

# Note for the record: Webinar Access to Treatment Options for Women Living with HIV

## 1. Introduction

Salamander Trust recently received funding from UNAIDS to bolster civil society's advocacy, communications and consultations with women living with HIV and partners on two key issues: *Dolutegravir* (DTG) and cervical cancer. On November 15<sup>th</sup> Salamander Trust organised a webinar on **Access to Treatment Options for Women Living with HIV**.

## 2. Background

The WHO 2017 Consolidated [Guideline](#) on the Sexual and Reproductive Health and Rights (SRHR) of women living with HIV is a ground-breaking document, which upholds the rights of women in several key areas. Since 2013, Salamander played a major role facilitating the global values and preferences survey on the SRHR of women living with HIV. This fed into the development of the new consolidated guideline. As part of this process, WHO Department of Reproductive Health and Research asked Salamander to develop a [checklist](#) tool (currently being updated), to support women in countries to ensure the full implementation of the guideline. This tool has now been endorsed by the heads of 5 UN agencies.

## 3. Reason for this work

UNAIDS has now asked Salamander to take this process further. No matter how great the guideline is, women continue to face challenges in accessing treatment options. Barriers to access and 'options' for women have become even more visible over recent months, following mixed reactions to the WHO HIV Department warning on May 8, 2018 citing a potential risk of neural tube defects (NTDs) for babies born to women taking Dolutegravir (DTG) during conception and pregnancy in Botswana.

This was from preliminary unscheduled analysis of an ongoing birth surveillance study in Botswana – the study is called Tsepamo, which reported an increased risk of NTDs among infants of women who became pregnant while taking DTG. Defects were reported in four out of 426 infants born to women who were put on DTG in pregnancy. The next formal analysis will occur after 31 March 2019 and will include women already exposed to DTG from conception before the recent change in guidance. Tsepamo has expand the study from 8 to 18 sites, increasing from 45% to 72% of births in Botswana. The next analysis will include: NTDs; all major malformations; and other adverse birth outcomes (stillbirth, preterm, small for gestational age and neonatal death).

## 4. What we will produce

As an outcome of our work the following is to be delivered before the end of this year:

- Create an advocacy brief that can be **owned by all of us** to move access forward before the end of this year. This will highlight recommendations to: governments at the national level; technical partners such as UNAIDS and WHO to strengthen messaging and actions to support it; and reflect and communicate diverse realities, priorities and rights of women living with HIV around treatment and service options.
- Set up a virtual sharing platform (probably on whatsapp as this is easy for many women to engage) where information on what is happening can be shared in real time and support and linkages can be made across countries and regions.
- Develop a series of 15-minute podcasts called The WHAVE (Women with HIV: Advocates, Voices, Empowered). These will be recorded by women living with HIV from around the world and will include a specific podcast on DTG.
- Support those most active to join as national or regional coordinators of this work.

## 5. Key Documents and Advocacy in chronological order

- May 8: [WHO Statement on DTG](#)
- June 28: [National Empowerment Network of people living with HIV in Kenya \(NEPHAK\) – Letter to MoH Demanding DTG](#)
- July 2018 Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV: [interim guidance](#)
- July 1: [Comparative safety of dolutegravir-based or efavirenz-based antiretroviral treatment](#) started during pregnancy in Botswana: an observational study: The Lancet
- July 13 - 14: IAS2018: [Communique of the Kigali Dolutegravir Stakeholder Meeting](#) of African Women Living with HIV, hosted by African Community Advisory Board (AfroCAB)
- July 16: [NOTHING FOR US WITHOUT US](#): Statement by the AfroCAB on Dolutegravir and neural tube defects in women living with HIV of child bearing age
- July 18: [Time to realise our sexual and reproductive health and rights](#) – the Lancet
- July 23 - [Give Women Living with HIV full information on the benefits and risks of DTG, Contraceptives for them to exercise choice – ICW East Africa??](#)
- Aug: [IPPF TECHNICAL BRIEF](#): Dolutegravir for women living with HIV of reproductive age
- Aug 3 I-base: [No additional neural tube defects among a further 170 preconception dolutegravir exposures in Botswana](#): Tsepamo study (July 2018)
- August 20: [Dolutegravir drug is safe for women living with HIV](#): Martha Akello – New Vision??
- 1-4 October 2018 European Medicines Agency (EMA) 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
- Sept - Nov 2018: [Forum on the risks of preconception dolutegravir exposure: an IAS - CDC](#).
- 13 Nov: I-base: [Insufficient data on risk of neural tube defects](#) with exposure to elvitegravir or bictegravir exposure during preconception or first trimester
- 13 Nov: I-base [No additional neural tube defects with preconception dolutegravir](#): data from three birth outcome cohorts

## 6. Webinar Outcomes

The webinar ended with consensus that this group will develop a global advocacy brief that can then be adapted if desired for more individual national level advocacy. This advocacy brief will speak to key issues that we think are essential for governments and technical partners to take serious note of whilst we wait for more results on DTG. Salamander will start working-on the advocacy brief and will come back to everyone with a first draft.

Some of the key issues raised that we agreed would go into the advocacy brief include:

- All of these discussions sit in a broader framework of upholding and respecting the SRHR and treatment options of women living with HIV.
- The recommendations offer an opportunity for countries to address the lack of integration around HIV and sexual reproductive health rights and services for women living with HIV – these are important for our reproductive health decisions and choices. Women living with HIV should define what 'effective contraception' in this context looks like

- Women living with HIV must be included in research
- We need to learn from the experiences around DTG and prepare for new evidence as ARVs evolve. What message do we send to WHO to ensure that our options, realities and treatment priorities are taken onboard and respected BEFORE warnings are issued that have serious implications for women living with HIV?
- Again, we are more than just mothers - Women have the right to full information and options to make their own voluntary choice and balance potential risks of DTG against its potential benefits
- Countries need to break down the 15-49 age group that blanket all women as having the same sexual reproductive health needs and desires.

Click [here](#) to listen to the webinar and click [here](#) to access the webinar slides.

#### **7. Webinar Participants**

*19 participants joined the webinar, from Africa, Europe and Latin America, including: Almadeleon; Dorothy Onyango; Florence Anam; Francine Ngahnale; Fungai Muru; Hajjarah Nagadya; James Cole; Jenny Vaughan; Joyce Ouma, Kiny Yaa, Lillian Mworeko; Longet Kwardem; Martha Akello; Mwenya Chiti; Patricia Ochieng; Resty Nalwanga; Tendayi Westerhof; Violeta Ross; Zoe Bulls. The Salamander Secretariat was represented by Alice Welbourn and Sophie Dilmitis*