Medicines Control Authority of Zimbabwe

**PVF 16**

# PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

## MEDICINES SAFETY AND EFFICACY MONITORING FORM FOR COVID-19 TREATMENT

This form should be completed for medicines obtained under Section 75 of the Medicines and Allied Substances Control Act [Chapter 15:03] in order to assess the medicine's treatment outcomes and safety in the treatment of COVID-19 disease or any other medicines deemed necessary by the Authority. Identities of reporter, patient and institute will remain CONFIDENTIAL. This form is to be completed for EACH patient who is prescribed/or dispensed a medicine for the treatment COVID-19 disease. Adverse Drug Reactions experienced by the patient should be reported by completing (SECTION D) below or submitted electronically on https://e-pv.mcaz.co.zw.

## SECTION A

**Patient details**

| | |
|---|---|
| Patient Initials: | Date of Birth/ Age: |
| Weight *if known*: Height *if known*: | Gender: ☐ Male ☐ Female |

## SECTION B

**COVID-19 Diagnosis**

Date of diagnosis: ……. /……. /…….

Diagnosis of COVID-19: ☐ Positive PCR ☐ Positive Antigen ☐ Positive Antibody
☐ Possible (Clinical signs and symptoms/ pending PCR)

COVID-19 disease severity: ☐ Mild ☐ Moderate ☐ Severe

SPO2 (on ambient air) Resp rate Pulse Temperarture

Comorbid conditions that negatively affect prognosis and survival?

☐ None ☐ Diabetes Mellitus ☐ Cardiovascular disease
☐ Malignancy ☐ Chronic lung disease ☐ Pregnancy
☐ Unknown ☐ Hypertension ☐ HIV
☐ Asthma
☐ Other: …….

**SECTION C**

**Details of COVID-19 Medicine of interest**

| Generic name | Brand name | Batch number | Dose | Route and frequency | | Date started | Date stopped |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**Concomitant (other) medicines taken, including herbal medicines**

| | Generic name | Brand name | Batch number | Dose | Route and frequency | | Indication | Date started | Date stopped |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

**SECTION D**

**Outcome**

Date of follow-up: …. / …. /…….

Was the medicine effective? ☐ Yes ☐ No

Outcome

☐ Recovered ☐ No change ☐ Condition worsened

☐ Death ☐ Other (*explain*): …….

Test results post treatment (if done)

Date of test: …. / …. / ……

☐ Negative PCR test ☐ Negative antibody test ☐ Positive PCR test

☐ Negative Antigen test ☐ Positive Antigen test ☐ Positive Antibody test

☐ Other (*explain*): …….....

……..

……..

Symptoms Observed post treatment

Date of observation: …. / …. / ……

☐ None ☐ Body ache ☐ Shortness of breath ☐ Diarrhoea

☐ Tiredness ☐ Headache ☐ Nasal congestion ☐ Sore throat

☐ Cough ☐ Runny nose ☐ Loss of smell ☐ Fever

☐ Other: ……

COVID-19 disease severity post treatment

☐ Mild ☐ Moderate ☐ Severe

SPO2 (on ambient air) Resp rate Pulse Temperature

## SECTION E

### Safety evaluation
### Adverse events/Side effects

Did the patient experience any side effects/adverse events while taking this medicine? □Yes □ No

If yes proceed to complete the attached ADR reporting form, alternatively adverse drug reactions experienced by the patient may be submitted electronically on https://e-pv.mcaz.co.zw

### Reporter details

Forename(s): …….. Surname: …….....

Institution: ……...

Designation: ……

Email: ……. Mobile/Telephone number: ……...