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Republic of Botswana

MINISTRY OF HEALTH & WELLNESS
PRIVATE BAG 0038
GABORONE

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TO: All Media Houses

PRESS RELEASE

The Ministry of Health and Wellness wishes to inform the general public regarding the potential safety issues of the antiretroviral medicine called Dolutegravir (DTG). The medicine has been used since June 2016.

The potential safety issue is related to the development of the spinal cord, the brain and the bone and surrounding tissues (neural tube development) within the first 28 days of conception (one month). This is when the neural tube fails to completely form. However, it is important for the public to note that these findings are preliminary and that the data is very limited at this time. There have been four cases of neural tube defects identified out of 426 women who were taking DTG before they became pregnant from an ongoing study in Botswana. Neural tube defects maybe related to folate deficiency, other medications, obesity or genetic factors.

Preliminary data suggests that the potential safety issue arises from a woman's exposure to DTG only at the time of conception. There has been no infant born with a neural tube defect from women who started DTG after their first three months of pregnancy. To date more than 2,500 women who began taking DTG after the time of conception have not reported any cases of neural tube defects.

Despite these preliminary findings, DTG has proven to be a highly effective medication in Botswana and around the world. The use of DTG was introduced in the country because it is better tolerated, leads to faster and sustained viral suppression.

The Ministry of Health and Wellness continues to monitor the use of DTG among women of childbearing age and will inform the public appropriately of any developments. These women are advised to use the medication, Dolutegravir with caution, with advice from their clinicians. Until then, the Ministry recommends the following to health care providers and HIV positive women who are pregnant or desiring pregnancy:

- HIV positive women who are currently on DTG and desiring pregnancy should visit their healthcare providers for appropriate advice.
- HIV positive women, who are pregnant and have conceived while on DTG, should alert their healthcare providers so they can be counselled and advised appropriately.

Vision: *A Healthy Nation by 2023.*

Values: *Botho, Equity, Timeliness, Customer Focus, Teamwork, Accountability.*



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- HIV positive women, who are currently on DTG and do not desire pregnancy at this time, should consult their health care providers for effective contraception in addition to the use of condoms.
- All women of child bearing age should be tested for pregnancy before initiating any DTG containing regimens.

For additional information or concerns, please contact the Ministry of Health and Wellness, Public Relations Office on 0800 600 740

Thank you.

A handwritten signature in black ink, consisting of a large loop and a horizontal line extending to the right.

Dr Morrison Sinvula
Deputy Permanent Secretary/Health Services Management

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