



Vietnam Network of People living with HIV

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To whom it might concerns

I, the undersigned, on behalf of community of PLHIV in Vietnam is pleased to invite you all to submit generic TLD registration dossier in Vietnam as to the Govt. of Vietnam has adopt the optimal HIV treatment regimen **Tenofovir DF 300mg/lamivudine 300mg/dolutegravir 50mg** as a Fixed Dose Combination (FDC) in the Vietnam National HIV Treatment Guidelines 2019 as the preferred first-line ART regimen for adolescents and adults, a policy revision that aligns with WHO recommendations at the end of 2019. As the first choice for first line regiment Vietnam is planning to put 25,000 patients on TLD by the end of 2020 is going to shift 2/3 of total 103K patients to this optimal regimen. More ever, this drug will be prescribed through Social Health Insurance (SHI) in the near future, which will maintain the sustainability of HIV treatment through very sustained domestic resource when foreign Donors eventually withdraw from our country.

The current policy framework is pretty promising. Marketing Authorization (MA) is cleared recently for generic FDC TLD made by Mylan company, due to strong advocacy pressure of Donor groups including PEPFAR, GFATM and UN- the generic drug can quickly get through the fast track process of MA approval by Drug Administrative of Vietnam (DAV), it bypass the strict conditions of DAV Vietnam to be granted MA, which means not necessary having clinical evidence of drug use in Vietnam, as approval or tentative approval from FDA US is sufficient etc. The advocacy for inclusion of TLD in the Vietnam SHI reimbursement drug-list is also going well and expect this can be included in SHI drug-list by the end of 2020.

The advocacy efforts from PEPFAR programs at this moment offer huge advantage and monopoly for Mylan for Vietnam market both with commercial market and SHI drug procurement. As currently Mylan is the only company that have MA in Vietnam and as such, GF and PEPFAR also have to procure drug from this company only for Vietnam market while SHI source is not available. Also, in the coming days, when SHI can procure TLD, if the current situation is not change and only one MA available, there will be no competition in the market for this drug-TLD, then the PRICE NEGOTIATION with Mylan will be only the channel that provide favourable condition for this company to monopolise the price. It is also unfair for Vietnam to buy generic TLD in an exorbitant monopolise price when there are around 9-10 generic TLD producer in the market

That said, both Community and MOH managers wants all advocacy efforts made over the last two years to bring TLD into country and transition all other regimens to this superior one for our Vietnam HIV patients will benefit all of Interested company but not limited to one company. Therefore, we urge the company to submit a drug registration dossier to Vietnam if you are interested because we want an open market for all interested company to provide transparent & healthy competition in Vietnam.

Best regards,

Do Dang Dong

Chairman of Vietnam Network of People living with HIV (VNP+)