



FDA/SMC/SMD/RMU/20/0386

1st September 2020

FOURTH (4TH) UPDATE ON THE SAFETY MONITORING OF MEDICINES FOR THE TREATMENT OF COVID-19 FROM 1ST APRIL TO 31ST AUGUST 2020

BACKGROUND

The Food and Drugs Authority has put in place a safety monitoring plan to guide healthcare professionals to follow up patients with COVID-19 being treated with any of the medicines issued with “Emergency Use Authorization” in line with the Provisional Standard Treatment Guidelines (STG) for Novel Coronavirus Infection, 2020. This is to ensure that local data on the safety of these medicines is gathered to facilitate early detection of safety signals to promote patient safety.

Individual Case Safety Reports (ICSRs) for patients who tested positive for Novel Coronavirus Infection including therapeutic failure are being collected.

Submission of ICSR is not an attribution of causality, all reports submitted are reviewed by the Technical Advisory Committee on Safety of Medicines to determine if there are any relationship and feedback provided to the Treatment Centres.

UPDATES SINCE 30TH JUNE 2020

Since the last (i.e. 3rd) update presented on 30th June 2020, information has been received from thirty-seven Treatment Centres and Districts out of the fifty on the records, during the two months period with five ICSR received from the University of Ghana Medical Centre in the Greater Accra Region. The cumulative number of ICSR received as at 31st of August 2020 is therefore sixty-two.

The number of reports and the reporting facilities is shown in Table 1.



Table 1: Cumulative Number of ICSRs and Reporting Facilities

No	Reporting facility	Region	No. of ICSRs received
1	Ga East Municipal Hospital	Greater Accra	1
2	Tamale Teaching Hospital	Northern	11
3	Greater Accra Regional Hospital	Greater Accra	18
4	University of Ghana Medical Centre	Greater Accra	23
5	Akuse Government Hospital	Eastern	3
6	Nkwanta South Municipal Hospital	Oti	2
7	Korle-Bu Teaching Hospital	Greater Accra	1
8	Koforidua Regional Hospital	Eastern	1
9	Cape Coast Teaching Hospital	Central	1
10	37 Military Hospital	Greater Accra	1
TOTAL			62

The five new cases were pharmaceutical care issues that were identified and addressed by the clinical pharmacists.

These ICSRs were classified as medication errors and circumstance or information capable of leading to medication error, no adverse drug reactions occurred from the 5 ICSRs submitted.

OUTCOME OF ADVERSE DRUG REACTIONS

All patients who had adverse drug reactions have fully recovered without sequelae.

CALL TO REPORT

All healthcare professionals should report adverse drug reactions including therapeutic failures for drugs being used in the treatment of patients with COVID-19.

In addition, information on patients treated with any of the medicines during pregnancy should also be reported with follow up on the outcome of the pregnancy.

The reports should be submitted through the following means:

- Complete Adverse Reaction Reporting Form (which can be obtained from all health facilities)
- Download the Med Safety App from the Apps Store or Google Play
- Submit report online using the link <http://adr.fdaghana.gov.gh>
- Call mobile No: 024 431 0297
- Send email to drug.safety@fda.gov.gh or safetymonitoring220@gmail.com



REPORTING TIMELINE

All suspected adverse drug reactions including therapeutic failure should be reported within 24 hours.