**South Africa Intervention**

**Informal TRIPS Council 19 January 2020**

Thank you, Madam Chair for your introductory remarks and for giving us the floor.

I would like to take this opportunity to welcome Zimbabwe and Egypt as cosponsors of the waiver proposal. At the outset the cosponsors would like to recognise the immense importance we attach to this discussion and wishes to commend the membership of the WTO for the level of engagement we have been able to have on this important issue. We feel that it is imperative for all issues and questions raised by Member to be answered. Indeed, the cosponsors have consistently endeavoured to respond to issues raised by Member in an honest attempt address genuine concerns raised both from the floor and in statements. On behalf of cosponsors, we have the honour to introduce three written submission contained in documents, IP/C/W/672, IP/C/W/673 and IP/C/W/674. The objective of these documents is to answer questions raised by Members and to further demonstrate the arguments that cosponsors have raised in their statements and submissions. In addition to these submissions, we also submitted document IP/C/W/670 which is supplemental and contains various details regarding the emerging landscape for patents that affect therapeutics as well as other examples where IP operates as barriers to access. The preliminary patent landscape offers a non-exhaustive snapshot of the patent filing and granting status on five selected therapeutics candidates that are under review by the WHO Access to COVID-19 Tools Accelerator (ACT-A) therapeutics pillar.

I will try to be as succinct as possible in introducing these documents.

Document IP/C/W/672 entitled ‘*WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19 – Responses to Questions.’,* reacts to questions posed by various delegations. This document contains responses to questions raised on the waiver proposal in the TRIPS Council meetings of 16 October, 20 November, 3 and 10 December 2020. I will revert to some of the issues raised in this document a bit later in the statement, however in a very cursory way I wish to point out that many of the questions and concerns raised by Members overlap with regard to substance and process. There are several issues raised in questions and comments by Members include some of the following that:

1. the waiver proposal is not needed since TRIPS flexibilities already provide various options for Members, including through Article 31 and Article 31bis,
2. the waiver proposal is not needed since global voluntary mechanisms will ensure that Members have access vaccines, therapeutics and diagnostics,
3. the waiver proposal is not needed since pharmaceutical companies are already entering into licensing agreements to produce vaccines, that such companies have pledged not to enforce their IP rights or gave undertakings not to profit until COVID-19 comes to an end,
4. the waiver proposal will destroy innovation, research and investment in the pharmaceutical sector and will act as a disincentive for pharmaceutical companies,
5. practical issues were also raised regarding how the waiver will be implemented as well as the scope of the waiver as currently formulated,
6. some delegations have suggested that there is no evidence that IP is a barrier to accessing vaccines, treatments, or technologies in the global response to COVID-19,
7. others have suggested that the waiver will facilitate trade in counterfeit medicines,

Our responses cover 30 pages and explain many of the rationales for our proposal, including dealing in great detail with each of the areas of questions raised by Members. Many of the successes in recent times to address COVID-19 cannot be attributed to IP system as such, innovations and the development of vaccines, therapeutics and diagnostics were achieved through collaboration and generous support of states and ordinary people, in the end the generosity of the human spirit delivered outcomes and solutions that now seem to narrowly favour those that have the means to pay upfront to the detriment of poorer nations.

In the past interventions several Members opposing the Waiver proposal have pointed to COVAX as a mechanism that will provide timely equitable access to COVID-19 vaccines. In response, the co-sponsors have welcomed every effort towards achieving equitable access for COVID-19 products. However, we have stressed that the ACT-A as well as COVAX initiatives are insufficient to ensure timely and equitable access to COVID-19 products and technologies. The aim of ACT-A including the COVAX is to provide two billion vaccine doses (for one billion people if we consider two-dose vaccine regimen) to the world by the end of 2021. Of this, according to Gavi, 1.3 billion doses will be made available to 92 economies eligible for the Gavi COVAX Advance Market Commitments, targeting up to 20% population coverage by the end of the year. These initiatives are obviously inadequate to meet public health goals of immunity and the needs of the 7.8 billion people of this world of which about 6.4 billion are low-and-middle income countries.

On 8th January the Director General of WHO expressed serious concern, pointing out that 36 high income countries and 6 middle income countries were rolling out vaccines and “So there’s a clear problem that low- and most middle-income countries are not receiving the vaccine yet” adding that “At the outset, rich countries have bought up the majority of the supply of multiple vaccines” and that this is at the “expense of COVAX”. The DG of WHO points out that countries engage in bilateral deals, potentially bumps up the price for everyone” adding that “No country is exceptional and should cut the queue and vaccinate all their population while some remain with no supply of the vaccine.” This is a stark warning that the world is on the brink of “catastrophic moral failure”, as poor countries fall behind richer nations in accessing the vaccines needed to protect their populations against Covid-19.

TRIPS flexibilities, including those confirmed in the Doha Declaration on TRIPS and Public Health, have undoubtedly, played a crucial role in promoting access to medicines. However, the present COVID-19 global pandemic presents exceptional circumstances. In our view, though the TRIPS flexibilities do allow limited policy space for public health, they were never designed to address a health crisis of this magnitude. As is already apparent, many countries lack the institutional capacities to utilise such flexibilities.

Madam Chair,

We have also provided a written respond to Document IP/C/W/673 entitled ‘RESPONSE TO QUESTIONS ON INTELLECTUAL-PROPERTY CHALLENGES EXPERIENCED BY MEMBERS IN RELATION TO COVID-19iIN document IP/C/W/671.’In document IP/C/W/671, Australia, Canada, Chile and Mexico raised eight questions for the consideration of the Council for TRIPS. In this document there are various questions that overlap with our previous responses. For the sake of completeness, we nonetheless endeavoured to answer the questions posed in W/671.The responses should be read together with communication titled Examples of IP issues and barriers in COVID-19 pandemic (document IP/C/W/670), and interventions made at the formal and informal sessions of the Council for TRIPS clarifying and responding to issues and concerns raised with respect to the waiver proposal.

As proponents we encourage Members to implement TRIPS flexibilities to fullest extent possible including under Article 31 and Article 31bis. However, Article 31 and Article 31bis was never designed to address the global access challenge of a pandemic as its primary focus is to empower individual countries to solve domestic problems with production and supply. In this pandemic, as we have collectively experienced and witnessed to date, supply of essential medicines, vaccines and diagnostics requires actions beyond national borders. Using compulsory licensing under Article 31 and Article 31bis will not leverage uninterrupted collaboration for countries to share production and supply capacity and to walk out of this pandemic together. In the current situation where every country is suffering and in desperate need of adequate supplies, relying mainly on Article 31 and Article 31bis to address IP challenges in ensuring global access is seriously ill-advised. Article 31 and 31bis offers a country-by-country, case-by-case and product-by-product solution. However, what we have seen is that COVID-19 is a global pandemic that required global cooperation, individual countries are incapable of addressing this issue by themselves.

We need to deploy all tools to ensure governments and manufacturers all over the world have full freedom to operate, to do what is necessary to expand production and diversify supply. It is in this context the proposed waiver is required. There is clear evidence of existing and potential intellectual property barriers as presented in IP/C/W/670. For instance, a new anti-viral drug called Molnupiravir which is in Phase II/III trials is reportedly able to completely suppress the virus transmission within 24 hours. It has primary patent applications filed in at least 28 jurisdictions, including two regional patent offices, expiring between 2035-2038. Two other drugs – tocilizumab and sarilumab, have reportedly been found to curb the mortality rate in people with severe COVID-19 and also accelerate patients’ recovery time but are not widely available especially in developing countries. As mentioned in document IP/C/W/670, the primary patent on tocilizumab expired in 2017, but multiple secondary patents remain granted in many countries. While for sarilumab, the primary patent on the drug and secondary patents on its formulation have been granted or filed in at least 55 developing countries. This situation poses a challenge for more affordable generic supply of these medicines.

These matters create significant uncertainty for manufacturers. In addition, the current situation of restrictive, non-transparent and limited voluntary licenses cannot be relied on to deliver equitable access. And as has been discussed extensively, in a global crisis, current flexibilities are simply insufficient.

In document IP/C/W/674 cosponsors raise various questions to various delegations. These questions are posed to further understand the positions that various delegations have taken and the evidence that they rely on to substantiate such positions. It would be helpful for delegations to provided answers to the questions posed.

Madame Chair,

The challenge the world is facing currently has been anticipated. We have consistently expressed our concern over this exact situation. At the core of this problem is limited production and supply options, caused by non-transparent, restrictive IP management and the lack of international solidarity in the sharing of technology, know-how and related IP. Instead, intellectual property related monopolies approaches have been allowed to prevail, limiting supply options and jeopardizing global public health.

We have stressed that the global needs are massive and can only be addressed with global sharing of technology, knowledge, and a clear and consistent direction for addressing any emerging IP barriers, which is what our waiver proposal seeks to achieve. We also expressed concern that aiming to vaccinate merely a small proportion of population i.e. 20% will be insufficient to bring this pandemic under control. The level of immunity across the population needed to stop the virus spreading isn’t precisely known but it is thought to be between 60% and 80% meaning billions around the world will need to be vaccinated to achieve herd immunity and break the cycle of transmission. We urgently need to expand and diversify supply options and therein addressing challenges posed by intellectual property is a crucial component.

The emergence of new variants and its rapid global spread reaffirms the need for global solidarity. According to WHO “It is normal for viruses to mutate, but the more the SARS-CoV-2 virus spreads, the more opportunities it has to change. High levels of transmission mean that we should expect more variants to emerge”. COVID-19 requires global cooperation and responses, individual countries acting alone are unlikely to address the common interest that all of us have to defeat COVID-19 and to save lives.

In closing Madam Chair, Members opposing the waiver proposal are prioritizing intellectual property monopolies over the lives of many people around the world and even over their own interest. As Dr Tedros points out the “me-first approach” is also “self-defeating” as ultimately it will only prolong the pandemic. With the emergence of at least three new variants in the last few months, it is clear that so long as the virus is circulating among unprotected populations, no one is truly safe.

Moreover, the IP monopolies have no basis given the extensive public funds poured into the development of these products and the significant profits that are being made. We are of the view that the call for a waiver is justified. We are in a truly unprecedented and an “exceptional circumstance” and this is the very basis for granting waiver under Art. IX of the WTO Agreement. The TRIPS Council has extensively and exhaustively discussed the various issues pertaining to the proposed waiver. We now need to move rapidly towards the adoption of the proposed waiver. Any delay in adopting the proposal merely serves to further prolong the pandemic. This is the moment for the World Trade Organization to urgently deliver concrete action.