FAQ: What you need to know about the pricing deal for generic viral hepatitis medicines

1. What is the agreement?

Viatris and Hetero will supply WHO-prequalified generic versions of Sofosbuvir and Daclatasvir at or below the ceiling price to the public sector, for a minimum order quantity (MOQ) per order of 2,500 packs of each product for Viatris and 3,500 packs of each product for Hetero. One pack is 28 tablets – 4 weeks treatment course.

Viatris and Hetero will offer WHO-prequalified and/or US FDA-approved Tenofovir disoproxil fumarate (TDF) 300 mg single tablets, used for Hepatitis B treatment (once-daily lifelong oral treatment) at a ceiling price of US$2.4 per 30 tablets – a month's course of treatment.

2. Are there any minimum order quantity requirements associated with the agreements?

Yes. Pricing will be available for WHO-prequalified generic versions of Sofosbuvir and Daclatasvir for a minimum order quantity (MOQ) per order of 2,500 packs (1 pack is 28 tablets – 4 weeks treatment course) of each product for Viatris and 3,500 packs (1 pack is 28 tablets – 4 weeks treatment course) of each product for Hetero. There is no MOQ for the supply of TDF.

3. Which countries are eligible to access the terms of the agreements?

Low-middle-income countries which satisfy the below condition:

- Permitted under Amended and Restated License Agreement between Gilead Sciences Ireland UC, and generic manufacturers governing the license of Sofusbuvir ("SOF Agreement") for the permitted countries; For this *list of countries* – see here:
  Sofosbuvir: country list in appendix 1 (page 31) of Gilead licensing agreement - https://www.gilead.com/-/media/files/pdfs/other/form-ar-hcv-license-agmt-gild-11202017.pdf

- Permitted under the sublicense and technology transfer agreement between Bristol-Myers Squibb (BMS), Medicine Patent Pool and generic manufacturers governing the license of daclatasvir ("DAC Agreement") for the permitted countries – see here:
  Daclatasvir: country list in daclatasvir License Agreement (Schedule D) through MPP - https://medicinespatentpool.org/licence-post/daclatasvir-dac#country-list0
  Note, in 2020, BMS announced that the marketing authorizations for Daklinza® (daclatasvir) will be withdrawn or will be allowed to lapse in countries where the product is no longer routinely prescribed or where there are other therapeutic options available. This means that patients

diagnosed with hepatitis C in additional countries will soon have access to generic versions of daclatasvir[1].

- Eligible products are registered in the country by manufacturers. This would vary country by country.

4. Which purchasers are eligible to access the terms of the agreements?

Any organization or entity that is purchasing these medicines on behalf of public sector patients in the territory as per the agreement with Gilead and MPP. Public sector is defined to include all governments (including any agency or political subdivision thereof), nongovernmental organizations, and entities that purchase products on behalf of the public sector (e.g., The Global Fund to Fight AIDS, Tuberculosis and Malaria, USAID, UNICEF, PAHO, etc.).

5. Are there any additional costs associated?

The ceiling price mentioned above is Ex-works International Commercial Terms (INCO terms); additional costs would include shipping, storage, import taxes/duties, insurance, and any other cost to ship the product from origin to final destination.

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7. How much of a price reduction does this pricing deal represent?

These ceiling prices are the lowest prices for WHO-prequalified hepatitis B and C drugs globally. They represent over a 90 percent reduction from the lowest cost of hepatitis C treatment by originators in 2016[2] and align the price of TDF for hepatitis B with that of TDF used in HIV treatment.

Previously, no ceiling prices were set for Sofosbuvir, Daclatasvir and Tenofovir for hepatitis treatment. Prices at which these drugs were procured varied and depended on agreement between specific buyer

[1] https://medicinespatentpool.org/news-publications-post/affordable-versions-of-hepatitis-c-medicine-daclatasvir-soon-available-in-additional-countries

[2] https://www.who.int/publications/i/item/9789240019003

and these manufacturers. This has led to significant variability in prices accessed across LMICs. Refer to CHAI's Market intel reports for more detail on pricing across countries.

Hepatitis C: https://www.clintonhealthaccess.org/news/hepatitis-c-report-2021/ | https://www.clintonhealthaccess.org/report/chai-releases-the-2022-hepatitis-c-market-memo/

Hepatitis B: https://www.clintonhealthaccess.org/report/2022-hepatitis-b-market-report/