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

Med Safety App FAQs

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Topic 1 – Adverse events

- What is an adverse event?
  Answer: An adverse event is an unintended or harmful reaction experienced by a patient after the administration of a medicine or vaccination. Adverse events do not always have a causal relationship with the suspected medicine or vaccine.

- Why do adverse events occur?
  Answer: There are different reasons for why adverse events may occur and many are linked to the way the medicine works to treat a patient. It can be a result of the as the dose that was administered to the patient, an individual patient's reaction to an ingredient in the medicine or vaccine, or an interaction between different products used by the patient.

  Some adverse events are not clearly linked to how the medicine works in the body and so are more unpredictable. As individuals, different patients may respond in different ways to the same medicine and so it is very difficult to predict whether a patient will experience any adverse events.

- Why is it important to report adverse events?
  Answer: Reporting adverse events encourages dialogue between patients and healthcare professionals and helps to identify unknown or poorly described adverse events.

  Before a medicine is marketed, any experience of its safety and efficacy is limited to its use in clinical trials. The conditions under which patients and medicines are studied in clinical trials does not necessarily reflect the way medicines and vaccines are used once they are marketed. Some adverse events may not be seen until a very large number of people have received the medicine. Reports of adverse events can be used to identify previously unknown issues with vaccines or medicines once they are made available on the market. Reporting adverse events can prevent harm on other patients who may experience similar reactions.

- What are the benefits of reporting adverse events?
  Answer: By reporting an adverse event, you are making an important contribution to ensuring the safety of medicines and vaccines. Reporting adverse events can help prevent further harm on yourself or on other patients who may experience similar reactions.

- Besides using the Med Safety App, how can I report an adverse event?
  Answer: You can report adverse events directly to your healthcare provider. Healthcare professionals may also submit adverse event reports through the existing paper form system. [include any other reporting channels in your country]

- Which adverse events should I report?

Answer: You should report any 'suspected' adverse events following the administration of medicines or vaccines. When in doubt of whether to report an adverse event, you should consult your doctor. Adverse events may vary between patients and in their degree of harm from mild to severe cases - for severe adverse events, patients should seek immediate medical attention. For more information on known adverse events for a product, you can read the information leaflet for the medicine or vaccine.

Topic 2 – Med Safety App

2A. General information about the Med Safety App

- What is the Med Safety App?
  Answer: The Med Safety App is a mobile application for healthcare professionals and members of the public to submit reports of suspected adverse events from medicines and vaccines. The Med Safety App has been developed by the Medicines and Health products Regulatory Agency (MHRA) in the UK in conjunction with World Health Organization (WHO) and Uppsala Monitoring Centre (UMC).

- What can the Med Safety App be used for?
  Answer: The Med Safety App's primary function is to report suspected adverse events from medicines and vaccines via the medicines reporting form and the Adverse Events Following Immunisation (AEFI) form. The Med Safety App also allows users to access safety related news articles by [insert NRA name], view global safety data of all registered medicines and vaccines in your country, and create a watch list of products of interest.

- Who can use the Med Safety App?
  Answer: The Med Safety App can be used by both healthcare professionals and members of the public.

- What are the benefits of using the Med Safety App?
  Answer: The Med Safety App provides a quick and easy way to report suspected adverse events, compared to traditional paper reporting systems. The Med Safety App acts as a two-way channel of information and also provides users with instant access to global safety information on medical products as well as direct news alerts from [insert NRA name].

- Can I still submit a report if I don't have all the information available?
  Answer: Yes, reports can be submitted even if every field is not fully completed. However, you must complete all mandatory fields (marked with *) before you can submit a report. Reporters are encouraged to complete as much information as possible when reporting an adverse event to help with the analysis of all reports.

- In what languages is the Med Safety App available?
  Answer: In [Insert country name], the Med Safety App is available in [Insert available languages].

- Where can I get more information on how to use the App?
  Answer: For more information on the Med Safety App, you can visit www.web-RADR.eu [if your country has information about the Med Safety App on a different website, replace the link above with your country's website]. For more information on reporting adverse events, contact your healthcare provider.

2B. The Med Safety App in the context of COVID-19

- Is the Med Safety App only meant to be used during the COVID-19 pandemic?
  Answer: The Med Safety App is used for reporting adverse events for any medicine or vaccine, including but not limited to COVID-19 vaccines and medicines.

- How can I use the Med Safety App during the COVID-19 pandemic?
  Answer: You can use the Med Safety App to report any adverse events experienced after receiving a COVID-19 vaccine or treatment medication. The Med Safety App can also be used to view global safety data on COVID-19 vaccines and keep up to date with COVID-19 related news alerts published by [insert NRA name].

2C. How to get the Med Safety App

- How can I get the Med Safety App?
  Answer: 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:

- Do I have to pay to get the Med Safety App?
  Answer: The Med Safety App is free to download.

- Which devices can I use the Med Safety App on?
  Answer: The Med Safety App is available for use on Android and Apple smartphones and tablets. The Med Safety App cannot be used from a computer or laptop. For Apple devices, iOS 9.0 or later is required to use the Med Safety App. For Android devices, Android 5.0 'Lollipop' or later is required to use the Med Safety App.

- What should I do if my operating system is not compatible with the Med Safety App?
  Answer: If you are unable to download the Med Safety App due to Operating System incompatibility, you may need to update the Operating System on your device. This can be accessed in the "Settings" menu of your device. You can view the required operating system for your device from the App Store (if you are using an Apple device) or the Google Play Store (if you are using an Android device). For Apple devices, iOS 9.0 or later is required to

use the Med Safety App. For Android devices, Android 5.0 'Lollipop' or later is required to use the Med Safety App.

- What should I do if the Med Safety App fails to install?
  Answer: Common causes of installation failure are due to Operating System incompatibility and insufficient memory on your device. You can update the Operating System on your device in the "Settings" menu. The Med Safety App download file is 18MB. Please ensure you have sufficient available storage on your device and that you are connected to a stable internet source when downloading the app.

- What should I do if the Med Safety App does not work as expected on my device?
  Answer: In the event that the Med Safety App is not functioning correctly, you should first close the app and re-open it. If there is still no improvement, restart your device and open the Med Safety App again. If there is still no change in functionality, re-install the app by uninstalling it from your device and downloading the app again from the App Store for Apple devices or Google Play Store for Android devices. You can also email the MHRA (WEB-RADR@mhra.gov.uk), including as much information as possible in your message. This includes the mobile phone you are using, the operating system you are using, and more information on the specific challenges you are encountering.

2D. How to use the Med Safety App

- Do I need internet connection to use the Med Safety App?
  Answer: You do not need internet access to create and save a report. However, internet connectivity is required to submit a report. Reports can be saved at any time in the process and accessed later. Saved reports can be found in "Pending Reports" in the app and submitted upon regaining internet connection.

- How can I report an adverse event using the Med Safety App?
  Answer: In the "Report tab", click on "New report" and select whether you are reporting a suspected side effect to a medicine or reporting an adverse event following immunization. Then, complete the form with as much detail as possible before submitting the information.

- Can I save an unfinished report in the Med Safety App?
  Answer: Yes. Reports can be saved at any time during the process and accessed again later. Saved reports can be found in "Pending Reports" in the app.

- What happens to my report after I submit it?
  Answer: Information is sent from the reporter's phone, through Med Safety App, to the national center for pharmacovigilance where potential risks are identified. Together with the [relevant authority], the center can then take measures to minimise identified risks. Countries participating in WHO Programme for International Drug Monitoring then forward anonymous reports to VigiBase, the WHO global database of reported suspected adverse events maintained by Uppsala Monitoring Centre (UMC).

2E. Data privacy

- How will my personal data be used and shared with other organisations?
  Answer: The information you provide through the Med Safety App is kept safe and secure. Data is held by UMC and MHRA. All data contained in your Med Safety App report will be shared with the MHRA. This data is shared to help in the detection of new safety information from aggregated data. Shared data includes personal data such as the reporter's name and surname, designation, and email address, and the patient's name and surname (if this is included in the report). Reports generated by the MHRA from this data will not include any identifiable personal data, such as names. The MHRA will not publish, transfer, or sell your identifiable personal data for any purpose, including direct marketing. [Name of NRA] will not otherwise disclose, give, sell, or transfer your personal information unless it is required by law, or regulation, or for law enforcement reasons.

- Will my data be saved on the Med Safety App?
  Answer: If you create an account, your personal details and submitted reports will be saved on the app. This allows you to refer to previously submitted reports in future and help save time when completing new reports. The information you provide through the Med Safety App is kept safe and secure and is only available to yourself when you login in via your device.

Topic 3 – Reporting an AEFI using the Med Safety App

- Is the AEFI reporting form in the Med Safety App the same as the paper reporting form?
  Answer: Yes, the AEFI reporting form in the Med Safety App is based on the paper forms currently used in [country name] and contains all 25 World Health Organization (WHO) core variables.

- If the patient received more than once vaccine on the same day, which vaccine should be included when reporting an AEFI?
  Answer: If more than one vaccine was administered to a patient at the same time, all administered vaccines should be reported.

- The name of the vaccine(s) that the patient received is not known or cannot be found in the list of vaccines in the app – how should the form be completed?
  Answer: In this case, type in as much information as you know about the vaccine the patient received and select the most appropriate option from the list. 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".

- Should the name of any medication the patient has used in the last 3 months be included when reporting an AEFI?

Answer: Yes, all medicines and vaccines used in the last 3 months should be included in the report. This is important to help identify possible drug interactions.

- The batch number of the vaccine that the patient received is not known, how should I complete this field?
  Answer: The batch number can be found in the vaccination card which is given to the patient after the vaccine has been administered. If you are unable to access this card or still do not know the batch number, enter "Unknown" into this field. [Include any other country-specific systems where reporters can access this information]

  The batch number is important to include as it helps identify whether there might have been any issues with a specific batch of products which may need to be recalled.

- I do not have information on the diluent used when the patient was vaccinated, how should I complete this section?
  Answer: ~~You may refer to the WHO Guidance Note on Vaccine Diluents (link) annex which contains a list of diluents used for specific vaccines. [Include any other country-specific systems where reporters can access this information]. If the necessary information on the diluent is not known or cannot be easily found, enter "Unknown" into the relevant fields.~~

  Information on the diluent is important to include as it helps identify whether there might have been any issues with the use of a specific diluent in a population. If the necessary information on the diluent is not known or cannot be easily found, ~~enter "Unknown" into~~please leave the relevant fields blank.

- What should I do if I do not want to report an adverse event from the drop-down list? Is it mandatory to select an adverse event from this list?
  Answer: The selection of an adverse event is mandatory; however, this can be entered from the "Select the adverse event(s)" drop down list **OR** from the free text "Reaction details" field.

  On the "Reaction details" page, the top field "Select the adverse event(s) from the list" should only be used to report ~~serious~~ adverse events of special interest (AESIs). This field contains a drop-down list of possible ~~adverse events of special interest (AESIs)~~AESIs which can be selected.

  If you ~~are reporting a non-serious adverse event or~~ cannot find the adverse event experienced by the patient in the given list in the above field, do not select any options from this list. Instead, click on the "Add" button on the "Reaction details" page to add the adverse event experienced by the patient. In the top field, type in the reaction experienced and select the correct option from the list which will appear as you type. After you have selected the correct option, fill in the additional information in the relevant fields on the screen and click on "Add" to add these details to the report.

- If the patient experienced multiple adverse events, which one(s) should be reported?
  Answer: All serious and non-serious adverse events that the patient experienced should be reported. Click on "Add" in the "Reactions details" page to add any additional adverse events experienced by the patient to the report.

- What information should I include when providing a more detailed description on the patient's adverse events?
  Answer: The report should include symptoms experienced by the patient, the date and time that these symptoms were first experienced, how long they lasted, and what the outcome was. If the adverse event was experienced after the third or fourth dose of a vaccine, also indicate the dose number. Do not include any patient identifier information (such as the patient's name, contact details, or physical address) in the adverse event description field.

- What information should be included about the patient's medical history?
  Answer: In this section you should include any history of similar reactions, allergies, names of medication that the patient is currently using, and dates of vaccine administration. Also include any relevant family medical history.

- Who can I contact for assistance in reporting an AEFI through the Med Safety App?
  Answer: You can contact your healthcare professional for support in reporting an AEFI. For more information on the Med Safety App, visit www.web-RADR.eu [if your country has information about the Med Safety App on a different website, replace the link above with your country's website].

Topic 4 – Safety monitoring

- What is safety monitoring?
  Answer: Safety monitoring is the continuous process of monitoring, assessing, and understanding adverse events of vaccines and medicines to ensure that they are safe for use.

- Why is safety monitoring important?
  Answer: Safety monitoring allows for an improved awareness and understanding of the adverse events of medicines and vaccines. This, in turn, allows [The NRA] to make informed decisions on all safety aspects related to products on the market. This process helps protect the population against harmful adverse events from medicines or vaccines.

- How are medicines and vaccines tested and monitored to ensure they are safe to use?
  Answer: During the drug development process, vaccines and medicines undergo various safety and efficacy tests (which are closely monitored by [regulatory bodies]) to prove that they are safe to use and effective in treating a disease or condition. Once vaccines and

medicines are publicly available, national authorities continuously monitor them to ensure they are safe to use and any additional adverse events are captured.

Even though most adverse events are identified during drug development, it is unlikely that rare adverse events are observed since only a limited number of patients receive treatment in this phase. Reports of adverse events can be used to identify previously unknown issues with vaccines or medicines once they are made available on the market.

- What is the NRA? What is their role in safety monitoring?
  Answer: [The NRA] is the national medicines regulatory authority in [country] who is responsible for ensuring that medical products and vaccines are continuously evaluated to meet the required standards of quality and safety. The NRA is ultimately responsible for making safety decisions and implementing regulatory action which aims to minimize safety risks. Actions could include:
  - Limiting dosage administered
  - Changing information in drug leaflet
  - Suggesting vaccines or medicines not be used by particular groups of patients
  - Removing the medicine from the market

- What is the EPI? What is their role in safety monitoring?
  Answer: [The EPI] is responsible for protecting the population against vaccine-preventable diseases. [The EPI] is further responsible for overseeing and implementing vaccine programs in [country]. [The EPI] plays a key role in orchestrating the reporting of all adverse events and following-up on serious adverse events.