provider can make it very easy to track back to the origins of the report.

52. In the respect of the AEFI information, Medsafe released the age ranges of patients apparently suffering adverse reactions to the influenza vaccines, but not their locality or their health practitioners' names.
53. Dr Turner concluded that the releasing of the 'identifiable data' she referred to –
- has the potential to identify individuals, offers [no] benefit and furthermore could potentially be harmful to both providers, individuals, and the programme ... [R]eleasing this additional information could destabilize a well-functioning system that relies on confidence and sensitively handling private data that is provided via the goodwill of [d]octors, [n]urses, and the NZ public.*
54. In relation to an analysis of certain ADR reports submitted during the 2010-2011 influenza season vaccinations, Dr Michael Tatley, Director, New Zealand Pharmacovigilance Centre, states:
- 1. Reports received by CARM are handled in terms of the Privacy Act (1993) and associated Code of Practice. Reports are understood to be submitted for the purpose of extracting adverse event related data into a database. The purpose of the database is to support the analysis of pharmacovigilance patterns and trends to inform Medsafe to assist in their decisions in their regulatory activities. Reports are therefore intended to provide a source of information for populating the database and not for the sharing of the raw original data. It is the database that is regularly made available for research, not the source reports.*
 - 2. The reports contain personal identifiers of both the patient and reporter and may also contain confidential or sensitive clinical information about the patient's medical, social, or psychiatric history. It should be noted that many reports themselves are headed 'Confidential'. Confidential patient details are an essential component of reports as these are used to confirm the identity of a patient for whom CARM may record a Medical Warning or Danger Alert on the National Medical Warning System where a medicine and an associated adverse reaction reported is assessed to reflect a caution or contraindication to its further use for that patient. This System provides critical information to prescribers to ensure that patients are not re-exposed to a potentially life threatening medication.*
 - 3. ... Only the anonymised extracted data at an individual level or an aggregate level across reports is used for pharmacovigilance analysis and when data is requested from the CARM database it is this coded data that is provided. The caveat on the CARM webpage states that original reports are never released and the details of the report or patient are never divulged. This is routinely stated by CARM staff in any presentation or promotion of CARM. The purpose of the original reports was never envisaged as potentially being shared, in even redacted format, outside of the Pharmacovigilance Team.*

4. *In the event that some cases reported may be so rare or unique such that it may be possible to identify an individual, then for these cases even anonymised details coded into the CARM database are not being included in some database extract requests.*
- ...
7. *CARM has grave concerns that providing access to original reports will negatively impact on reporters willingness to report adverse events to CARM and adversely affect not only the rate of reporting, but also the quality of clinical information provided that is crucial for assessing reports. As Director of CARM, I am concerned that the provision of original reports is contrary to the caveat we publish [on the Pharmacovigilance Centre website] and statements and reassurances my staff and I have made about the sanctity of the original reports and could have repercussions including legal consequences that may arise from such a precedent.*
55. Based on information provided by Medsafe, Dr Turner’s opinion and Dr Tatley’s advice, I am satisfied that there is a real and substantial risk that releasing the information at issue would undermine the CARM system and prejudice the supply of information contained in ADR reports or similar information.
56. Medsafe accepts the limitations of ADR reports:
- ...reports sent to CARM often only contain limited details about the suspected adverse reactions. Reports vary in quality, completeness and detail. Some reports may include inaccurate information despite efforts by CARM to verify the information and some reports may contain private information unrelated to the medicine taken or reaction experienced. Although CARM analyse each report to determine the association between the medicine and the adverse reaction, this is not a root cause analysis as seen in sentinel reports. Medsafe would consider that the safety concerns highlighted in Prescriber Update are more similar to District Health Boards sentinel reports than the information contained in individual ADR reports.*
57. Despite the limitations of ADR reports identified by Medsafe, it is in the public interest that the information contained in ADR reports or similar information should be continued to be supplied. Release of the requested information is likely to compromise Medsafe’s ability to monitor the safety of medicines, and thus negatively impact on public health. It is in the public interest for Medsafe to provide health practitioners with advice about adverse reactions to medicines in a timely manner, so that they can adopt or modify a prescribing practice, to decrease the risk of harm to patients.
58. Having accepted that section 9(2)(ba)(i) applies to the information at issue, I must consider whether, in terms of section 9(1), the withholding of that information is outweighed by other considerations rendering it desirable, in the public interest, to make that information available.

59. The issue under section 9(1) is not simply whether there is a '*public interest*' in making the information available, but rather whether any public interest considerations favouring disclosure outweigh the interest protected by withholding the information at issue.
60. Section 5 of the OIA recognises the principle that the information '*shall be made available unless there is good reason for withholding it*'. In the present case, I am not satisfied that any considerations favouring disclosure of the information at issue outweigh the strong public interest in ensuring the continued provision of the information contained in ADR reports or similar information. The information released by Medsafe, including the information publicly released, satisfies the public interest.

Opinion

61. For the reasons given above, I conclude that Medsafe was entitled to rely on section 9(2)(ba)(i) to withhold the information at issue.

Reliance on section 18(f)

62. Medsafe advised that, at the time of Mr Law's request, CARM had received about 1900 ADR reports relating to the influenza vaccines.
63. Two Medsafe staff members reviewed 20 ADR reports to ascertain the time it would take taken to redact the information in the ADR reports to protect, in terms of section 9(2)(a), the privacy of patients. On the basis of that exercise, Medsafe estimated it would take about 126 hours to redact all the reports.
64. On that basis, provision of redacted ADR reports would require substantial collation and research.
65. In the light of my conclusions regarding Medsafe's reliance on section 9(2)(a) and 9(2)(ba)(i), it is unnecessary to consider whether Medsafe should have fixed a charge under section 18A(1) to provide the withheld information.

Opinion

66. For the reasons given above, I conclude that Medsafe was entitled to rely on section 18(f) to withhold the information at issue contained in the ADR reports.

Professor Ron Paterson
Ombudsman

Appendix: extracts from Medsafe's April 2014 report

Pharmacovigilance is a practice carried out around the world by other medicines regulators and pharmaceutical companies. Other medicines regulators, such as Health Canada, the Medicines and Healthcare Products Regulatory Agency ("MHRA") (UK) and the Therapeutic Goods Administration ("TGA") (Australia), also routinely publish ADR information on their websites

The MHRA will release further information under the Freedom of Information Act 2000 (UK), which is equivalent to the Official Information Act ("OIA"), when requested, provided that there are more than five cases (the same medicine and reaction). If there are less than five cases then it has been determined as being potentially identifiable for both the reporter and the patient and only a limited summary of the cases is provided. Please note that this restriction is in place in the UK where there is a significantly larger population than in New Zealand.

Freedom of Information Act data fields that can be released (when there are more than five cases):

- Patient age categories.
- Patient gender categories.
- Suspect drug(s).
- Dose of suspect drug(s).
- Route of administration.
- Duration of treatment.
- Suspected adverse drug reaction(s).
- Adverse drug reaction outcome(s).
- Time to onset.
- Past medical history.
- Year of receipt.

Further details such as dates of suspect medicine administration, test results and the case narrative are only releasable for research requests that have been considered by the Independent Scientific Advisory Committee ("ISAC"). The remit of the ISAC is to consider the method of study, its appropriateness and the implications of the Freedom of Information Act and Data Protection Act on data release (ie, this committee is similar to an ethics committee).

The five case threshold for releasing certain data fields and not releasing other data fields has been enacted due to breaches of privacy, whereby in isolation redacting the name of the patient and reporter may mean the report is unidentifiable, however, using this information in

conjunction with other information may lead to the patient being identified. Mr Law has previously requested information from Medsafe to enable him to match and supplement information obtained from other sources such as the Coroner's Office

...

Health Canada also do not release dates of suspect medicine administration or adverse reactions (date report received only), test results or full case correspondence due to privacy concerns. The TGA will release further information if requested, additional to that provided online, but will redact any information that could possibly identify an individual as this information is considered to be personal, as defined under the Privacy Act 1988 (Australia).