John F Milligan
Chief Executive Officer
Gilead Sciences
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USA
cc. John C. Martin, Executive Chairman, Gilead Sciences
Gregg H. Alton, Executive Vice President and Commercial and Access Operations ALA, Corporate and Medical Affairs, Gilead Sciences

European AIDS Treatment Group
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The PrEP in Europe Initiative
c/o NAM/ Aidsmap
Acorn House
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April 11, 2017

Dear Mr Milligan,

**Re: availability of Truvada or generic equivalents for HIV pre-exposure prophylaxis**

EATG, as Europe's transnational HIV treatment and prevention advocacy group, and the PrEP in Europe Initiative (PEI), a partnership of European prevention and policy NGOs, are writing this letter as a request to Gilead to perform one single, specific action: that you make it possible for Truvada®, or for generic equivalents of the Truvada fixed-dose combination (FDC), to be offered at generic prices to all European healthcare systems so they can be used as HIV pre-exposure prophylaxis (PrEP).

This letter is a follow-up to EATG's letter of 03 November 2016 which asked Gilead to clarify whether they intended to surrender or enforce their patent rights over Truvada to enable PrEP access. Here we outline the current dilemma more specifically and suggest ways forward. There are several ways forward, but all depend on Gilead. We do not imply the blocks to implementation of PrEP are entirely Gilead's responsibility.

EATG, PEI and our partner organisations will continue to exert pressure on national governments and advocate for healthcare systems to provide PrEP. However it is clear that most governments will only allow this to happen if PrEP is available at a greatly reduced price. In other words, PrEP will remain unavailable for the majority of people who need it in Europe as long as any way through to a price reduction remains blocked.

At present the continuing legal action concerning the Supplementary Protection Certificate for Truvada, which has been referred to the Court of Justice of the European Union with no set hearing date, is making this impossible. Generic companies will not market a Truvada-equivalent FDC pill while at risk of

patent infringement. National plans for provision of PrEP free or at reimbursement rates affordable to most users, and whether provided directly by physicians or via implementation studies, are stalled.

This is a very different situation to the provision of tenofovir and tenofovir-based FDCs for treatment. It will be possible to combine generic tenofovir with lamivudine or other drugs as the single drug is approved for treatment. Only Truvada, however, is licensed for PrEP and there are no alternatives to it. This creates, at present, an effective monopoly for Gilead over its supply and price.

The simplest thing Gilead could do, would be to apply to withdraw from the legal action concerning the Truvada Supplementary Protection Certificate and surrender its remaining patent rights to Truvada. This would instantly unblock the logjam that may prevent open access to PrEP in Europe for four to five years.

However we understand that Gilead may regard this as an important test case that must be pursued, and also that they did not initiate the legal action so may not be free agents. If this case really cannot be withdrawn, there are alternatives. We disagree with the often-repeated assertion that charging a lower price for Truvada, if it is prescribed as PrEP, is unfeasible. In a centralised system like the UK, which runs separate sexual health and HIV clinics, it is perfectly feasible to supply a reserved fraction of Truvada for PrEP at a much-reduced price and internal and external monitoring can ensure it is only prescribed as that. In reimbursement-based systems such as the Netherlands Gilead can agree to arrange a lower reimbursement price for Truvada if it is prescribed to HIV-negative people.

We believe that Gilead's current patent and pricing strategy for Truvada is short sighted. Mathematical models, and the US experience, show us that the eventual market for PrEP may be at least as large as the market for HIV treatment. A significant minority of PrEP users will have intolerance of tenofovir DF or generic equivalents and will need to use Descovy® (TAF/FTC). Gilead has clearly anticipated this by its launch of the DISCOVER study. Truvada or Truvada equivalents are likely to remain the predominant and approved medicine for PrEP for several years to come; but Gilead, by blocking PrEP access in Europe, may also be blocking itself off from a part of that market in the shape of Descovy, and a possibly much larger market in the future, including for drugs further down the pipeline. Does Gilead seriously wish to limit Europe's future market for PrEP?

We feel that Gilead should also consider its corporate image and responsibility to public health at this juncture too. Evidence from the UK and US is beginning to suggest that PrEP is enabling us to reach a tipping point where infections are finally starting to decline in men who have sex with men. With adequate testing, treatment and PrEP provision the same may start to apply to MSM and other at-risk populations in other parts of Europe. But PrEP may be necessary: by encouraging frequent testing for HIV and STIs, and regular monitoring and contact with healthcare, PrEP may be acting as a catalyst for a dramatic downturn in HIV infections and vulnerability to HIV.

Does Gilead want to be remembered as the company that stopped PrEP for Europe – or as the company that enabled it?

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Yours sincerely,

Jackie Morton, chair, EATG, and for PEI

Deborah Gold, Chief Executive, National AIDS Trust, for PEI

Aurélien Beaucamp, President, AIDES, for PEI

Mitchell Warren, Executive Director, AVAC, for PEI

Anke van Dam, Chair of the Steering Committee of AIDS Action Europe, for PEI

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