

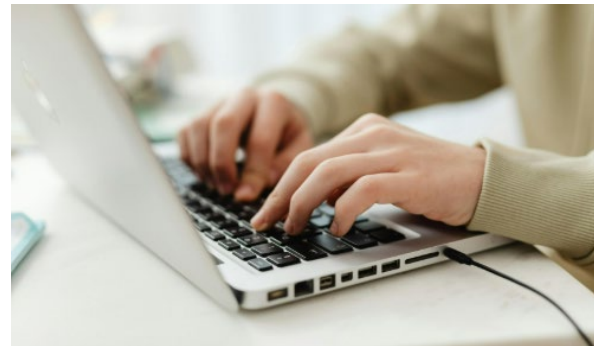
Adverse Reaction Reporting

<https://pophealth.my.site.com/carmreportnz/s/>

- Version 1 26 January 2026

Overview

- Submitting adverse reaction reports contributes to medicine safety
 - What to report, how to report
- What happens to an adverse reaction report
 - How does Medsafe monitor medicine and vaccine safety




Submission of adverse reaction reports

- ☞ **Anyone** can report a suspected adverse reaction.
- ☞ You can report adverse reactions with:
 - ☞ medicines or vaccines
 - ☞ natural health products and supplements
 - ☞ herbal medicines
- ☞ A suspicion of an adverse reaction is all that is required to prompt a report.
- ☞ Ways to report:
 - ☞ Using the [reporting web-form](https://pophealth.my.site.com/carmreportnz/s/) (preferred)
 - ☞ By emailing CARMreport@health.govt.nz
 - ☞ [Paper form](#)

Completing the Web-Form

- The reporting web-form has multiple pages to move through.
- The first page contains the privacy statement.
- Fill in as much as you can but do not worry if you don't know everything. Not all fields are required.
- Click Continue or Save on each page.

Web-Form – About this report



About this report

About this report

* Are you submitting a new or follow-up report?

☒ New ☐ Follow-up

* Are you a health professional completing this form for someone else?

☒ Yes ☐ No

* Do you have the patients authorisation to report on behalf of them?

☒ Yes ☐ No

Select these required options as appropriate

If you are submitting follow up information, enter the report number after selecting 'Follow-up'. However, this won't populate the original report for privacy reasons.

Use the status bar along the top or the 'Back' button at the bottom to move to a previous page

Web-Form – Reporter details

Reporter

Please provide your name and contact details in case we need to contact you for more information about the report.

Title

*First name(s)

*Last name

Your profession

Your workplace or facility name

Your contact details

The minimum required contact details are either an email address, phone number or postal address. Please note if you do not provide an email address, you will only receive correspondence if further information is required.

Your email address

The reporters first and last names are required

Your profession is useful if we need to ask you for more information

One contact method is required. Email is preferred as this provides you with an immediate confirmation email and copy of the information submitted


Web-Form – Person affected

Provide details about the person who took the medicine that caused the adverse reaction. Last name or Initials field must be filled in. You can use the patient's name, initial, NHI number, or your own patient identifier.

First name(s) or initial

* Last name or initial

Date of birth (DD/MM/YYYY)

If you don't know the person's date of birth, please select an age group 

Sex

* Ethnicity

Last name, initials, NHI or your own reference number can be used in the last name field.

Required fields

'Don't know' can be selected when ethnicity is unknown

Web-Form – Medicines

▼ Medicine/vaccine details 1

*Select type

☒ Medicine ☐ Vaccine

*Medicine name

Required field

Batch

Dose number (e.g. 250)

Dose unit (e.g. mg)

Select an option ▼

Frequency number (e.g. 4)

Route of administration

Select an option ▼

Date started taking

Choose medicine.
Complete known fields.
Press Save. Then repeat for
other medicines being taken.

At least one medicine or vaccine
must be added.

If reporting a **dose**, complete both dose number and unit fields.

Record **frequency** as follows: if the medicine is taken twice a day, use '12', then 'hour' as the frequency unit, if the medicine is taken three times a day use '8' 'hour', if the medicine is taken every second day, use '2' 'day'.

Suspect: the medicine was suspected to have caused the reaction

Concomitant: the medicine was being taken at the same time

Interacting: the medicine interacted with another medicine, food, drink or herbal product

Web-Form – Medicines (continued)

Date started taking

Estimated start date

Is this medicine still being taken?

Reason (illness or health issue) for taking the medicine

What role do you think this medicine played in the adverse reaction?

- ☐ Suspect
☐ Concomitant
☐ Interacting
☐ Drug not administered

What action was taken with the medicine?

Suspect: the medicine was suspected to have caused the reaction

Concomitant: the medicine was being taken at the same time

Interacting: the medicine interacted with another medicine, food, drink or herbal product

Web-Form – Vaccines

*Select type

Medicine

Vaccine

*Vaccine name

Required field

Batch

Dose (include dose number in series if known)

Injection site

Select an option ▼

Date received vaccine

What role do you think this medicine played in the adverse reaction?

- ☐ Suspect
- ☐ Concomitant
- ☐ Interacting
- ☐ Drug not administered

Cancel

Save

Choose vaccine.
Complete known fields.
Press Save. Then repeat for
other medicines or vaccines
being taken.

At least one medicine or vaccine
must be added.

Suspect: the vaccine was suspected to have caused the
reaction

Concomitant: the vaccine was being taken at the same
time

Interacting: the vaccine interacted with another
medicine, food, drink or herbal product

Web-Form – Reaction

▼ Reaction details 1

* Describe the reaction symptoms in 250 characters (If you want to tell page)

Start date

End date

What was the outcome?

If the reaction was more than mild or unpleasant, please choose one of the following: 1) Life-threatening: if the person could have died from the reaction, 2) Disabling/incapacitating: if the person was unable to complete daily activities for more than one week, 3) Other medically important condition: if the person sought health-care professional help and got treatment.

Cancel

Save

Required field (250 characters max).
Press Save, then repeat for other reactions.

Note: after you press Save, there is space to tell us more about the reaction(s). You can add as many reactions as needed. If there are different outcomes and timings it is helpful to add the reactions individually.

Only if the reaction was more than mild or unpleasant, choose one of the seriousness criteria from the dropdown list.

Web-Form – Additional details

Additional details

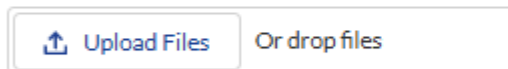
Use this section to provide additional information about the adverse event, any treatment provided or any other relevant information such as medical and medicines history, test results, known allergies or rechallenge if performed. You can also upload supporting documents or files, such as medical records, test results, x-rays or photos.

Additional information



Medical history, test results, rechallenge information can be included here when known.

Upload supporting documents or files



Documents can be uploaded here

Do you want to send a copy of this report to the person affected/your patient?



Select Yes, and add email address, to send a copy of the report to one additional email

Person/patients email address



Web-Form – Review and submit report



Review and submit report

Review and submit report

Review the information you have provided and make sure it is accurate before submitting your report. You can edit the information in each section if you need to.

Review the report before pressing 'Submit report' at the bottom of the page.

Click 'Back' or choose the status bar dots at the top of the page to edit a previous page.

Once you are happy, submit the report. If you provided your email you will get a confirmation email with the report reference number and a pdf copy of the information provided.

What happens to an adverse reaction report

- ☞ Physicians at the Centre for Adverse Reactions Monitoring (CARM) medically assess **serious** and significant reports.
- ☞ A letter will be sent to the reporter if further information on a report is required.
- ☞ CARM physicians may also add dangers or warnings to the national Medical Warning System for the patient.
- ☞ Deidentified reports are sent to the World Health Organization (WHO) as part of Medsafe's international obligations.
- ☞ Deidentified information is published on the Medsafe website <https://www.medsafe.govt.nz/SMARS/Disclaimer>
- ☞ Important cases are highlighted in the Gathering Knowledge section of *Prescriber Update*.
<https://www.medsafe.govt.nz/profs/subscribe.asp>

Safety Monitoring

- ☞ Suspected adverse reaction reports are used to detect safety signals.
- ☞ Medsafe analyses adverse reaction reports with other information to confirm if a safety signal is real and whether action is required. We may ask for further reports through a monitoring communication.
<https://www.medsafe.govt.nz/safety/SafetyCommunications.asp>
- ☞ Medsafe can (list not exhaustive):
 - ☞ Provide information to healthcare professionals and consumers directly or ask companies to do so.
 - ☞ Ask companies to update their medicine date sheets.
 - ☞ Ask companies to restrict the use of a medicine.

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- Thank you for your interest in reporting suspected adverse reaction reports, and helping Medsafe monitor the safety of medicines and vaccines in New Zealand.