Dolutegravir: follow-on to the WHO statement from 18 May 2018

On 18 May 2018 WHO issued a statement on potential safety issue affecting women living with HIV and using dolutegravir (DTG) at the time of conception.
http://www.who.int/medicines/publications/drugalerts/Statement_on_DTG_18May_2018final.pdf?ua=1

In July 2018 WHO released new interim guidelines containing recommendations regarding preferred first-line regimens for adults, adolescents and children initiating antiretroviral therapy (ART), which now include DTG and raltegravir (RAL). The recommendations include a note of caution on using DTG during the periconception period and for women and adolescent girls of childbearing potential. The recommendation related to DTG use will be updated as soon as relevant evidence becomes available.

The US FDA is evaluating the potential risk of neural tube birth defects with HIV medicine DTG, and has implemented labelling changes to include current knowledge and advice to patients and healthcare professionals on DTG. (https://www.fda.gov/Drugs/DrugSafety/ucm608112.htm)

At its monthly meeting in October 2018, the European Medicines Agency’s Pharmacovigilance Risk Assessment Committee (PRAC) confirmed its precautionary advice issued earlier this year on the use of DTG in pregnant women and for use of effective contraception while taking DTG in women who can become pregnant. (https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-1-4-october-2018)

In the meantime, and subsequent to its statement in May 2018, WHO has set up a sub-committee on the safety of DTG under the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP), to review new data and information as these become available globally. The results of this review will be made public in due course. (http://www.who.int/medicines/regulation/medicines-safety/adv_com-smp/en/)