

A lower price for rifapentine is just a start—communities need more than discounts to access TB preventive therapy!

Hyderabad, India | October 31, 2019— We, the undersigned civil society and community-based organizations, welcome the availability of lower-priced rifapentine, an essential medicine for preventing tuberculosis (TB). This discounted price is a welcome step forward, but we are concerned that it does not apply to all countries.

A recently signed agreement between Sanofi and two global health financing mechanisms—Unitaid and the Global Fund—has resulted in a 66% discount on the price of rifapentine for 100 countries (see end for list of eligible countries).

Rifapentine is the backbone of two short-course regimens for preventing TB known as 3HP and 1HP. These regimens pair rifapentine (P) with a second TB drug, isoniazid (H). The 3HP regimen consists of 12 doses taken once a week. In the 1HP regimen, people take rifapentine and isoniazid together once a day for one month. At the discounted price, the rifapentine component of 3HP will cost \$15/patient course.¹ The 1HP regimen, which is taken daily, requires more rifapentine and will cost more. The World Health Organization already recommends 3HP among other TB preventive therapy (TPT) regimens, and is evaluating 1HP as part of a guidance update expected early next year.

National TB programs must adopt newer TB preventive regimens like 3HP and 1HP if we hope to end TB in our communities. We applaud Unitaid and the Global Fund for supporting the uptake of rifapentine-based TPT by negotiating a discounted price with Sanofi. This is a major step toward ensuring that all people at risk of TB can access the highest-available standard of TB prevention. It follows two previous negotiations with Sanofi that brought down the price of rifapentine. In the first, a campaign by civil society in the United States led Sanofi to voluntarily reduce the price of rifapentine for the U.S. public health market to \$75/patient course of 3HP, a 57% reduction from the original price.² In the second, the Global Drug Facility (GDF) and Sanofi reached an agreement to offer rifapentine for \$45/patient-course of 3HP in 2018.

Despite these successive steps forward, we are far from a world where rifapentine-based regimens are available, accessible, and affordable to all. We call attention to other barriers limiting access to rifapentine that must be overcome, including:

- *The difference between a discount for some and a lower price for all.* The lower price established by the agreement between Sanofi, Unitaid, and the Global Fund is a discount, rather than a new, lower price ceiling. This improves the affordability of 3HP for public sector purchasers in low-income-, lower-middle-income-, and some upper-middle-income countries with high burdens of TB and TB/HIV. But the

¹ Under the agreement, the discounted price is €4.62/pack of 24 tablets, roughly equivalent to \$5/pack or \$15/patient course of 3HP.

² DeLuca A, Frick M, Lessem E, et al. Activism on rifapentine pricing: removing cost barriers to improve the uptake of tuberculosis research innovations. *Public Health Action*. 2014;4(4):238–242. doi: 10.5588/pha.14.0089.

discount does not apply to other jurisdictions, where the price of rifapentine will remain high. These include countries in Eastern Europe and Central Asia as well as places with sizable TB burdens such as Malaysia, among others. In the United States, Sanofi sells rifapentine for \$75/patient-course of 3HP. Setting one price for one band of countries, and a higher price for another set of countries, for the same product manufactured in the same facility, makes little sense in a world where TB programs everywhere are inadequately resourced.

We call on Sanofi to turn this discount into a true price decrease by setting a single global access price available to all countries.

- *The limited numbers of countries in which Sanofi has registered rifapentine with national regulatory authorities.* As of September 1, 2019 Sanofi had only registered rifapentine in ten countries.³ Many countries currently can access rifapentine pre-registration through import waivers, particularly when purchasing with donor support and procuring through the GDF. However, registration remains a critical prerequisite for access in several countries. For example, lack of registration has stymied TB programs seeking access to rifapentine in the European Union, and has forced Canadian provinces to resort to obtaining rifapentine through a special program designed for responding to public health emergencies.^{4,5}

We call on Sanofi to expedite the registration of rifapentine, focusing on countries where registration is a requirement for accessing the product, as well as those that have hosted clinical trials of rifapentine.

- *The limited supply of rifapentine.* Currently, Sanofi manufactures rifapentine at a single facility in Italy. We understand that global demand for rifapentine could quickly outpace what this facility is able to produce. While Unitaid and the Global Fund have a plan to manage supply and demand, working through the inter-agency ARV Procurement Working Group, sustainable access to affordable rifapentine will require long-term solutions, including generic competition.

We call on Sanofi to expand rifapentine production capacity, and on generic manufacturers to expedite the development and introduction of quality-assured generic versions of rifapentine and rifapentine-isoniazid.

- *The need for generic, patient-friendly formulations of 3HP and 1HP.* Currently, rifapentine and isoniazid are only available as single tablets, which results in the 3HP and 1HP regimens carrying high pill burdens. Lowering the pill burden of 3HP and 1HP would improve acceptability by making it easier for people to complete therapy. There is also the need to develop pediatric formulations of 3HP

³ Hong Kong SAR, India, Indonesia, Mongolia, Philippines, Singapore, South Africa, Taiwan, Thailand, United States.

⁴ Letter to Dr. Olivier Brandicourt, CEO Sanofi, re. importance of rifapentine (Priftin®) for TB elimination in Europe from European national TB programme managers. 2016 June 27.

<https://www.kncvtbc.org/uploaded/2017/02/Letter-to-Sanofi-re-Rifapentine-in-Europe.pdf>

⁵ Houston A, Blais CM, Houston S, Ward B. Reforming Canada's Special Access Program (SAP) to improve access to off-patent essential medicines. JAMMI. 3(2):100-107. doi: 10.3138/jammi.2018.01.04.

to make the regimen acceptable for children. Generic manufacturers are reportedly developing new formulations that would reduce pill burden e.g., a fixed-dose combination (FDC) tablet of rifapentine and isoniazid. Based on what it costs to manufacture rifapentine, and assuming sufficient volumes of sales, we understand that 3HP could cost as little as \$10/patient course.

We call on generic companies to expedite the development and introduction of patient-friendly formulations of rifapentine and isoniazid, including pediatric formulations, and to price these new formulations affordably.

For our part, we commit to continuing to build demand for TB preventive therapy and rifapentine-based regimens in our communities. All of our organizations are deeply engaged in community mobilization, awareness raising, treatment literacy, political engagement, policy reform, and advocacy aimed at ensuring all people at risk of TB can access preventive therapy without discrimination.

In closing, we wish to remind the global community that the development of 3HP and 1HP was overwhelmingly financed by the public sector.⁶ Moreover, rifapentine and isoniazid are old drugs, neither of which was discovered or developed by Sanofi.⁷ Rifapentine is now off patent, and isoniazid was never patented. As such, we consider rifapentine and isoniazid to be global public goods. It is imperative that all actors approach this discount as an opportunity to ensure TPT reaches everyone in need. In the future, donors should ensure that agreements with suppliers uphold principles of equity, transparency, and affordability for all.

Signed by:

Coalition of Women Living with HIV/AIDS (COWLHA), Malawi
Community Research Advisors Group (CRAG), Global
Dandora Community AIDS Support Association (DACASA), Kenya
Global TB Community Advisory Board (Global TB CAB), Global
Grupo de Apoio à Prevenção da AIDS (GAPA Rs), Brazil
Jointed Hands Welfare Organisation, Zimbabwe
Tanzania Network of Women Living with HIV/AIDS (TNW+), Tanzania
Rede Paulista de Controle Social da Tuberculose, Brazil
Stop TB Partnership—Kenya, Kenya
TB Proof, South Africa
Treatment Action Group, New York, USA
Zimbabwe National Network of People Living with HIV (ZNNP+), Zimbabwe

⁶ Frick M. The TB prevention pipeline. New York: Treatment Action Group; 2018. http://pipelinereport.org/sites/default/files/pipeline_2018_tb_prevent_mf_web2.pdf

⁷ Treatment Action Group. An Activist's Guide to Rifapentine for the Treatment of TB Infection. New York: Treatment Action Group; 2019. <http://www.treatmentactiongroup.org/content/activists-guide-rifapentine-treatment-tb-infection>

Countries eligible for discounted rifapentine under the agreement between Sanofi, Unitaid, and the Global Fund:

Low-Income Countries		
Afghanistan	Guinea-Bissau	Sierra Leone
Benin	Haiti	Somalia
Burkina Faso	Korea, Dem. People's Rep. ^[1]	South Sudan ⁴
Burundi	Liberia	Syrian Arab Republic ⁴
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	
Lower-Middle Income Countries		
Angola	India ^[2]	Papua New Guinea
Bangladesh	Indonesia ⁵	Philippines
Bhutan	Kenya	São Tomé and Príncipe
Bolivia	Kiribati	Senegal
Cabo Verde	Kyrgyz Republic	Solomon Islands
Cambodia	Lao PDR	Sudan ⁴
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	
Upper-Middle-Income High Burden TB and TB/HIV Countries		
Brazil	Namibia	Thailand
Botswana	Russian Federation	
China	South Africa ³	
Other Upper-Middle-Income Countries		
Cuba	Guatemala	Nauru
Dominican Republic	Guyana	Peru
Ecuador	Iraq	Sri Lanka
Fiji	Marshall Islands	Suriname
Tonga	Tuvalu	Venezuela