

21 June 2018

Circular 8 of 2018

To:

- 1) Retail and Hospital Pharmacies
- 2) Zimbabwe Medical Association (ZiMA)
- 3) Pharmaceutical Society of Zimbabwe (PSZ)
- 4) Retail Pharmacists Association

Dear all

Re: Notification of a potential risk of neural tube defects in infants born to women who were taking Dolutegravir at the time of conception

The Authority hereby notifies all of the above on a potential risk of neural tube defects which has been reported in infants born to women who were taking Dolutegravir at the time of conception. The safety issue was identified from a preliminary unscheduled analysis of an ongoing observational study in Botswana, which has found four cases of neural tube defects out of 426 women who became pregnant while taking DTG. This rate of approximately 0.9 percent compares with a 0.1 percent risk of neural tube defects in infants born to women taking other antiretroviral medicines at the time of conception.

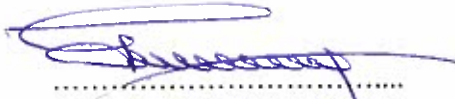
As a result, health care professionals are being advised of the following:

- i. To inform women of childbearing age about the potential risk of neural tube defects when a Dolutegravir-containing regimen is used at the time of conception and early in pregnancy.
- ii. An appropriate alternative treatment regimen must be considered if pregnancy is confirmed in the first trimester while a woman is taking Dolutegravir. The risks and benefits of the selected treatment regimen should be discussed.
- iii. To advise women of child bearing age who are taking Dolutegravir on the consistent use of effective contraception throughout treatment.
- iv. A pregnancy test must be performed before initiating a Dolutegravir-containing regimen in women of childbearing age to exclude pregnancy.

Ongoing monitoring will continue as part of the strengthening of Pharmacovigilance of this medicine including monitoring of birth outcomes. Please note that the identified potential risk was based on preliminary findings, and more information may be availed at a later date.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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G N Mahlangu (Ms)
DIRECTOR-GENERAL
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