

17 August 2023

To: Deborah Waterhouse, CEO, ViiV Healthcare  
Harmony Gargess, VP, Chief Medical Officer, ViiV Healthcare

Cc: Stephen Rea, Head of External Affairs and Communications, ViiV Healthcare  
Helen McDowell, Head of Government Affairs and Global Public Health, ViiV Healthcare  
Thomas Van Every, Director, Government Affairs and Global Public Health, ViiV Healthcare  
Carissa Vados, Director, Access to Medicines Strategy and Programmes, ViiV Healthcare  
Isla Harrap, Manager, Access to Medicines, ViiV Healthcare

**Re: CAB-LA for PrEP supply to MSF**

Dear Ms. Waterhouse,

We write to you on behalf of Médecins Sans Frontières/Doctors Without Borders (MSF) to ask you to facilitate access to injectable cabotegravir long-acting (CAB-LA) for our medical programmes that are seeking to provide the drug for the prevention of HIV in key and vulnerable populations in a number of countries.

As you are aware, ViiV is the only global supplier of CAB-LA. MSF has been negotiating to procure the drug since January 2022 as MSF does not accept donations as initially proposed by ViiV. In fact, a purchase order was placed more than a year ago in June 2022. Since then, our team has been in contract negotiations in good faith for a Purchase Agreement to facilitate such purchase orders as required by your team for CAB-LA.

The Purchase Agreement for our procurement was near final in December 2022. However, after informing us of the very limited supply of CAB-LA for low- and middle-income countries, on 12 May 2023, your team introduced last-minute changes to the Purchase Agreement that are not standard in MSF purchase agreements with manufacturers, delaying access to CAB-LA for pre-exposure prophylaxis (PrEP) for the most vulnerable communities. We draw your attention to significant reasons why the Purchase Agreement as now proposed by ViiV are preventing our signing of the agreement.

ViiV retains the power to terminate the contract or refuse the purchase order (PO) without just reasons, undermining the value of such purchase agreements for supply security. The normal reasons for refusal of a PO have been removed from the contract, allowing ViiV to refuse a PO from MSF without any valid reason. The time for ViiV to approve a PO was also increased from 5 to 45 days, prolonging the already long 6-month lead time. Additionally, ViiV has introduced a 'termination for convenience' clause with a 90-day notice. This addition undermines supply security as our standard procurement contracts with manufacturers typically permit termination solely in the event of breach of contract.

Secondly, the addition of confidentiality clauses akin to a non-disclosure agreement (NDA), including on the drug's price and the terms of the agreement, is highly problematic. Such clauses in procurement agreements for vaccines and therapeutics were heavily critiqued during the COVID pandemic for undermining the right to information, hindering transparency and accountability of procurement made with public funds, and hampering governments and procurers' ability to negotiate lower prices

with manufacturers. Such NDAs in purchase agreements are now the subject of a constitutional legal challenge in South Africa.<sup>1</sup>

MSF has not signed such NDAs for HIV antiretroviral medicines, which would block the disclosure of the prices we pay for medical products from our donors or the public. MSF has published the ['Untangling the Web'](#) report series of HIV antiretroviral drug prices for over 20 years, supporting countries, stakeholders and the public in accessing prices of antiretrovirals transparently.

**We request that you withdraw the confidentiality clauses inserted on 12 May 2023, and amend the terms to ensure supply security and timely availability of CAB-LA.**

Furthermore, regarding the limited supplies of CAB-LA and as the European Medicines Agency (EMA) has just announced approval of CAB-LA for PrEP in Europe, we call on ViiV once again to commit to transparency around manufacturing capacity and supply allocation to countries with relatively higher rates of HIV infection, and therefore need for better PrEP as compared to those countries with financially more lucrative markets.

MSF is committed to providing medical care to people who would otherwise not have access to it. Our humanitarian medical operations rely on securing agreements like these to procure essential medicines. Any obstruction or delay in reaching reasonable terms will directly impact our ability to deliver much-needed assistance.

As this Purchase Agreement is required by ViiV for MSF to purchase CAB-LA at the access price, we sincerely hope that ViiV shares our commitment and can find a solution to the issues raised in this letter. We request your response by 30 August 2023.

Sincerely,



Dr Sidney Wong  
Executive Co-Director  
Médecins Sans Frontières Access Campaign



Philip Aruna  
Team Leader  
Southern Africa Region  
Médecins Sans Frontières

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<sup>1</sup> Health Justice Initiative v Minister of Health and Anr, High Court of South Africa, Gauteng Division, Pretoria available at <https://powerlaw.africa/2023/07/24/health-justice-initiative-v-minister-of-health-and-another/>