TLD Transition: South Africa

ARV Tender

- **The transition is planned for July 2019**
- **147-million patient packs of TLD over the three years from July 1, and has been split between eight companies:**

1. **Adcock Ingram (Aspen Pharmacare Sonke Pharmaceuticals**
2. **Mylan**
3. **Hetero**
4. **Aurobindo**
5. **MacLeods**
6. **Cipla Medpro**

Guidelines

- According to draft 2 of the Guidelines, transition/rollout will happen as in the following slides:

Scenario	Regimen	Comments
a; All men; adolescent boys, women on reliable contraception	**TLD (Provide as FDC)**	
b; and women and adolescent girls not of childbearing potential	**TLD (Provide as FDC)**	**Prior to DTG initiation, all women and adolescent girls of childbearing potential (WOCP) must be appropriately counselled on the potential risk of NTDs with DTG use during the periconception period and provided with consistent and reliable contraceptives as desired. The neural tube closes by the end of the fourth week of pregnancy thus, there is no risk of NTDs after this period.**
ARV-naïve pregnant women and adolescent girls from 12 weeks after conception (after the first trimester), provided 1) they are willing to take reliable contraception post-delivery, and 2) do not plan to have more children in (near) future	**TLD (Provide as FDC)**	

Breastfeeding women and adolescent girls newly initiating ART provided they are using reliable contraception	**TLD (Provide as FDC)**	**TB screening must be done in pregnant women and adolescent girls, it is recommended that they are screened using TB-GXP regardless of TB symptoms.**
Women of Child Bearing Potential who: Wish to become pregnant, and/ or Are not on reliable contraception. Have been counselled and choose to use DTG after informed choice	**TLD (Provide as FDC)**	**WOCP should be counselled about the potential risks of NTDs with DTG use during the periconception period and provided with consistent and reliable contraceptives as desired.**
Women of Child Bearing Potential who: Wish to become pregnant, and/ or Are not on reliable contraception. Have been counselled and choose to use EFV after informed choice	**TLE or TEE**	**WOCP should be counselled about the potential risks of NTDs with DTG use during the periconception period and provided with consistent and reliable contraceptives as desired.**

Pregnant women and adolescent girls presenting already on ART	**Stay on current regimen**	**Only switch an existing, stable client from EFV to DTG if her VL is < 1000 copies/mL, and she is no longer in the 1st trimester. A switch to DTG needs to be preceded by appropriate counselling on the risk for NTDs for subsequent pregnancies, post-partum contraception, and the new side effects that may be experienced when switching to a new drug**
Women and adolescent girls diagnosed HIV-positive in labour	**TLD**	**Give a stat single fixed dose combination tablet of TLD and a stat single dose of NVP. Combination ART to be started the following day after understanding her fertility intentions and counselling her appropriately on the possible risk of NTDs with DTG use, for her subsequent pregnancies. TLD to be prescribed if she is willing to use effective contraception, alternatively TEE if DTG-containing regimen not appropriate**

Not on ARVs, acquiring TB	**TLE or TEE**	**Once TB treatment has been successfully completed, if VL is suppressed and undetectable within last six months, consider switching to TLD, with counselling on side effects. If WOCP, provided they do not desire to fall pregnant.**
On EFV-based ART acquiring TB	**TLE or TEE**	**Once TB treatment has been successfully completed, if VL is suppressed and undetectable within last six months, consider switching to TLD, with counselling on side effects. If WOCP, provided they do not desire to fall pregnant.**
On DTG-based ART acquiring TB	**TLD + DTG 50 mg**	**DTG has a significant interaction with rifampicin. As such, DTG must be dosed 50 mg 12-hourly (instead of daily) in TB/HIV co-infected patients being treated with rifampicin.**

Thank You