**Enc 2 Appx 1**

**Company Response to the Preliminary Appraisal Recommendation**
**Emtricitabine/tenofovir alafenamide (as fumarate) (Descovy®)**
**200 mg/25 mg film-coated tablets**

The following response was communicated via email from Gilead Sciences Ltd:

**Gilead response to New Medicines Group (NMG)**

Thank you for the opportunity to respond to the NMG preliminary recommendation for emtricitabine/tenofovir alafenamide (as fumerate) (Descovy®) for pre-exposure prophylaxis (PrEP)

- Descovy® is the only licenced alternative option to emtricitabine/tenofovir disoproxil (TD/FTC) available to people who would benefit from PrEP and are intolerant of or have contraindications (such as renal or bone issues) to TD/FTC. Gilead are aware from several health care professionals in Wales that there are individuals waiting to receive Descovy® as they are unable to take TD/FTC for the above reasons.

- The NMG's advice to AWMSG to not recommend Descovy® for PrEP will cause inequity for people in Wales who would benefit from PrEP and are unable to take TD/FTC, as Descovy is available in England (https://www.england.nhs.uk/wp-content/uploads/2020/10/2112-PrEP-policy-statement-version-2.pdf) and Scotland (https://publichealthscotland.scot/publications/eligibility-criteria-for-tenofovir-afemtricitabine-descovy-for-pre-exposure-prophylaxis-for-hiv-prep-in-scotland/)

- The HIV Action Plan for Wales includes prevention as one of the five priority areas for action and includes PrEP as a prevention initiative to support eliminating all HIV in Wales by 2030. The Action plan states that ***PHW will support wider use of and access to PrEP (including different regimens*** and formulations in development). By not recommending Descovy® for PrEP, those individuals who would benefit from PrEP but are unable to take TD/FTC are at risk of HIV infection, putting at risk the Welsh Government's targets to end new HIV transmissions by 2030.