President Cyril M Ramaphosa

Union Buildings

South Africa

18 March 2022

Dear President Ramaphosa

We are writing you as concerned academics and researchers in Southern Africa about the current negotiations on the South Africa/India proposed temporary waiver of intellectual property protections on COVID-19 health technologies at the WTO, and the disastrous leaked <u>draft text</u> of a proposed "compromise" on the waiver proposal. Regrettably, the draft text accomplishes little to actually ensure expanded supply and technology transfer of COVID-19 vaccines, and it totally excludes vitally needed medicines and diagnostic tests for six months, and in all likelihood much longer. We urge you not to agree to the draft text in its current form and to continue to show the resolve that might deliver a meaningful waiver that will give freedom to operate for companies in South Africa and elsewhere to manufacture, sell, and equitably distribute COVID-19 countermeasures to the populations that have suffered devastating shortages and inequality during the entire pandemic.

We applaud your past, steadfast support for a meaningful WTO waiver and your domestic efforts to increase South Africa's biomedical manufacturing capacity and to share the fruits of scientific progress with the rest of the world, through your support for the WHO mRNA Vaccine Technology Transfer Hub. You, Dr. Tedros, and UNAIDS Executive Director Winnie Byanyima have led the global public forum in calling out medical apartheid and demanding adoption of the waiver, expanded production, and equitable access to scarce and over-priced vaccines, tests, and medicines.

Unfortunately, the draft text is defective both in its fundamentals and in its details. In terms of fundamentals, the draft text fails to deliver meaningful progress even on vaccines, its stated, exclusive focus. Although it partially, but imperfectly, addresses some patent-related issues, it fails in all regards to address the problem of technology transfer – access to the confidential information, data, trade secrets, and manufacturing know-how that is essential to quickly enable development of vaccine manufacturing capacity. Overriding patents alone will not get South Africa or any other country expanded access to COVID-19 health products. Instead, as is already happening with the Technology Transfer Hub, vaccine developers are having to reinvent the wheel of product development and quality-assured manufacturing at a commercial scale. Major vaccine producers like Pfizer and Moderna have refused to share their mRNA vaccine technologies with the Hub or other independent producers, adding years of delay to the production of needed vaccines.

In addition to failing to deliver vaccines, the draft text totally excludes medicines and diagnostics, both of which are widely available in rich countries but in scarce supply in the Global South. The consequences of patent protection on diagnostics were acutely experienced in South Africa with delayed testing due to the capture of diagnostic reagents by developed economies – resulting in the inability to access or manufacture our own diagnostics. Late or missed diagnoses mean amplified transmission and worse prognosis, adding to our disease and mortality burdens due to COVID-19. Countries that have suffered the ravages of vaccine apartheid are now asked to wait at least six months and probably much longer for the WTO to even consider whether intellectual property barriers on these medical essentials will be waived. Many countries, and South Africa's private sector, are excluded from voluntary licenses on promising outpatient antiviral treatments from

Merck (molnupiravir) and Pfizer (Paxlovid). In addition to equitable access in licensed countries being delayed by the arduous process of product development and regulatory permission, countries under the companies' exclusive monopoly control will be left at the end of the line once again and charged needlessly high prices.

There are other flaws in the draft text. For example, all countries self-designated as "developed countries," including some surprising examples such as Kenya, are excluded from participation either as manufactures/exporters or importers/users of the proposed "solution." China, a major global supplier, is also excluded, and even Least Developed Country Member States and non-WTO members are not expressly listed as eligible countries. In addition, there are many elements that are actually TRIPS-plus (not otherwise required by the TRIPS Agreement), such as the obligation to list all patents on vaccine components and final products and the obligation to report multiple details to the WTO, even in circumstances where Article 31 bis of the TRIPS Agreement would not otherwise require such notice. The requirement to list patents is particularly onerous and impractical. There are 280 components to mRNA vaccines sourced from 19 countries. Patents would have to be listed for each patented component and for the final vaccine itself. The patent landscape would have to be examined and re-examined not only in South Africa, but in the countries of production and export of components not manufactured here. Many patents would be unpublished and new patents could be filed even on existing vaccines, meaning that compulsory licensing applications would need to be continuously amended to add new patents in order to comply with mandatory conditions in the text. This requirement is TRIPS-plus and, as a pragmatic, procedural matter, totally eviscerates the "solution."

There are other, even more detailed technical glitches in the draft text. However, it is because of the more fundamental issues listed above that we urge you to not accept the "compromise" text. It is not the waiver that South Africa championed for the rest of the world and its marginalised people. It is not a waiver that delivers anything meaningful except perhaps the temporary waiver of Article 31(f) of the TRIPS Agreement which prevents unlimited supplies to other countries when a compulsory license on a patent is issued. In its current form, the "compromise text" is frankly misleading and a failure. Many of us strongly believe that it is not worth signing and that it would be an embarrassment – an admission of capitulation to unreasonable demands from the United States and European Union – to do so. Please leave the door open to further urgent negotiations to engineer a waiver that you and other South Africans can be proud of, by refusing to endorse this sham of a waiver.

Yours sincerely,

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