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

CARM

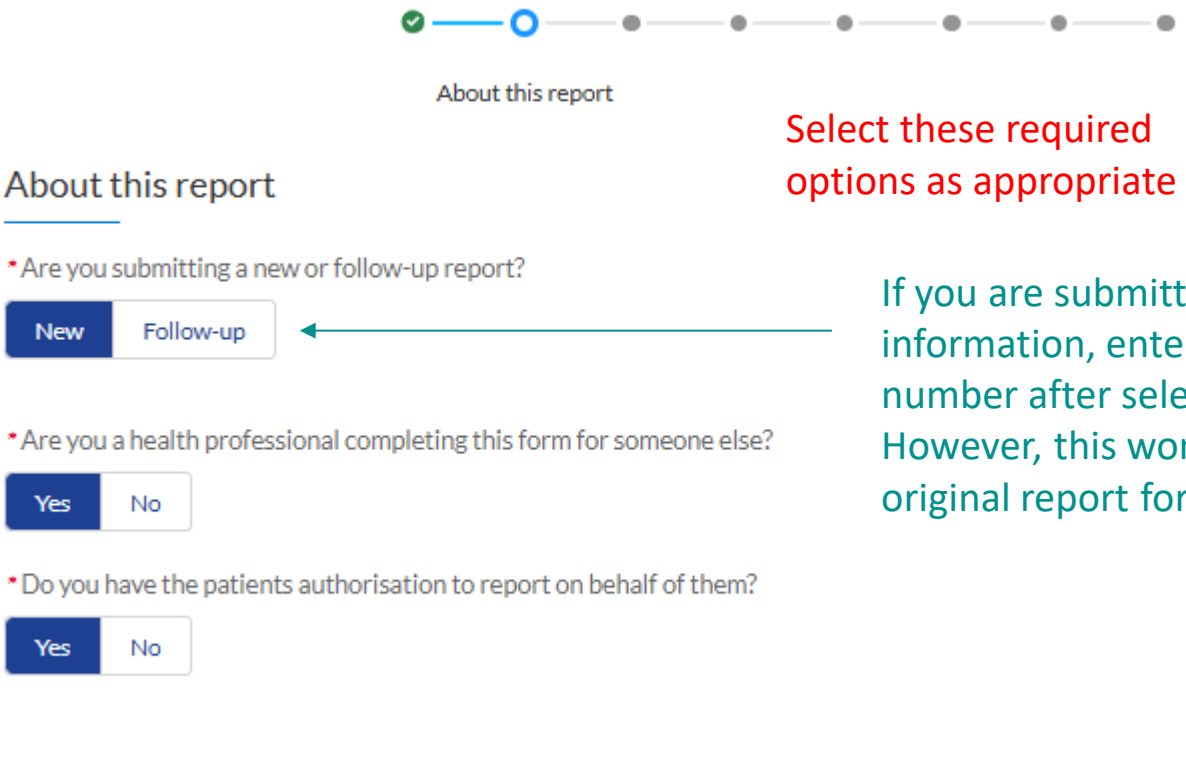
Submission of adverse reaction reports

- **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 (preferred) (https://pophealth.my.site.com/carmreportnz/s/)
  - 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

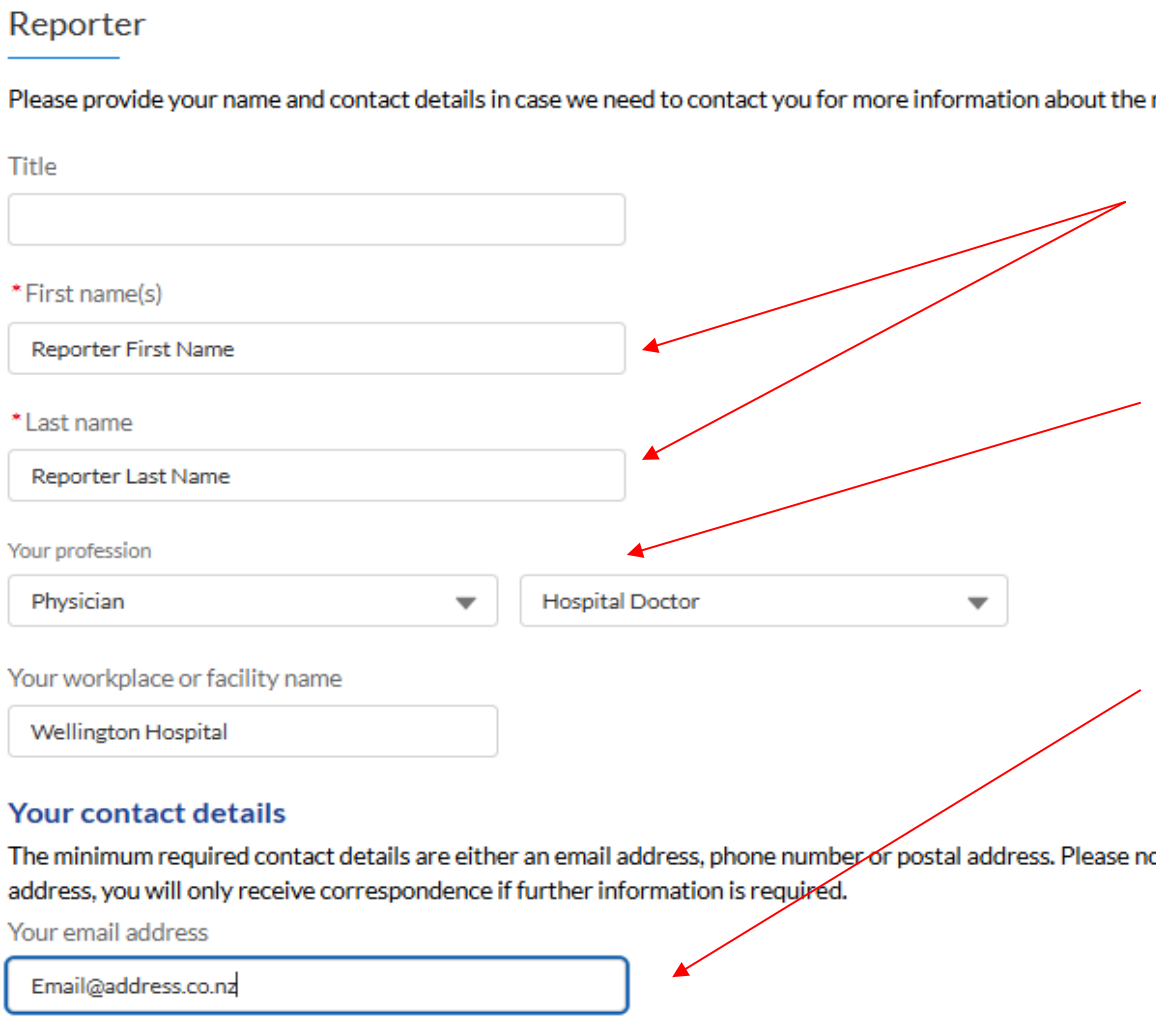


Select these required options as appropriate

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

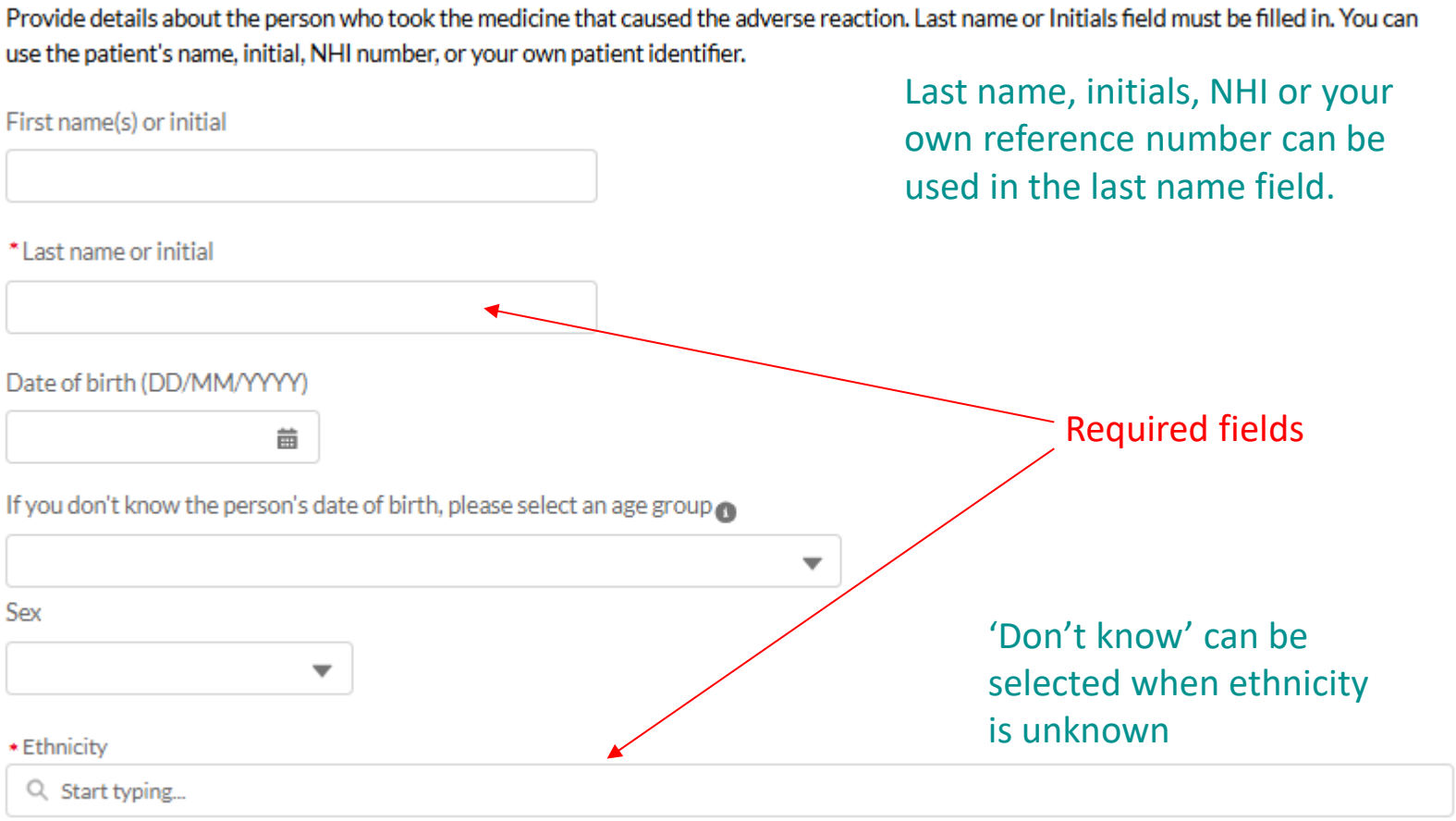


The reporters first and last names are required

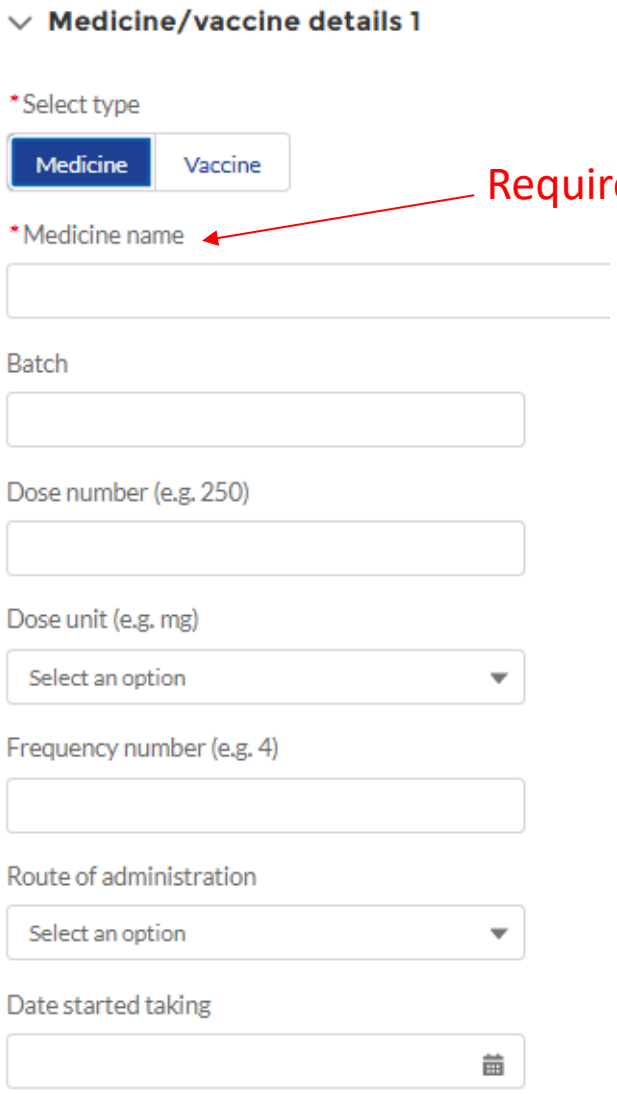
Your profession is useful if we need to ask you for more information

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



Web-Form – Medicines



Required field

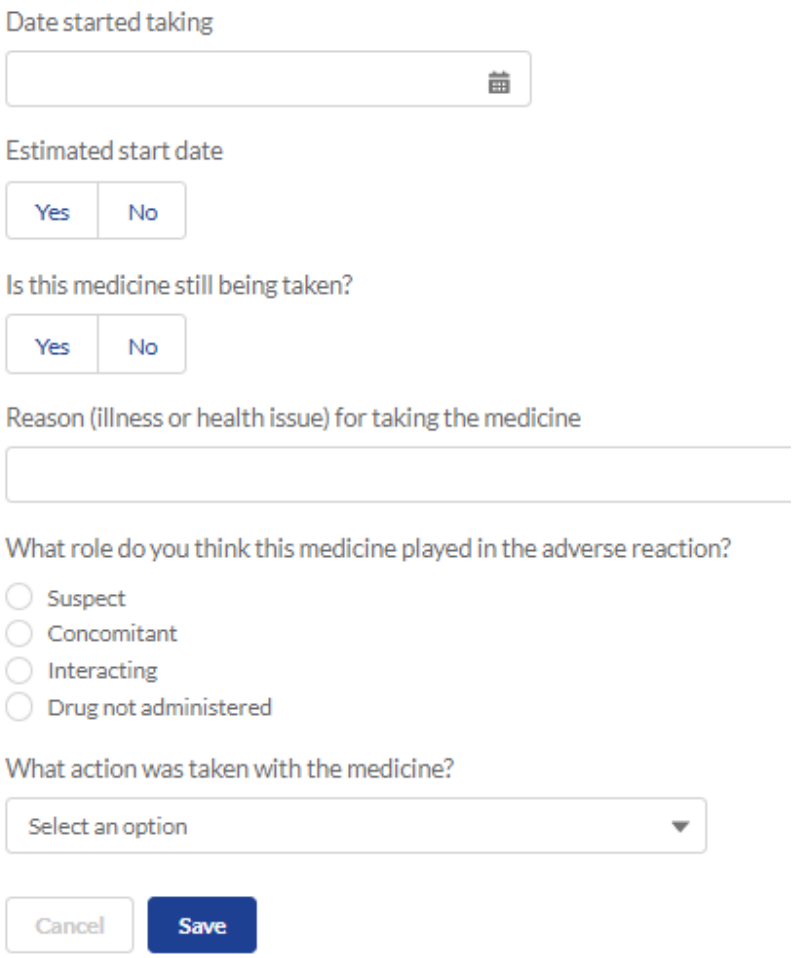
Choose medicine.
Complete known fields.
Press Save. Then repeat for other medicines being taken.

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'.

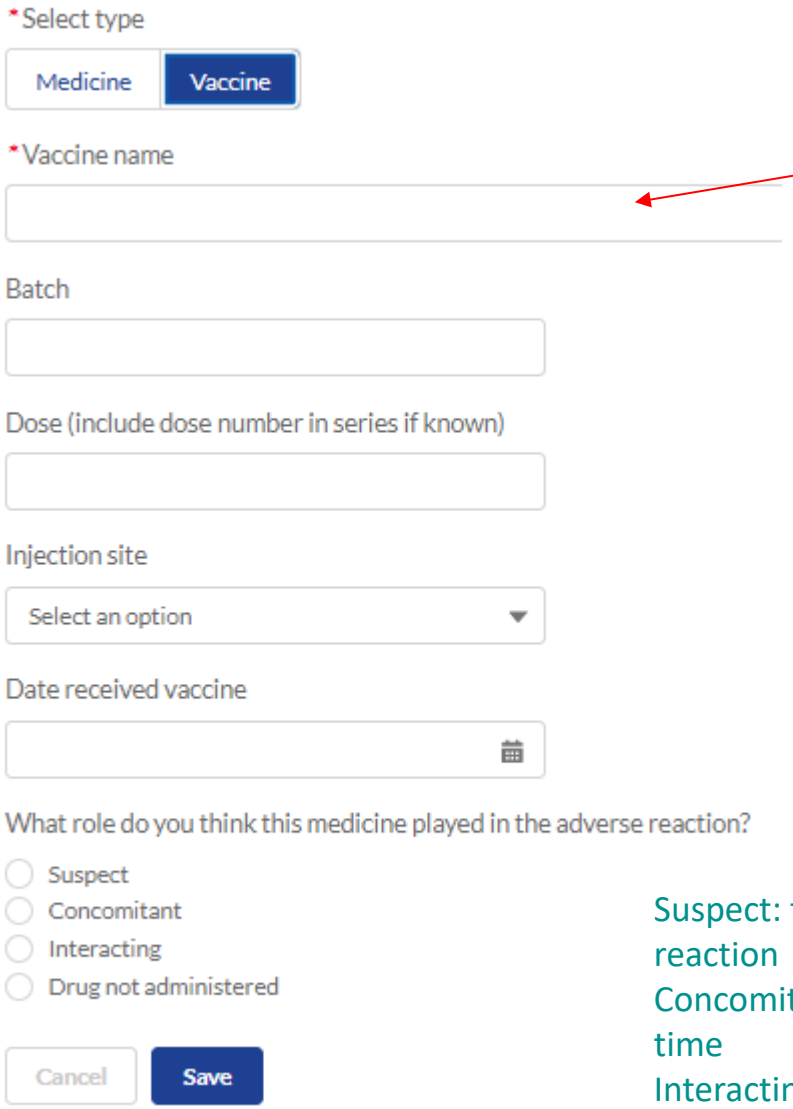
Suspect: the medicine was suspected to have caused the reaction
Concomitant: the medicine was being taken at the same time
Interacting: the medicine interacted with another medicine, food, drink or herbal product

Web-Form – Medicines (continued)



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



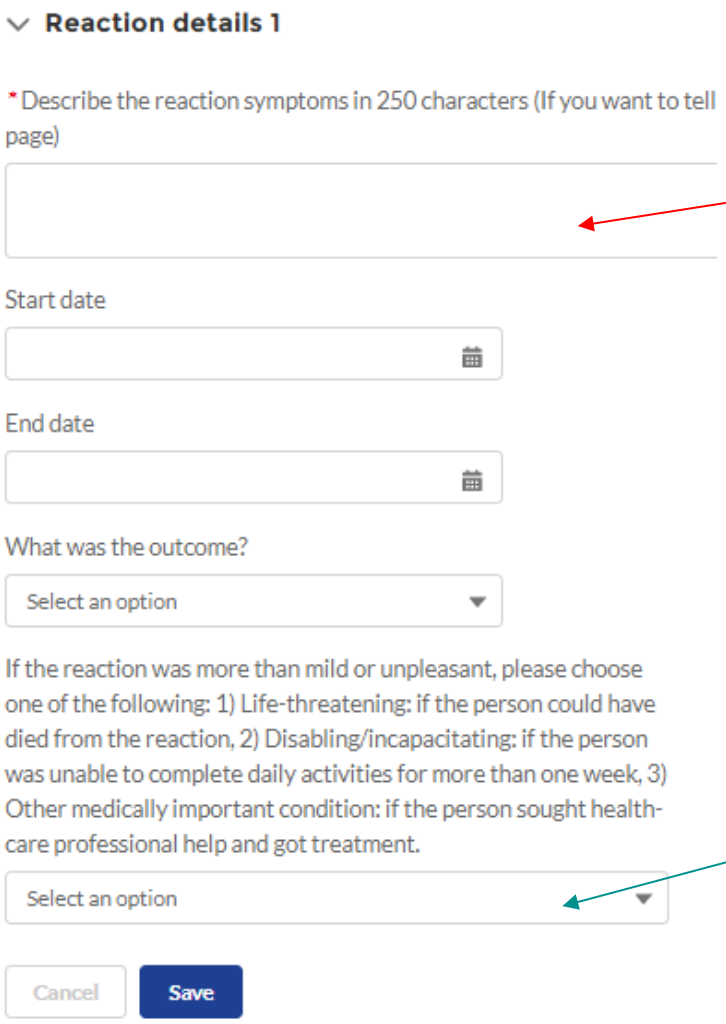
Required field

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

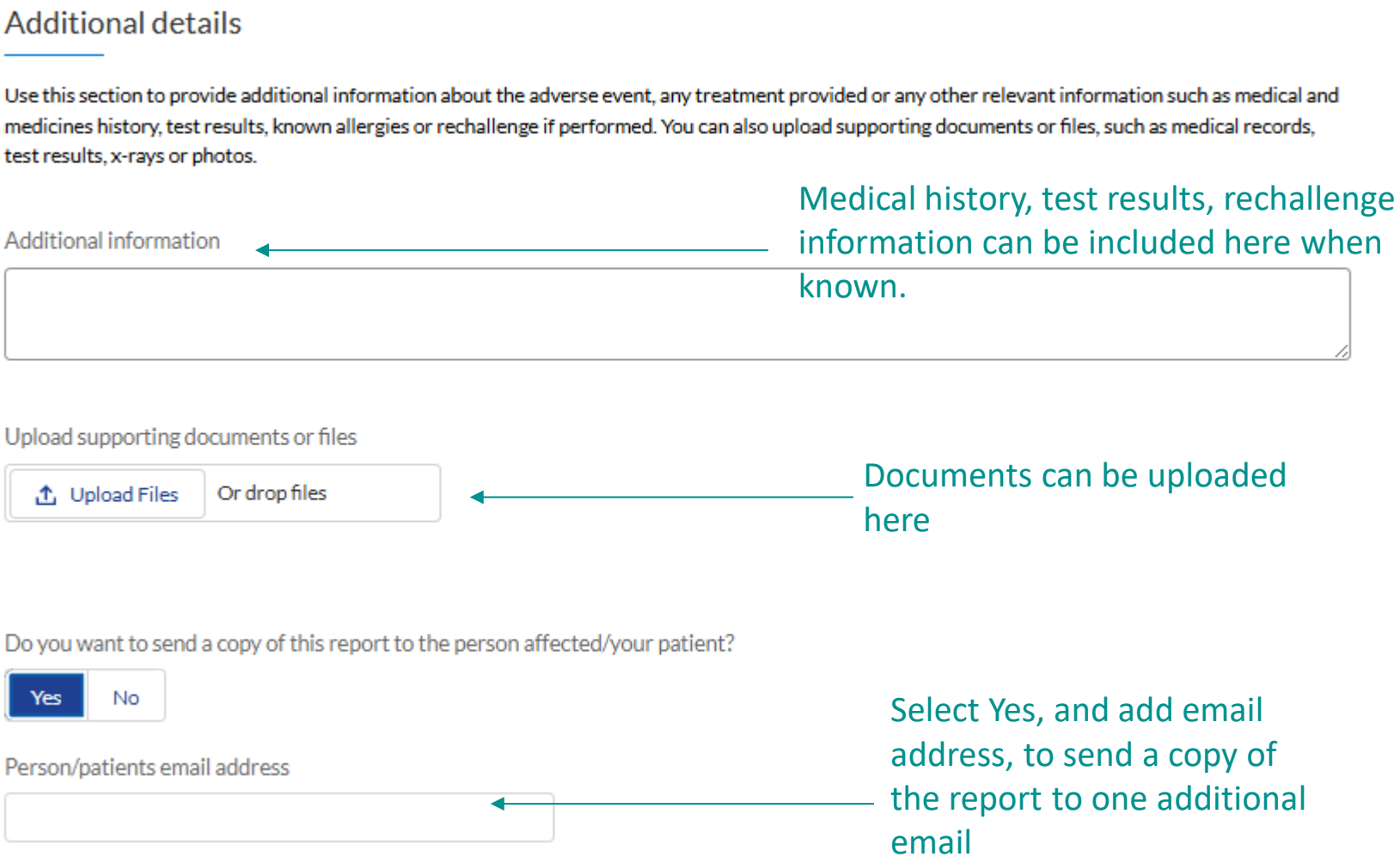
Web-Form – Reaction



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



Web-Form – 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.

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