

# THE ACCESS TO MEDICAL COUNTERMEASURES

The Lynchpin Of The Reforms To Health  
Emergencies Governance



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# The Access To Medical Countermeasures – The Lynchpin Of The Reforms To Health Emergencies Governance

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As countries head deeper into the negotiations of the Pandemic Accord, they are beginning to tackle the some of the most difficult lessons from COVID-19, namely the access to medical products, among a range of other competing priorities from matters on compliance, financing to prevention and preparedness measures. While discussions are getting technical and more specific, the suggestions on potential provisions from stakeholders, experts and countries themselves reveal a rich array of possibilities. WHO member states will convene for the [fifth meeting of the Intergovernmental Negotiating Body](#) in Geneva next week.

A number of dedicated intersessional meetings on specific articles of the [Zero Draft of the Pandemic Accord](#), were conducted this month by the INB, set up to establish a pandemic accord. While these discussions were behind closed doors, Geneva Health Files, has been able to review some of the sessions, based on information shared by those present in these discussions.

The intersessional meetings delved into issues including predictable global supply chain and logistics network [Art.6]; One Health and the Quadripartite [Art.18]; Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how [Art.7]; WHO Pathogen Access and Benefit Sharing System [PABS], with the Pandemic Influenza Preparedness Framework as an example [Art.10].

In this story we look in detail on the various facets to the access question in the pandemic accord discussions. We also bring you opinions from experts at the IP discussion held at the Informal Focused Consultations from October last year. [We will follow up on PABS in the coming weeks]

We try to capture the emerging narrative on some of the key issues on supply, production, intellectual property, tech transfer, licensing, among others. These matters are mostly articulated in Chapter III on equity, including Articles 6, 7 in the zero draft of the pandemic treaty.

(Also see ours earlier: [\*Pandemic Accord Negotiations: Away from Public Glare, but Center of Attention\*](#); [\*The Zero Draft of the Pandemic Accord: A Discursive Journey into Equity\*](#))

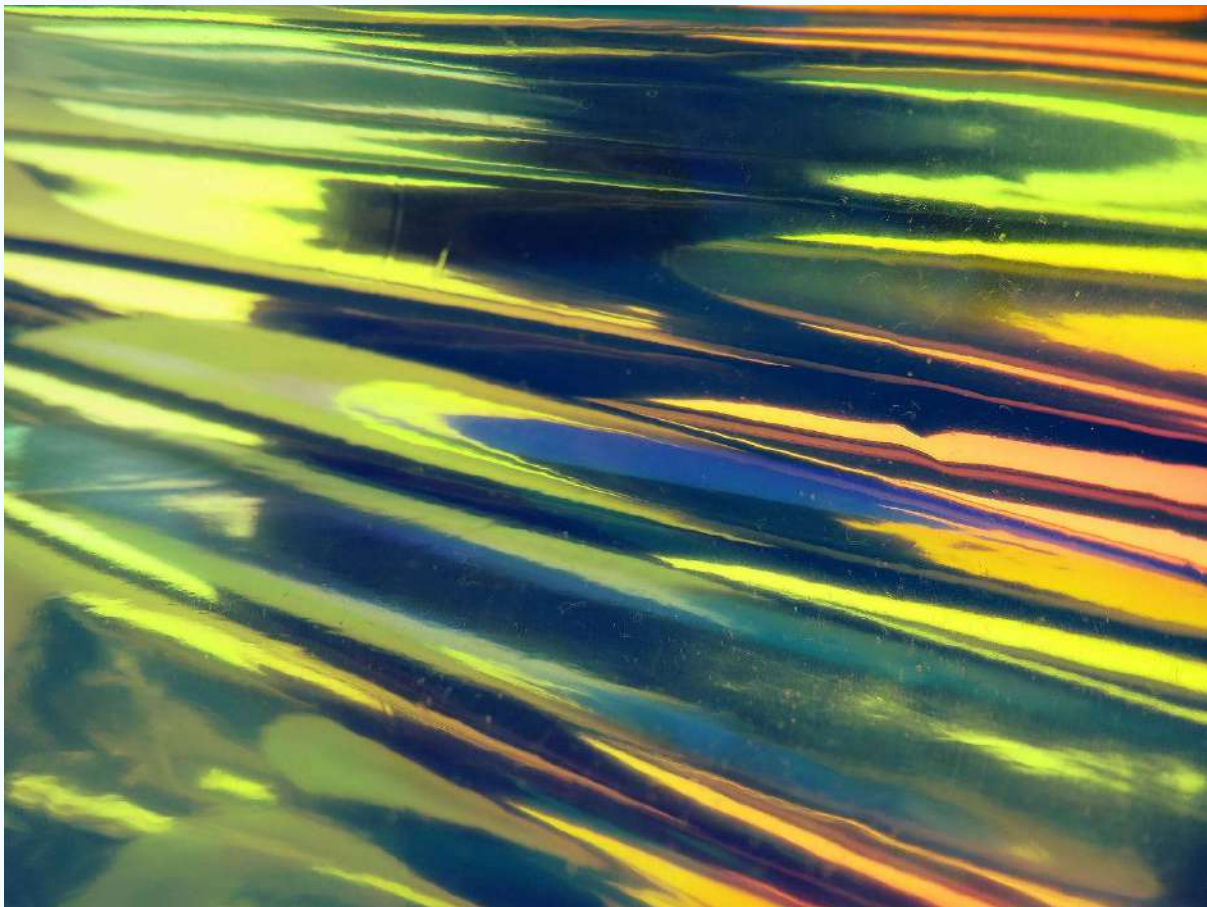


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## **SUPPLY CHAIN**

Article 6 on global supply chain and logistics network, proposes to establish “The WHO Global Pandemic Supply Chain and Logistics Network” and to develop a mechanism “to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs”.

According to sources, much of the discussion during the intersessionals on supply chain focused more on the issues of logistics, especially on shipments and delivery. Experts deeply involved in the operational aspects of the international response to COVID-19, acknowledged that the commercial sector on logistics clearly collapsed during the pandemic. However, they also emphasized the reliance on commercial actors while designing the supply chain network.

Issues of production were discussed and there have been suggestions that outcomes on production must be incorporated into the legal texts especially when it comes to new products.

Questions were raised on how the supply chain network will connect to the Medical Countermeasures Platform that is being proposed potentially as an “end-to-end” solution for health emergencies.

Among those who presented were, Paul Molinaro, Chief, Operations Support and Logistics at World Health Organization. World Health Organization; and Shanelle Hall, Founder of The Yellow House, a consulting firm with an emphasis on global public health and former UNICEF Deputy Executive Director, as well as Director of UNICEF’s Supply Division.

Participants also highlighted the need for a minimum agreed and guaranteed stockpiling of medical products, and to find a way to ensure a predictable response irrespective of commercial dynamics. Suggestions were also made for a greater coordination role for WHO. There were also calls for “unhindered access” to medical products during emergencies.

## **WAIVERS OF IP RULES AS A POLICY TOOL**

Waivers of intellectual property rules during health emergencies have been proposed by a number of countries. And this was extensively discussed at the intersessional. Although the TRIPS Waiver discussions at the WTO did not succeed in contributing to a faster access to COVID-19 medical products, the “waiver-approach” is very much on the agenda for WHO member states. (The decision adopted by the WTO in [June 2022](#), was a shadow of what was [originally proposed](#).)

While developing countries do want the Pandemic Accord to automatically trigger a waiver, experts are not convinced about the feasibility of doing so. But it has been suggested that the Accord could have commitments for all countries to support a waiver, at international and national levels.

WTO, WIPO and WHO, made interventions on this topic during the discussion, even as it was pointed out by one of the co-chairs of the INB that the representatives are bound by the organizations they represented.

South Centre, an intergovernmental organization with 55 developing countries as members, asked of the three organizations for a more precise wording for the obligation under this provision [Art. 7]. The suggested language from South Centre is: “to require that each party suspend the enforcement of IPRs that may create barriers to manufacture and supply of products during a pandemic, and that no Party shall challenge these measures based on international obligations that the Party suspending the obligation may have. (The latter would cover for FTAs and investment agreements.)

### **INTERVENTION BY WTO**

Speaking on the inequities witnessed during the pandemic, a WTO official pointed out the countries do not agree on the precise causes of the inequities. He said that access and the flow of technology is determined by a wide range of complex interlocking factors. “No single one of which can be the entirely the cause of the inequity.”

While the high concentration of production capacity needs to be addressed, but the means to diversify production capacity requires coordination, planning, cooperation in both establishing and maintaining this capacity, he added.

He also pointed out that technology, transfer and intellectual property dimension of access this will be most effective when undertaken in combination with procurement and financing strategies, regulatory cooperation and facilitating the flow of inputs and finished products across borders as well as strengthening domestic health infrastructure.

Experts also pointed out the lack of clarity around the status of patents as the pandemic unfolded. Where patents are in force it presents a legal obstacle for generic production, but this subject to different contexts and jurisdictions.

“The scope, availability, and actual implementation of measures to curb or limit or override the exclusive effect of pattern rights can come into play. This is the array of interventions which are generally clustered together under the term flexibilities,” the expert said.

It was recognized that the use of these measures have been a contentious and politically sensitive debate and raised questions on the adequacy of the measures for a pandemic response.

Speaking on the waiver proposal at the WTO, the expert emphasized the importance of the capacity of national governments to take action. And that a waiver mechanism, seeking suspension of certain obligations, was not self-executing and that governments need to take action within domestic legal systems.

“Ultimately the impact of the IP system, and even of international rules, will depend on choices made and implemented within domestic laws and jurisdictions,” he explained.

He also raised questions on the uncertainty about their legitimate scope of such measures. “...about how and when they can and should be implemented, and even about their very legal character within domestic law, which can be quite diverse; and it depends on very much on domestic circumstances and constitutional considerations.”

Explaining the TRIPS decision, the expert said that it is legitimate within the TRIPS framework to provide parallel mechanisms under domestic law to enable patented technology to be used without the patent holders consent. He also said that the TRIPS decision recognizes that countries will still be interdependent when it comes to the diversified production of vaccines. In other words, equitable access entails opening new pathways between potential exporters and importers.”

He also explained the Ministerial decision addressed the availability question from a supply perspective, than from a demand point of view. “If importing countries did work together, especially in the context of pooled or coordinated procurement to notify their expected import needs as soon as those needs are identified that would itself open up via viable alternative pathways for it equitable access.” But the difficulty in predicting and managing supply and demand during the pandemic was also pointed out.

Any waiver of international obligations require connected action, if they are to have any practical effect, he added.

### **INTERVENTION BY WIPO**

While there are references to the technology transfer hubs such as the mRNA hub in the zero draft, the representative from WIPO cautioned against “duplication of efforts” at tech transfer hubs. “We need to avoid duplication or creating structures that complicate the innovation process and intent access,” the expert said. WIPO also sought clarity on “the legal content of certain expressions such as the waiver”.

In prior interventions at INB meetings, WIPO has also emphasized its role in these matters. “Enabling access to the fruits of innovation while preserving incentives to innovate cuts to the core of the international intellectual property framework of which WIPO and WTO agreements form part. References to intellectual property in any future international instrument should therefore be guided by these existing international agreements and decisions, as relevant. We support the reference, in Article 2, to consistency with existing international instruments and respect for the competencies of other organizations and treaty bodies,” according to one intervention at a previous meeting of the INB.

### **INTERVENTION BY WHO**

At the meeting, the expert from WHO spoke about the trilateral collaboration between WTO, WIPO and WHO. The WHO official also laid out mechanisms that place public health over trade objectives.

“The lack of access to health products, is not only due to a single factor...The IP system is at the center of the debate on innovation and access. So how IP is managed, can determine its impact on health and particularly in pandemic times, when global access of key products is needed in a timely and affordable manner.” The expert added that “IP challenges should also be solved in a different manner in the future.”

The expert suggested a number of safeguards built into the IP system to pursue public health objectives. Apart from TRIPS Flexibilities, she suggested mechanisms such as IP transition periods for Least Developed Countries; IP exhaustion regimes; refining criteria, making available pre- and post-grant oppositions; exclusions, exceptions and limitations to patent rights. She also mentioned the use of competition policy and law would also be effective to promote innovation and support access.

She noted that manufacturers from different continents indicated their readiness to produce, but they needed licenses or transfer of how to scale up. The expert also discussed the COVID-19 Technology Access Pool that was set up in early 2020, to promote voluntary technology transfer, licensing of IP and sharing know-how. But it has not been used much in the current pandemic. She pointed out that public research institutes had demonstrated more commitment towards the Pool and more licenses are being currently negotiated. The mechanism is being reviewed currently to see how it can be developed for future needs, she added.

(Some countries have pointed to language in the WIPO Marrakesh Treaty for the Blind, which mandates its members to use exceptions in intellectual property rights permitted in existing international trade agreements and treaties, to enhance global access to works made accessible to persons who are blind or have other disabilities.) [Article 4: National Law Limitations and Exceptions Regarding Accessible Format Copies.]

## **TECH TRANSFER:**

Article 7 on Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how,



acknowledges the role of equitably, geographically and strategically distributed manufacturing capacity.

We [reported](#) earlier that significant parts of the provisions in this article is weak with riders such as mutually agreed terms. Voluntary licensing approaches characterized the response to COVID-19 pandemic, with less-than-optimal outcomes for equitable access, many have said, given that the model favors manufacturers to determine the terms of such arrangements.

A number of questions were raised during these discussions on having binding obligations on tech transfer.

At the session, an official from the Medicines Patent Pool said, that one of the learnings during the pandemic was that MPP's traditional licensing model took too long (Low-and-Middle Income Countries had availability one year after availability in High Income Countries). The only way to shorten the time is to start earlier getting a licence before phase 3 and to sub-license, a senior official from MPP said, also suggesting that generic companies have indicated a willingness to develop at risk. "This might mean having a licensing template and an already agreed set of generic companies (different for different types of products) ready to go," the expert said.

It was also revealed that in the early days of COVID-19, MPP was "asked to take a backseat", allegedly because its licensing model was not appropriate for vaccines.

On the Zero Draft, MPP pointed out that licensing only gets one mention in Article 7 (royalties are mentioned with no reference to licensing) and that should be corrected, the expert said.

NGOs such as Médecins Sans Frontières also raised questions on transparency in licensing, and tech transfer. It also cautioned on the scope for potential confusion in the interpretation of tech transfer provisions in inter- and intra-pandemic time periods.

Others asked on how a treaty could articulate obligations on voluntary licensing and whether tech transfer obligations would apply to other global health agencies such as CEPI, for example.

## TECH TRANSFER HUBS

To prevent inequities in the access to medical products, regional and distributed manufacturing in low and middle income countries is gaining support from a number of different stakeholders in these discussions. The most debated model is WHO's mRNA hub.

A senior WHO official explained the significance of the hub in South Africa. He indicated that generic mRNA vaccine technology is being shared with 15 countries and these spokes in the model will have know-how abilities in the coming months. He also highlighted the many barriers to local manufacturing, especially for biologicals like vaccines. From infrastructure to investments, from workforce to sustainability, from regulatory capacity to local IP regimes, these were some important considerations while thinking about distributed manufacturing, apart from choices on what to produce, and how to deal with questions of acquiring technology.

## THE POOLING OF RIGHTS AS A PROVISION

There are also discussions at incipient stages on expanding the concept of pooling of IP rights taking off from the C-TAP at WHO. Experts believe that governments should consider structurally changing the rules of the game for the future pandemics by expanding mechanisms such as C-TAP for pandemic preparedness in the international treaty.

KEI, for example, has made a case for a Tech-Sharing pool. See [below](#).

*“Article X. Pooling of rights in and access to inventions, data, biologic resources and how-how*

*1. Parties recognize the value of global sharing of rights in and access to inventions, data, biologic resources and know-how, and also the need to provide both mandates and incentives to share. 10 WHA72.8 1(4). 9 WHA72.8, 1(3). 8 WHA72.8 1(2) 7 Declaration of Helsinki (2013), and WHA72.8. 6 WHA72.8 1(1). 5 WHA72.8 2(3); 2(4) and 2(6). 9 of 13*

2. *The WHO shall create a technology sharing pool for rights in and access to inventions, data, biologic resources and know-how, known as the Technology Sharing Pool (TSP).*

#### *Global Public Goods*

*a. One component of the TSP shall be for global licenses, where the rights in inventions, data, biologic resources and know-how are considered royalty free public goods.*

#### *Remunerative licenses*

*b. One component of the TSP shall be for global licenses, where the rights in inventions, data, biologic resources and know-how are licensed to qualified manufacturers subject to reasonable remuneration.*

#### *Share-and-share-alike licenses*

*c. One component of the TSP shall be for an opt-in cross-license of government rights in inventions, data, biologic resources and know-how relevant to pandemic preparedness and response. This component will be referred to as the share-and-share-alike pool. The cross licenses will allow any party that joins the pool to use or have used the rights in a field of use for pandemic preparedness and response, and in a geographic area that is limited to the parties that join the cross licensing pool.*

*To join the share-and-share-alike pool, a government would have to commit to a standard cross licensing agreement in a field relating to pandemic preparedness and response for all federal level R&D funding.*

*3. Parties agree to levy a fee on all products that are not licensed to TSP, and use that revenue solely to compensate developers of products that are licensed to the TSP. The amount of the levy shall be set and periodically modified by the Governing Body.]*

## **LINKING TECH TRANSFER TO PRODUCTION CAPACITY**

During the intersessionals, senior WHO officials also pointed out that much of the production capacity in the world was not fully utilized to solve the problem during this pandemic, and that was a function of often corporate decisions, but also by some countries.

At the peak of acute access challenges faced by developing countries, experts had repeatedly called for linking technology transfer to production capacity. Many believe that the access to technology has been one of the central failures in the COVID-19 response.

*At a session organized by WHO exclusively to discuss IP issues, at an [informal focused consultation](#), in October last year, Carlos Correa from the South Centre said, “There is an absolute need to address the access to technology and intellectual property in the Treaty; otherwise the Treaty would not provide a real solutions to the problems as we have seen.”*

Key developed countries including Switzerland, Japan, UK, the EU, have pressed for evidence on IP as a barrier to access. Correa drew attention to numerous litigations between big vaccine manufacturers. “It is quite clear that manufacturing vaccines raises the issue of patent protection and patent litigation and therefore, there is need to address them. There is a need to have concrete provisions on this. I would say that the Pandemic Treaty gives a major opportunity to overcome the major fragmentation of international law system,” Correa said during the session last year.

Padmashree Gehl Sampath, who also spoke at the October session that was webcast, said, “One of the key things that we can say confidently after the pandemic, which we couldn’t say before is that the question the intellectual property is very closely linked not just to innovation but also to supply and production.”

Sampath is also Chair of the C-TAP Secretariat. She argued that there is a tendency to view technology transfer as something that is end-product related and needs to be shared by company or institute that invested in R&D. And called for a broader view that links to production, innovation and supply.

“There are undeniable links between innovation choices, production capacities and access. New vaccine technology and drug technologies that we have today, like the DNA and mRNA platforms, they provide a basis for geopolitic or more oligopolistic production capacity globally. It would continue to impact global demand for years if not decades to come. So, options like compulsory licenses that we have gone to always and relied on are not sufficient. What we really need is a broader focus on initiatives for technology transfer with a strong focus on not just licensing the end products but looking at blocks of technologies at various stages of development because it helps to create a level playing field for all new entrants who are not incumbent companies, not just from the developing world but also from the developed world. Thus, in such a context the role of technology sharing is to level the field, to increase the competition, to increase innovation and then also increase access to medicine.”

The link between scarcity and concentration of manufacturing was also pointed out. Citing data on export bans and stock-piling during the pandemic, Sampath said, “Those countries that didn’t have production capacity didn’t have bans, they didn’t stock pile but those countries that have production capacity were the ones that had export bans and stock piled which simply means that the only way to solve this is to set up the diversified production capacity so that different regions in the world can actually have that production capacity and we don’t have illusion of limited capacity that leads to stock piling of life-saving medicines, therapeutics and diagnosis in the time of need.”

## **THE MEDICAL COUNTERMEASURES PLATFORM**

Given the evidence of the limitations of existing approaches during COVID-19, many stakeholders hope that the international community will take the right lessons forward while conceptualizing and putting in place mechanisms for the future.

[As we reported last month](#), WHO and partners are working towards a new medical countermeasures platform. A prototype of this mechanism is now being put together. (See the [description of a job announcement](#) to lead on the work around the MCMs put out by WHO.)

While this is being referred to as an interim mechanism, there are expectations that this will tie into the on-going negotiations at the INB and work of the Working Group on the amendments to the IHR. (“This interim platform could be activated in the near term, if needed, but then adjusted, based on the outcomes of the INB and WGIHR negotiations,” according to FAQs on the platform, seen by Geneva Health Files).

The process led by WHO, has powerful backers with high-level support from G7 and the G20.

It appears this process has divided civil society actors – while some believe that lessons of the ACT Accelerator can be taken to build a new platform, while others calling for a clean break from the past.

Focusing on stockpiling will not address the unpredictable needs that a health emergency brings. Any mechanism must tackle the questions on IP, and even pathogens access and benefits-sharing, experts say.

*Nishant Sirohi contributed to this article.*