

## RIFAPENTINE GLOBAL PRICE DISCOUNT

Unitaid, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Sanofi SA, and the Stop TB Partnership are pleased to announce a significant reduction in the price of rifapentine (Priftin<sup>®</sup>) manufactured by Sanofi SA.

The agreement establishing this price discount was recently concluded by Unitaid, the Global Fund and Sanofi SA. The agreement is founded on extensive engagement with Sanofi SA over the past 12 months by multiple actors, including the Stop TB Partnership/Global Drug Facility, all of whom share a collective vision to establish a more affordable price for rifapentine-based treatment of Latent TB Infection (LTBI). This is key to kick-start global roll-out of more effective TB preventive therapy, in accordance with the political declaration of the high-level meeting of the United Nations General Assembly on the fight against Tuberculosis in September 2018.

The volume-based agreement ensures that a net discounted price of €4.62/pack of 24 tablets<sup>1</sup> ex works (66% discount off the existing price of 13.60€) for rifapentine (Priftin<sup>®</sup>) 150mg tablets is available to the public sectors of 100 low and middle-income countries burdened by TB and TB/HIV co-infection (See appendix 1 for details). As a result, a three-month treatment course of rifapentine (Priftin<sup>®</sup>) will now cost approximately US \$15 (instead of US\$ 45).

Priftin<sup>®</sup> is currently the only WHO prequalified rifapentine formulation available for short-course treatment of LTBI (in combination with Isoniazid). Unitaid, the Global Fund, the Stop TB Partnership/Global Drug Facility and other partners will collaborate with all relevant stakeholders to facilitate access to Priftin<sup>®</sup> at this new price through public sector-led programs delivering the intervention in eligible countries.

Unitaid, through the [IMPAACT4TB](#) project (led by The Aurum Institute), will take the lead on the execution of the associated terms and conditions of this price discount. A summary of the associated terms and conditions is presented below.

### **Summary of terms and conditions:**

<u>Product description:</u>	Rifapentine 150mg tabs (Priftin <sup>®</sup> ); box of 24 tablets
<u>Incoterm:</u>	FCA Croissy (France)
<u>Shelf life:</u>	36 months
<u>Quality assurance status:</u>	WHO Prequalification; USFDA Approval
<u>Procurement channels:</u>	Global Fund/PPM (through i+Solutions), Stop TB Partnership/Global TB Drug Facility (GDF), MSF, PAHO, PEPFAR/USAID-GHSC-PSM <sup>2</sup> , large volume national procurement bodies (not using a third-party channel) e.g. Republic of South Africa, Government of India.

<sup>1</sup> Equivalent to US\$5/pack based on current exchange rate of EUR 1 = USD 1.09 on 03 October 2019 ([https://www.ecb.europa.eu/stats/policy\\_and\\_exchange\\_rates/euro\\_reference\\_exchange\\_rates/html/eurofxref-graph-usd.en.html](https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-usd.en.html)). The discount enables pricing of a 3-month treatment course of rifapentine in a 3HP regimen at US\$ 15. It will be possible to issue purchase orders in US\$ using the reference price in Euro.

<sup>2</sup> Other procurement channels may be considered on a case by case basis.

<u>Procurement Mechanism:</u>	<p>Minimum order quantity is 5,100 packs (order should be a multiple of 60 packs per carton).</p> <p>Existing sales conditions with each procurement agent will apply.</p>
<u>Volume commitment:</u>	<p>900,000 packs for 2020 (corresponding to 300,000 adult rifapentine treatment courses in a 3HP regimen).</p>
<u>Sanofi's annual production capacity:</u>	<p>1,800,000 packs per year (corresponding to 600,000 adult rifapentine treatment courses in a 3HP regimen). NB: the price discount will apply to this full annual volume, irrespective of eligible procuring country or channel, as a result of the volume commitment.</p>
<u>Eligible countries/ procurers:</u>	<p>Government institutions in and international organizations procuring for Low-Income Countries, Lower-Middle Income Countries, Upper-Middle-Income Countries with High Burden of TB and TB/HIV, and select Upper-Middle-Income countries. See appendix. These countries collectively account for &gt;90% of the global need for latent TB infection preventive therapy. Sanofi shall pursue best efforts to register Priftin® locally but cannot guarantee securing Marketing authorization in all the listed countries.</p> <p>To facilitate demand coordination in the context of annual supply capacity maximized at 1,800,000 packs (600,000 treatment courses of a 3HP regimen) in 2020, Sanofi has agreed to a streamlined list of eligible procurement channels that will ensure prioritized access to Priftin® in eligible countries. This list may be expanded further, if essential, to achieving the overall access goals.</p>
<u>Coordination:</u>	<p>The ARV Procurement Working Group (APWG),<sup>3</sup> hosted by the Global Fund, in collaboration with other relevant procurement stakeholders, shall liaise with Sanofi to validate monthly rolling forecasts and support prioritization of orders based on objective criteria.</p>
<u>Offer period:</u>	<p>Initial discount period of 12 months<sup>4</sup>. Renewal for 2021 will be confirmed on or before 30 September 2020.</p>

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<sup>3</sup> Current APWG members are Unitaid, Clinton Health Access Initiative (CHAI), the Global Fund, Ethiopia Pharmaceuticals Fund and Supply Agency (PFSA), Kenya Medical Supply Agency (KEMSA), Partnership for Supply Chain Management (PFSCM), Pan-American Health Organization (PAHO), Global Health Supply Chain - Procurement and Supply Management Program (GHSC-PSM), U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through United States agency for international Development and Centers for Disease Control and Prevention United Nations Children's Fund (UNICEF) and United Nations Development Programme (UNDP)

<sup>4</sup> Sanofi aims to maintain the price discount beyond 2020 based on sustained market demand and potential portfolio expansion.

**Appendix: List of eligible countries**

The 100 countries below comprise all LICs, LMICs and UMICs with a high burden of TB and TB/HIV as well as select additional countries, which collectively account for >90% of the global need for latent TB infection preventive therapy.

<b>Low-Income Countries</b>		
Afghanistan	Guinea-Bissau	Sierra Leone
Benin	Haiti	Somalia
Burkina Faso	Korea, Dem. People's Rep. <sup>5</sup>	South Sudan <sup>5</sup>
Burundi	Liberia	Syrian Arab Republic <sup>5</sup>
Central African Republic	Madagascar	Tajikistan
Chad	Malawi	Tanzania
Congo, Dem. Rep	Mali	Togo
Eritrea	Mozambique	Uganda
Ethiopia	Nepal	Yemen, Rep.
Gambia, The	Niger	
Guinea	Rwanda	

<b>Lower-Middle Income Countries</b>		
Angola	India <sup>6</sup>	Papua New Guinea
Bangladesh	Indonesia <sup>6</sup>	Philippines
Bhutan	Kenya	São Tomé and Príncipe
Bolivia	Kiribati	Senegal
Cabo Verde	Kyrgyz Republic	Solomon Islands
Cambodia	Lao PDR	Sudan <sup>5</sup>
Cameroon	Lesotho	Timor-Leste
Comoros	Mauritania	Tunisia
Congo, Rep.	Micronesia, Fed. Sts.	Ukraine
Côte d'Ivoire	Moldova	Uzbekistan
Djibouti	Mongolia	Vanuatu
Egypt, Arab Rep.	Morocco	Vietnam
El Salvador	Myanmar	West Bank and Gaza
Eswatini	Nicaragua	Zambia
Ghana	Nigeria	Zimbabwe
Honduras	Pakistan	

<sup>5</sup> Countries subject to further import validation by Sanofi due to international embargo.

<sup>6</sup> Sanofi to define access price for procurement through local distributor. The price shall take into consideration the FCA INCOTERM as well as tax and distribution fees that need to be legally applied, in agreement with local authorities.

<b>Upper-Middle-Income High Burden TB and TB/HIV Countries</b>	
Brazil	Botswana
China	South Africa <sup>6</sup>
Russian Federation	Thailand
Namibia	

<b>Other Upper-Middle-Income Countries</b>		
Cuba	Guatemala	Nauru
Dominican Republic	Guyana	Peru
Ecuador	Iraq	Sri Lanka
Fiji	Marshall Islands	Suriname
Tonga	Tuvalu	Venezuela

## Frequently Asked Questions:

**1. Are eligible countries and procurers required to meet a particular volume threshold to qualify for the discount?**

The volume commitment underwritten by Unitaid ensures that no such thresholds are required. Moreover, all procurement of Priftin® for eligible countries and/or through eligible procurement channels will contribute towards realizing the 900,000 packs (300,000 treatments) volume requirement.

**2. What will be the role of the APWG?**

Many of the initial large-volume orders are projected to be placed by members of the APWG, the Republic of South Africa and the Stop TB Partnership/Global Drug Facility. The supply planning role of the APWG has recently been expanded to include commodities for the management of Advanced HIV Disease, which includes LTBI treatment for PLHIVs. As such, the APWG will work with collaborating partners and eligible procurers to establish a coordinated process to support effective demand and supply management for LTBI treatment. Sanofi will consult with the APWG to secure the consolidated future demand of the eligible procurement channels.

**3. What can be expected beyond 2020?**

Sanofi, Unitaid and the Global Fund are committed to maintaining affordable access to rifapentine beyond 2020 and will aim to reach agreement in the second half of 2020 on extending the discount, taking into consideration the market entry of additional suppliers of rifapentine-based LTBI treatments in new formulations.

**4. What are the implications of this agreement for ensuring a healthy market place for other manufacturers of rifapentine-based formulations?**

Unitaid is maintaining a multi-pronged engagement strategy to ensure a healthy market for all manufacturers that wish to develop and commercialize rifapentine-based products for LTBI treatment. This strategy aims to ensure sufficient global capacity for rifapentine Active Pharmaceutical Ingredient as well as Finished Drug Formulations, recognizing that the potential global market for LTBI treatment could grow to almost 7,000,000<sup>7</sup> treatments per year by 2025. Negotiations with generic developers of rifapentine-based products (including Isoniazid-Rifapentine fixed-dose combinations) are ongoing.

**5. Are there any efforts towards ensuring availability of rifapentine-based pediatric products for LTBI treatment?**

Unitaid has identified at least two manufacturers that have indicated interest in the development of appropriate, quality assured, pediatric rifapentine-based products for LTBI treatment and is working with these manufacturers to facilitate access to these products.

### For enquiries, please contact:

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<sup>7</sup> Per WHO Guidelines and IMPAACT4TB market modelling, the eligible population primarily includes PLHIV, child, adolescent and adult contacts that do not have active TB. The potential global market model uses past IPT uptake to set a baseline for 2015-2017. Estimates include countries that represent 90% of need for LTBI treatment and 93% of uptake.