Dolutegravir-containing products – New warning

- On September 6, 2018, the FDA announced an update to the *Warnings and Precautions* section of dolutegravir-containing products drug labels regarding embryo-fetal toxicity.
    - Previously, the FDA announced a safety communication about neural tube birth defects in May of 2018.
- Dolutegravir-containing products include Tivicay® (dolutegravir), Juluca® (dolutegravir/rilpivirine) and Triumeq® (abacavir/dolutegravir/lamivudine).
    - Tivicay, Juluca, and Triumeq are approved to treat human immunodeficiency virus type 1 infections.
    - Refer to individual drug labels for specific indications.
- Preliminary data from an observational study showed that dolutegravir, was associated with increased risk of neural tube defects when administered at the time of conception and in early pregnancy. As there is limited understanding of reported types of neural tube defects associated with dolutegravir use and because the date of conception may not be determined with precision, avoid use of dolutegravir-containing products at the time of conception through the first trimester of pregnancy.
    - If there are plans to become pregnant or if pregnancy is confirmed within the first trimester while on dolutegravir-containing products, if possible, switch to an alternative regimen.
    - Perform pregnancy testing before initiation of dolutegravir-containing products in adolescents and adults of childbearing potential to exclude use of dolutegravir-containing products during the first trimester of pregnancy.
    - Advise adolescents and adults of childbearing potential to consistently use effective contraception.