Generic tenofovir disoproxil fumarate and emtricitabine tablets obtained from the internet – are they what they say they are?

Xinzhu Wang¹, Will Nutland³, Michael Brady⁴, Ian Green¹, Myra McClure¹, Marta Boffito¹,⁵
¹Imperial College London, London, UK ²PrEPster, London, UK ³Terrence Higgins Trust, UK ⁴Chelsea and Westminster Hospital, London, UK

Background
Pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate (TDF):emtricitabine (FTC) has been shown to reduce dramatically the risk of HIV acquisition⁶. However, the National Health Service (NHS) in England has declined to commission PrEP, leading high-risk individuals to purchase generic versions on-line. Our team at Imperial College London provided therapeutic drug monitoring for tenofovir (TFV) and FTC in 2016-2017 for 293 individuals taking generic PrEP and reported that plasma concentrations were all above the target values⁶. More recently, concerns have arisen over the authenticity of generic PrEP purchased online. In the present study, we sampled generic PrEP from mainstream brands and suppliers and measured TDF and FTC in the purchased tablet form.

Methods
Generic PrEP tablets in sealed bottles of different brands and from different suppliers were purchased from the internet through test purchases. Truvada® from Gilead was purchased from Imperial College Healthcare NHS Trust. The brand and supplier of the generic PrEP samples were blinded from the researcher carrying out the analysis. The active pharmaceutical ingredient TDF and FTC was quantified using a fully validated ultra-performance liquid chromatography assay.

Results
• A total of 14 samples were obtained for analysis, including Truvada® from Gilead. PrEP used in the IMPACT trial and 13 generic PrEP tablets obtained from Mylan, Cipla, Hetero Healthcare, Emcure, Adcock ingram and GPO (Figure).
• The suppliers were All Day Chemist, Dynamix International, Green Cross Pharmacy, In House Pharmacy, Silom Pulse and United Pharmacy (in alphabetic order).
• As summarised in the table, all the PrEP tablets contained 94.3% to 104.9% of the 200 mg of TDF claimed on the label and 97.3% to 104.4% of the 300 mg FTC claimed on the label.

Conclusions
All the PrEP tablets sampled in this study contained the stated amount of TDF and FTC. We were able to confirm the stated content of the PrEP tablets from various manufacturers and suppliers. This study provides reassurance to the community purchasing generic PrEP online and is a good example of a close collaboration between academics, clinicians, HIV charities and PrEP advocates.

References
4. https://www.prepimpacttrial.org.uk/