German Bundestag Monitoring Committee COVID-19-Pandemic

Public hearing on the subject: "Development, Production, Approval and Procurement of Vaccines and Pharmaceuticals" on June 3, 2021

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(These are the personal views of Prof. Abhijit Das and do not represent the views of the Government of India).

A. Developing countries have been disproportionately impacted by COVID-19, but are struggling to contain the spread

1. No country seems to have remained untouched by the COVID-19 pandemic. As of 1 June 2021, there have been 170,426,245 confirmed cases of COVID-19, including 3,548,628 deaths, reported to WHO. Developing countries, including the least developed countries, have been disproportionately impacted by the pandemic. An effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.

2. As more transmissible variants take hold around the world, the challenges posed by the COVID-19 pandemic become more formidable. The longer we wait to act, the more likely it is that dangerous variants could emerge that can evade the protections offered by current vaccines. The public in any country, including the developed countries, will not be truly safe as long as the pandemic continues to rage and surge overseas. From moral and practical perspectives, this emergency demands immediate action- widespread vaccination of those most vulnerable where the threat is greatest.

3. According to the WHO dashboard, as of 31 May 2021, a total of 1,579,416,705 vaccine doses have been administered. However, the reality of the vaccination roll-out in different countries strongly suggests that most developing countries are struggling to contain the spread of the pandemic and provide health care services to those affected.

4. In the global scramble for access to COVID-19 vaccines, in late 2020 and early 2021, advance purchase commitments were the primary determinant of who would get vaccines and who would be left behind. The trend in the percentage of population vaccinated in different countries, by region and incomes, continues to reveal glaring disparities. As of 31 May, 2021, 18% of the population in the European Union and 25.8% in North America have been fully vaccinated. On the other hand, 0.51% of population in Africa and 2.3% in Asia have been fully vaccinated. Less than 0.1% of the population in Low Income countries, 2.1% in Lower Middle Income countries and 3.4% in Upper Middle Income countries have been vaccinated. In sharp contrast, 21.8% of the population in High Income countries have been vaccinated.[1]

[1] https://ourworldindata.org/grapher/share-people-fully-vaccinated-covid?tab=table&region=Europe&country=~OWID_WRL

There are 6.4 billion people in LMICs, but presently most of the supply is for high income countries. Countries with the highest incomes are getting vaccinated 25 times faster than those with the lowest.[2] These figures leave us in no doubt that only a miniscule fraction of the 84% of the world population, residing in the developing countries, including LDCs, can be said to be protected through vaccines.

5. To the extent most of the world population remains unvaccinated, variants are likely to continue to proliferate and circulate. This situation is not tenable. Until we replicate the success of the vaccination programmes in some developed countries across the world, all of us will remain vulnerable to new COVID-19 variants.

B. Vaccine production and availability remain a matter of deep concern

6. An effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need[3]. Despite the pace at which vaccines against COVID-19 were developed and regulatory approvals for their emergency use obtained, the shortfall in production and availability of vaccines remains staggering. Some estimates suggest that in 2020, against the projected production of COVID-19 vaccines of 837 million doses, the amount actually produced was 31 million doses - merely 4% of the projected production. To meet the global total of more than 12 billion doses projected in 2021, production will need to increase on an unprecedented scale, something not seen before. In addition, on account of various imperatives, including unforeseen reasons, global needs for vaccines can change at a rather short notice. To illustrate, the emergence and spread of new variants could mean that we might need a new generation of vaccines before the end of 2021[4]. We also do not yet know how long immunity from vaccines will last and we may need regular booster shots to maintain immunity and to target new variants.

7. Nothing illustrates the acute shortage in availability of vaccines than the COVAX facility. By May, 255 million doses of vaccines were supposed to have been supplied via COVAX. But as of 27 May only 72 million COVID-19 vaccines had been delivered. This means that COVAX has only delivered 3.6% of the 2 billion doses that is its goal for 2021.

C. Voluntary licensing agreements constrain vaccine production

8. The current approach to production and supply of vaccine is based on voluntary licensing agreements between the originators of vaccines and the manufacturers. Most of these agreements are contract manufacturing agreements wherein the contractor maintains control over the technology and know-how and hence production and supply. This does not provide a sustainable approach to access. Most of the voluntary licensing agreements are shrouded in secrecy and very little information exists in the public domain regarding the terms of the agreement, the duration, the volume, and countries that will be supplied under

[2] https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/
[3] WTO document IP/C/W/699 dated 2 October 2020.
[4] https://launchandscalefaster.org/covid-19/vaccinemanufacturing

the agreement. Some voluntary licenses even exclude the manufacturing countries from supplying their home country markets. [5] Hence, conventional voluntary licenses do not offer a sustainable path to resolving the COVID-19 pandemic.

9. A concern with respect to these agreements is that they are artificially limiting production and supply. The companies holding the technology may refuse to license, and this is the situation in which we find ourselves. Some of vaccine originator companies have been extremely reluctant to grant voluntary licenses to manufacturers in developing countries, thereby failing to leverage the global vaccine manufacturing capacity. This is contributing to huge demand-supply gap and also resulting in inequitable vaccine distribution. Based on an analysis of UNICEF data, a study by Oxfam suggests just 43 per cent of reported COVID-19 vaccine production capacity is currently being used for the approved vaccines[6]. Several manufacturers in developing countries have indicated their willingness to manufacture these vaccines, but voluntary licenses are just not forthcoming.

10. Business as usual, based on voluntary licensing agreements, is likely to be grossly inadequate to deliver timely access to vaccines against COVID-19 to countries in need of them. Unless we leverage all available production capacities, the global demand is extremely unlikely to be met in 2021 and beyond. Till the eligible population of the world is fully vaccinated, the demand for various medical products for prevention, treatment and containment of COVID-19 (diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture) will remain very high, with demand likely to exceed the supply of many products. Fifteen months into the pandemic calls for a rethink of the overwhelming dependence on voluntary licensing agreements for meeting the needs of these medical products and technologies.

D. Intellectual Property Rights are a significant barrier for scaling up production of medical products to address health challenge posed by COVID-19 pandemic

11. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need. However, several reports highlight the role of intellectual property (IP) rights in hindering or potentially hindering timely provisioning of affordable medical products to the patients.[7] Owners of IP rights can decide whether, or not, to grant a license for the technology, designs and knowhow required for manufacturing the medical products required for COVID-19. At the core is the use of intellectual property rights, including patents, copyrights, trade secrets etc., and other exclusivities to restrict manufacturing and supply options that would lower drug prices and increase patient access. By enforcing exclusive rights backed by IP, companies are able to charge high prices and profiteer from the pandemic or prioritise wealthier countries over ones with less financial capacity.[8] Further, the use of restrictive voluntary license terms limits the catching up and innovation made by generic competitors. In

[5] WTO document IP/C/W/672 dated 15 January 2021.

[6] https://www.oxfam.org/en/press-releases/monopolies-causing-artificial-rationing-covid-19-crisis-3-biggest-global-vaccine.

[7] See e.g. https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots; https://eu.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/.

[8] WTO document IP/C/W/670 dated 23 November 2020.

addition, patent thickets and IP disputes create legal uncertainty, and consequently delay alternative and independent development and production of various medical products.

12. Addressing each of the IP-related challenges mentioned above can be extremely time-consuming, thereby diminishing the possibility of scaling up the production of medical products for combating COVID-19. This provides the rationale for temporarily waiving the rules of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) at the WTO.

E. Proposal by India, South Africa and 50 other countries seeking a temporary waiver from certain obligations under the TRIPS Agreement for prevention, containment and treatment of COVID-19

13. On 2 October 2020, India and South Africa made a detailed proposal seeking a temporary waiver from certain obligations under the TRIPS Agreement for prevention, containment and treatment of COVID-19.[9] Given the exceptional circumstances created by the pandemic, the two countries have sought a waiver from the implementation, application and enforcement of certain provision of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19. Subsequently, 50 other countries formally joined India and South Africa in the proposal. In a further development, the proponents have submitted a revised proposal focusing the text on "health products and technologies" and specifying that the duration of the temporary waiver should be at least three years.[10]

F. Existing flexibilities under the TRIPS Agreement are inadequate to address the challenges related to prevention, containment and treatment of COVID-19

14. An important question that needs to be addressed is – why are the existing flexibilities under the TRIPS Agreement inadequate to facilitate scaling up of production of health products and technologies relevant for prevention, containment or treatment of COVID-19? Although the TRIPS flexibilities do allow limited policy space for public health, they were never designed to address a health crisis of this magnitude. Invoking them for a range of health products and technologies, required for treatment and prevention of COVID-19, is not a feasible option. In this regard, several illustrations can be provided highlighting the inadequacy of flexibilities under TRIPS Agreement.

15. First, many developing country countries face legal, technical and institutional challenges in using TRIPS flexibilities. This is especially true for countries that have never utilised flexibilities such as a compulsory licenses (CL). Further, as compulsory licenses are issued on a country by country, case by case and product by product basis, practically making collaboration among countries for the development and manufacturing of medical products (where different components are sourced from different countries) extremely onerous.[11]

16. Second, a particular concern for countries with insufficient or no manufacturing capacity are the cumbersome requirements and lengthy process under Article 31*bis* of the

[9] WTO document IP/C/W/669 dated 2 October 2020.
[10] WTO document IP/C/W/669/Rev.1 dated 25 May 2021.
[11] WTO document IP/C/W/672 dated 15 January 2021.

TRIPS Agreement for the trade of pharmaceutical products. The mechanism under Article 31*bis* waives the condition in Article 31(f) that a compulsory license should be predominantly for the supply of the domestic market. In this context, it is relevant to mention that despite this mechanism having been established in 2003, it has been invoked just on one occasion. This suggests that this mechanism is neither expeditious nor practical.

17. Third, the use of TRIPS flexibilities in other areas of intellectual property, beyond patents, is less understood at the national level. There is no legal certainty that CLs can be granted for trade secrets. In the specific context of vaccines, merely granting a CL for patents may not be sufficient to facilitate expeditious manufacture of vaccines. What may also be crucial is access to know-how protected by trade secrets.

18. Fourth, the possibility of invoking the security exception under Article 73 of the TRIPS Agreement is fraught with legal uncertainty. Article 73 of the TRIPS Agreement which states "[N]othing in this Agreement shall be construed to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests……..(iii) taken in time of war or other emergency in international relations". Further it is unclear whether the measures taken by countries in the context of the COVID-19 pandemic can be treated as being necessary for the protection of "essential security interests", which has been interpreted at the WTO to mean interests relating quintessential functions of the state, namely the protection of territory and its population from external threat, and maintenance of law and public order internally.

19. Fifth, even if the Least-Developed Countries have the flexibility under the TRIPS Agreement to manufacture generic versions of some pharmaceutical products by not being required to implement the product patent regime, these cannot be sold in countries where these products are protected by product patents. Consequently, an important source of supply of some of the medical products relevant for addressing the challenges arising from the pandemic remains largely shut.

20. Overall, the options available to countries through existing TRIPS flexibilities are limited. It is also a reality that very often the implementation and use of flexibilities is accompanied by pressures from trading partners as well as other stakeholders.[12]

G. Endorsement of the proposal for a TRIPS Waiver will not undermine innovation

21. Some concerns have been raised that the TRIPS Waiver will negatively impact the IP system and incentives for innovation. These appear to be misplaced, particularly in the context of the ravages of the ongoing COVID-19 pandemic and the need for expeditious action to prevent, treat and contain it.

22. The proposal for a TRIPS Waiver is neither open-ended in terms of scope of the products covered nor the time for which it will be implemented. A waiver is a tool to be used in "exceptional circumstance". The COVID-19 pandemic certainly meets this requirement. Further, the proposed waiver is time-limited, and would be annually reviewed. In addition, the proposed waiver is only for COVID-19. It does not extend to any other aspects.

[12] WTO document IP/C/W/672 dated 15 January 2021.

23. Protecting IP rights and rewarding innovation is a recognition of the risks taken by an innovator. It is relevant to mention that many of the vaccines for COVID-19 have benefited from generous financial support from governments, thereby underwriting the much of the risk involved in their development and manufacture. At least 97% of the funding for the development of the Oxford/AstraZeneca COVID-19 vaccine has been identified as coming from taxpayers or charitable trusts.[13] Astra Zeneca has also made clear that "expenses to progress the vaccine are anticipated to be offset by funding by governments."[14] Moderna's vaccine is also publicly funded, reportedly 100%[15]. Further, there is also no transparency with respect to costs of R&D. It should also be noted that some of the vaccine manufacturers have asked governments to take over their liability and have requested for indemnity. This has further reduced the risk for them.

24. WTO Members have a legal right under the Marrakesh Agreement of the WTO to grant waivers from some of the obligations under the various WTO agreements. This is a right that must be operationalised in this time of great global suffering and need.

H. Conclusions

25. An acute shortage of vaccines will not only threaten to prolong the COVID-19 pandemic, but also put the lives of billions at risk and cause many avoidable deaths. Shortage of vaccines will makes the timely availability of therapeutics for treatment of the pandemic an important necessity.

26. The ongoing COVID-19 pandemic has highlighted the need for joint action by countries at the global level to prevent, contain and treat the pandemic. Certain collaborative initiatives, such as COVAX facility are useful, but certainly not adequate. Presently, high-income countries have bought up the majority of the existing vaccine supplies, which poses a significant challenge for COVAX, and consequently for supply to low- and middle-income countries (LMICs) and other developing countries. However, the COVAX has only delivered 3.6% of the 2 billion doses that is its goal for 2021. Obviously, substantial reliance on COVAX is not a sustainable solution for expeditious access to vaccines.

27. In their pursuit of access to vaccines at affordable prices, countries remain completely at the mercy of companies holding the technologies for manufacturing vaccines and the voluntary licensing agreements of these companies. Given the huge shortfalls in production of vaccines, the conventional model of production through voluntary licensing agreements cannot be the solution for addressing the needs during the ongoing COVID-19 pandemic. Countries need to depart from the "business as usual" approach and instead should endorse the proposal for TRIPS Waiver, presently under consideration of the WTO Membership.

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[13] https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded

[14] https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-advances-response-to-global-covid-19-challenge-as-it-receives-first-commitments-for-oxfords-potential-new-vaccine.html

[15] https://eu.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002/; https://www.axios.com/moderna-barda-coronavirus-funding-disclosure-2775a517-a775-485a-a509-b6906c8535a9.html?eType=EmailBlastContent&eId=a156de0d-5e0e-477d-acb3-ad8efea8551d&eType=EmailBlastContent&eId=a363f8a5-20b1-4609-bca0-72579f573204

28. The TRIPS Waiver proposal seeks to ensure that all WTO Members have all tools available to them to act rapidly in addressing the barriers they might face in prevention, containment and treatment of COVID-19. It would also help create an environment where independent production and supply can thrive, thereby expeditiously scaling up the production of vaccines, therapeutics and diagnostics and to ensure affordability of these products.

29. Early in the pandemic, some developed country Members (e.g., Canada, Australia, Germany, Hungary etc.) amended their domestic laws to enable quicker and easier procedures for the grant of compulsory licenses to overcome possible IP barriers to COVID-19 technologies. These law revisions were done to enable and prepare the governments to act rapidly to address IP barriers, if they were to arise. This is also a testament to the reality that voluntary licensing agreements are unlikely to be the panacea for ensuring expeditious and appropriate responses to the health challenges created by the pandemic.

30. As intellectual property, especially patents and trade secrets, are important barriers in scaling up production, these needs to be addressed. The TRIPS Wavier proposal provides a useful way forward for the world to effectively confront some of the health-related aspects of the COVID-19 pandemic. This is both and health and moral imperative. Let future generations not say that while the world was grappling with the COVID-19 pandemic, the advanced nations put profits of pharmaceutical companies before the lives of billions in the world.

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