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TRIPS COUNCIL DISCUSSIONS ON COVID-19 THERAPEUTICS AND DIAGNOSTICS: EVIDENCE AND QUESTIONS ON INTELLECTUAL PROPERTY CHALLENGES EXPERIENCED BY MEMBERS

COMMUNICATION FROM MEXICO AND SWITZERLAND

1 INTRODUCTION

1. Even though we are not in the same place as we were in 2020, COVID-19 is still prevalent. With its new mutations, the COVID-19 pandemic continues to demand a high toll, first and foremost with regard to its humanitarian costs but also with regard to its economic and social costs. It is therefore of utmost importance that we continue to seek holistic solutions that allow us to rein in the COVID-19 pandemic and to be better prepared for future pandemics. Ensuring global, equitable, affordable and rapid access to health technologies is one element of such solutions. To that end and with regard to our mandate on whether or not to extend the MC12 Decision to include COVID-19 therapeutics and diagnostics, basing our discussions on the concrete situation regarding access to COVID-19 therapeutics and diagnostics is key.

2 EVIDENCE

2.1 Supply and Demand Landscape

2. Available information shows that no shortage of therapeutics exists. Instead, large parts of innovators' production capacity remain idle due to a lack of demand. According to Airfinity data[1], Pfizer would be able to produce 120 million doses of its Paxlovid therapeutic in 2022. The contracted supply stood in August 2022 at only 41.5 million doses, i.e. at 35% of the production capacity. The situation is similar with MSD's Molnupiravir, where demand amounted to a mere 45% of the company's production capacity. Governments and NGOs have purchased 35 million COVID-19 treatments for LMIC for 2022 but have only been able to administer 10 million as of September this year.[2]

3. Global demand for tests has reduced and there is no evidence to suggest that supply is constrained relative to actual demand.[3] Diagnostics companies working closely with WHO, and providing them with sample collection kits, have reported there is a high level of product surplus to order. This involves issues with logistics and distribution, which are not IP-related, but that need to be addressed. The Access to COVID-19 Tools Accelerator (ACT-A) Working Group Paper on Therapeutics and Diagnostics[4] noted that recurring challenges for access to therapeutics and diagnostics are regulation, manufacturing, allocation, funding, procurement and deployment, forecasting, and demand. The paper recommended actions including assessment of national

[1] "Key Figures: COVID-19 Treatments and Diagnostics" prepared for IFPMA by Airfinity, 30.08.2022.

[2] "Expanding the TRIPS Waiver Is Unnecessary and Harmful" prepared for PhRMA by Airfinity, September 2022.

[3] 'Key Figures: COVID-19 Treatments and Diagnostics', Airfinity, 30th August 2022

[4] "Report of Access to COVID-19 Tools Accelerator Facilitation Council Working Group on Diagnostics and Therapeutics", WHO, September 2022, available at https://www.who.int/docs/default-source/coronaviruse/act-accelerator/council-working-group-on-diagnostics-and-therapeutics-v4.pdf?sfvrsn=920f4bf9_2&download=true

strategies, closer multilateral collaboration including on licensing and technology transfer and financing initiatives, and improving regulations. It is therefore clear to see that access to therapeutics and diagnostics requires a holistic response to addressing these factors.

2.2 Voluntary Licensing

4. The fight against the COVID-19 pandemic is a global effort. As of 11 October 2022, 138 bilateral or Medicines Patents Pool-based voluntary licensing agreements comprising some of the most highly demanded treatments, have been signed between innovators and companies all over the world enabling them to join this fight by producing therapeutics.[5] These agreements cover more than 127 countries collectively.

5. The MPP-licenses are royalty-free. Thanks to these agreements, 191 production sites for COVID-19 therapeutics exist worldwide, i.a. in India, Bangladesh, the Philippines, Brazil, Paraguay, Egypt, South Africa or Kenya.[6]

a. MSD's agreement with the MPP for its oral COVID-19 antiviral medicine Molnupiravir allows for sublicensing deals to supply to 106 low- and middle-income countries.[7] Agreements have been signed with 31 companies located in 10 countries.

b. Pfizer's agreement with the MPP covers 95 countries[8], and the MPP has signed sublicensing agreements for the generic version of Pfizer's oral COVID-19 treatment with 38 manufacturers in 13 countries.

c. Japanese company Shionogi has also just agreed to voluntarily license its product via the MPP.[9]

6. In the case of MSD, 31 voluntary license agreements across 10 LMIC countries provide Molnupiravir availability in 106 LMICs.[10] 38 companies produce generic versions of Pfizer's Paxlovid for 95 LMIC.[11]

7. In May 2020, Gilead entered voluntary licensing agreements with nine generic pharmaceutical manufacturers based in India, Pakistan, and Egypt to manufacture and supply Remdesivir to 127 LMICs.[12] These licenses are currently royalty-free, and licensees receive Gilead's technology transfer. The licenses enable the manufacture of generic Remdesivir by generics companies and subcontractors in any country.

2.3 Affordability and Accessibility

8. Innovators bring their products to the different markets of the world based on a tiered-pricing system, like that offered by Pfizer and MSD. Therefore, prices for the same product are significantly lower in LMIC than they are in developed countries – in many cases the products are being offered for a non-profit price.[13] International organizations and NGOs also support LMICs with the procurement and distribution of COVID-19 therapeutics to ensure fair and equitable access. MSD

[5] "Key Facts and Figures: Therapeutics" prepared for IFPMA by Airfinity, October 2022.
[6] "Key Facts and Figures: Therapeutics" prepared for IFPMA by Airfinity, October 2022.
[7] "Molnupiaravir (MOL)", Medicines Patent Pool, available at https://medicinespatentpool.org/licence-post/molnupiravir-mol
[8] "Nirmatrelvir", Medicines Patent Pool, available at https://medicinespatentpool.org/licence-post/pf-07321332
[9] "Ensitrelvir Fumaric ACID", Medicines Patent Pool, available at https://medicinespatentpool.org/licence-post/ensitrelvir
[10] "EFPIA Factsheet on COVID-19 Therapeutics", September 2022, efpia, 29.09.2022.
[11] "Covid-19 Therapies at the Crossroads", Katherine E. Bliss and J. Stephen Morrison, CSIS, 06.07.2022, available at https://www.csis.org/analysis/covid-19-therapies-crossroads
[12] "Voluntary Licensing Agreements for Remdesivir", available at https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir?_sm_au_=iVV3rM63ZjssVkHrvMFckK0232C0F. See also "Key Facts and Figures: Therapeutics" prepared for IFPMA by Airfinity, October 2022.
[13] "Pfizer to share license for covid-19 pill, potentially opening up treatment to millions in low-income nations", Adam Taylor and Claire Parker, The Washington Post, 16.11.2021, available at https://www.washingtonpost.com/world/2021/11/16/pfizer-license-covid-pill-paxlovid/

has made available 3 million units of Molnupiravir for shipment through UNICEF.[14] The first shipment by UNICEF took place in August – more than 20,000 units to Cambodia[15], the first of 14 countries that placed orders through them.

9. In March 2022, Pfizer signed a supply agreement with UNICEF for procurement of up to 4 million treatment courses for distribution to 95 LMICs.[16] In September 2022, Pfizer signed a deal with The Global Fund for the procurement of up to 6 million treatment courses for supply to 132 Global Fund-eligible countries (subject to regulatory authorization).[17] Through 'the Accord for a Healthier World', Pfizer is offering its patent-protected medicines and vaccines filed in EU or US on a not-for-profit basis to 45 LMICs, alongside collaborating with country governments and global health organizations to remove barriers to access for these products, e.g. lack of diagnostics, training, and storage.[18]

3 CONCLUSION

10. The information provided above is a non-exhaustive snapshot of the current landscape. It aims at providing a foundation for further discussion on whether or not an extension is required to improve access. The Doha Declaration confirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health," and that it "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all". Mexico and Switzerland stand by these commitments. If a systemic problem regarding the access to COVID-19 therapeutics and diagnostics is demonstrated conclusively and such lack of access is caused by the current IP system, steps have to be taken to improve the situation to ensure unimpeded access. However, based on the information laid out above, we do not face a situation where we have an IP-induced lack of access to or a lack of manufacturing capacity of COVID-19 therapeutics and diagnostics. As a consequence, no adjustments to the IP system seem to be required. If the decision were extended nonetheless, it would even have a detrimental effect and leave us ill-equipped to fight the COVID-19 pandemic and potential future pandemics effectively. This is because inventors would have no incentive to shoulder the risks and costs associated with R&D of such products. It would also jeopardize the further development and the production of many of the over 1,800 COVID-19 therapeutics that are currently in different stages of the R&D-pipeline.[19] Mexico and Switzerland therefore respectfully submit the following questions to proponents of an extension of the MC12 TRIPS Decision for their consideration and response.

4 QUESTIONS

1. Against the background of the demonstrated availability of therapeutics like Molnupiravir and Paxlovid, especially with regard to the idle production capacity, what would be the added benefit of an extension of the MC12 TRIPS decision?

2. Given that already 138 bilateral or MPP-based voluntary licensing agreements have been signed, many with LMICs, no systemic hurdles seem to exist that prevent other companies from also signing voluntary licensing agreements. Why do proponents of an extension consider

[14] "Merck and Ridgeback Announce New Data For Investigational LAGEVRIO™ (molnupiravir) From Phase 3 MOVe-OUT Study", Merck press release, 07.06.2022, available at https://www.merck.com/news/merck-and-ridgeback-announce-new-data-for-investigational-lagevrio-molnupiravir-from-phase-3-move-out-study/

[15] "UNICEF Executive Director Catherine Russell's remarks at the event on ending the COVID-19 pandemic through equitable access to vaccines, tests, and treatments", UNICEF, 23.09.2022, available at https://www.unicef.org/press-releases/unicef-executive-director-catherine-russells-remarks-event-ending-covid-19-pandemic

[16] "UNICEF signs supply agreement with Pfizer for oral COVID-19 treatment", UNICEF, 22.03.2022, available at https://www.unicef.org/cuba/en/press-releases/unicef-signs-supply-agreement-pfizer-oral-covid-19-treatment

[17] "The Global Fund Signs Agreement with Pfizer to Expand Access to PAXLOVID™ Antiviral", The Global Fund, 22.09.2022, available at https://www.theglobalfund.org/en/news/2022/2022-09-22-the-global-fund-signs-agreement-with-pfizer-to-expand-access-to-paxlovid-antiviral/. See also " The Global Fund Signs Letter of Intent with Pfizer for Oral COVID-19 Treatment", The Global Fund, 20.05.2022, available at https://www.theglobalfund.org/en/news/2022/2022-05-20-global-fund-signs-letter-of-intent-with-pfizer-for-oral-covid-19-treatment/

[18] "Pfizer Launches 'An Accord for a Healthier World' to Improve Health Equity for 1.2 Billion People Living in 45 Lower-Income Countries", Pfizer, 25.05.2022, available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-launches-accord-healthier-world-improve-health

[19] "EFPIA Factsheet on COVID-19 Therapeutics", September 2022, efpia, 29.09.2022.

it necessary to facilitate the issuing of compulsory licenses that do not contain technology transfers, training and other benefits that come with most voluntary license agreements?

3. Given that already a large number of producers for therapeutics and their generic versions exist and that these producers face declining demand for their products, why do proponents consider it necessary to facilitate the issuing of compulsory licenses so that additional producers can produce for an already saturated and shrinking market?

4. As the market for therapeutics is already saturated and served by many companies including producers for generic versions of therapeutics, the profit margins are small. How likely do the proponents consider it that a company bestowed with a compulsory license would be willing to make large upfront investments just to have very modest returns on investment and a break-even point in the very distant future?

5. For many months, we have discussed a potential waiver and whether such a waiver is necessary to improve access to COVID-19 vaccines. Yet, since the adoption of the MC12 Decision, no country has made use of the possibilities provided for by the Decision to grant a compulsory license for the export of COVID-19 vaccines. Against this background and taking into consideration that supply of therapeutics exceeds their demand, how do the proponents of an extension justify the need for such extension?

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