**Pakistan Statement**

**Informal TRIPS Council Meeting, 3 December**

Thank you Chair!

Pakistan would like to thank you for convening us and to allow the opportunity to discuss this very important issue further. Chair, in our view this issue is one of, if not the most critical and urgent issue to be considered at the moment. For nothing can be more important than the question of saving human lives.

Chair, we also take this opportunity to thank all members who have engaged on this subject, and have allowed us the opportunity to delve into more detail by answering their questions.

Chair, Pakistan has made a strong case for the waiver in our statements made on previous occasions. We have highlighted how the waiver is necessary and how current flexibilities in the TRIPS agreement are inadequate to meet the current challenges. We would like to address some of the questions and concerns raised by certain members on the waiver.

**Brazil: International collaboration and voluntary licensing could and should be used for the purposes of scaling up production of medical products and guaranteeing sufficient and affordable supply.**

**UK: Voluntary licensing is supporting the availability of medical equipment and existing mechanisms that facilitate the sharing of Ip and know how are being geared to address covid-19.**

**Response:** Chair, several countries have repeatedly suggested that voluntary licensing should be used or is being used to scale-up production suggesting that such VLs are providing sufficient affordable supply and facilitating the sharing of Intellectual Property to address Covid19 challenges.

We find these assertions to be divorced from reality. Nine months into the pandemic, VLs have proven to be either non-existent or insufficient.

For instance, there is the case of Remdisvir, a drug reported to have been effective in the treatments of Covid-19 patients. Despite receiving significant public funding, Gilead signed bilateral licenses with a few generic companies of its choosing. Even though it was claimed that the licenses would allow export to more than 100 countries, the excluded countries cover nearly half of the world’s population including many developed and large developing countries such as Brazil and Mexico.[[1]](#footnote-1) Moreover, the limited supply of the drug has been reserved mainly for wealthy nations who have secured stocks up front.[[2]](#footnote-2) While the WHO has recently delisted the medicine from COVID-19 treatment, this shows a typical example of the selective and non-inclusive application of VLs.

It has been noted that VLs, where they exist are shrouded in secrecy. Usually, their scope is limited to specific amounts or for a particular country or for a limited subset of countries, thereby encouraging nationalism rather than international collaboration. Notably, some companies have not signed any agreements to expand manufacturing and supply. Each country is in a race with others to secure supply. This is the exact opposite of international collaboration. For example, at least 82% of the recent Pfizer/BioNtech vaccine that is claimed to be 90% effective has been pre-booked by developed countries representing 14% of the global population[[3]](#footnote-3). To date, there is no public commitment to share its vaccine knowledge, technology and related intellectual property, so that affordable supply may be expanded.[[4]](#footnote-4)

Moderna has announced that “while the pandemic continues, it will not enforce COVID-19 related patents against those making vaccines intended to combat the pandemic” adding that “we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period”.[[5]](#footnote-5) While this announcement is a step forward, manufacturers need a firmer commitment for the sake of legal certainty. Some other companies also hold mRNA technology patents, and Moderna’s non-enforcement announcement alone is not sufficient to provide legal certainty.[[6]](#footnote-6) Furthermore, there is also no commitment to share the know-how that would also be protected. Uncertainty also prevails over what is meant by “while the pandemic continues” and what licensing arrangements will be applicable post-pandemic etc.

Chair, we are extremely concerned that these ad hoc, non-transparent and unaccountable initiatives only lead to artificially limit supply and competition. In a global pandemic, these “business as usual” approaches will surely cost more lives.

Earlier this year, WHO launched a solidarity call to action that calls on holders of knowledge, intellectual property or data to existing or new therapeutics, diagnostics and vaccines to voluntarily license such rights on a non-exclusive and global basis or voluntary non-enforcement of intellectual property rights, to facilitate the widescale production, distribution, sale and use of such health technologies throughout the world. About 41 governments and several international agencies have supported this initiative, but such collaboration has been rejected by the pharmaceutical industry. [[7]](#footnote-7)

We have to ask ourselves, how can we sincerely say that this current situation amounts to international collaboration?

**UK: On test data and other undisclosed information or to article 39.3 of the TRIPS agreement sets out that undisclosed test for other data shall be protected against disclosure unless necessary to protect the public.**

**UK: It is also important to note that the way the regulatory framework is inextricably linked to the IP framework and has an integral role to play in ensuring the efficacy and safety of covid-19 treatments as they are developed. How would a waiver be able to ensure that these standards particularly safety and quality standards or maintain an essential question relevant to another pressing challenge vaccine hesitancy.**

**Response**

On another issue, Chair, certain members mentioned that the regulatory framework is linked to the IP framework and plays a role in ensuring efficacy and safety of Covid-19 treatment and queried how a waiver would ensure standards of safety and efficacy and address vaccine hesitancy.

We would like to clarify that the objective of the regulatory system is to ensure quality, safety, and efficacy of medical products. Intellectual Property, on the other hand, has nothing to do with quality, safety, and efficacy of a product. For instance, the grant of a patent does not guarantee quality, safety or efficacy. The primary purpose of IP is to prevent third parties from using the protected subject matter without the permission of the IP holder.

The waiver would greatly contribute in ensuring transparency in Covid clinical trial data which

in turn will increase confidence in the use of Covid therapeutics and vaccines especially vaccines hesitancy. Art. 39.3 of TRIPS states “Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”. While disclosure is allowed to protect the public, there is constant pressure from trading partners and the pharmaceutical industry to limit the flexibility allowed under Art. 39.3 of TRIPS.

The 2020 EU Report on the protection and enforcement of intellectual property rights in third countries, finds that “[a]nother area of continued concern reported by right holders is the absence of an effective system for protecting undisclosed test and other data generated to obtain a marketing approval for pharmaceuticals […….] This problem affects the European industry mainly in Argentina, Brazil, China, India, Indonesia, Malaysia, Russia, Saudi Arabia, Ukraine and the United Arab

Emirates.”[[8]](#footnote-8)

Similar pressures have been seen from the US as well.

In view of this, from the perspective of public health, the waiver would be a very positive development. It would give regulatory agencies the confidence to disclose clinical trial and other relevant data in the public interest which in turn generates confidence in using the relevant diagnostics, therapeutics and vaccines. This is especially important given the rapid processes involved in the development and approval of therapeutics and vaccines, that may give rise to vaccine hesitancy and other uncertainty over the safety and efficacy of a product.

Chair, we have tried to address some of the concerns raised by members on the proposal, and we hope that these will give them a chance to reflect on the issue more deeply. We will continue to carry on the discussion in a hope that this urgent issue strikes a chord with everyone in the immediate interest of saving millions of human lives.

At the end, Chair, as you have proposed, we are happy for you to report an objective assessment of the current state of play on this proposal to the General Council in its upcoming meeting. At the same time, we are also thankful to you and the secretariat for sharing the proposed language of the report and we would need some time to consider this language. We will provide substantive feedback on this within the stipulated time. I thank you, Chair.

1. <https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/> [↑](#footnote-ref-1)
2. <https://edition.cnn.com/2020/07/01/health/remdesivir-drug-supply-us-intl/index.html> [↑](#footnote-ref-2)
3. <https://www.independent.co.uk/news/health/covid-pfizer-vaccine-doses-latest-uk-supplies-b1721162.html> [↑](#footnote-ref-3)
4. A shot at recovery Measuring corporate commitments towards a free, fair, and accessible COVID-19 vaccine, <https://www.oxfamamerica.org/explore/research-publications/shot-recovery/> [↑](#footnote-ref-4)
5. <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19> [↑](#footnote-ref-5)
6. <https://www.nature.com/articles/d41573-020-00119-8> [↑](#footnote-ref-6)
7. <https://www.ft.com/content/9ed5ca5e-9360-11ea-899a-f62a20d54625> [↑](#footnote-ref-7)
8. <https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf> [↑](#footnote-ref-8)