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COVID-19 drug recommended by WHO remains unaffordable and inaccessible for most people

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NEW YORK/GENEVA, JULY 6, 2021—As the World Health Organization (WHO) recommended today the drug tocilizumab for people with severe COVID-19, the international medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières (MSF) called on the Swiss pharmaceutical corporation Roche—the world's sole producer of the drug—to lower the price and make it accessible for everyone who needs it. Additionally, Roche must end its monopoly and urgently share the know-how, technology, and additional information necessary for other manufacturers across the world to produce the medicine as well, which would ensure adequate supply and access for people everywhere, said MSF.

Tocilizumab is only one of three drugs recommended by the WHO for COVID-19 treatment; WHO recommended dexamethasone in September 2020 and sarilumab today. Tocilizumab belongs to the class of drugs called monoclonal antibodies (mAbs), which are used in the treatment of

various diseases, including cancers. However, most existing mAbs have been priced extremely high and are virtually impossible for people and treatment providers in low- and middle-income countries to access.

“Medical practitioners in many countries in Africa and Latin America, who are grappling with newer and more transmissible variants of coronavirus, are struggling to keep their patients alive,” said Julien Potet, Neglected Tropical Diseases policy advisor at MSF’s Access Campaign. “This drug could become essential for treating people with critical and severe cases of COVID-19 and reduce the need for ventilators and medical oxygen, which are scarce resources in many places. Roche must stop following a business-as-usual approach and take urgent steps to make this drug accessible and affordable for everyone who needs it by reducing the price and transferring the technology, know-how, and cell lines to other manufacturers. Too many lives are at stake.”

Even though tocilizumab has been on the market since 2009 for treatment of rheumatologic diseases, access has remained a challenge. Roche prices this drug very high in most countries, ranging from $410 in Australia, $646 in India, and $3,625 in the US per dose of 600mg for COVID-19. The cost to manufacture tocilizumab is estimated to be as low as $40 per dose of 400mg. Given that the manufacturing costs of mAbs are often below $100 per gram when produced on a large-scale, Roche should agree to sell tocilizumab for COVID-19 at a much more affordable price than they currently do.

Along with lowering the price, the company must allow and make it easier for other manufacturers across the world to produce the medicine as well. In this raging pandemic—as many people in low- and middle-income countries continue to fall severely sick due to surges in COVID-19—demand for this drug is expected to increase. Shortages of tocilizumab have been observed in many countries that have already started using it for COVID-19 treatment. During India’s second COVID-19 wave in May, for example, Roche's distributor ran out of the drug and not a single vial was available in the country for patients in critical condition.

While the main patent on tocilizumab expired in 2017, several secondary patents remain on the medicine in a number of low- and middle-income countries—preventing other manufacturers from making more affordable versions of the medicine. Several “biosimilar” versions are under development, but none have been approved by a regulatory authority, meaning that, despite being off-patent, Roche continues to have de facto market exclusivity that impacts the availability of the drug in the absence of sufficient supply.

“Over the last few months, we have helplessly witnessed people in South Asia scrambling to get hold of tocilizumab for patients with severe forms of COVID-19,” said Leena Menghaney, global

IP advisor for MSF's Access Campaign. "Manufacturers based in low- and middle-income countries urgently need to register and scale up production to increase the global supply. With more than 3.9 million lives already lost to COVID-19, the world cannot wait any longer for access to treatments that can help in increasing the chances of survival."

While there are few mAbs that have been approved by the US Food and Drug Administration for treatment of COVID-19, there are many newer mAbs that are currently being investigated as potential treatments. However, high prices and limited volumes of mAbs are expected to remain a barrier for accessing these drugs in low- and middle-income countries. Besides tocilizumab, two new antiviral mAbs, casivirimab, and imdevimab—produced as a cocktail by the US pharmaceutical corporation Regeneron—have recently demonstrated in a clinical trial to decrease the risk of death among hospitalized seronegative COVID-19 patients who were in severe or critical condition. While these mAbs are not yet recommended by the WHO, Regeneron has priced this cocktail at $820 in India, $2,000 in Germany, and $2,100 in the US.

Another mAb recommended by WHO today for COVID-19, sarilumab, is also under wide patent protection globally. Regeneron has applied for and been granted patents on sarilumab and its formulation in at least 50 low- and middle-income countries, raising immediate challenges of ensuring uninterrupted production and supply by diverse producers in these countries.

"With several monoclonal antibodies in the pipeline that could potentially be useful in preventing and treating COVID-19—but also many others already available or in development for treating many other diseases including various cancers—governments need to step up to ensure wider accessibility and affordability for this critical class of drug," Potet said. "MSF is also calling on all governments to overcome the intellectual property barriers on these crucial drugs by supporting the 'TRIPS waiver' at the World Trade Organization and pushing pharmaceutical corporations to transfer technology to other manufacturers in low- and middle-income countries so that more people can access the drugs they need during the pandemic and beyond."

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