DEPARTMENT OF HEALTH
Republic of South Africa

SAHPRA
South African Health Products Regulatory Authority

Press Release

MEDICINES SAFETY COMMUNICATION

Recommendations about the use of the HIV medicine DOLUTEGRAVIR in Pregnancy in response to the Potential Risk of Birth Defects

TO ALL CONSUMERS

From: The Acting CEO of SAHPRA

Date: 22 May 2018

The South African Health Products Regulatory Authority (SAHPRA) is informing health professionals and the public that four cases of neural tube defects (a group of birth defects involving the brain, spine and spinal cord) have been reported in babies born to women who were taking the antiretroviral medicine dolutegravir at the time of conception (Trade names: Tivicay®, Trelavue). Dolutegravir is used in combination with other antiretroviral medicines in the management of Human Immunodeficiency Virus (HIV) infection.

The early findings of a study that is ongoing in Botswana identified 4 (four) cases of neural tube defects out of 426 women who became pregnant while taking dolutegravir in combination with other antiretrovirals. This rate of 0,9 % is higher than the rate of approximately 0,1 % seen in women who were taking other non-dolutegravir antiretroviral combination medicines in this setting. There were no reported cases of neural tube defects in women who were started on dolutegravir later in pregnancy. Additional data is expected from the Botswana study and other settings where women have already been exposed to dolutegravir at the time of conception or early in the first trimester but who have not yet delivered. Based on these preliminary findings, women who fall pregnant while on dolutegravir or who are initiated on dolutegravir early in the first trimester may be at increased risk of giving birth to babies with these specific birth defects.

In light of this new concern about the safety of dolutegravir use in pregnancy, SAHPRA is issuing the following precautionary advice:

- Women who are trying to fall pregnant should not be prescribed dolutegravir.
- Pregnancy should be excluded in women of child-bearing age who are being initiated on dolutegravir-based HIV treatment.
- Women of child-bearing age who are taking dolutegravir should consistently use a highly effective method of contraception.
- Pregnant women who are taking dolutegravir should not stop their ARV therapy and should speak with their health care professional for additional guidance.

- Antiretroviral (ARV) therapy for women of childbearing age, including pregnant women, should be based on medicines for which adequate efficacy and safety data are available.

In addition, SAHPRA has asked manufacturers of dolutegravir-containing products to urgently distribute a letter to health care professionals informing them of these new findings.

Data on the safety of medicines in pregnancy is often lacking or inadequate at the time of marketing approval of a medicine, and post-marketing surveillance is essential to ensure that these medicines are safe, including in pregnancy, and are effective and of good quality. Health professionals in South Africa are urged to report any adverse reactions including birth defects associated with dolutegravir to the National Adverse Drug Event Monitoring Centre at (021) 4471618 or using the reporting form which can be accessed at http://www.mccza.com/documents/14ed44a46.04_ARF1_Jul16_v4.pdf. SAHPRA also supports the National Department of Health's initiative to monitor the safety of medicines used in pregnancy through the National Pregnancy Exposure Registry/Birth Defect Surveillance programme.

SAHPRA will continue to collect more data on the safety of dolutegravir in pregnancy as it becomes available and will review its recommendations and update the public accordingly.

For further enquiries / information contact:
Portia Nkambule
Acting CEO: SAHPRA
E-mail: portia.nkambule@health.gov.za
Tel: 012 395 8126

Tohlang Sehloho
Acting Director: Clinical Evaluations and Trials
E-mail: tohlang.sehloho@health.gov.za
Tel: 012 395 8767

Or

Florah Matlala
Deputy Director: Pharmacovigilance Unit
E-mail: florah.matlala@health.gov.za
Tel: 012 395 9133

Website: http://www.mccza.com

Address:
Physical: South African Health Products Regulatory Authority, Department of Health, Civitas Building, 42 Thabo Sehume Street (formerly Andries), Pretoria, 0002
Postal: Private Bag x 828, Pretoria, 0001