

Switzerland and Mexico's Communication to the TRIPS Council Is Replete with Disinformation and Their Questions Easily Answered

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Switzerland and Mexico have recently filed a communication entitled "*TRIPS Council discussions on COVID-19 therapeutics and diagnostics: Evidence and questions on intellectual property challenges experienced by Members*" at the TRIPS Council. This communication ([IP/C/W/693](#)) purportedly provides evidence on the supply and demand landscape of therapeutics and diagnostics, voluntary licensing and the affordability and accessibility of these products, but it does so on a highly misleading basis. Switzerland and Mexico claim, based on their self-selected information, that the international community is not facing a situation where there is an IP-induced lack of manufacturing capacity or affordable access to COVID-19 therapeutics and diagnostics. As a consequence, they argue that no adjustments to the IP system are required and further that the [WTO TRIPS Decision](#), if extended, would have a significant detrimental effect leaving the world ill-equipped to fight the COVID-19 and future pandemics effectively.

False/Misleading Claims:

"Available information shows that no shortage of therapeutics exists." Switzerland and Mexico, relying on PhRMA supplied data, focus on false evidence of suppressed demand rather than actual need and further calibrate supply availability according to option agreements rather than actual purchase orders.

- Demand for tests and treatments in low- and middle-income countries (LMICs) has been suppressed by rich countries hoarding initial supplies and big biopharmaceutical and diagnostic manufacturers prioritizing higher-price sales to powerful high-income countries and blocs. For example, virtually all of the first six months supply of nirmatrelvir+ritonavir was committed to high-income countries (HIC), most especially the [U.S. which reserved 20 million courses of treatment](#).
- PhRMA's estimates of supplies available to LMICs is based in substantial part on what are essentially options agreements with UNICEF and the Global Fund. The estimates are also based on supply largely to upper-middle-income countries that purchased first-generation treatments with limited therapeutic efficacy and that were largely unaffordable and unavailable in lower-middle and low- income countries.
- The proper metric for needed quantities is not artificially suppressed demand (caused in substantial part by limited and delayed supplies and unaffordable pricing, discussed further below), but rather the number of people infected globally, especially those at highest risk of disease progression, hospitalization, and death. Even at current rates of infection, which may accelerate again in the near future, there are tens of millions of people in LMICs being newly infected who are older, immune-suppressed, or living with dangerous co-morbid conditions. Their risks are even higher because many, especially in low-income countries, remain unvaccinated.
- Switzerland and Mexico rely on the old canard of pointing to additional factors impacting distribution (regulation, manufacturing, allocation, funding, procurement and deployment, forecasting, and demand) to obscure the fact that IP rightholders' control over supply negatively impacts accelerated scale-up and equitable access to meet the true level of need.

The 138 voluntary licenses collectively covering 127 LMICs and licensed to multiple LMIC companies are, by implication, sufficient to meet the need for expanded supply. There are bilateral voluntary licenses with Gilead (remdesivir) and three voluntary licenses agreements negotiated with the Medicines Patent Pool, MSD (molnupiravir), Pfizer (nirmatrelvir+ritonavir), and Shionogi (ensitrelvir fumaric acid), but they all suffer from common defects particularly in terms of geographic scope.

- All of the licenses exclude a significant number of MICs, especially U-MICs, from their licensed territories, even though there are provision allow supply to addition countries if no granted or

pending IPRs (patents and technical know-how) are violated. The excluded U-MICs, most of which are excluded from all relevant voluntary licenses, have large populations and have suffered some of the most damaging rates of infection, but they can source only from the rightholders, who have maintained unilateral control over allocation and price.

- The licenses often have additional troubling restrictions, for example Pfizer's license preventing R&D on combination regimens, coformulation, and even co-packaging.

Innovators bring their products to different markets of the world based on a tiered pricing system, by implication resulting in price that are affordable to LMICs. While it is true that most of the companies are offering tiered prices, their tiered prices are not necessarily affordable and are in almost all instances significantly more expensive than what competitive generic prices would be.

- Pharma companies sometimes offer so-called no-profit prices to certain LICs and L-MICS, but even those no-profit prices are often multiples more expensive than the true cost of production and the price that would be available from generic producers. For example, MSD has a listed no-profit price of \$85 per course of treatment, but the expected [generic price is estimated](#) at under \$20 or [even \\$10](#) and could go as low as under \$5. Pfizer's alleged not-for-profit price is not yet disclosed, but it is not expected to be anywhere close to the \$25 or less already negotiated by the [Clinton Health Access Initiative](#) with several generic producers.
- For the MICs that pharma companies exclude from "no-profit pricing," the companies state that they negotiated on a country-by-country tiered-price basis. However, those prices can still be unaffordable according to any reasonable metric. For example, the [price of molnupiravir to Thailand was \\$300](#) a course of treatment and the price of nirmatrelvir+ritonavir to [Brazil is reported to be near \\$250](#) a course of treatment. Even though these countries have GDP/capita that is a fraction of that in the U.S., they are asked to pay more than 40% of the U.S. price.
- It is no exaggeration to say that the issue of affordability is at the center of the failed launch of test-and-treat in LMICs with new outpatient antiviral medicines. Most LMICs appear to be sitting on the sidelines waiting for the eventual entry of licensed generic antivirals as their dossiers wind their way through a laborious WHO prequalification process and national regulatory processes as well. Instead of bragging that demand for tests and treatments is suppressed and thus that everything is okay, Switzerland and Mexico should be hanging their figurative heads in shame that HICs have had broad and affordable access to out-patient antiviral medicines for nearly 10 months while LMICs have barely received any supplies or global support for a robust test-and-treat rollout.

The threat to the therapeutics pipeline requires preservation of the status quo in terms of IPRs. Switzerland and Mexico exaggerate the risk of the extension of the WTO TRIPS Decision to cover therapeutics and diagnostics, arguing that the whole IPR stack of card might come tumbling down.

- In fact, the Decision is incredibly narrow – it only effectively lightens one compulsory licensing requirement restricting quantities of product that can be exported and it extends that relaxation to only eligible "developing countries."
- The vast bulk of biopharmaceutical profits from COVID-19 medical counter-measures are earned off of sales to HICs, most especially the US, EU and other rich European countries, Canada, and Japan. Pfizer alone is expected to make nearly [\\$22 billion this year from its sales of Paxlovid](#), 90+% of which derived from HIC-sales. Given the prospects of continued highly profitable sales in high-income markets, there would be no discernable impact of an extended Decision on the continued development of the therapeutic pipeline.

Switzerland and Mexico also posed a series of questions to proponents of the extension. These questions, though a frivolous waste of time, are easily answered.

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?

- There are products beyond molnupiravir and Paxlovid that are likely to be important to the prevention and treatment of acute infection and long-COVID. There could be faster access to such pipeline therapeutics if the Decision were extended, especially for U-MICs that are traditionally excluded from voluntary licenses.
- U-MICs would be able to source at competitive generic prices, at a fraction of what innovators are now charging under tiered-pricing schemes.

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 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?

- Contrary to the assumptions in this question, many biopharmaceutical companies have not and do not license their therapies bilaterally or through the Medicines Patent Pool. It is well known that covid vaccine manufacturers did not do so, and there is no guarantee that developers of pipeline covid therapeutics will do so either.
- Compulsory licenses that address patents only can still be highly effective with respect to small-molecule therapeutics. For such medicines, generic licensees often do not need or want technology transfers even when they are offered. In fact, relevant technology transfer provisions in MPP licenses always make acceptance of technology transfer optional and many licensees do not take technology transfer, though some do. An additional reason why some licensees reject technology transfer is that the rightholder uses the fact of such transfer to impose restrictions on licensees to supply countries outside the licensed territory even when there is no blocking patent or when a compulsory license is issued.
- Contrary to the assumptions in this question, the TRIPS Agreement contains no prohibition against involuntary access to trade secrets/confidential information. Thus, the absence of technology transfer coverage in the WTO TRIPS Decision is not as decisive as the question suggests.

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?

- Demand is constrained by limited initial supplies, unaffordable prices, delayed WHO guidance and prequalification, and inadequate advocacy, preparation, and financial support for robust test-and-treat programming. An oversupply of over-priced originator products and structurally suppressed express demand does not mean that there is no need for an expanded supply of more affordable covid therapeutics now and in the future.

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?

- Generic industries in India and elsewhere have been built on a business model of closer to cost-of-production pricing with a still profitable markup. If countries and donors were to actually commit resources to express effective demand for affordable diagnostics and therapeutics, the resulting volumes will predictably be sufficient, and sufficient over a significant period of time, to allow companies to recoup the costs of product development and marketing approval.

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?

- It is incredibly irresponsible for Switzerland, which actively delayed adoption of the original WTO TRIPS Decision with its repetitive, already answered questions, and its insistence on narrowing the scope and potential impact of the Decision adopted to now use the relative failures of the flawed Decision it helped to engineer to argue against the extension of the Decision to cover therapeutics and diagnostics.
- Proponents of a comprehensive waiver advocated for an earlier decision and for a decision that more broadly removed IP barriers, including with respect to trade secrets/know-how essential to the production of vaccines. Fortunately, this same kind of access to trade secrets/know-how is not essential to compulsory license-based production of generic small molecule medicines. Switzerland knows this, but pretends it doesn't.
- Again, the assertion that supply exceeds true demand based on need is simply wrong.