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**SECOND UPDATE ON THE SAFETY MONITORING OF MEDICINES FOR THE TREATMENT OF COVID-19 FROM 1ST APRIL TO 30TH MAY 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.

Information being collected from the Treatment Centres include cumulative positive cases reported, cumulative number of patients treated with medicines recommended by the STG for Novel Coronavirus Infection and number of side effects (adverse drug reactions) including treatment failure.

Please, note that the side effects that have been reported does not been that they are absolutely caused by drugs. The FDA has experts known as the Technical Advisory Committee on Safety of Medicines who continuously review the data collected and make recommendations which will be shared with the healthcare professionals involved with treatment of COVID-19 to ensure patient safety.

## REPORTING FACILITIES

Information was received from 33 Treatment Centers across the country with seven of them reporting a total of 31 adverse drug reactions. The remaining 25 reported that none of the patients has suffered from a side effect form the medicines being used to treat COVID-19 patients (i.e. zero reporting).

Table 1 represents the reporting Treatment Centres and the number of side effects reported. Please, note that a hospital with more side effects does not mean that they have more of it, but rather they are identifying and reporting more to the FDA.

**Table 1**: Reporting facilities and side effects / adverse drug reactions reported

| No | Reporting facility | Region | ADR reports received |
|---|---|---|---|
| 1 | Greater Accra Regional Hospital | Greater Accra | 13 |
| 2 | Tamale Teaching Hospital | Northern | 7 |
| 3 | University of Ghana Medical Centre | Greater Accra | 5 |
| 4 | Akuse Government Hospital | Eastern | 3 |
| 5 | Koforidua Regional Hospital | Eastern | 1 |
| 6 | Ga East Municipal Hospital | Greater Accra | 1 |
| 7 | Nkwanta Government Hospital | Oti | 1 |

## SUSPECTED DRUGS AND ADVERSE DRUG REACTIONS

Thirty-one adverse drug reaction reports were received for the suspected drugs listed below:

**Table 2**: Suspected drugs and adverse drug reactions reported

| Suspected drug | Adverse drug reactions | No. of reports |
|---|---|---|
| Hydroxychloroquine alone or in combination with azithromycin | Diarrhoea / loose stool, stomach upset, Fast heartbeat, dizziness, breathlessness, skin rash, sleeplessness, dry throat, scrotal pain | 16 |
| Chloroquine alone or in combination with azithromycin | Dizziness, drowsiness, weakness, weak joint, fast heartbeat, itchy skin, breathlessness, fever, sleeplessness, diarrhoea, fever, breathlessness | 7 |
| Azithromycin alone or in combination with other drugs (e.g. vitamin C, zinc, cetirizine), chloroquine | Mild headache, diarrhoea, difficulty in breathing, skin rash | 4 |
| Liponavir/Ritonavir | Diarrhoea | 1 |
| Aminophylline and Magnesium sulphate used in COVID -19 patient with asthma. Patient was on other Covid-19 and asthma medicines | Abdominal pain, severe headache, breathlessness, vomiting with nausea | 1 |
| Zinc (patient was also on hydroxychloroquine, azithromycin and vitamin C). | Feeling of weakness | 1 |
| Ascorbic acid (patient was also on azithromycin and multivitamins) | Short lasting pain in upper chest region of the body | 1 |

## OUTCOME OF THE ADVERSE DRUG REACTIONS

All patients who had adverse drug reactions have fully recovered.

## 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.