

Subject: [tb-civil-society] New Rifapentine Formulations at New Prices! No Excuses for Not Scaling-Up TPT
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New Rifapentine Formulations at New Prices: No Excuses for Not Scaling-Up TB Preventive Treatment

August 1, 2022—We, the undersigned civil society and community-based organizations, welcome [the announcement](#) by Unitaid and its partners that they have reached an agreement with Lupin Limited and Macleods Pharmaceuticals to introduce two formulations of rifapentine at competitive prices. Rifapentine is an essential medicine and the backbone of shorter regimens for preventing and treating TB.

The prices set by the agreement apply to 138 countries, including many upper-middle- and middle-income countries with large burdens of TB: Brazil, India, Indonesia, Pakistan, the Philippines, and South Africa, among others.

The agreement applies to two formulations: the first is a fixed-dose combination (FDC) tablet of rifapentine paired with a second TB drug, isoniazid, each at 300 mg. The FDC is manufactured by both Lupin and Macleods and cuts the pill burden of the 12-week 3HP preventive treatment regimen to three pills per dose instead of the nine required using the original 150 mg formulation of rifapentine made by Sanofi. **Under the agreement with Unitaid, Lupin and Macleods will sell their 3HP FDC products for \$14.25.** This is a \$0.75 reduction from the \$15 price set in an earlier [2021 agreement](#) between Unitaid and Macleods. (Sanofi currently sells its rifapentine formulation for around \$18 per 3HP treatment course.)

The second formulation is a 300 mg rifapentine tablet made by Lupin. This 300 mg rifapentine standalone tablet is a new product and cuts the pill burden of a second preventive treatment regimen called 1HP from five to three pills per dose. **Under the agreement, Lupin will sell the 300 mg rifapentine formulation for \$33.90 per 100-tablets.** This will reduce the cost of the rifapentine component of 1HP to \$18.98 (down from nearly \$28 using the Sanofi 150 mg product). After adding the cost of isoniazid, about an additional dollar, governments will be able to offer a 28-day TB preventive treatment regimen for around \$20 in drug costs.

Lupin's 300 mg rifapentine tablet also slashes the pill burden of the 4-month TB treatment regimen of isoniazid/rifapentine/moxifloxacin/pyrazinamide (HPMZ) recently recommended by WHO for the treatment of active TB disease from 13 to 8 pills per dose. In addition, the 300 mg Lupin tablet will reduce the drug costs of the HPMZ regimen from \$235–265 per treatment course (with the Sanofi tablets) to \$226–\$234.

With pricing now in place, we call on governments and donors such as PEPFAR and the Global Fund to move quickly to purchase the Lupin and Macleods products. In

May 2022, Macleods received WHO prequalification for its 3HP FDC and the [Global Fund Expert Review Panel](#) recommended both of Lupin's formulations for use, assuring their quality and giving governments the greenlight to use Global Fund resources to buy these drugs.

In the view of civil society and communities, Lupin's entry to the TB preventive treatment market alongside Macleods will improve access to rifapentine along several lines: increased supply, competition between manufacturers, and regimen flexibility.

"The rifapentine market finally has some real, direct competition! Governments buying patient-friendly forms of 3HP now have a choice between Macleods and Lupin at a lower, more affordable price," said Mike Frick, TB project co-director at Treatment Action Group (TAG). "In addition, the 300 mg single is an improvement over the existing 150 mg formulation made by Sanofi in that it will reduce the pill count of 1HP, and it's cheaper too."

"The prices set by this agreement are a starting point, but not a stopping point," commented Lynette Mabote, TAG global advocacy advisor. "These are ceiling prices. **Based on what it costs to make rifapentine, we know that prices can come down further—much further—if governments work together with each other and bodies such as the Global Drug Facility to pool demand and purchase sufficient volumes of rifapentine. [TB preventive treatment is a human right!](#)** Communities need access to the right rifapentine formulations at the right prices to prevent TB."

Considering regimen flexibility, national TB programs can use the 300 mg Lupin rifapentine tablet to construct three regimens—1HP, 3HP, and HPMZ—unlocking the ability to prevent TB in less than one month and to treat TB in four months instead of the standard six-month treatment course that has been in place for decades.

"Lupin is the latest, but hopefully not the last supplier of rifapentine to come to market. **We need additional manufacturers to introduce rifapentine products. The top priority is a rifapentine formulation suitable for children.** We have hardly made any progress bringing 3HP to children. Parents have asked me: if I can prevent TB by taking 3HP once a week, how is it that my child must take a pill each day for three or sometimes even six months? Pediatric TB prevention requires much more advocacy and focus," said Patricia Ochieng Asero of Dandora Community AIDS Support Association in Kenya. The Pediatric Antituberculosis Drug Optimization expert group has recommended that manufacturers develop a 150 mg scored, dispersible tablet of rifapentine to meet the needs of children. Several manufacturers have reportedly begun developing such a product, but these timelines must be expedited.

"With existing rifapentine options we've managed to prevent a lot of TB among people living with HIV. **Now we need to maintain that progress and take new formulations of 3HP and 1HP into the community, reaching household contacts—people exposed to TB in the home—and direct our work toward young people, adolescents, and children who are particularly at risk of developing TB.** Let's expand our reach and engage a bigger community on TB prevention," commented Stephen Anguva Shikoli, director, Pamoja TB Group.

Endorsed by

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