African Union Smart Safety Surveillance (AU-3S) Programme

Instructions to download and use the Med Safety App

Table of Contents

1. About the Med Safety App

- The Med Safety App is a mobile application that can be used by healthcare professionals and members of the public to submit reports of adverse events after taking a medicine or receiving a vaccine. The Med Safety App can also be used to keep up to date with safety information on registered health products.

2. How to download the Med Safety App

You can download the Med Safety App for free from:

- App Store (for iOS devices)
- Google Play (for Android devices)
- Search for "Med Safety" and download the app with the below icon:

3. Opening the Med Safety App for the first time

- When opening the Med Safety App for the first time, select your country from the available list.
- We recommend that you create an account as this will allow you to view your previously submitted reports in the app and will make submitting further reports faster and easier. This is especially highly encouraged for healthcare workers who will likely submit more than one report. If you do not create an account, you can submit reports as a 'guest' but will not be able to view a copy of your report after submission.
- When creating an account, you will need to create a password that has a minimum length of 8 characters and contains at least 1 number and 1 uppercase character.
- You must acknowledge that you have read and understood the privacy statement before you can proceed to the App's home page.

4. How to navigate the Med Safety App

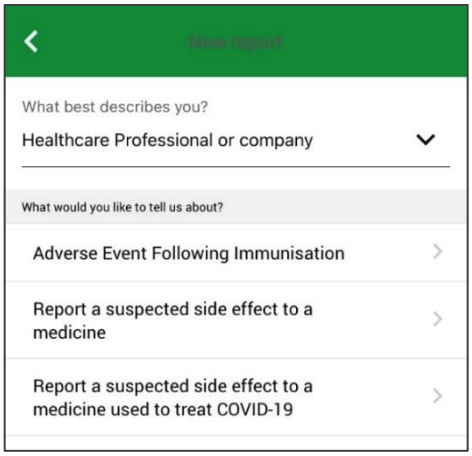
- The Med Safety App has five tabs which are found along the bottom of the screen: "News", "Products", "Watchlist", "Report", and "More".
- "News" displays medical products' safety information published by your country's health products regulator.
- "Products" displays information on all licensed medicines and vaccines in your country. You can also add products of interest to your watch list, allowing you to access this data without searching for it in the future.
- "Watch List" displays information on medicines and vaccines that you have added to your watch list.
- The "Report" tab is where you can submit a report of a suspected side effect, and view reports that you have previously submitted or saved.
- Under "More", you can view and amend your profile, read more about the App, and change your App settings.

5. How to navigate the navigate the reporting forms

- By clicking on the “Report” tab, you can create a new report of a suspected adverse event.
- You can save reports and update them at a later stage. You can find saved reports under “Pending reports”. You can save reports offline and submit them when you regain internet access.
- If you have created an account, you can view submitted reports at any time in “Sent reports”.
- Once you have completed all mandatory information on a page (fields that have been indicated with a *), click on “Next” at the bottom right of the screen to move to the next page.
- To return to a previous page at any point, click on “Back” at the bottom left of the screen.
- Before submission, use the “Back” arrow to review the full report and ensure that all information is as accurate as possible. Once you have reviewed your report, click “Submit” on the last page to submit the report.
- Upon submission, you will receive a message in the app to confirm your submission number and an email acknowledgement of your submission for your records.

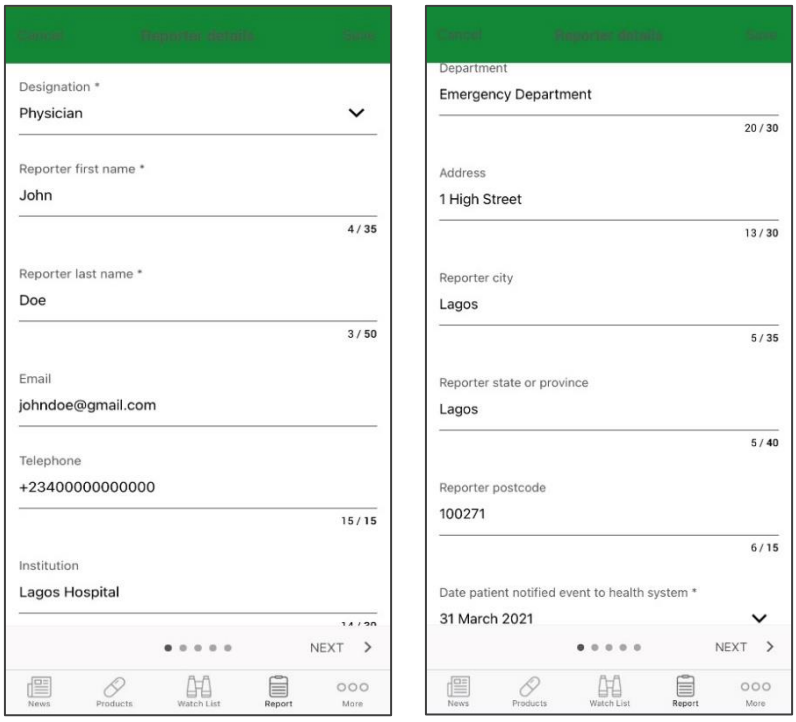
6. How to use the Med Safety App to report a side effect to a vaccine (for healthcare professionals)

- Click on “New Report” in the “Report” tab to create a new report.
- If you haven’t created an account, first indicate that you are a healthcare professional from the drop-down list on the screen.
- To report an adverse event from a vaccine, click on the option “Adverse Event Following Immunization”.



- On the first page, enter your personal detail as the reporter. You must also enter your appropriate designation (your specific profession) and the healthcare institution (and department) where you work.

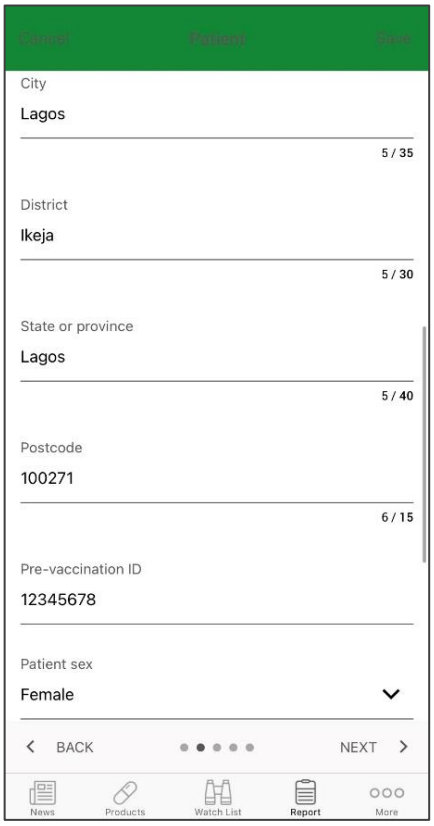
- *Your institution, city, and state (or province) are important to complete as this will help the EPI programme follow-up with you at the local level where this is required.*



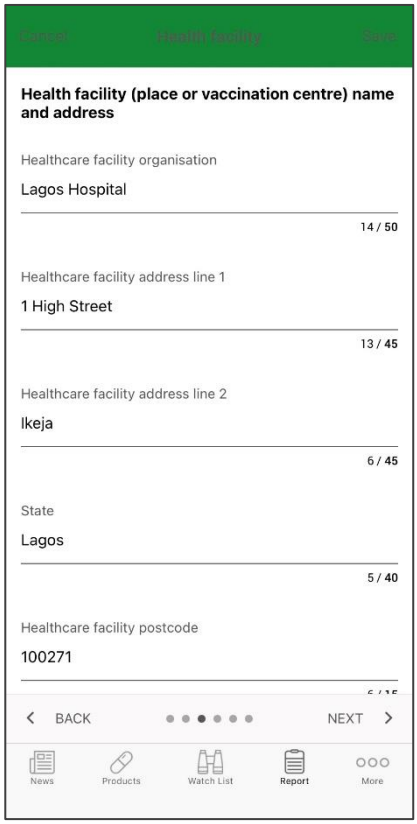
- On the second page, fill in the patient's details. This includes some information on the patient's location - at a minimum, include the patient's city, district, and state (or province).

- You will need to complete at least one of the patient identifiers to move onto the next page. These identifiers are patient initials, sex, age, and pre-vaccination ID number.

- *Please try to complete the pre-vaccination ID number as this helps regulators quickly access patient records if investigations are needed. If you indicate that the patient is female, you must further indicate whether the patient was pregnant or lactating at the time of vaccination.*



- On the third page, enter details of the health facility where the patient was vaccinated. This includes the health facility name, address, state or province, and postal code.



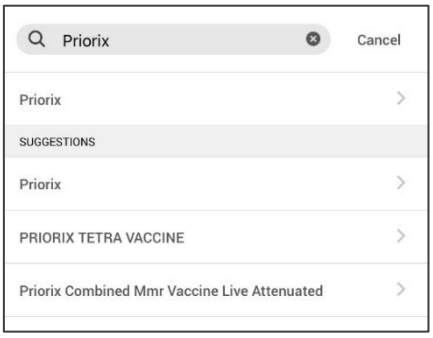
- On the fourth page, enter details of the vaccine which you suspect caused the adverse event. Click on “Add” to add a vaccine. First, fill in the name of the vaccine and select the correct option from the list (for example, Priorix). If you cannot find the vaccine name, type in as much information as you know about it in the search bar.
  - For example, if you know the patient received the Pfizer COVID-19 vaccine but cannot find the name of this vaccine in the app, type in “Pfizer COVID-19 vaccine”.

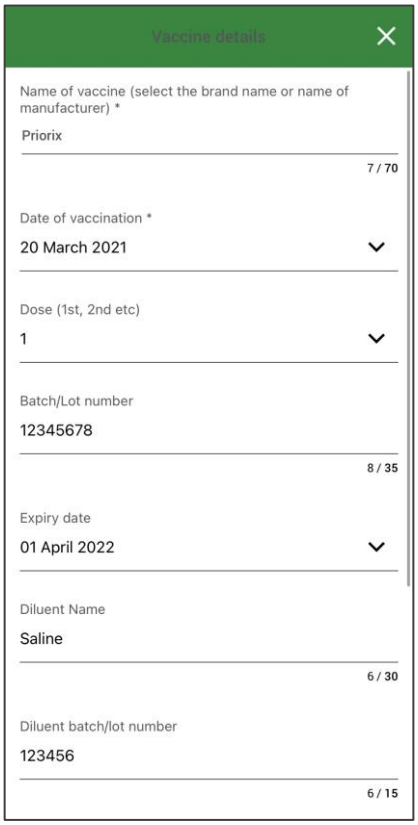
- Select the date the patient was vaccinated, and for which dose the adverse event was experienced. If the vaccine only requires one dose, select “First dose”. If the vaccine requires more than two doses and an adverse event was experienced after the third or fourth dose, do not make a selection in this field and rather specify the dose number in the “Describe AEFI” field on the “Reaction details” page of the form.

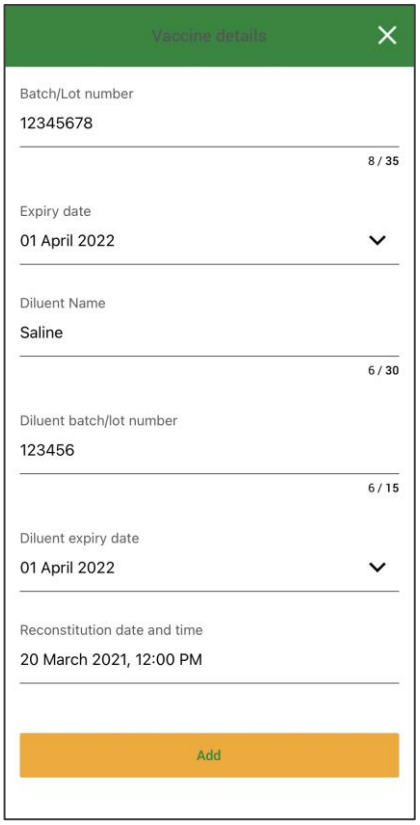
- Enter in the batch number for the vaccine which can be found in the patient’s vaccination card. If you are unsure of the batch number, type “Unknown” in this field.

- Enter information on any diluents used to reconstitute and administer the vaccine. Fill in the diluent name, batch number, expiry date, and reconstitution date and time. If you are unsure of any of this information, please leave the relevant fields blank.

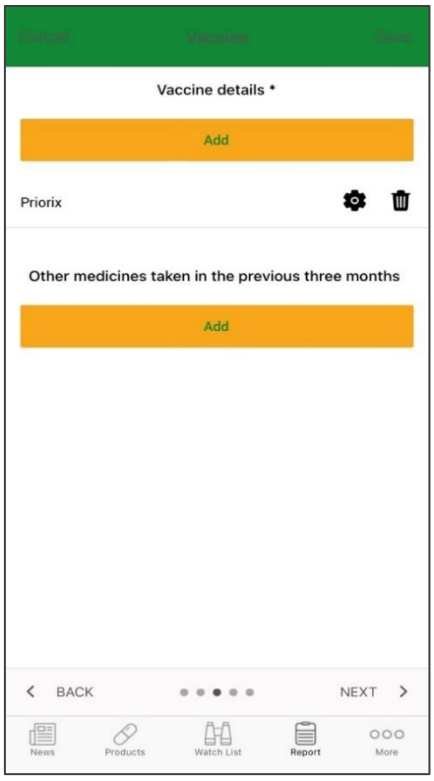
- Click on “Add” at the bottom of the screen to add these details into the report.



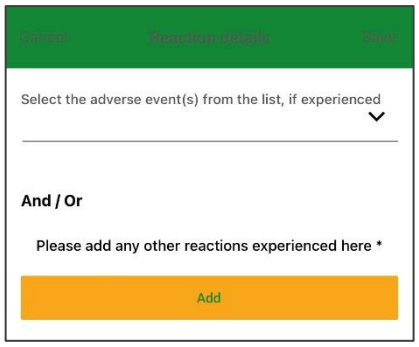




- In the case where more than one vaccine was taken at the same time, you must report all products administered to the patient. You will need to fill out all information on each vaccine you are reporting as well as any diluents used to reconstitute the additional vaccines. Please also include the names of any other medicines or vaccines taken by the patient in the last 3 months.



- On the fifth page, add details about any adverse events that the patient experienced. If the patient experienced adverse events of special interest (AESIs), select them from the list at the top of the screen. If other adverse events were experienced, include them by clicking on the “Add” button.

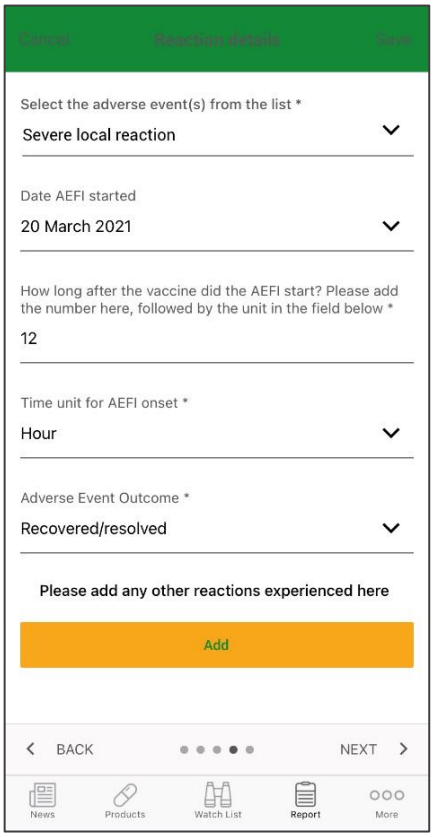


- If the patient experienced an AESI, click on the pre-defined drop-down list of AESIs in the first field and select the appropriate reaction(s).

- Once you have selected reactions from the drop-down list, fill in the remaining fields on this page to provide additional information on the adverse events.

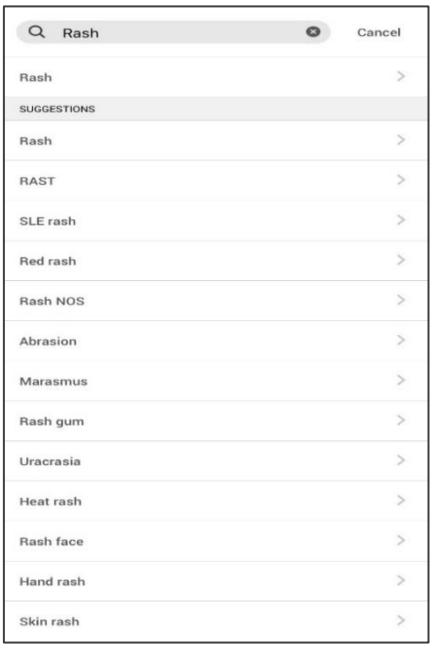
- You must specify the adverse event outcome in the appropriate field. Each option is explained in the table below.

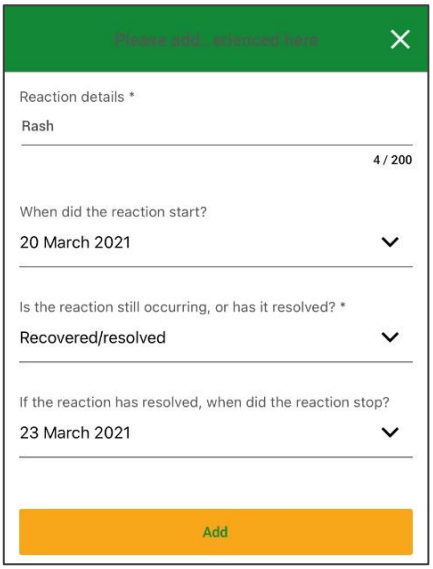
Adverse event outcome	Definition
Recovered/resolved	The patient has fully healed from the reaction without any lasting effects
Recovering/resolving	The patient is in the healing process and displaying clear positive signs of recovery but has not yet fully healed
Not recovered/not resolved	The patient has not yet healed from the reaction and is not yet showing clear positive signs of recovery
Recovered/resolved with sequelae	The patient has healed from the reaction but there are lasting effects or implications as a result of the reaction
Fatal	The patient has passed away (upon selecting this option, you must include the patient's date of death and indicate whether an autopsy was done)
Unknown	The patient's status is not known



- If you are reporting an adverse event not included in the previous pre-defined list, click on "Add" on the "Reaction details" page to fill in information on the reaction.

- Type the reaction into the text field and select the most appropriate term from the suggested list which will appear as you type.
  - For example, if the patient had a rash, type in "Rash" and select the most appropriate option.





- Complete the remaining details associated with the reaction and click "Add" to include these details in the report.

- You must specify the adverse event outcome in the appropriate field. Each option is explained in the table below.

Adverse event outcome	Definition
Recovered/resolved	The patient has fully healed from the reaction without any lasting effects
Recovering/resolving	The patient is in the healing process and displaying clear positive signs of recovery but has not yet fully healed
Not recovered/not resolved	The patient has not yet healed from the reaction and is not yet showing clear positive signs of recovery
Recovered/resolved with sequelae	The patient has healed from the reaction but there are lasting effects or implications as a result of the reaction
Fatal	The patient has passed away (upon selecting this option, you must include the patient's date of death and indicate whether an autopsy was done)
Unknown	The patient's status is not known

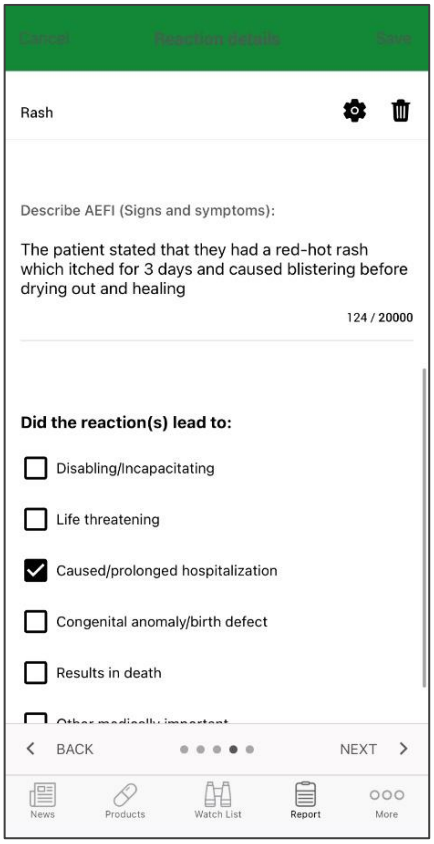
- Repeat this step to add any other reactions that the patient has experienced.

- Once you have added all reactions, provide a more detailed description in the relevant field.

- *In this field, do not disclose any patient identifier details (such as their name, contact details, or physical address). Using the example of a rash, you might enter a description such as "The patient stated that they had a red-hot rash which itched for 3 days and caused blistering before drying out and healing".*

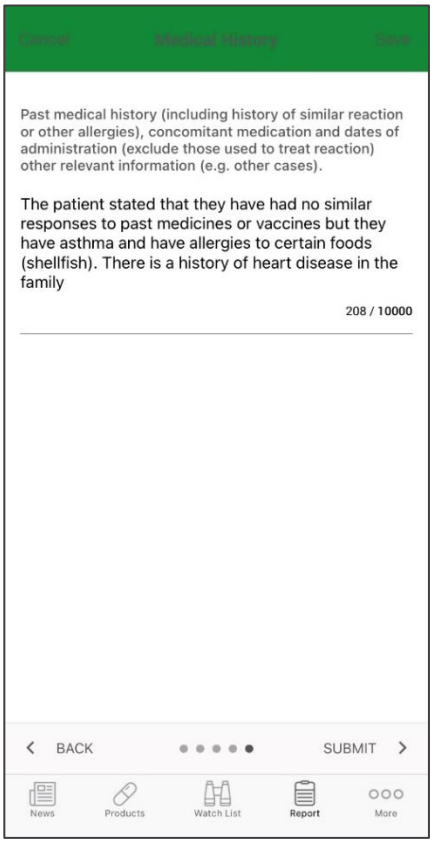
- You should also specify the dose number that the patient received if you are reporting an adverse event following a patient's third or fourth dose of a vaccine.

- To complete this page, select the outcome(s) of the reaction from the available options.
  - Note, multiple outcomes can be selected if applicable.



- On the last page, add details of the patient's relevant medical history before submitting the report. This includes information such as underlying medical conditions, allergies, family history, and any known adverse reactions to other medicines or vaccines in the past.

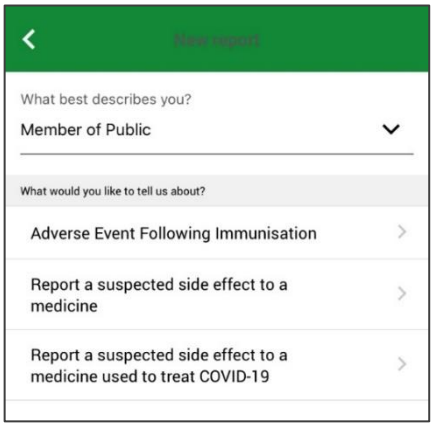
- *In this field, do not include any patient identifier information (such as the patient's name, contact information, or physical address) in this field.*



- Before submission, use the “Back” arrow to review the full report and ensure that all information is as accurate as possible. Once you have reviewed your report, click “Submit” on the last page to submit it. Upon submission, you will receive a message in the app to confirm submission and an email acknowledgement of your submission.

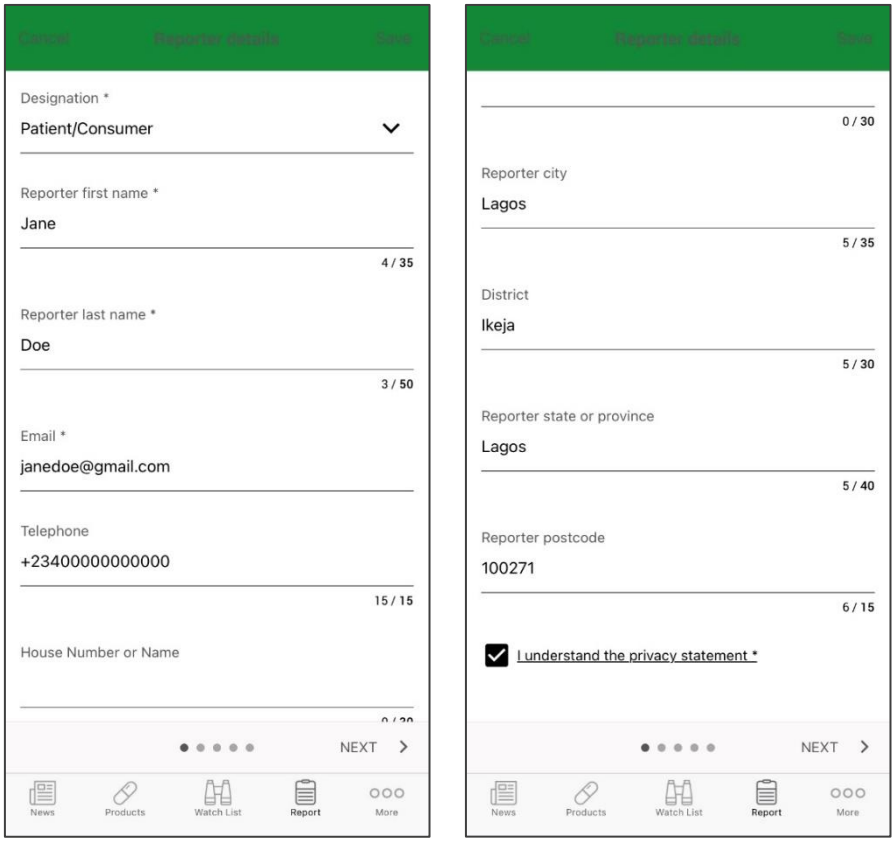
7. How to use the Med Safety App to report a side effect to a vaccine (for the public)

- Click on “New Report” in the “Report” tab to create a new report.
- If you haven’t created an account, first indicate that you are a member of the public from the drop-down list on the screen. To report an adverse event from a vaccine, click on the option “Adverse Event Following Immunization”.



- On the first page, enter your personal detail as the reporter. You must also enter your appropriate designation (whether you are a lawyer or a patient), your name, and your email address.
  - Note, if you have already created an account, information on this page will be automatically filled in.

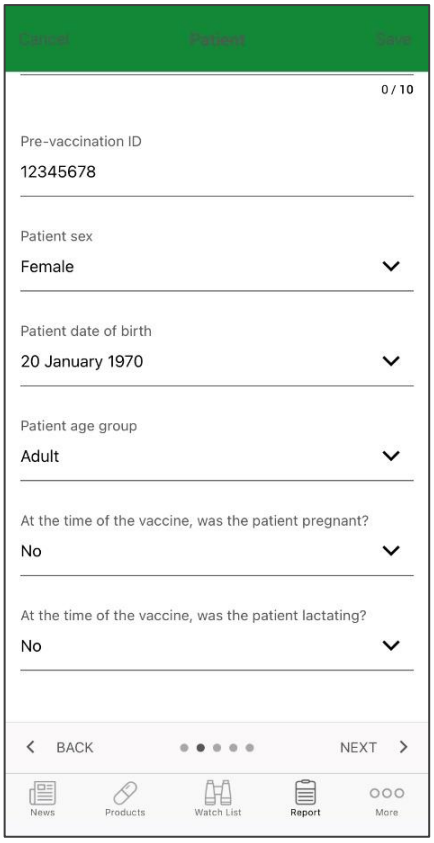
- *This page includes some information on your location - at a minimum, include your city, district, and state (or province).*



- On the second page, fill in more information about yourself as the patient if you are reporting an adverse event on behalf of yourself. You will need to complete at least one of the patient

identifiers to move onto the next page. These identifiers are patient initials, sex, age, and pre-vaccination ID number.
- Note, if you are reporting an adverse event on behalf of someone else, enter their information as the patient on this screen.

- *Please try to complete the pre-vaccination ID number as this helps regulators quickly access your medical records if investigations are needed. If you indicate that you are female, you must further indicate whether you were pregnant or lactating at the time of vaccination.*

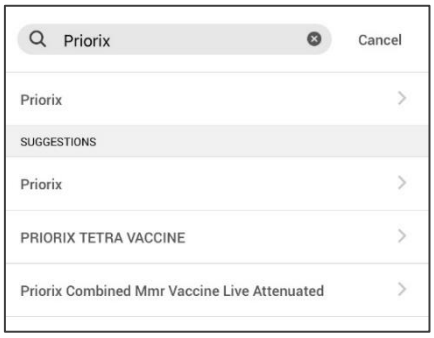


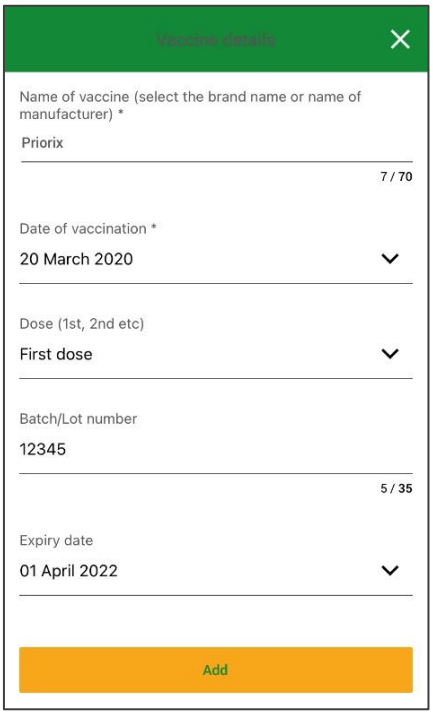
- On the third page, enter details of the vaccine which you suspect caused the adverse event. Click on “Add” to add a vaccine. First, fill in the name of the vaccine and select the correct option from the list (for example, Priorix). If you cannot find the vaccine name, type in as much information as you know about it in the search bar.
- For example, if you know that you received the Pfizer COVID-19 vaccine but cannot find the name of this vaccine in the app, type in “Pfizer COVID-19 vaccine”.

- Select the date that you were vaccinated, and for which dose the adverse event was experienced. If the vaccine only requires one dose, select “First dose”. If the vaccine requires more than two doses and an adverse event was experienced after the third or fourth dose, do not make a selection in this field and rather specify the dose number in the “Describe AEFI” field on the “Reaction details” page of the form.

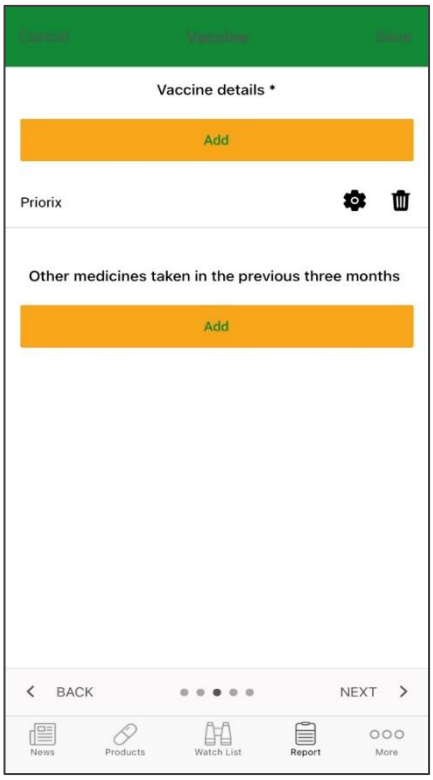
- Enter in the batch number for the vaccine which can be found in your vaccination card. If you are unsure of the batch number, type "Unknown" in this field.

- Click on "Add" at the bottom of the screen to add these details into the report.

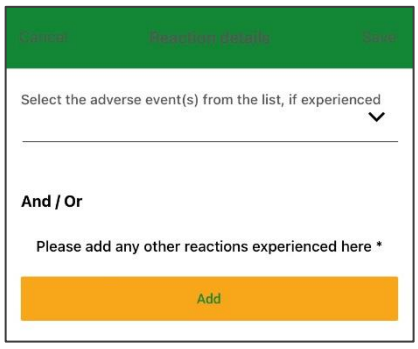




- In the case where more than one vaccine was taken at the same time, you must report all products administered to you. Please also include the names of any other medicines or vaccines that you have taken in the last 3 months.



- On the fourth page, add details about any adverse events that you experienced. If you experienced one or more of the events included in the list at the top of the screen, select them there. If you experienced additional or other adverse events, include them by clicking on the “Add” button.

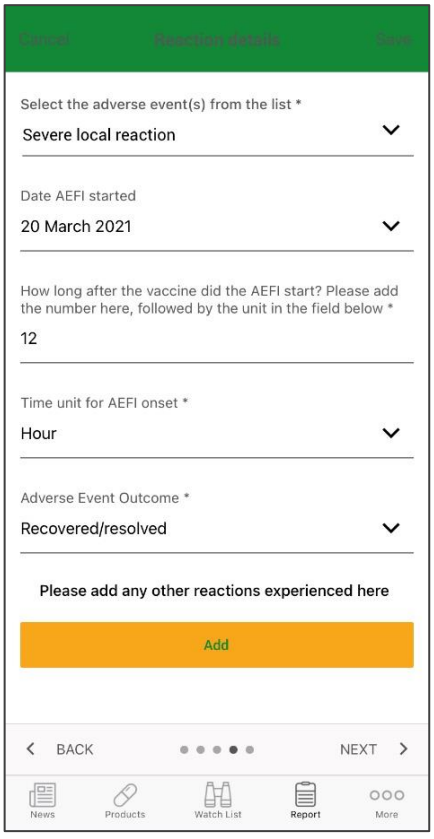


- Click on the pre-defined drop-down list in the first field. If you experienced one or more of the events included in the list, select the appropriate reaction(s).

- Once you have selected reactions from the drop-down list, fill in the remaining fields on this page to provide additional information on the adverse events.

- You must specify the adverse event outcome in the appropriate field. Each option is explained in the table below.

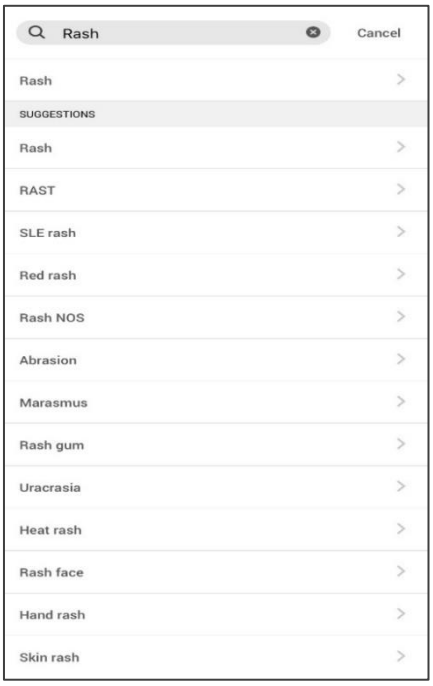
Adverse event outcome	Definition
Recovered/resolved	I have fully healed from the reaction without any lasting effects
Recovering/resolving	I am in the healing process and displaying clear positive signs of recovery but have not yet fully healed
Not recovered/not resolved	I have not yet healed from the reaction and am not yet showing clear positive signs of recovery
Recovered/resolved with sequelae	I have healed from the reaction but there are lasting effects or implications as a result of the reaction
Fatal	The patient has passed away (only select this option if you are reporting on behalf of someone who has passed away - upon selecting this option, you must include the date of death and indicate whether an autopsy was done)
Unknown	My status is not known

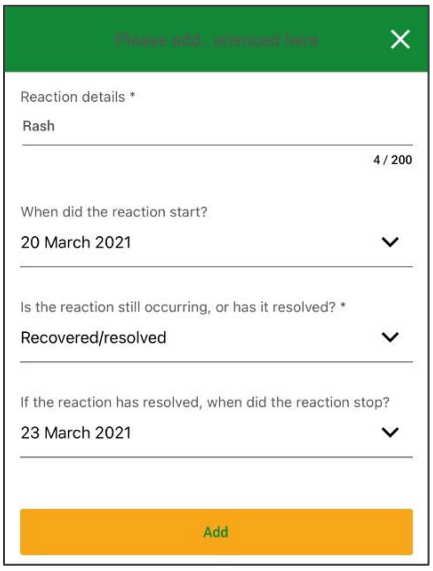


- If you are reporting an adverse event not included in the previous pre-defined list, click on "Add" on the "Reaction details" page to fill in information on the reaction.

- Type the reaction into the text field and select the most appropriate term from the suggested list which will appear as you type.
  - For example, if the patient had a rash, type in "Rash" and select the most appropriate option.

- Complete the remaining details associated with the reaction and click “Add” to include these details in the report.





- Once you have added all reactions, provide a more detailed description in the relevant field.

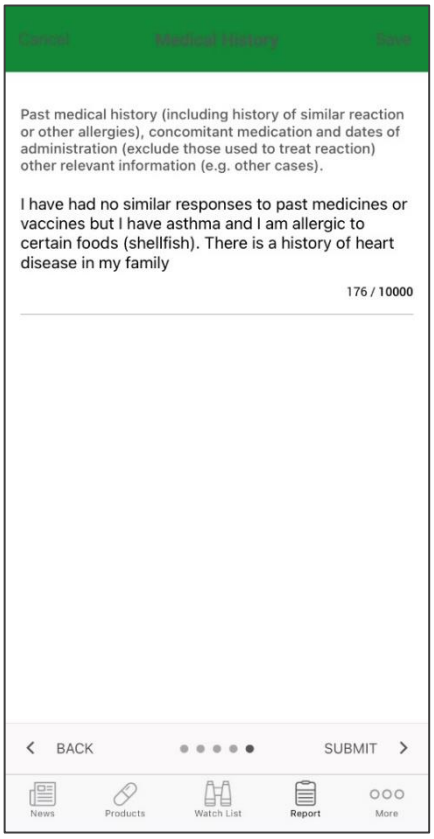
- *In this field, do not disclose any personal identifier details (such as your name, contact details, or physical address). Using the example of a rash, you might enter a description such as “I had a red-hot rash which itched for 3 days and caused blistering before drying out and healing”.*

- You should also specify the dose number that you received if you are reporting an adverse event following your third or fourth dose of a vaccine.

- To complete this page, select the outcome(s) of the reaction from the available options.
  - Note, multiple outcomes can be selected if applicable.

- On the last page, add details of your relevant medical history before submitting the report. This includes information such as underlying medical conditions, allergies, family history, and any known adverse reactions to other medicines or vaccines in the past.

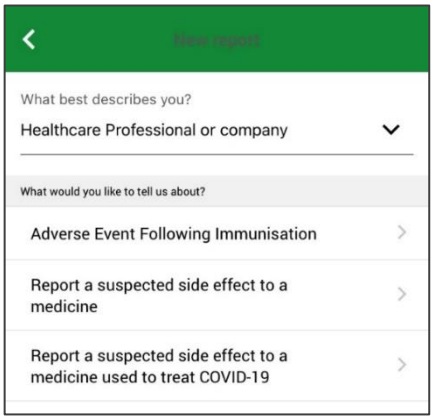
- *In this field, do not include any personal identifier information (such as your name, contact information, or physical address).*



- Before submission, use the “Back” arrow to review the full report and ensure that all information is as accurate as possible. Once you have reviewed your report, click “Submit” on the last page to submit it. Upon submission, you will receive a message in the app to confirm submission and an email acknowledgement of your submission.

8. How to use the Med Safety App to report a side effect to a medicine (for healthcare professionals)

- Click on “New Report” in the “Report” tab to create a new report.
- If you haven’t created an account, first indicate that you are a healthcare professional from the drop-down list on the screen.
- To report an adverse event to a medicine, click on the option “Report a suspected side effect to a medicine”.



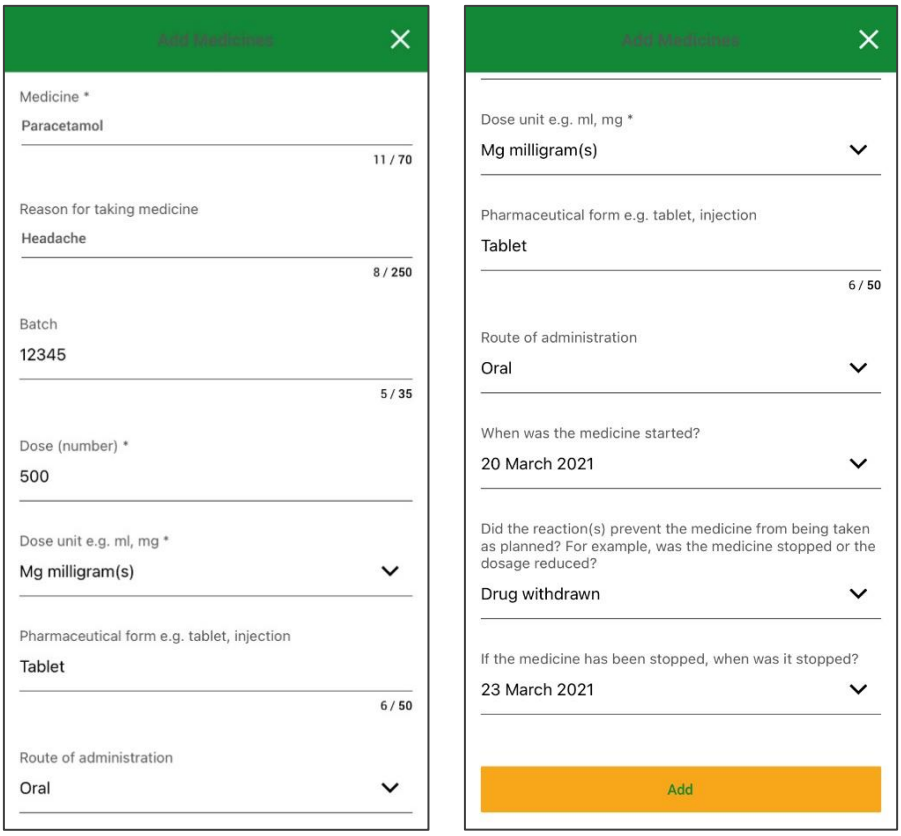
- On the first page, enter your personal details as the reporter as well as the patient's information. This includes some information on the patient's location - at a minimum, include the patient's city, district, and state (or province).
  - Note, if you have already created an account, your information (as the reporter) will be automatically filled in.

- *Your institution, city, and state (or province) are important to complete as this will help the EPI programme follow-up with you at the local level where this is required.*

- You will need to complete the at least one of the patient identifiers to move onto the next page. These identifiers are patient initials, sex, age, and local patient ID number.

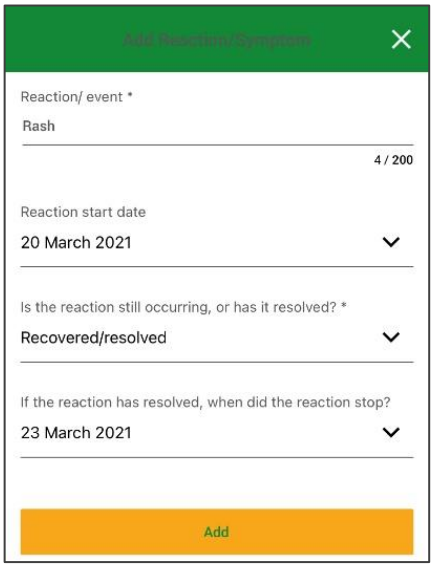
- *Please try to complete the local patient ID number as this helps regulators quickly access patient records if investigations are needed. If you indicate that the patient is female, you will need to further indicate whether the patient was pregnant at the time of the adverse reaction and (if known) the patient's last menstrual date.*

- On the second page, enter details of the medicine which you suspect caused the adverse event. First, fill in the name of the medicine and select the correct option from the list.
- If you cannot find the medicine's name, type in as much information as you know about it in the search bar. Fill in the remaining fields on this page to provide additional information on the medicine. In the case where more than one medicine is being used to treat a patient, you must report all medicines that the patient is taking.


Add Medicines
Medicine *
Paracetamol
11 / 70
Reason for taking medicine
Headache
8 / 250
Batch
12345
5 / 35
Dose (number) *
500
Dose unit e.g. ml, mg *
Mg milligram(s)
Pharmaceutical form e.g. tablet, injection
Tablet
6 / 50
Route of administration
Oral
Add Medicines
Dose unit e.g. ml, mg *
Mg milligram(s)
Pharmaceutical form e.g. tablet, injection
Tablet
6 / 50
Route of administration
Oral
When was the medicine started?
20 March 2021
Did the reaction(s) prevent the medicine from being taken as planned? For example, was the medicine stopped or the dosage reduced?
Drug withdrawn
If the medicine has been stopped, when was it stopped?
23 March 2021
Add

- On the third page, add details about any adverse events the patient experienced. Click on "Add" and fill in information on the adverse event. Fill in a description in the top field and select the correct option from the available list.
  - For example, if the patient had a rash, type in "Rash" and select the most appropriate option.

- Complete the remaining details associated with the reaction and click "Add" to include these details in the report. Then, fill in the remaining fields on this page to provide additional information on the adverse events.

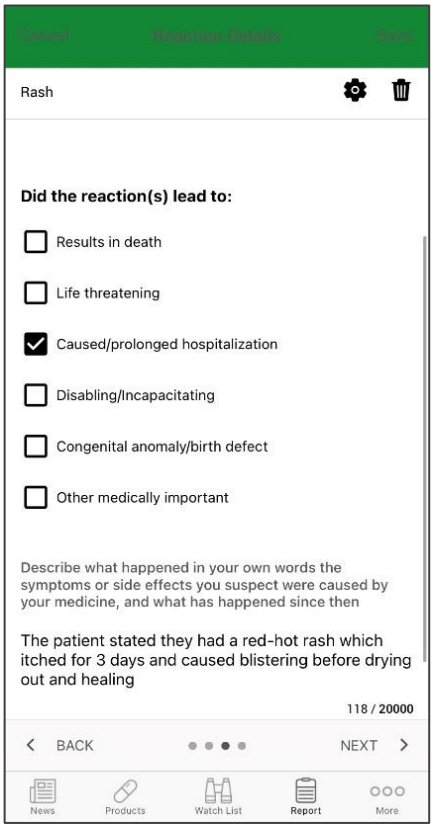


- If the patient experienced any other reactions, click on "Add" and fill in information on the adverse event, repeating the above process to add any other reactions that the patient has experienced.

- Once you have added all adverse events, select the outcome(s) of the reaction from the available options.
  - Note, multiple outcomes can be selected if applicable.

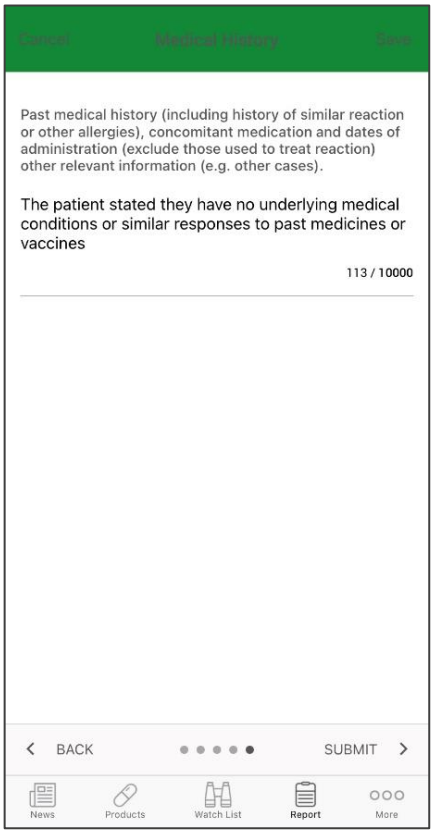
- To complete this page, provide more description on the reported adverse event in the relevant field.

- *Using the example of a rash, you might enter a description such as "The patient stated that they had a red-hot rash which itched for 3 days and caused blistering before drying out and healing". Do not include any patient identifier information (such as the patient's name, contact information, or physical address) in this field.*



- On the last page, add details of the patient's relevant medical history before submitting the report. This includes information such as underlying medical conditions, allergies, family history, and any known adverse reactions to other medicines or vaccines in the past.

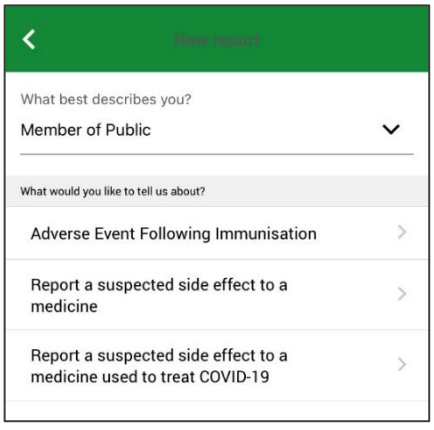
- *In this field, do not include any patient identifier information (such as the patient's name, contact information, or physical address).*



- Before submission, use the "Back" arrow to review the full report and ensure that all information is as accurate as possible. Once you have reviewed your report, click "Submit" on the last page to submit it. Upon submission, you will receive a message in the app to confirm submission and an email acknowledgement of your submission.

9. How to use the Med Safety App to report a side effect to a medicine (for the public)

- Click on "New Report" in the "Report" tab to create a new report.
- If you haven't created an account, first indicate that you are a member of the public from the drop-down list on the screen. To report an adverse event to a medicine, click on the option "Report a suspected side effect to a medicine".

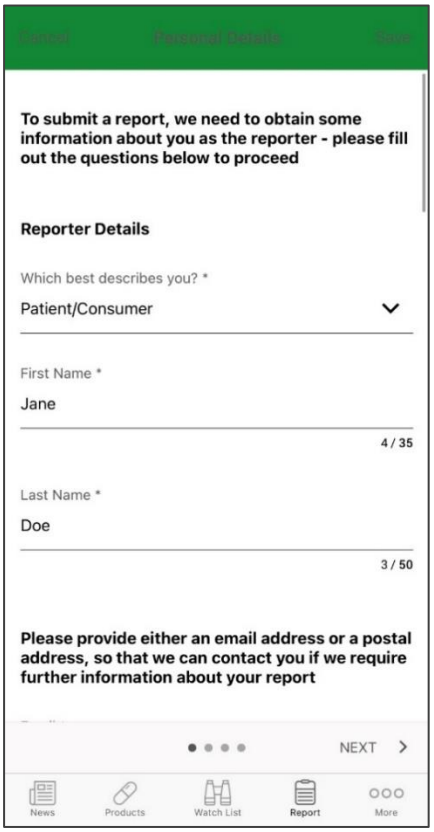


- On the first page, enter your personal detail as the reporter. First, enter your appropriate designation (whether you are a lawyer or a patient) and full name.
  - Note, if you have already created an account, information on this page will be automatically filled in.

- Then, fill in your contact information. This includes some information on your location - at a minimum, include your city, district, and state (or province). Lastly, you will need to complete at least one of the patient identifiers to move onto the next page. These identifiers are your initials, sex, and age.
  - Note, if you are reporting an adverse event on behalf of someone else, enter their information in the patient identifier fields.

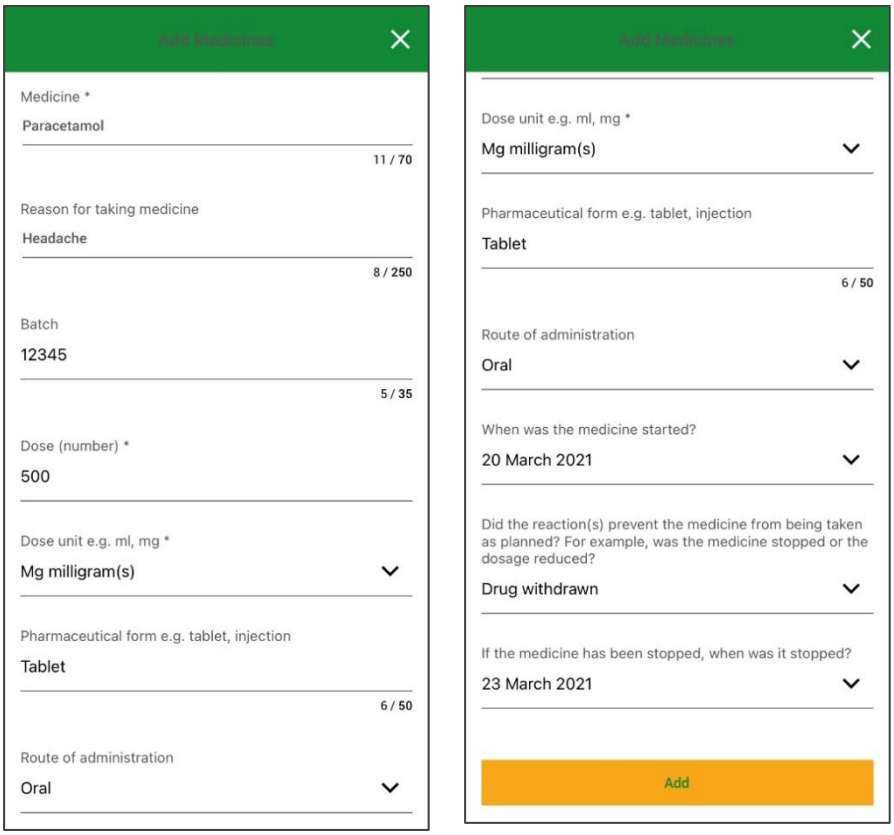
- If known, enter your weight and height (or the patient's weight and height if you are reporting on behalf of someone else).

- *If you indicate that you are female, you will need to further indicate whether you were pregnant at the time of the adverse reaction and (if known) your last menstrual date.*



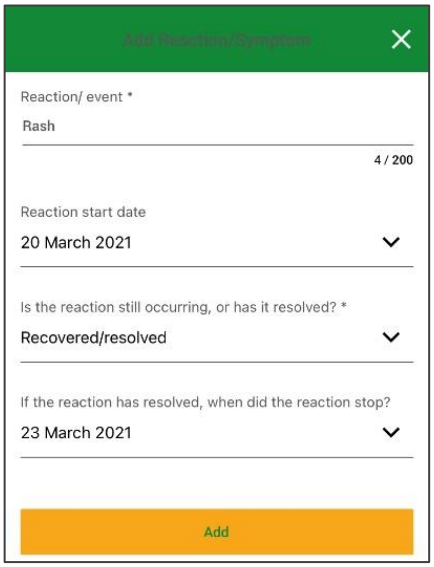
- On the second page, enter details of the suspected medicine. First, fill in the name of the medicine and select the correct option from the list. If you cannot find the medicine's name, type in as much information as you know about it in the search bar.

- Fill in the remaining fields on this page to provide additional information on the medicine. In the case where more than one medicine is being used, you must report all medicines that are being tak.



- On the third page, add details about any adverse events you experienced. Click on “Add” and fill in information on the adverse event. Fill in a description in the top field and select the correct option from the available list.
  - For example, if you had a rash, type in “Rash” and select the most appropriate option.

- Complete the remaining details associated with the reaction and click “Add” to include these details in the report. Then, fill in the remaining fields on this page to provide additional information on the adverse events.

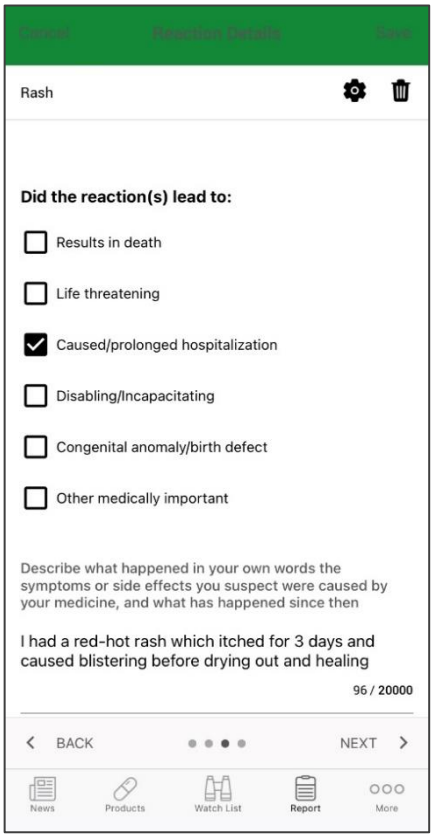


- If you experienced any other reactions, click on “Add” and fill in information on the adverse event, repeating the above process to add any other reactions that you experienced.

- Once you have added all adverse events, select the outcome(s) of the reaction from the available options.
  - Note, multiple outcomes can be selected if applicable.

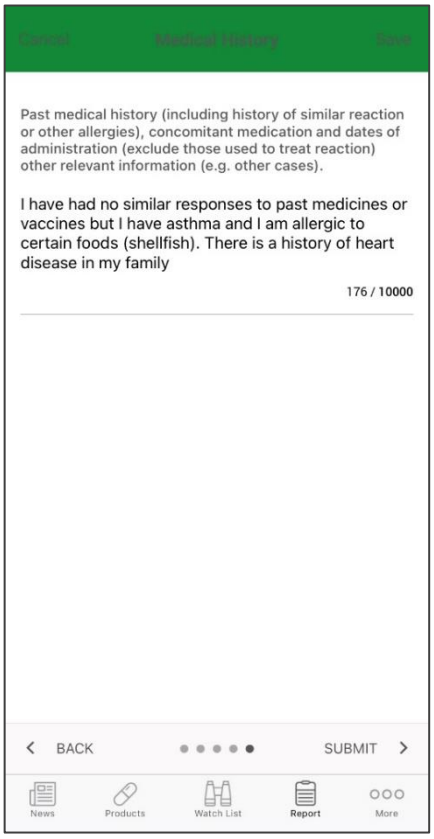
- To complete this page, provide more description on the reported adverse event in the relevant field.

- *Using the example of a rash, you might enter a description such as “I had a red-hot rash which itched for 3 days and caused blistering before drying out and healing”. Do not include any personal identifier information (such as your name, contact information, or physical address) in this field.*



- On the last page, add details of your relevant medical history before submitting the report. This includes information such as underlying medical conditions, allergies, family history, and any known adverse reactions to other medicines or vaccines in the past.

- *In this field, do not include any patient identifier information (such as your name, contact information, or physical address).*



- Before submission, use the “Back” arrow to review the full report and ensure that all information is as accurate as possible. Once you have reviewed your report, click “Submit” on the last page to submit it. Upon submission, you will receive a message in the app to confirm submission and an email acknowledgement of your submission.