

Launch of a New Mobile-Friendly Adverse Event Reporting Form



The Health Sciences Authority (HSA) is pleased to launch a new adverse event (AE) reporting form, which facilitates the submission of AE reports via mobile devices. This is in addition to our current modes of reporting, which includes the CMIS (Critical Medical Information Store) module*, hardcopy forms, email and online form.

**The CMIS module is part of the electronic medical record system that captures patients' drug allergies and medical alerts, to inform healthcare professionals of this critical information during the course of providing patient care.*

1 Why did HSA create a new AE reporting form?

Currently, the majority of the AE reports come through CMIS. The new form is created to encourage AE reporting from healthcare professionals without access to CMIS, as well as those who for specific reasons, prefer to report some AEs outside of the CMIS system. This is in response to the valuable feedback gathered from focus group discussions with healthcare professionals.

Healthcare professionals can submit AE reports using their mobile devices with this new form. The link can be saved as an icon onto the home screen of mobile devices for easy access (Figure 1).

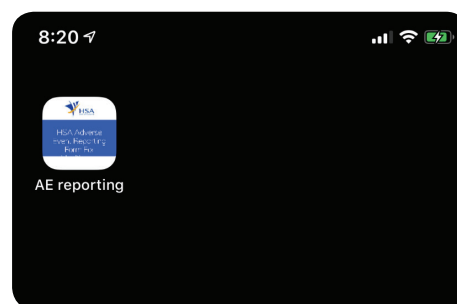


Figure 1: The form can be saved as an icon on mobile devices for easy access.

2 Who can use this form?

All healthcare professionals, including doctors, dentists and pharmacists, can use this form to report AEs to HSA.

4 Where does the report go?

The AE report will go directly to HSA, and the healthcare professional will also receive a copy via email. However, the report WILL NOT appear in CMIS.

3 Why should I report AEs?

When a drug is newly marketed, its safety profile is generally limited to that identified in clinical trials, where evidence is generated based on a small group of individuals who meet specified inclusion and exclusion criteria. Rare AEs may only surface when many more patients with varying medical conditions get exposed to the drug after it is approved for use in the market. With each AE report received, the safety profile of the drug becomes clearer. This allows HSA to better understand the risk factors of the AEs related to each drug. Such information is valuable for safety monitoring and facilitates prompt detection of potential safety signals, allowing HSA to take appropriate action in a timely manner.

5 I usually submit AEs via CMIS. How is this form different?

AEs submitted using this form WILL NOT be reflected in CMIS. As such, an alert will not appear on the patient's medical record (Figure 2). Any changes to be made to a record in CMIS has to be done via the CMIS system.

By providing a channel to report outside the CMIS system, AE reporting of the following scenarios is encouraged:

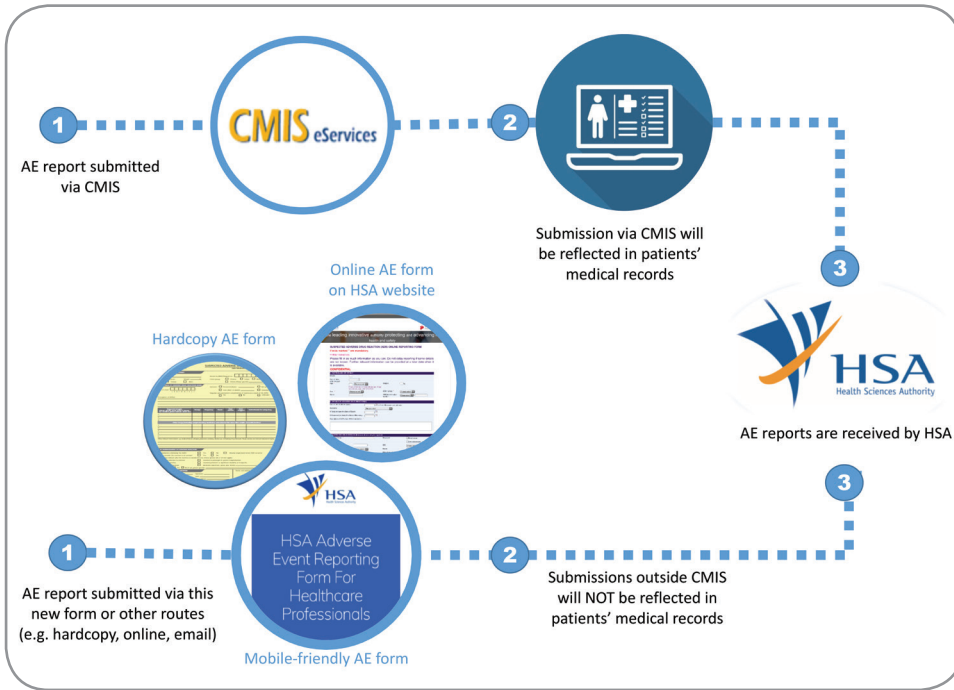
- **A situation when there is some suspicion that the AE may be drug-induced, but the healthcare professional has assessed that it may not need to be entered into CMIS due to various other considerations relating to the more permanent feature of CMIS**

HSA has received feedback that healthcare professionals may be hesitant to enter AEs into CMIS unless they are reasonably certain that the reaction is drug-induced. However, every AE report, even if based on slight suspicion, is valuable to HSA, as it helps to provide a more complete picture of the safety profile of the drug.

Remember: You do not need to be certain, just suspicious!

- **A situation when the AE could be due to an adulterated health product**

Healthcare professionals can submit an AE report to HSA for further follow-up. Photographs of the product will help in HSA's assessment, and these can be uploaded directly into the AE report via this mobile-friendly form.



6 How do I access the form?

The form can be accessed by scanning this QR code or through the web link: <https://go.gov.sg/AEreporting>

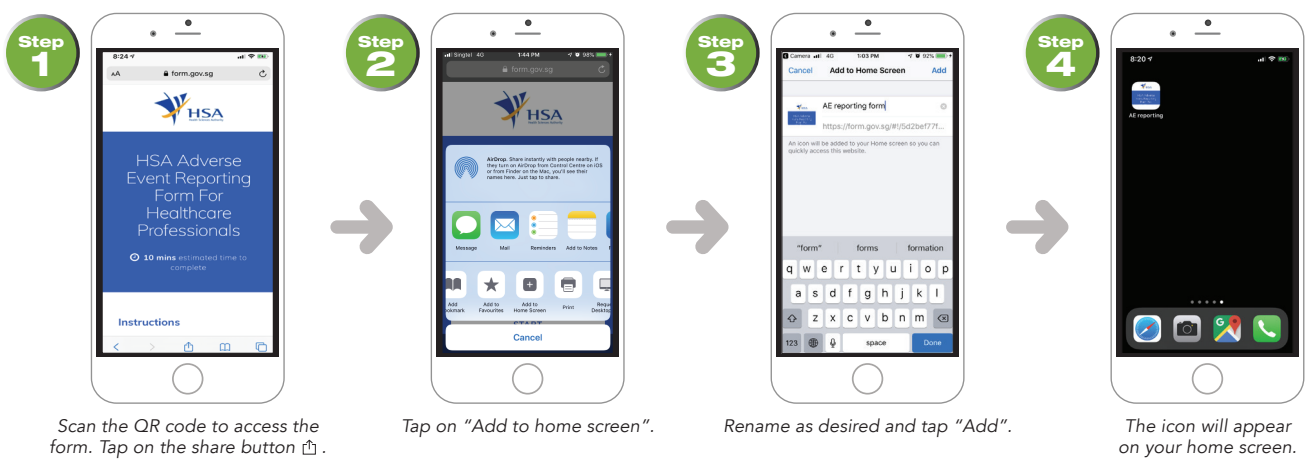


Figure 2: Differences between AE report submissions done via CMIS compared to non-CMIS routes, including the new mobile-friendly form.

If the intent is to document the AE in the patient's medical record for future avoidance of the suspected drug, you are encouraged to submit the AE report via CMIS. Submissions via CMIS will be transmitted to HSA as well.

How to save the AE reporting form as an icon on your home screen

For iPhone users:



For Android users:

