



COVID-19 vaccination training for healthcare workers

Module 4: Adverse events following immunisation (AEFI) monitoring for COVID-19 vaccination

**Use of the Med Safety App for AEFI reporting
3 May, 6 May, 10 May and 13 May 2021**



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Overall objectives of today's session



- To provide a short overview of the Med Safety App for reporting an adverse event following immunisation (AEFI)
- To provide hands-on experience using the Med Safety App
 - Download
 - Navigation
 - Reporting an AEFI
- To answer participants' questions posted to the Knowledge Hub or live during the session

Poll 1: Have you watched any of the Med Safety App videos available on the Knowledge Hub or SAHPRA website?



- A. YES all of them
- B. Some of them
- C. None

Poll 1 results



Poll 2: Have you already downloaded the Med Safety App?



- A. YES
- B. Attempted, but unsuccessful
- C. NO

Poll 2 results



Poll 3: Have you heard anything about the Med Safety App in the media?



If YES, select the option which provided you with the most useful information

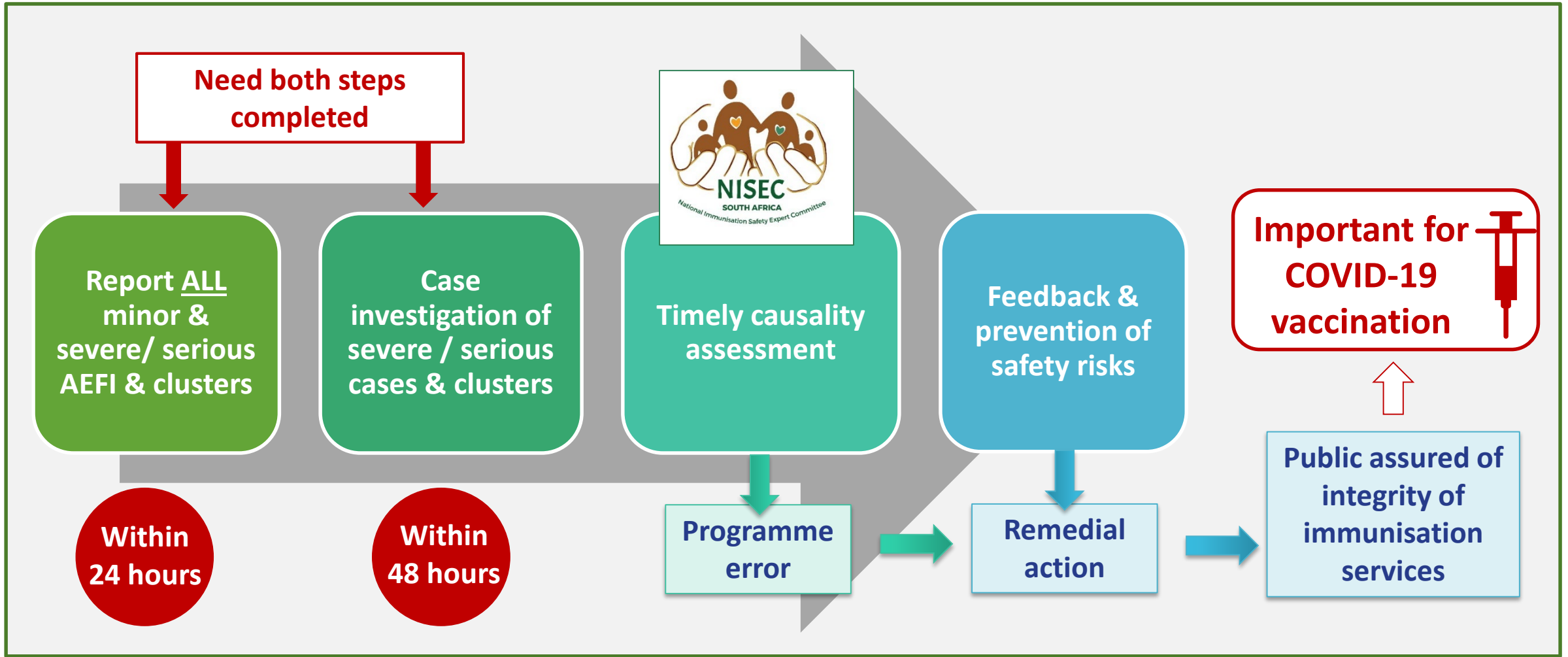
- A. Yes, social media (Facebook, Twitter, Instagram)
- B. Yes, radio
- C. Yes, TV
- D. Yes, newspaper
- E. Yes, online news
- F. No

Poll 3 results





Why report and investigate an adverse event following immunisation (AEFI) and an adverse event of special interest (AESI)?



WHO is responsible and WHEN to report an AEFI?



- All health care workers **providing immunisation** services
- Health workers **providing clinical treatment of AEFI and AESI** in health centres, hospitals, etc.
- **Vaccine recipients** who **report AEFI**
- **Researchers** conducting clinical trials or field trials

Report
within 24
hours

COVID-19
vaccines



For COVID-19 vaccines, reports on **severe or serious AEFI** must reach SAHPRA within 24 hours of identification or being notified about the AEFI through an expedited process. Reports of **minor AEFI** must reach SAHPRA within **7 days**.

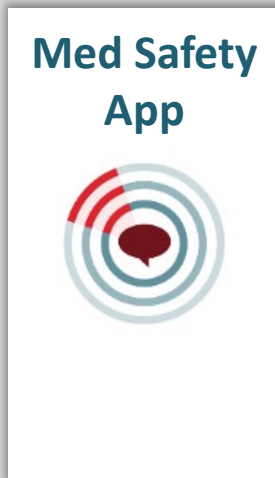
STEP 1:
MUST be completed for
ALL AEFI



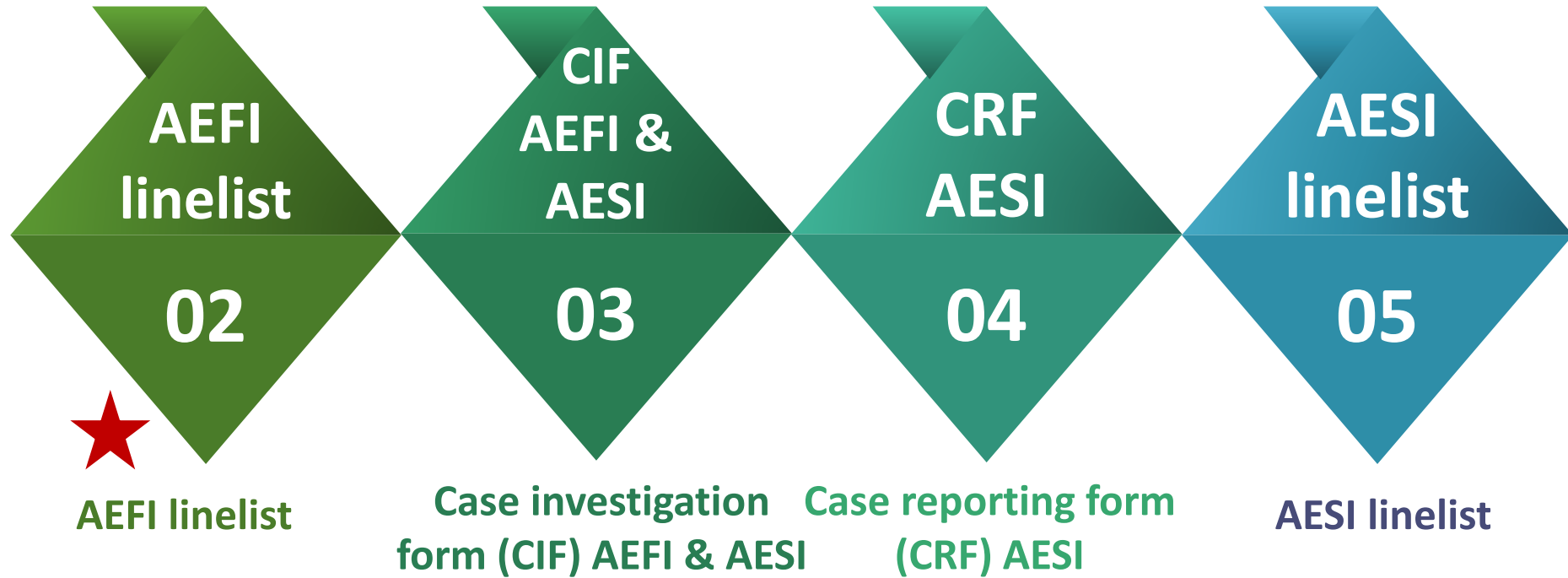
Case reporting form
(CRF) AEFI



Electronic
reporting
of AEFI



Which data collection tools should be used?



All documents available from:

- COVID-19 Vaccination Field Guide
- SAHPRA: <https://www.sahpra.org.za/health-products-vigilance/>
- NICD: <https://www.nicd.ac.za/diseases-a-z-index/adverse-event-following-immunization-aefi/>

Email address to submit documents: AEFI@health.gov.za

Case reporting form for AEFI

Report within 24 hours



health SOUTH AFRICA
ALL VACCINES including COVID-19
CASE REPORTING FORM (CRF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

EPIID Number: S O A - - - - -
Country - Province - District - Year - Case no

Today's date: DD/MM/YYYY
All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

SECTION A: IDENTIFYING INFORMATION
NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Patient (vaccinee) name & surname: _____
If child: Caregiver's name & surname: _____
Patient's residential address: _____
Mobile no: _____ Telephone no: _____
Email: _____
Sex: M F Other *If applicable:* Pregnant Lactating
Date of birth: DD/MM/YYYY
OR Age at onset: Years Months Days
OR Age group: 0 - <1 year 1 - 5 years >5 - 18 years
 >18 - 60 years >60 years
If applicable: Gestation: Full-term Premature

Reporter's name & surname: _____
Designation/Position: _____
Institution & Department: _____
Telephone no: _____
Mobile no: _____
E-mail: _____
Date patient notified to health system: DD/MM/YYYY

SECTION B: VACCINE INFORMATION (Please attach a copy of the Road to Health Booklet OR Vaccination Card)
NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

Health facility / vaccination center name: _____ DoH Private NGO
Address / location: _____

Vaccine's given (Use trade name)	Vaccine administered					Diluent (if applicable)				
	Date vaccinated	Time vaccinated	Dose number (1*, 2*)	Batch/ Lot number	Expiry date / Manufacture date (DD/MM/YY)	Stage (if applicable)	Manufacturer	Batch/ Lot number	Expiry date	Date & time of reconstitution

Consumables used: Needles Size: _____ Batch: _____ Expiry date: _____
Syringes Size: _____ Batch: _____ Expiry date: _____

SECTION C: TRIGGER EVENTS
Date & time AEFI started: DD/MM/YYYY HH:MM Min Adverse event (s): (Tick (✓) all boxes that apply)

Minor local reactions
 Swelling <5cm Induration / hardness
 Redness Rash
 Other (specify): _____

Minor systemic reactions
 Excessive crying (infant) Mild fever <38°C
 Mild headache Mild body aches
 Mild pain (to touch / on movement, but not interfering with daily activities)
 Other (specify): _____

Patient name & surname: _____ EPIID Number: _____

Severe local reactions
 Pain, redness and/or swelling >3 days
 Swelling >5cm
 Swelling beyond nearest joint
 Lymphadenitis
 Abscess
 Necrosis at vaccination site
 Other (specify): _____

Severe systemic reactions
 Hospitalisation Death Collapse/ shock-like state
 Fever ≥38°C Thrombocytopenia Anaphylaxis
 Seizures Febrile Afebrile Encephalopathy Sepsis
 Toxic shock syndrome Vomiting Diarrhoea
 Other (specify): _____

Foetal adverse reactions in the case of maternal immunisation:
 Decreased FHR variability Decreased foetal movement Foetus affected by maternal immunization (e.g. live vaccine administered to mother)
 Onset of preterm labour, assessed to be possibly/probably related
 Foetal anomaly assessed to be possibly/probably related (e.g. congenital and with pre-pregnancy or 1st trimester immunisation)
 Foetus affected by maternal immunization (e.g. live vaccine administered to mother)

NOTE: Severe or serious adverse event → Immediately notify District Office for Case Investigation

Describe patient's or caregiver's concern (AEFI signs and symptoms). Use additional sheet if needed

Were there any other similar AEFIs reported in the facility in the past 30 days? Yes No (If yes, specify)

SECTION D: PAST MEDICAL HISTORY
Past medical history (including history of previous similar reactions or other allergies), concomitant medication administration (exclude those used to treat reaction), any other relevant information. Use additional sheet if needed

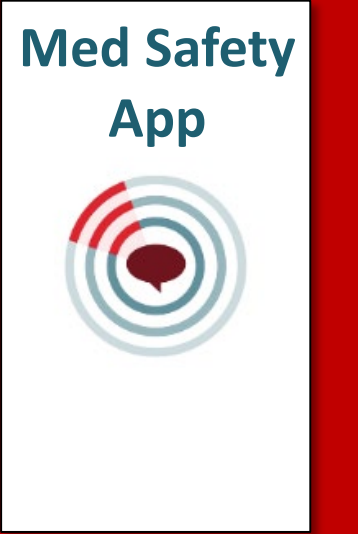
SECTION E: PRELIMINARY ASSESSMENT AND ACTIONS AT THE TIME OF REPORT
Is this event a serious AEFI? Yes No *If Yes, tick (✓) in the appropriate box below*
 Death Hospitalisation Disability Life threatening Congenital anomaly in off-spring of vaccinee
Comments: _____

SECTION F: WHAT WAS THE OUTCOME OF THE CASE FOLLOWING THE SUSPECTED AEFI in VACCINATION
 Recovering Recovered fully (no complications) Not Recovered Unknown
 Recovered with sequelae; Specify: _____
 Died → Date of death: DD/MM/YYYY → Autopsy: Yes No Unknown
 Hospitalisation → Date of admission: DD/MM/YYYY
→ Name of hospital: _____ Hospital number: _____

SECTION G: FIRST DECISION MAKING LEVEL TO COMPLETE
Case investigation needed: Yes No District Office notified: Yes No
Date investigation planned: DD/MM/YYYY If yes, date notified: DD/MM/YYYY

SECTION H: NATIONAL LEVEL TO COMPLETE
Date report received at National Level: DD/MM/YYYY AEFI worldwide unique ID: _____
Comments: _____

Electronic reporting using the Med Safety App is preferred!
Can be used off-line!
Only use paper-based reporting if you experience difficulties in using the App



Background on the Med Safety App



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



Med Safety App



Initiative by SAHPRA with support from EPI



Four countries participating

AU-3S COVID Response Working Group



South Africa



Ghana



Nigeria

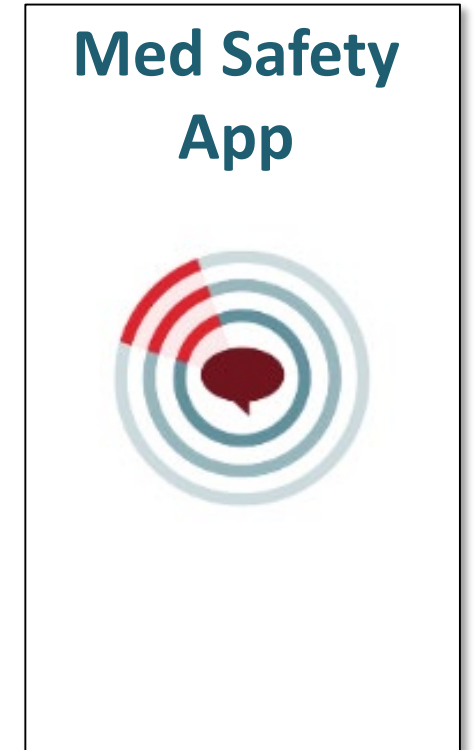


Ethiopia

What can we do with the Med Safety App?



- Report suspected AEFI and adverse drug reactions (ADRs) electronically
 - Replaces the need for paper forms → better **data quality**
- **Public** can report
 - **ADRs** for medicines
 - **AEFI** (coming soon)
 - **Minimise under-reporting**
- Reported cases can be **updated** with additional **information**
- Build a **watch list** of medicines
- Real time **data visibility**
 - View number of reports received in WHO database of suspected ADRs/AEFI
 - Track drug-related safety information



Safety signals or rare events

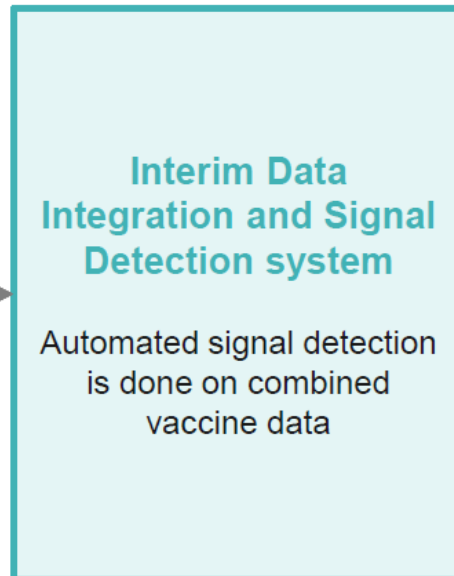


- **Safety signal** = when information becomes available from one or multiple sources
 - Could **potentially be associated with the vaccine**
 - Considered to be of sufficient likelihood to justify **investigation or verification**
- Requires **large populations** who received a particular vaccine → **pool data**
- **Signals** → **reviewed** by committee of experts from the four countries

AEFI data sources

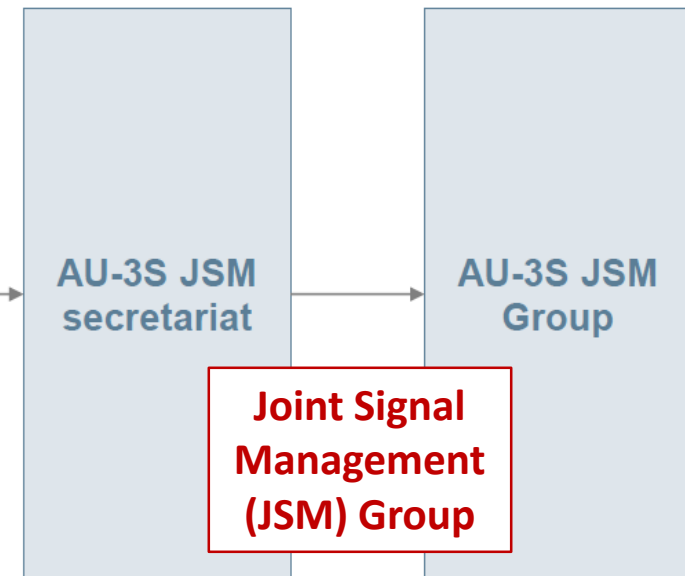


Cross-country database



Signal reports for combined COVID-19 vaccine safety data from all countries will be shared with the AU-3S JSM secretariat

Management of cross-country signals



Features of the Med Safety App?



Preferred
method of
reporting for
AEFI and
ADRs

Med Safety App

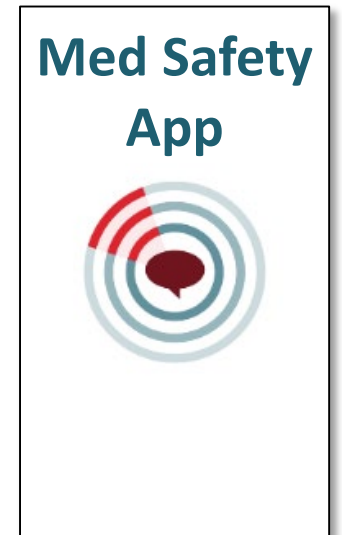


- **Mobile** application – free download
- Available for **Android** and **iOS** devices
- **Electronic reporting** of
 - Adverse drug reactions (**ADRs**) for medicines
 - Adverse events following immunisation (**AEFI**)
- Can be used by both **healthcare professionals** and the **public**
- Keep you up-to-date with information → **Drug safety news**
- Can function **offline** without internet connection
 - Create reports and submit when connected
 - Access newsfeed offline

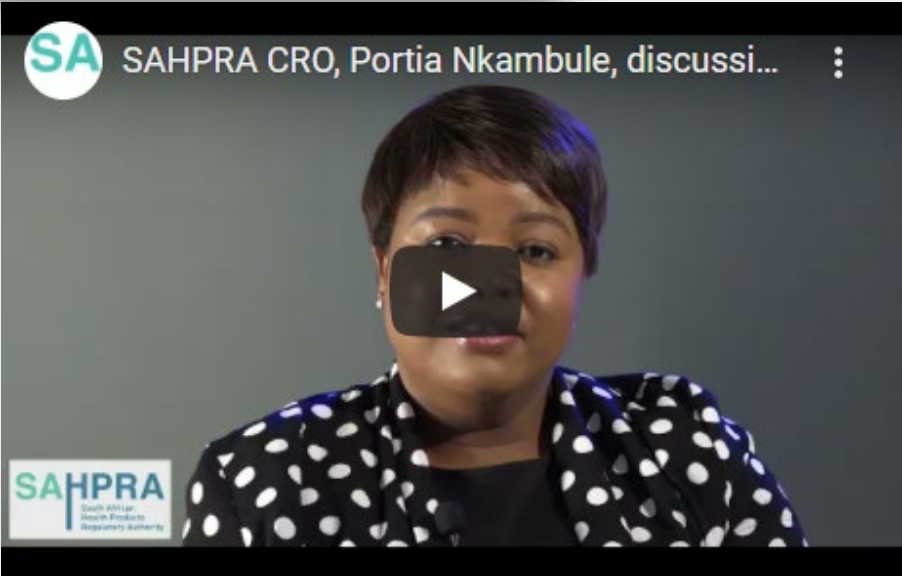
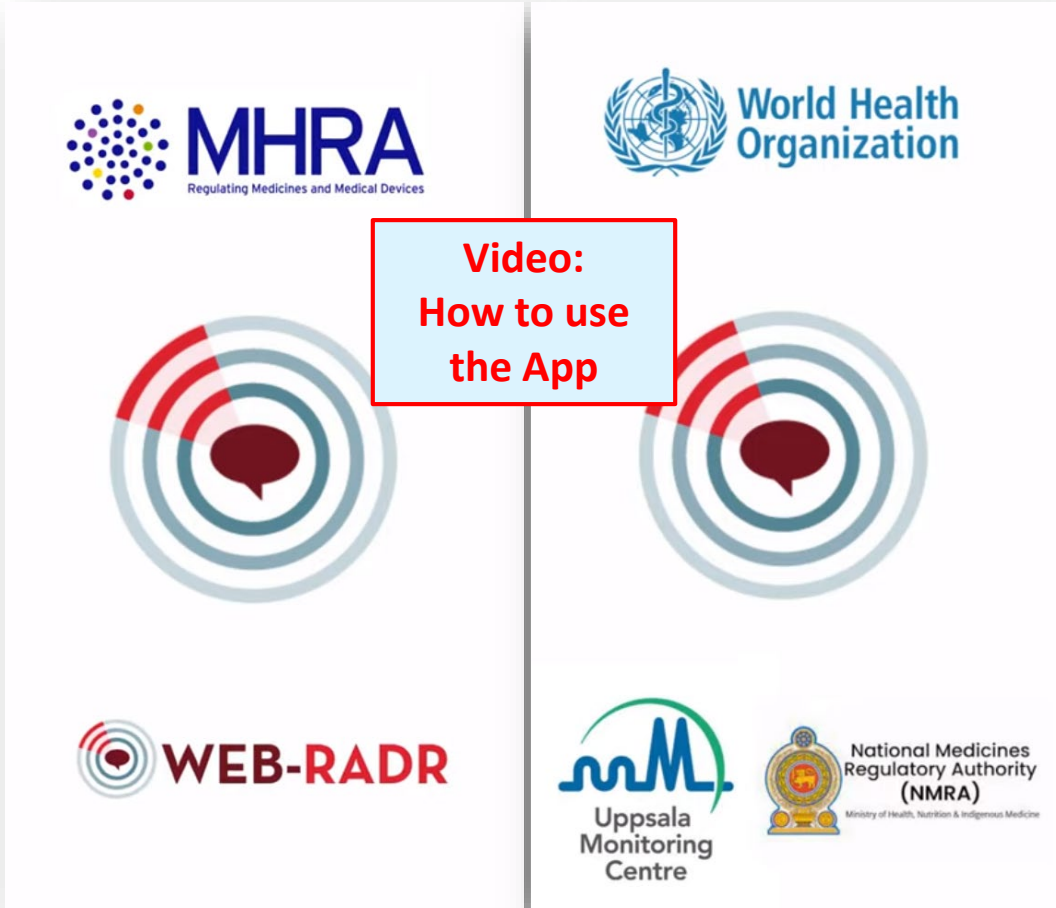
Where and how to download the Med Safety App



- Access **download instructions** and **information** videos about the App:
 - Knowledge Hub
 - <http://medsafety.sahpra.org.za/>
- **Questions** or **challenges** experienced with the use of the App:
 - Email: adr@sahpra.org.za
 - Helpline: **012-5010311** (weekdays; office hours)



What resources are available?



<http://medsafety.sahpra.org.za/>

What resources are available?



SAHPRA
South African
Health Products
Regulatory Authority

Med Safety App

Video:
**How to
report an
AEFI or ADR**



**How to report an
adverse event from
a vaccine**

**COMING
SOON:
Frequently
asked
questions
with answers**



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](#)
2. [How to download the Med Safety App](#)
3. [Opening the Med Safety App for the first time](#)
4. [How to navigate the Med Safety App](#)
5. [How to navigate the reporting forms](#)
6. [How to use the Med Safety App to report a side effect to a vaccine \(for healthcare professionals\)](#)
7. [How to use the Med Safety App to report a side effect to a vaccine \(for the public\)](#)
8. [How to use the Med Safety App to report a side effect to a medicine \(for healthcare professionals\)](#)
9. [How to use the Med Safety App to report a side effect to a medicine \(for the public\)](#)

Document:
**How to download
and use the App
to report an
AEFI or ADR**

Hands-on demonstration on how to use the Med Safety App for reporting an AEFI



Med Safety App



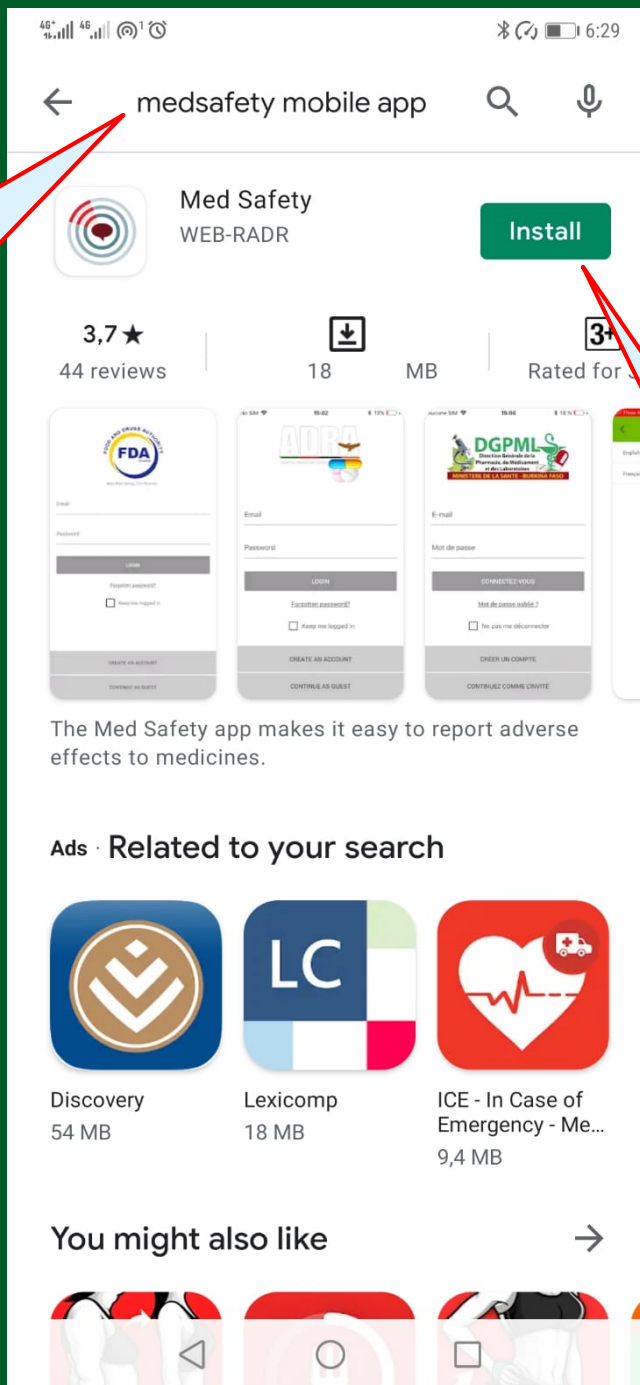
**Download the
Med Safety App
for free**



**App Store
(iOS devices)**

**Google Play
(Android devices)**

**Search for
"Med
Safety"**

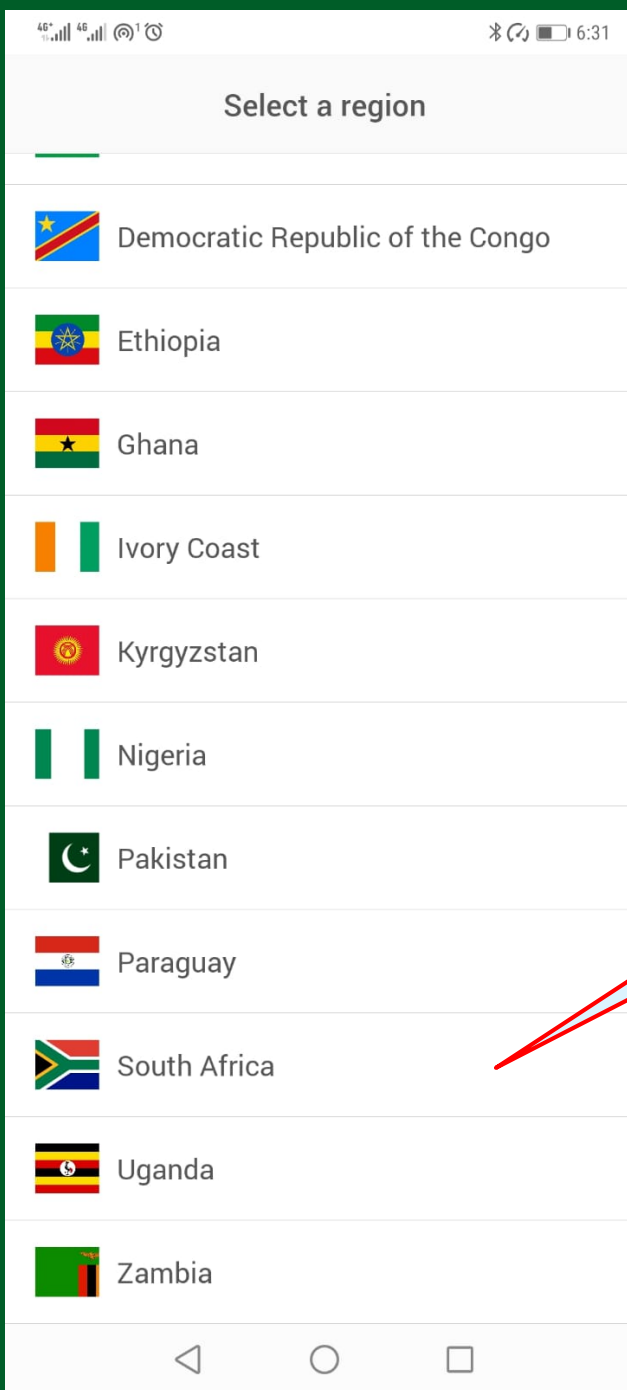
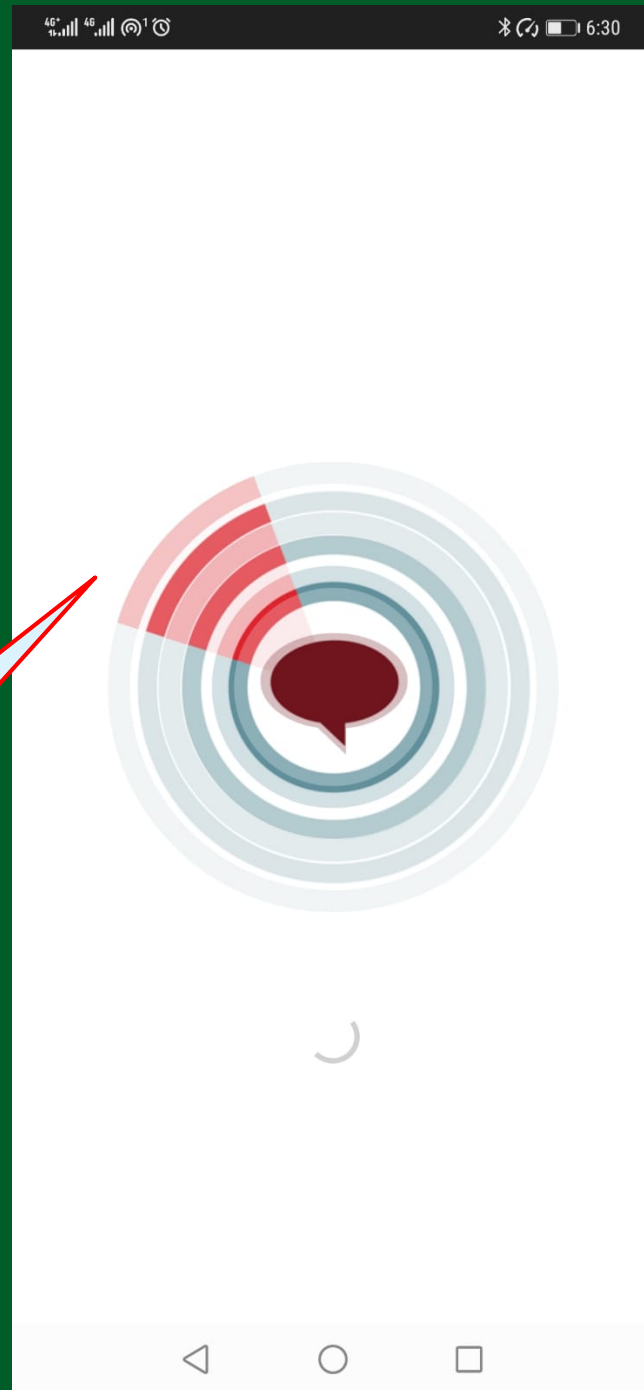


**Install Med
Safety**

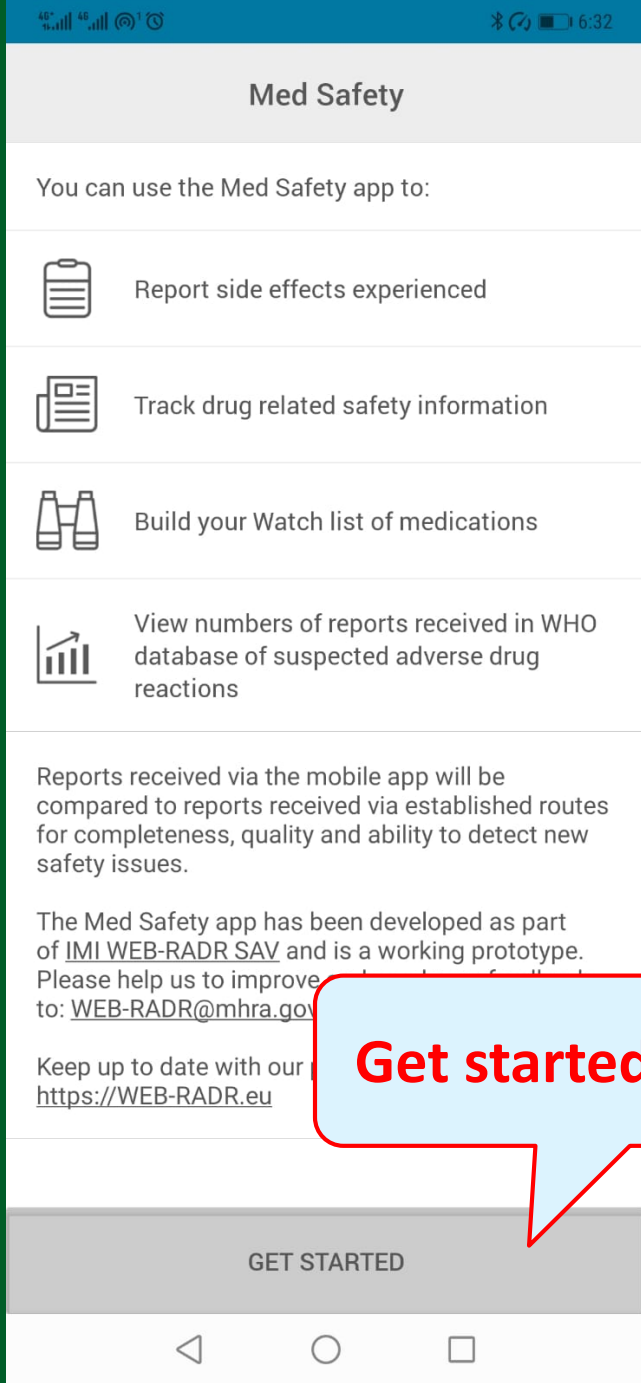


Open Med Safety App for first time

Download display



Select a country



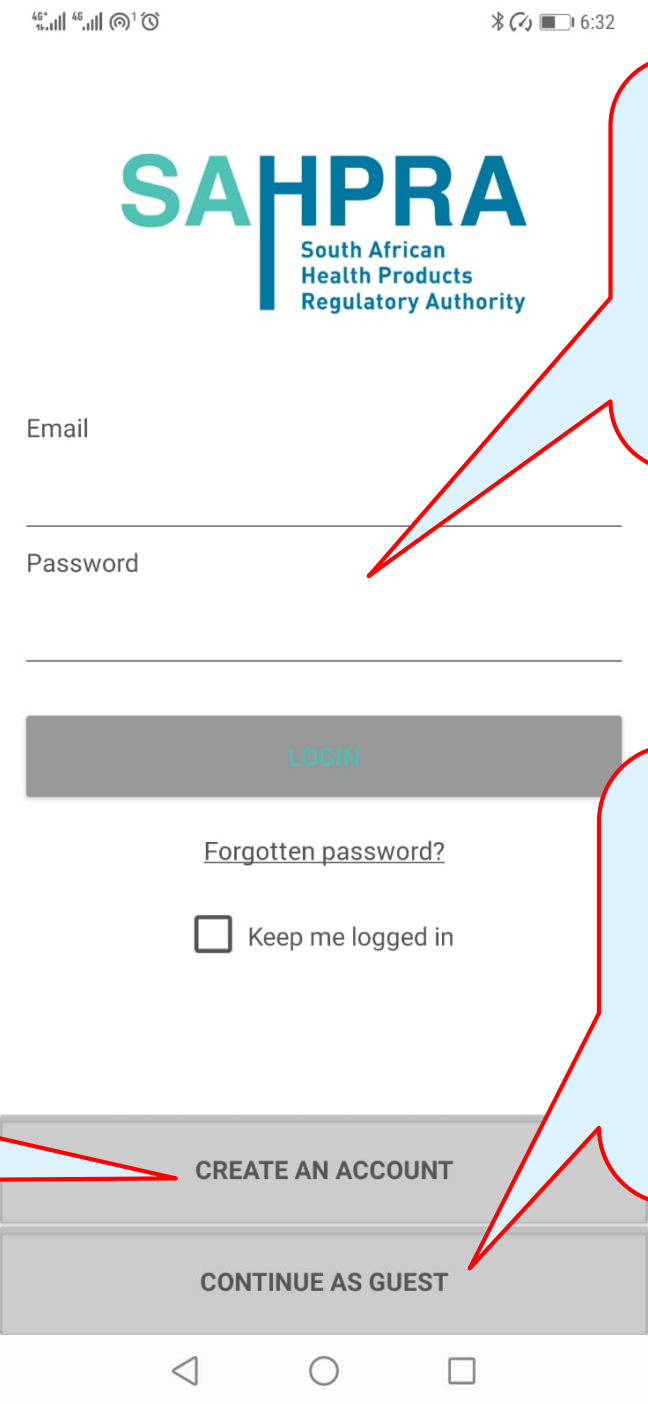
Get started

Create an account



View submitted reports
Faster & easier to submit future reports

Create an account



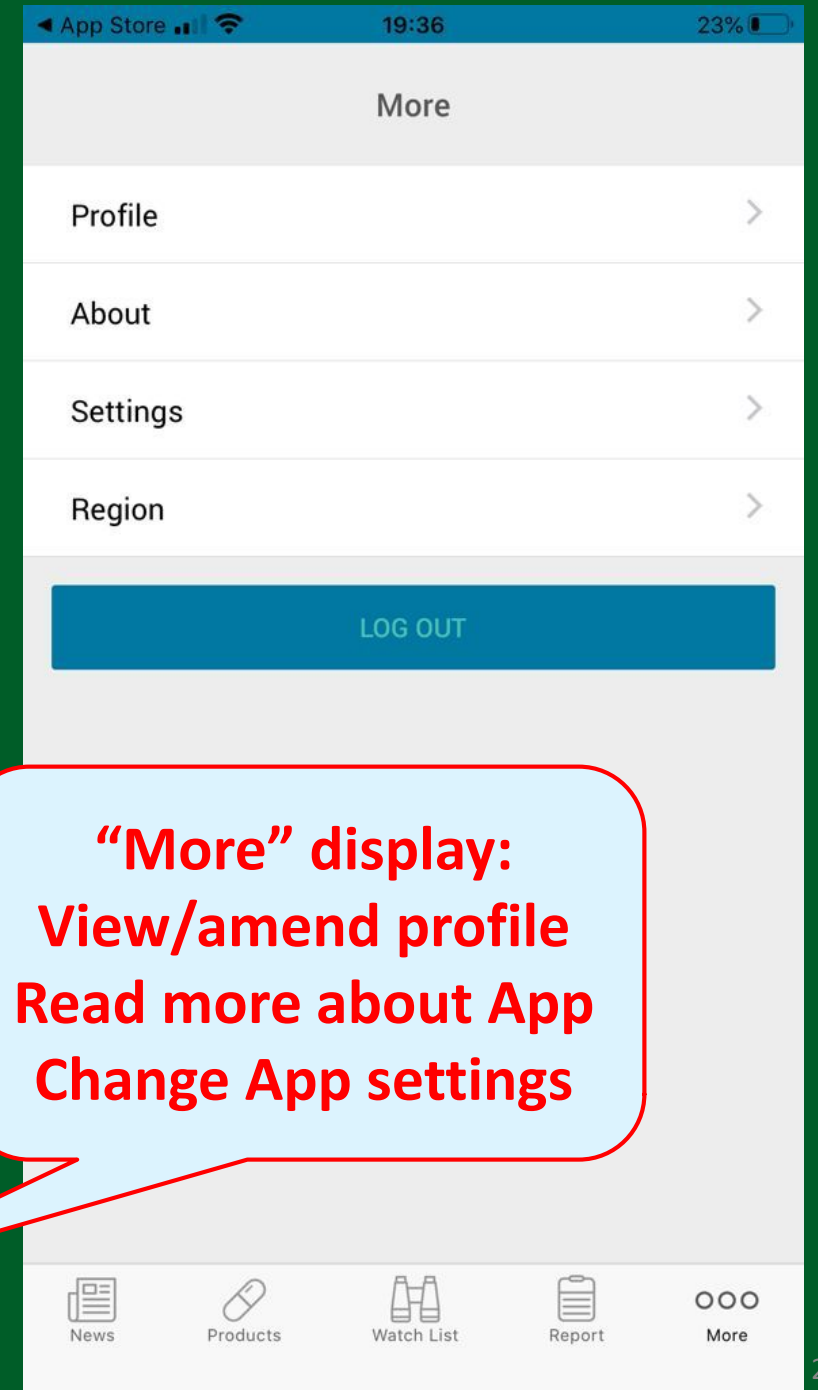
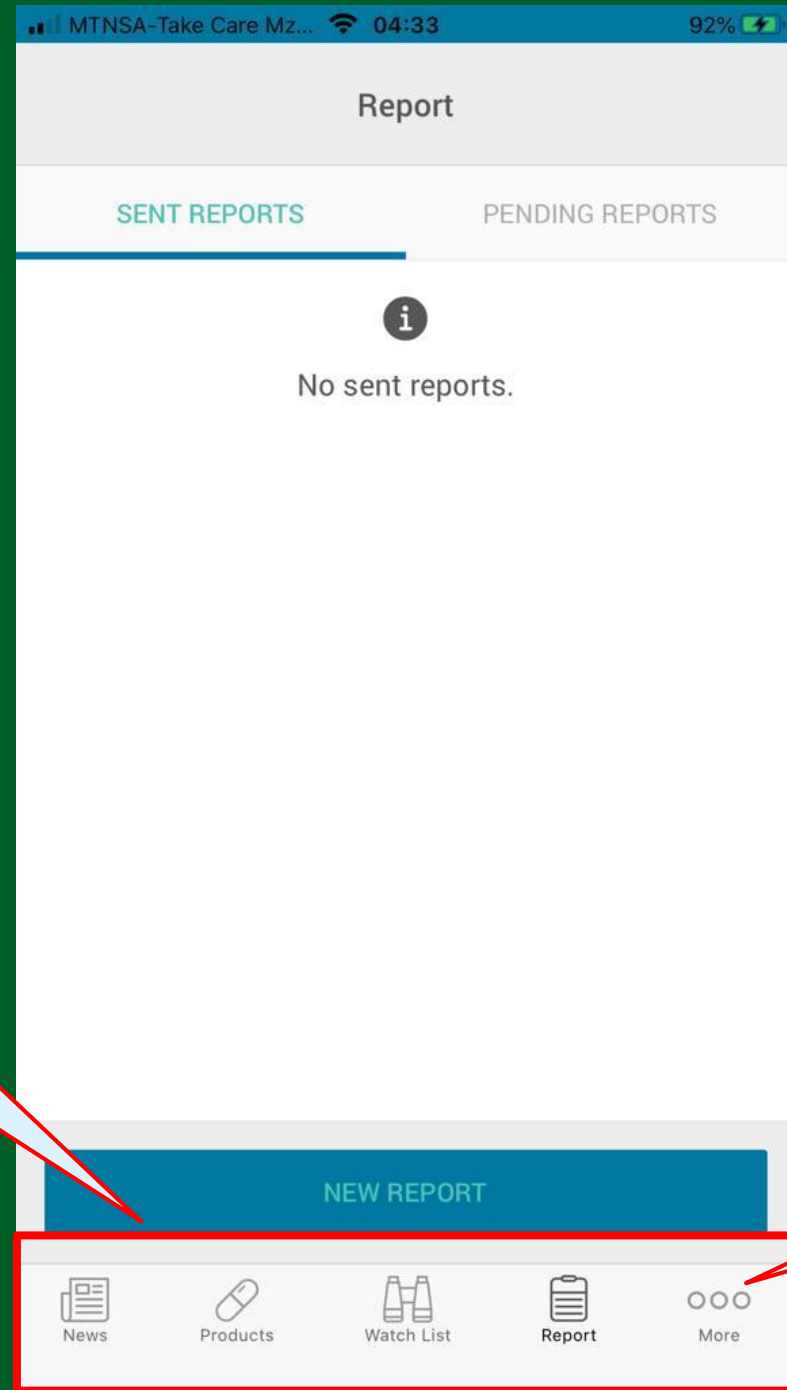
Password:
8 characters;
one uppercase letter;
one number
NO symbols e.g. @

Continue as guest
Will NOT be able to view submitted reports

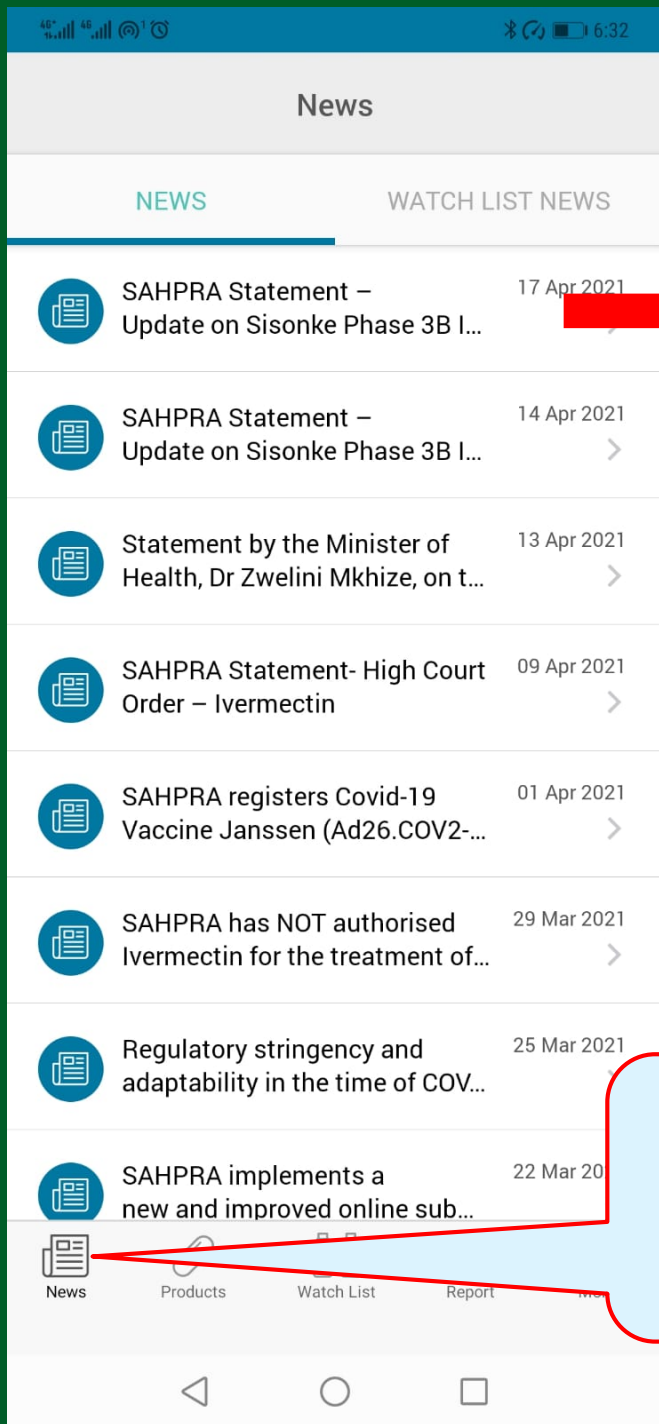
Navigate the Med Safety App

5 TABS

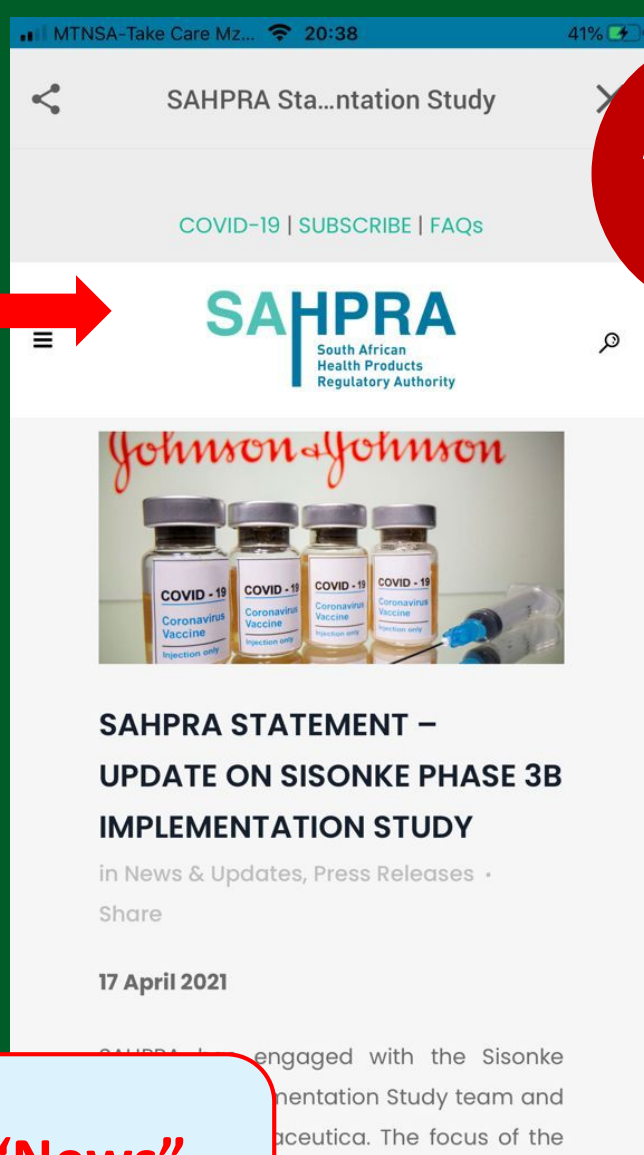
News
Products
Watchlist
Report
More



“More” display:
View/amend profile
Read more about App
Change App settings

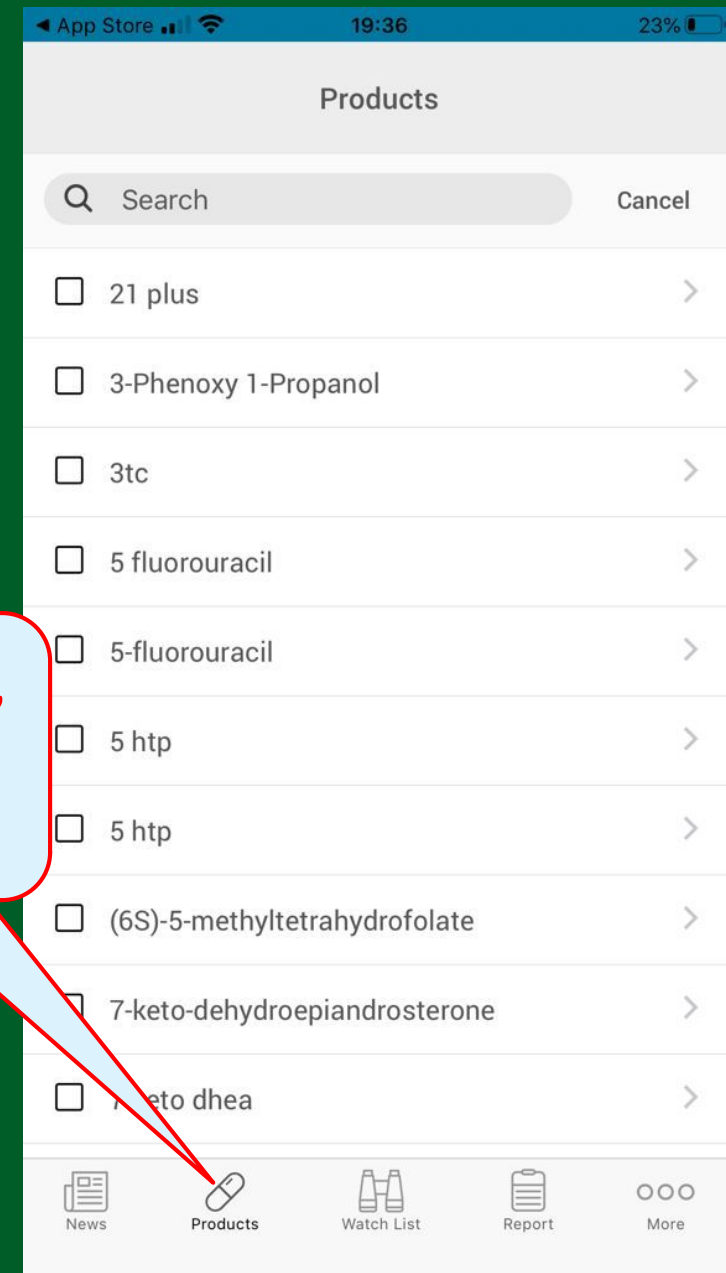


**“News”
display**

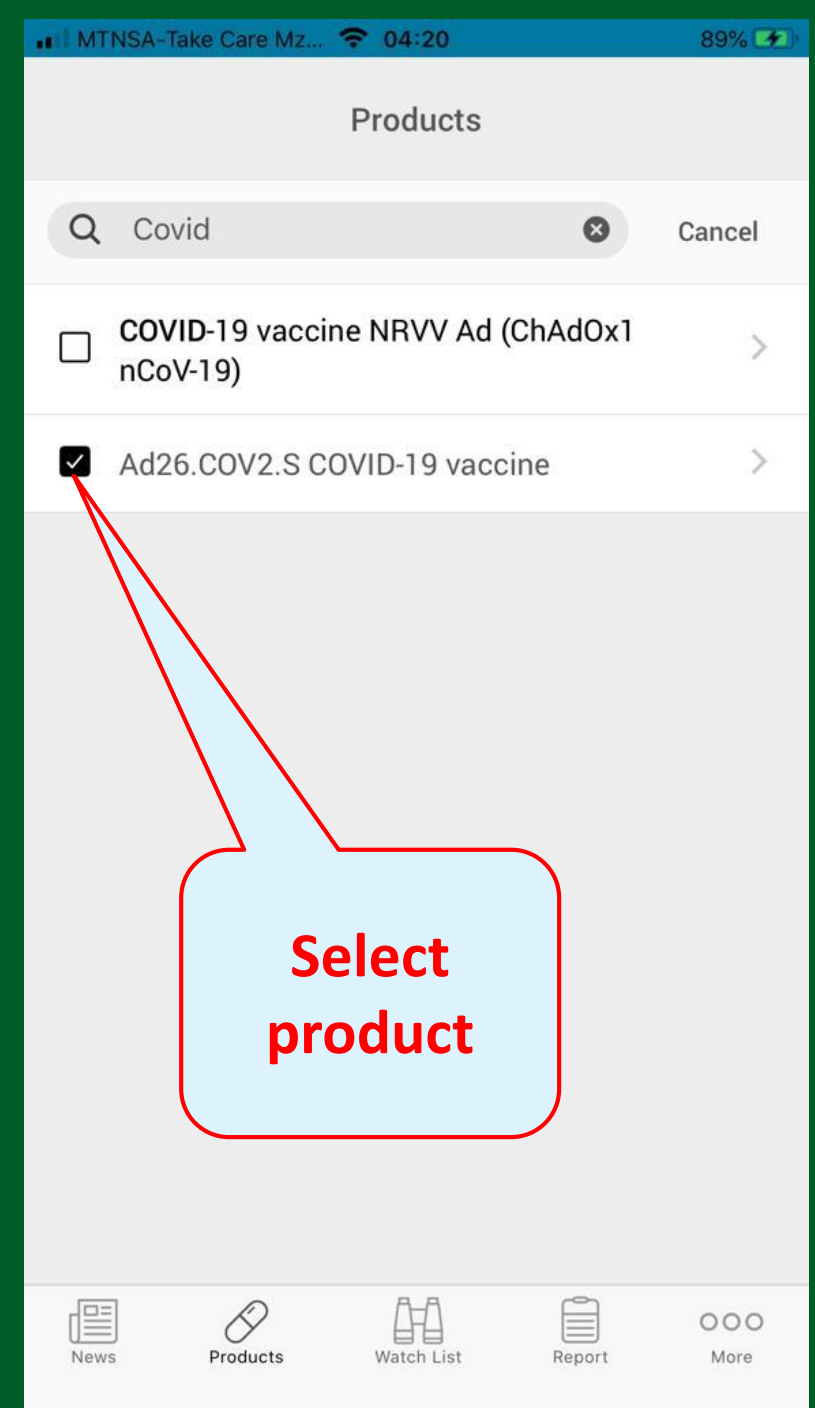
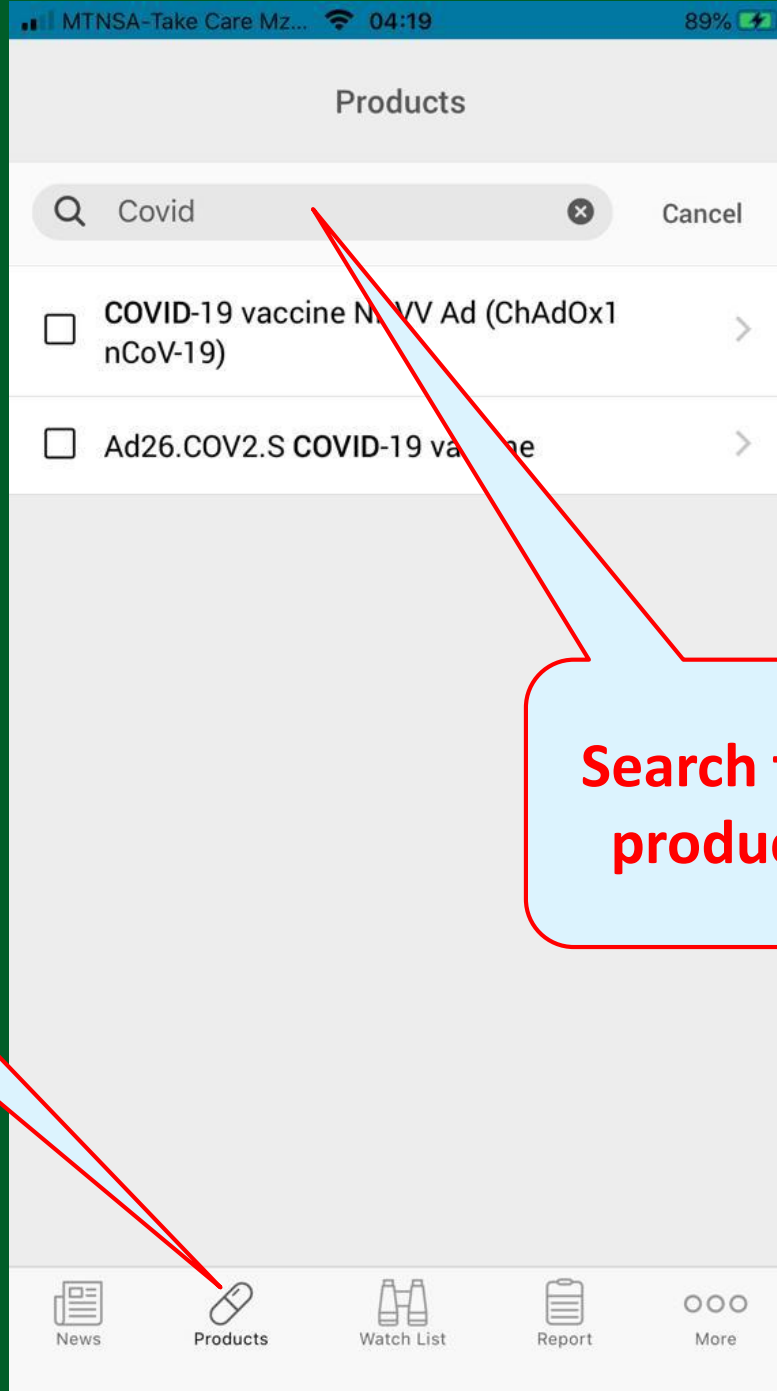


**Available
off-line**

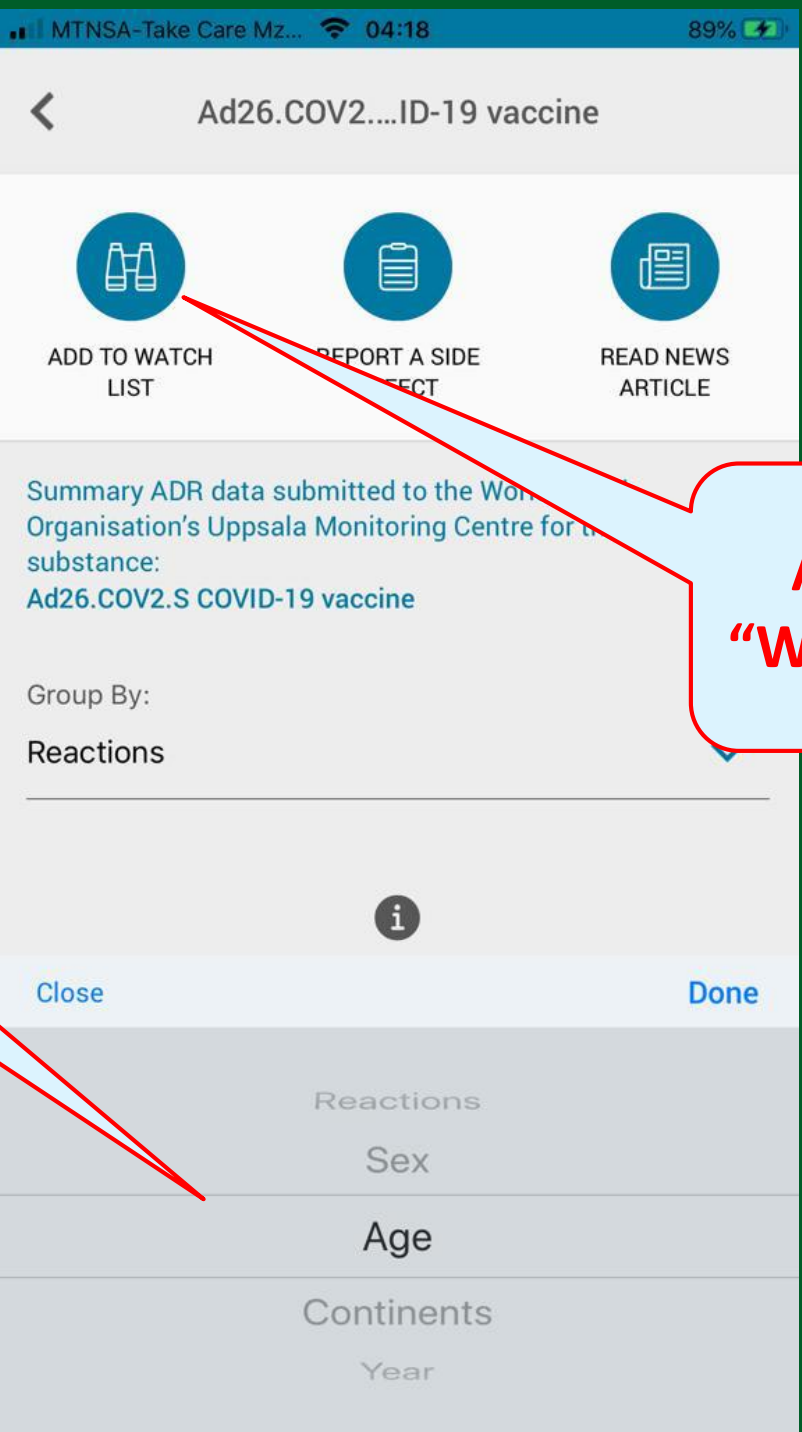
**“Products”
display**



Build own "Watchlist"



Add item to "Watchlist"



Group reactions

Add to "Watchlist"



"Watchlist" display

Navigate "Report"

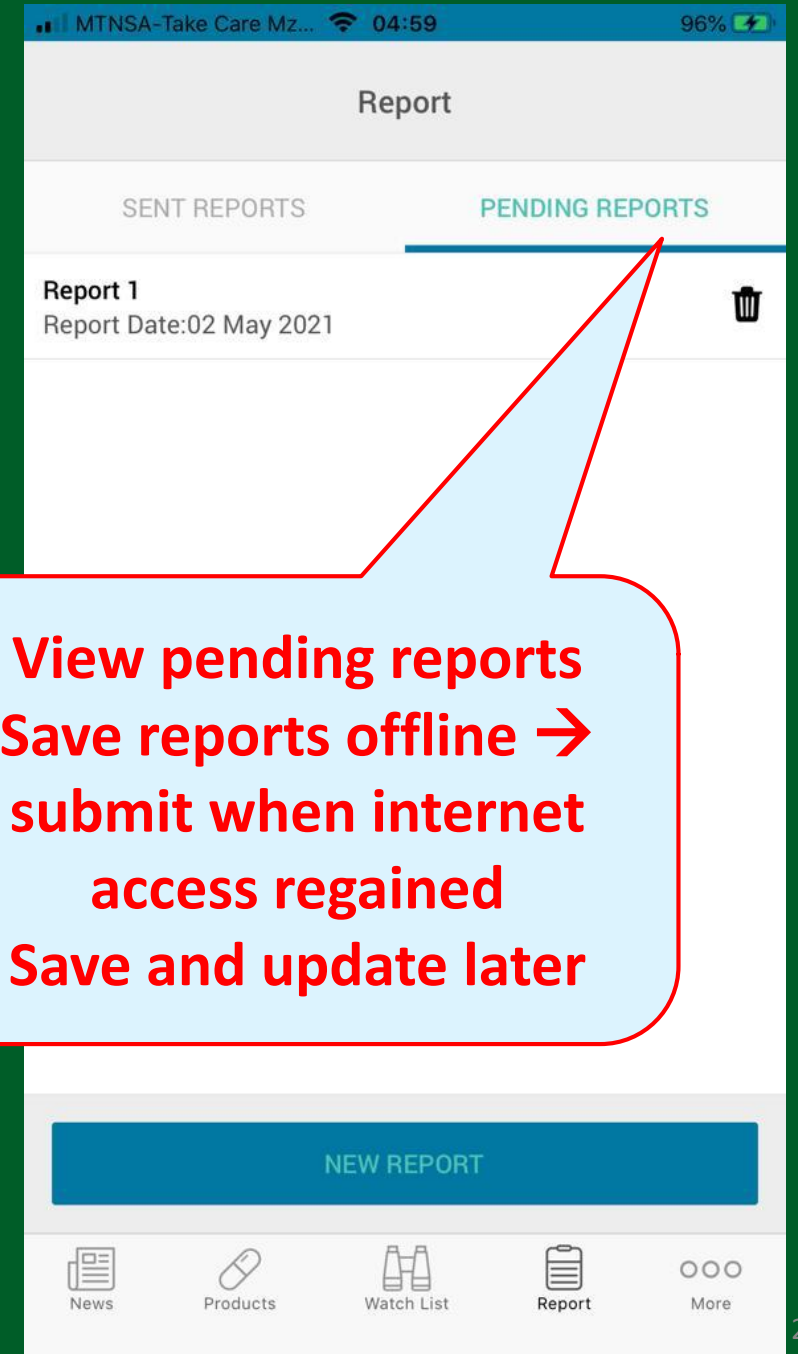


View reports
previously sent

Important to
create an
account

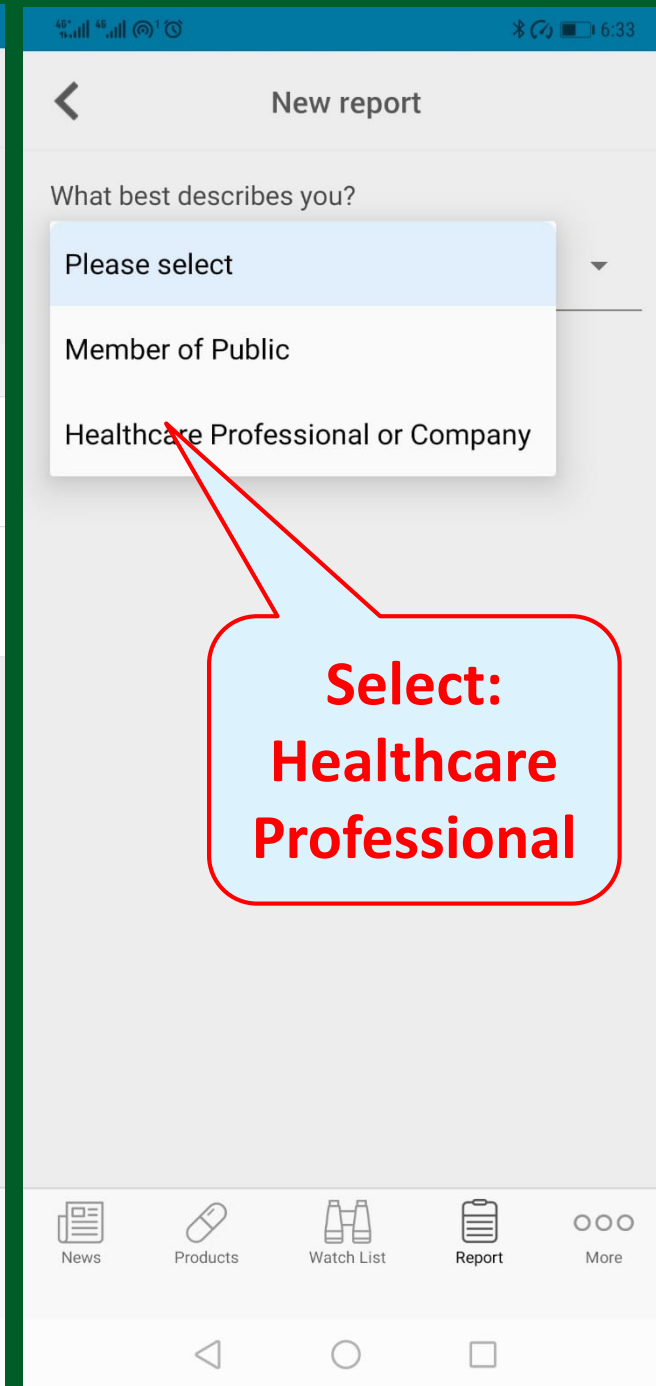
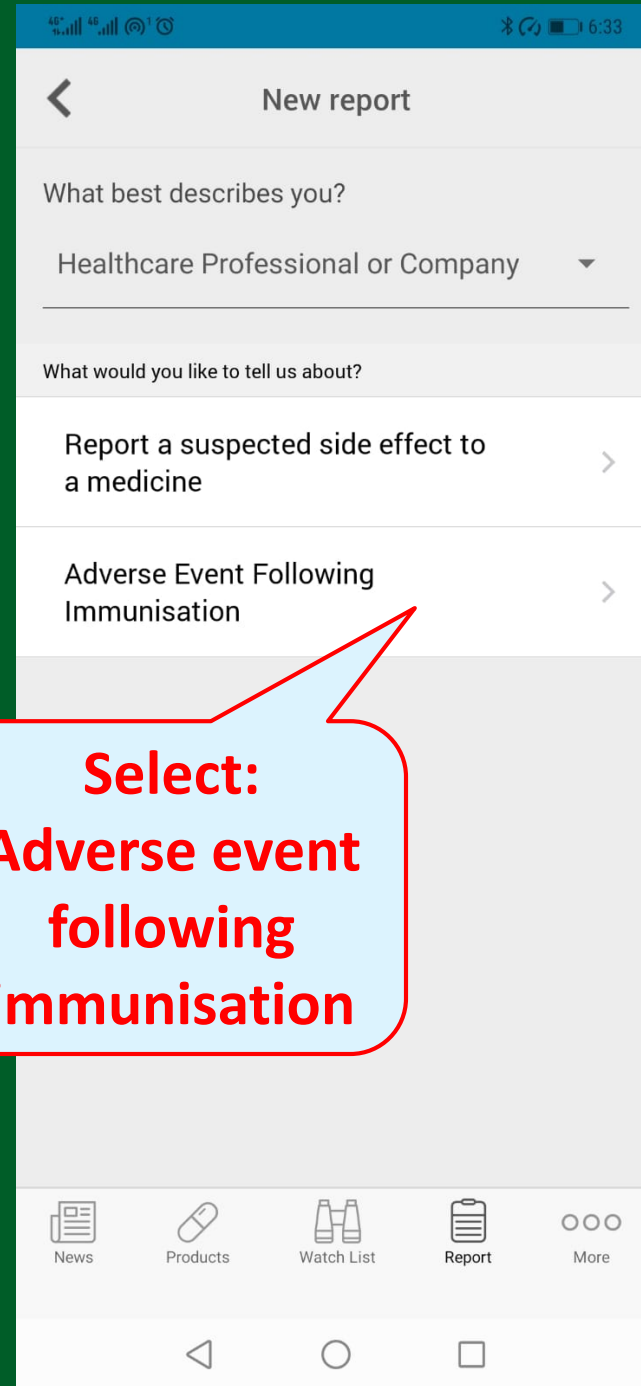
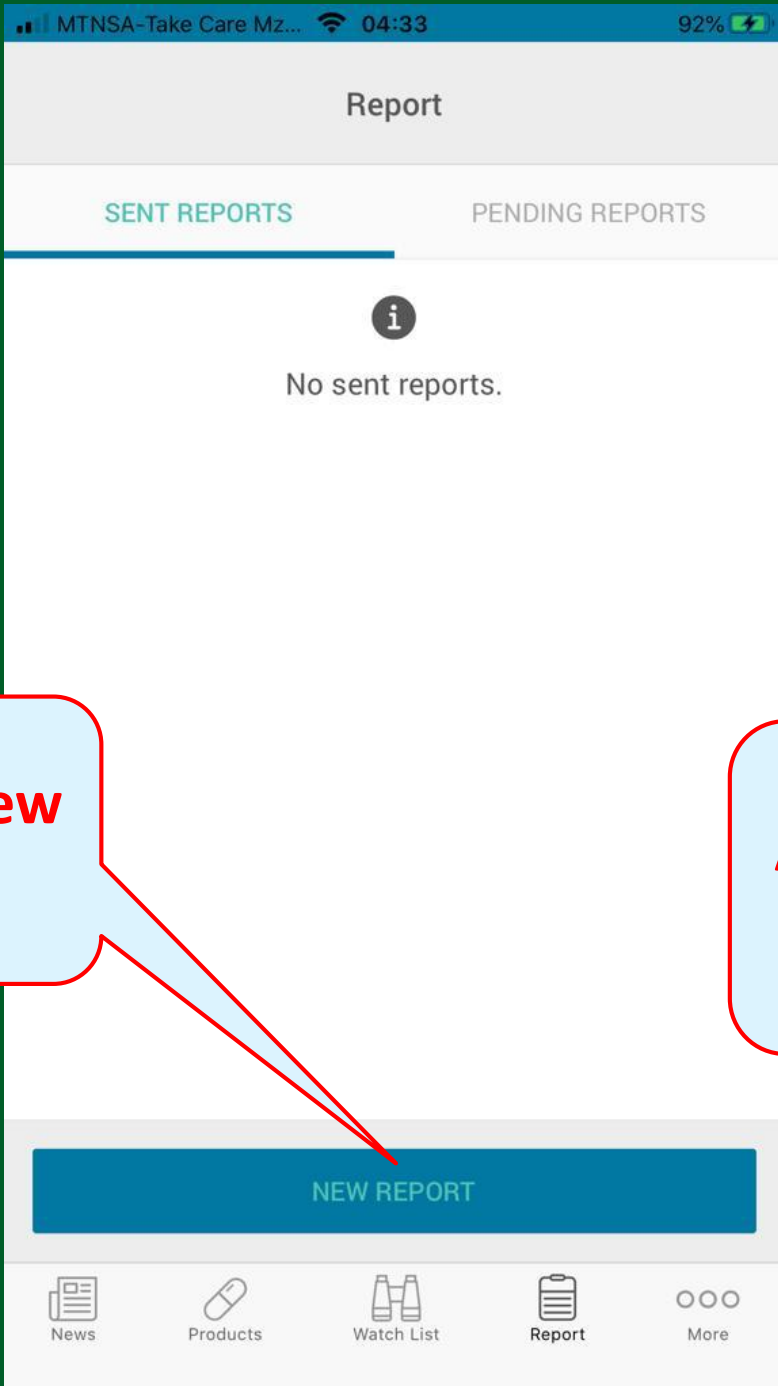
To submit a
new report

"Report"
TAB



View pending reports
Save reports offline →
submit when internet
access regained
Save and update later

Navigate reporting forms



Enter reporter details

Cancel Reporter details Save

Designation *
Pharmacist

Reporter first name *
AP

Reporter last name *
Teker

Email *
Apteker@apteek.com

Telephone
0820000000

● ● ● ● ● NEXT >

News Products Watch List Report More

Cancel Reporter details Save

Institution
0 / 15

Department
0 / 30

Address
0 / 30

Reporter city
0 / 30

● ● ● ● ● NEXT >

News Products Watch List Report More

Cancel Reporter details Save

Telephone
0820000000

Institution
Steve Biko Hospital

Reporter city
Steve Biko and Malan str

Province
Gauteng

Reporter postal code
0002

I understand the privacy statement *

● ● ● ● ● NEXT >

News Products Watch List Report More

Cancel Reporter details Save

Steve Biko and Malan str

Reporter city
Pretoria

Province
Gauteng

Reporter postal code
0002

I understand the privacy statement *

● ● ● ● ● NEXT >

News Products Watch List Report More

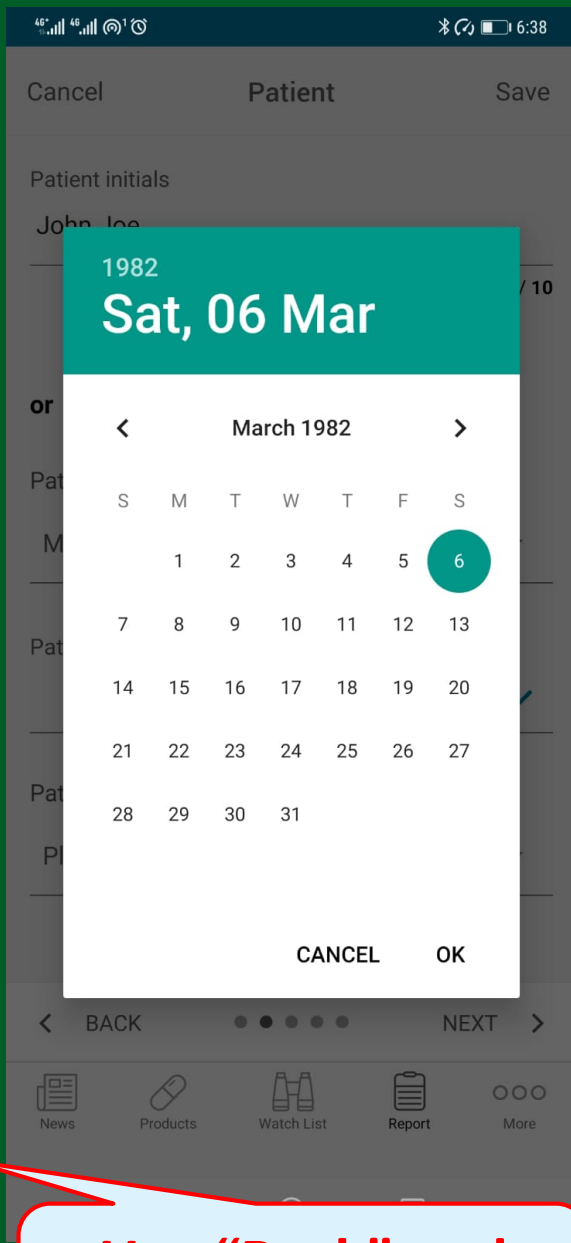
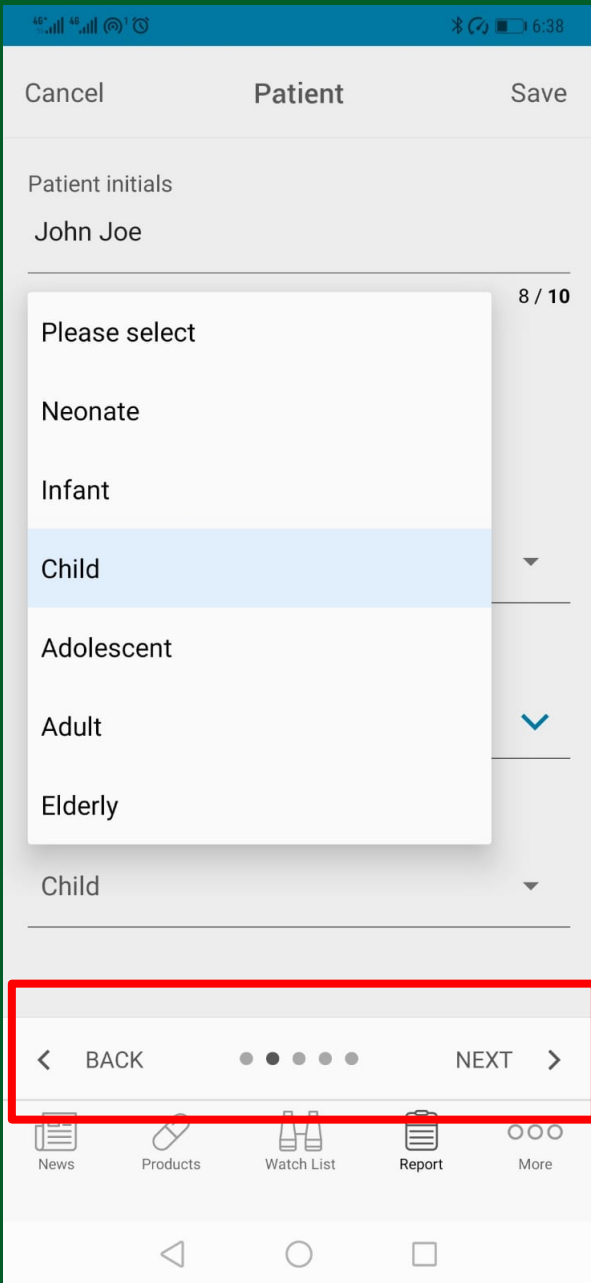
Mandatory fields

Important to complete

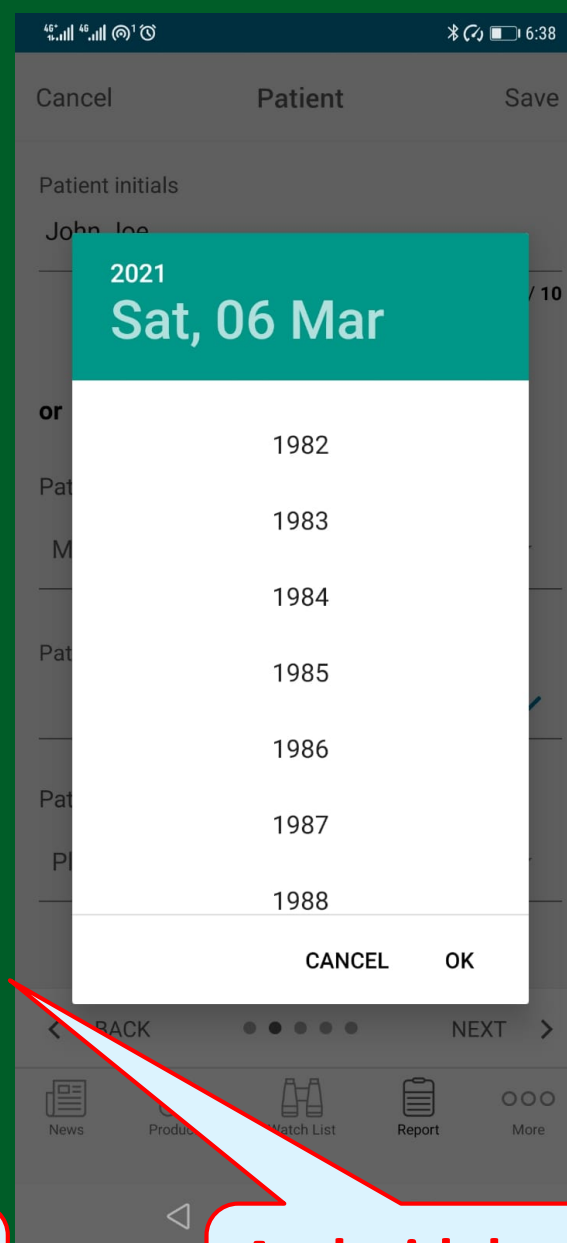
Help EPI programme to follow-up with reporter when required

Privacy statement

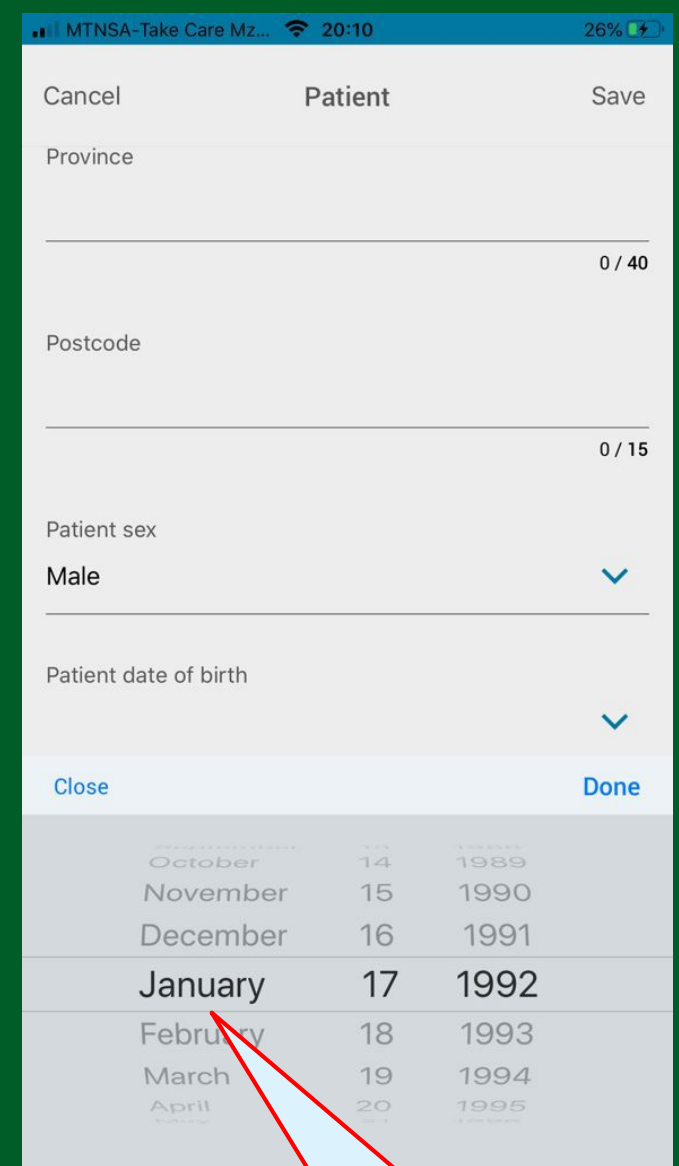
Patient details



Use "Back" and "Next" to navigate

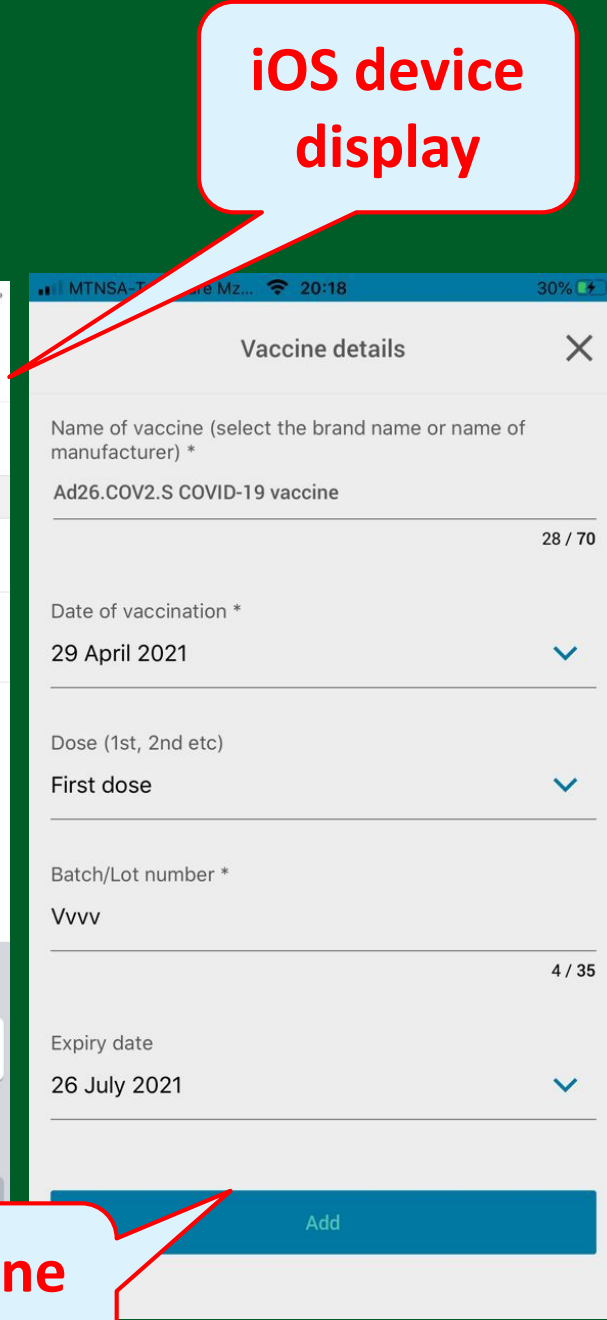
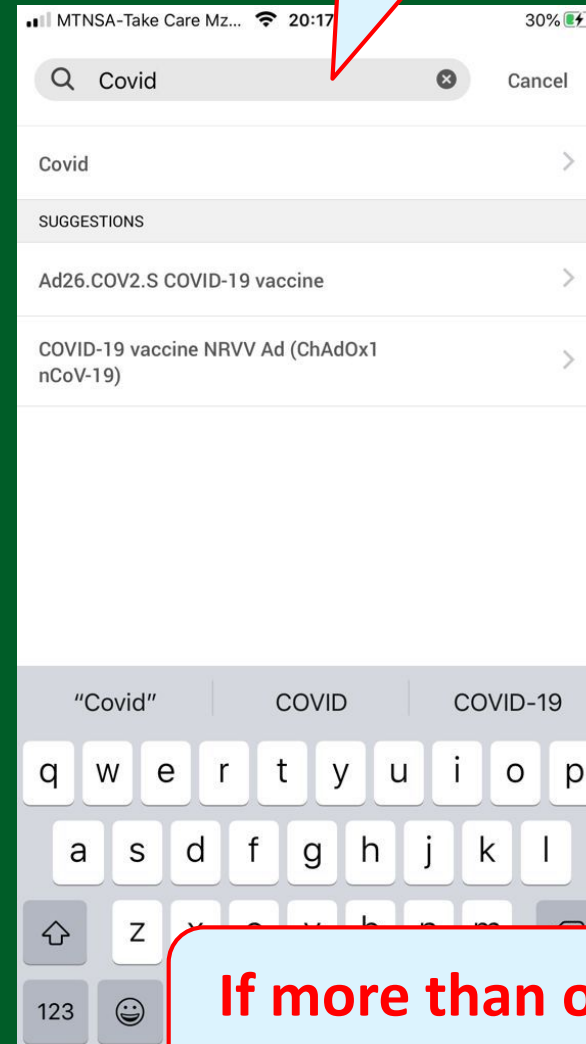
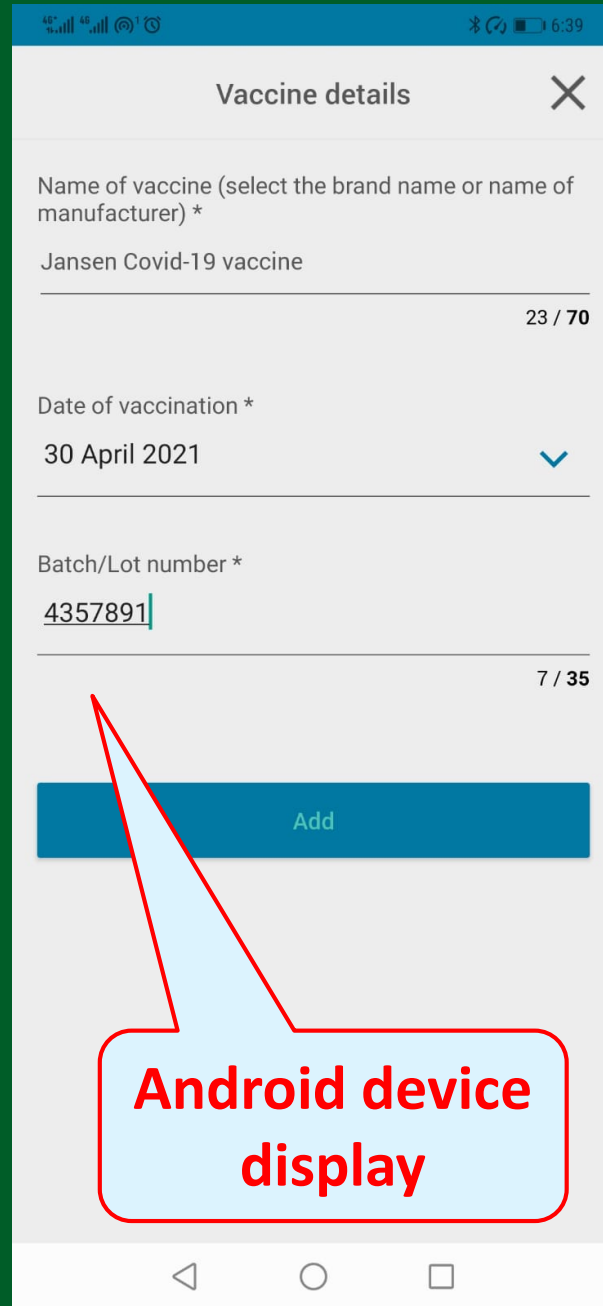
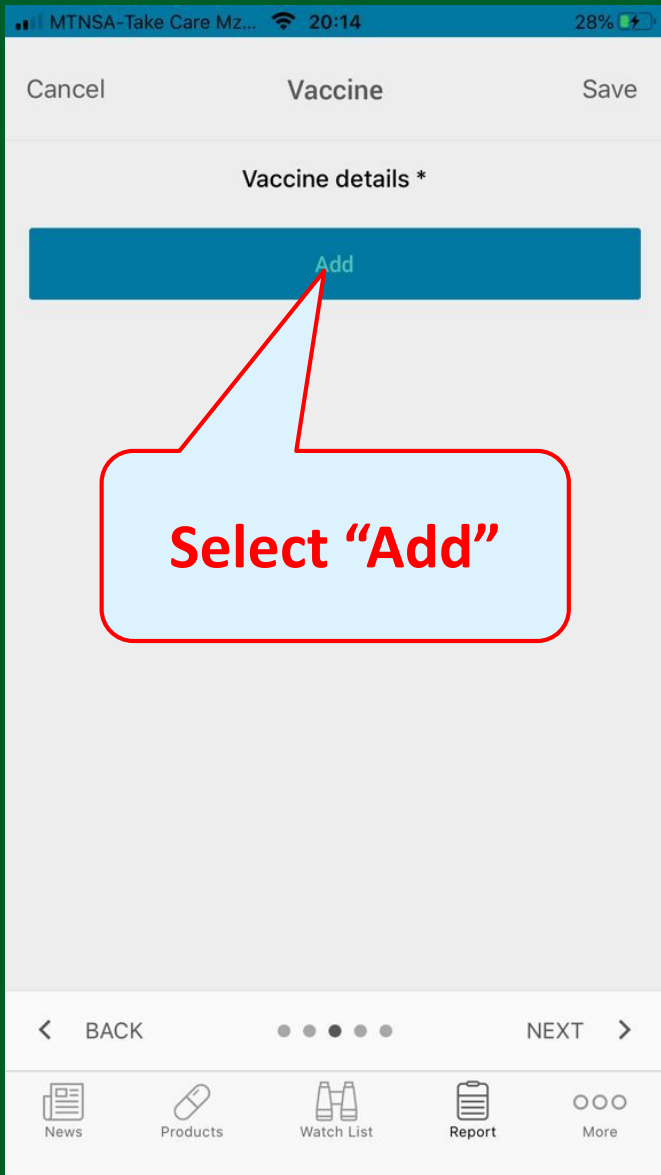


Android device display



iOS device display

Vaccine details



Reaction details

MTNSA-Take Care Mz... 20:27 35%

Cancel Reaction details Save

Select the adverse event(s) from the list * ▼

Please add any other reactions experienced here *
Add

Describe AEFI (Signs and symptoms):
Please enter details

Did the reaction(s) lead to:

Disabling/Incapacitating

Life-threatening

BACK NEXT

News Products Watch List Report More

Select one or more reactions from the list

MTNSA-Take Care Mz... 20:29 37%

Select the a...) from the list Done

Severe local reaction

Severe local reaction > 3 days

Severe local reaction beyond nearest joint

Afebrile seizure

Febrile seizure

Abscess

...osis

...cephalopathy

...toxic shock syndrome

Thrombocytopenia

Anaphylaxis

Fever >38°C

Add details about the reaction

MTNSA-Take Care Mz... 20:30 37%

Cancel Reaction details Save

Select the adverse event(s) from the list *
Severe local reaction, Fever >38°C ▼

Date AEFI started
30 April 2021 ▼

How long after the vaccine did the AEFI start? Please add the number here, followed by the unit in the field below *
6

Time unit for AEFI onset *
Hour ▼

Adverse Event Outcome *
Recovered/resolved ▼

Please add any other reactions experienced here

BACK NEXT

News Products Watch List Report More

Reaction details

Please add...enced here ✕

Reaction details *

Seizure

7 / 250

When did the reaction start?

01 May 2021 ▾

Is the reaction still occurring, or has it resolved? *

Recovered/resolved ▾

If the reaction has resolved, when did the reaction stop?

02 May 2021 ▾

Add

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



Indicate the outcome of the reaction

Reaction details

Cancel Reaction details Save

Please add any other reactions experienced here *

Add

Seizure  

Describe AEFI (Signs and symptoms):

Fever, Coughing, 2 seizures

27 / 20000

Did the reaction(s) lead to:

Disabling/Incapacitating

< BACK ●●●●● NEXT >

News Products Watch List Report More

Add other reactions
"Add" if reaction is not on the list

Describe the event
Do NOT include personal identifiers

Select the outcome of the adverse event
Can select multiple outcomes

Cancel Reaction details Save

27 / 20000

Did the reaction(s) lead to:

Disabling/Incapacitating

Life threatening

Caused/prolonged hospitalization

Congenital anomaly/birth defect

Results in death

Medically significant

< BACK ●●●●● NEXT >

News Products Watch List Report More

Add medical history

Cancel Medical History Save

Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction) other relevant information (e.g. other cases).

Known epilepsy on Epilim 500mg twice daily

42 / 10000

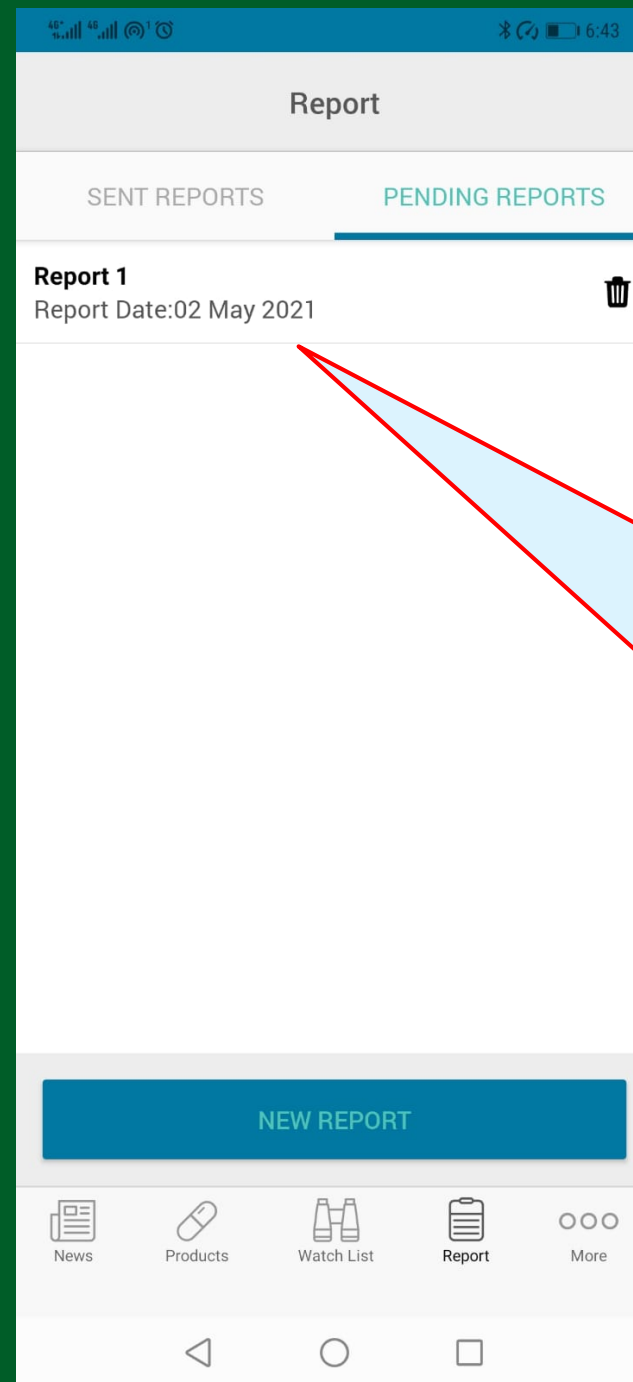
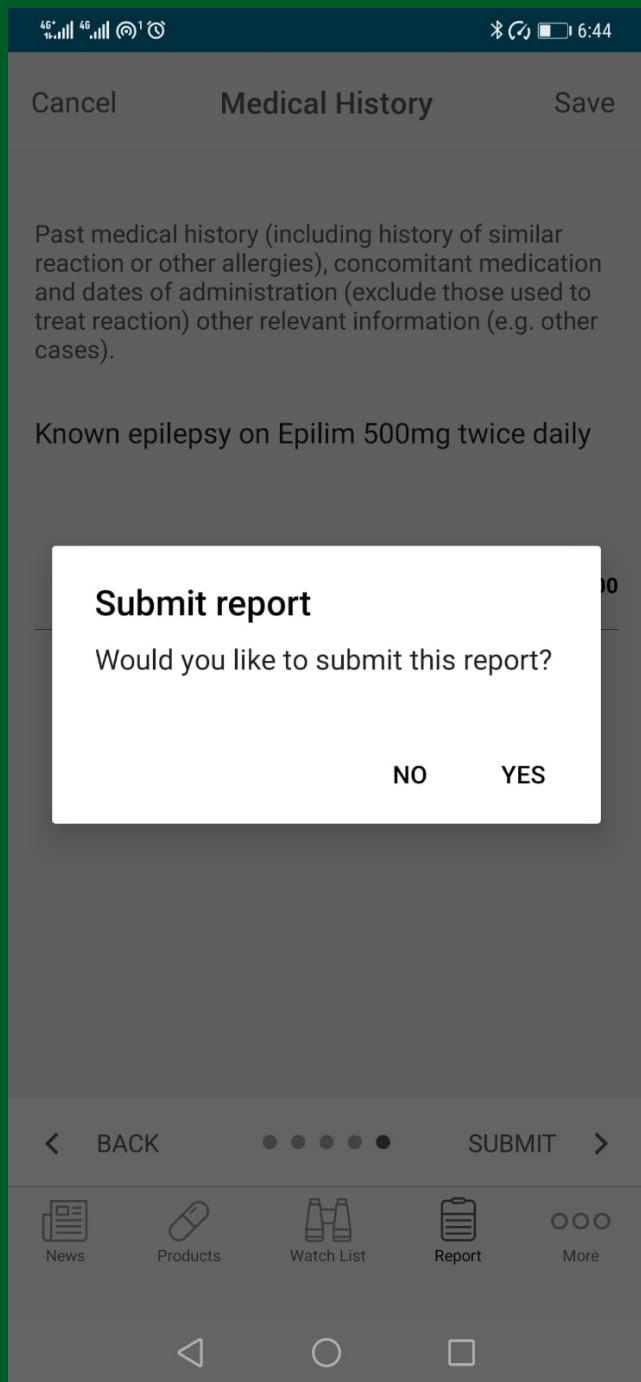
< BACK SUBMIT >

News Products Watch List Report More

Add medical history details

Before submission – use “Back” arrow to review full report

Submit report



Upon submission

Message in the App to confirm submission AND Email acknowledgement of submission

IMPORTANT!!

**Review the updated Module 4 materials available on
the Knowledge Hub**

**Make use of the Med Safety App resources available on
the Knowledge Hub and the SAHPRA website**



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

**ANY
QUESTIONS?**

SAHPRA
South African
Health Products
Regulatory Authority



THANK YOU



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

