



Deborah Waterhouse

CEO, ViiV Healthcare  
United Kingdom

1 December 2017

Dear Mrs. Waterhouse,

On behalf of Médecins Sans Frontières (MSF), we are sending this open letter to urge ViiV to register its paediatric HIV drug formulation of dolutegravir broadly across low and middle income countries as soon as possible, and to make transparent the registration plans, their status, and the price of DTG across all countries.

In 2015, 150,000 children became infected with HIV. While this represents a dramatic improvement in the last 15 years, paediatric HIV remains a neglected disease. Today there are still 1.8 million children living with HIV; 80% live in sub-Saharan Africa, and only half of them are on treatment.<sup>1</sup>

Access to dolutegravir for children living with HIV is critical to provide improved and optimal treatment options for children who often suffer from side effects and difficulty adhering to other regimens. Both the WHO's paediatric antiretroviral drug optimization (PADO) group and the Paediatric HIV Treatment Initiative (PHTI) have indicated dolutegravir as a priority ARV and that access should be accelerated for children. Therefore, paediatric access for DTG must be prioritized by ViiV, particularly for high-burden countries. A dolutegravir-based regimen could lead to improved adherence and reduced levels of resistance in first line, and provide a better chance at a salvage regimen for those already failing treatment.

In MSF's project in Chiradzulu, Malawi, for example, 30% of children and adolescents have unsuppressed high viral loads due to the above challenges of treating paediatric populations. Access to paediatric dolutegravir has the potential to improve the chance of survival for more than 1,700 children and adolescents in Chiradzulu.

#### *Registration*

Dolutegravir has been registered for treatment for adults in the US since August 2013, and in Europe since January 2014. While studies continue for younger children, 10 mg and 25 mg paediatric tablet formulations of DTG have been approved for use in children (down to 30 kg) since June 2016 in the US, and as young as 6 years since Feb 2017 by the European Medicines Agency (EMA).

While the adult formulation of dolutegravir has been filed for regulatory approval widely and registered in many countries hardest hit by HIV, the same effort has been severely lacking for the paediatric formulations. Filing variations with national drug regulatory authorities to expand the approvals to include children should be done urgently. ViiV should also file for WHOPQ approval of its paediatric formulations, enabling use of the WHO Collaborative Registration Procedure to expedite registration in participating countries.

*Compassionate Use (pending registration)*

MSF recognizes that Viiv has engaged with Medicines Patent Pool (MPP) and CHAI to allow access to generic paediatric DTG. However, until generic formulations are developed, made available and registered in countries, Viiv must make its formulation available on compassionate use grounds for organizations and governments who may want to use it as per already approved indications but in advance of registration in their countries. This will provide critical information to guide implementation and scale-up in countries, while providing children with the best possible ARV treatment regimens.

*Pricing*

In addition, Viiv has committed to pricing paediatric dolutegravir based on the cost of manufacture, and should share its pricing strategies to further aid countries and organizations like MSF in their treatment and scale up plans.

On the 29th World AIDS Day, MSF calls on Viiv to fulfil its commitment and make paediatric DTG available by submitting dossiers and variations for registration, making transparent its registration plans and status, as well as its pricing structure for dolutegravir.

Sincerely,



Els Torreele

Executive Director

MSF Access Campaign

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[http://www.unaids.org/sites/default/files/media\\_asset/FactSheet\\_Children\\_en.pdf](http://www.unaids.org/sites/default/files/media_asset/FactSheet_Children_en.pdf)