World Health Assembly Resolution On COVID-19 Response: The Stark Choices Faced In A Polarized World Of Global Health

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The World Health Assembly in Geneva, Switzerland.

As the 73rd World Health Assembly approaches, the European Union-sponsored draft resolution on the COVID-19 response is gathering steam and storm as it rolls closer to the planned opening of the Assembly on 18 May – with far less clarity about how it might actually hit the shores of the public debate.

The **resolution** aims to show unity in the face of a global pandemic – ensuring more equitable access for existing diagnostics and medical equipment as well as potential treatments. But hidden in the layers of diplomatic doublespeak are also multiple nuances, as well as minefields, that could befoul the whole negotiations.

Strikingly, the resolution also aims to address obvious weaknesses in the international pandemic response frameworks, and address criticism of the World Health Organization's own response, by calling for an "independent evaluation…to review lessons learnt" about the WHO-coordinated response, as well as the "effectiveness" of mechanisms at its disposal – namely the 2005 International Health Regulations.

The proposal for independent evaluation apparently has wide support. Although it remains to be seen if such a review can be undertaken in a way that satisfies very different blocs and political agendas – including the United States, which has

But some observers, including the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), have said that such an investigation should be postponed until after the pandemic wanes.

"When we emerge from this global crisis, it will be important to look back and build upon the lessons learned from multi-stakeholder collaboration around COVID-19 in order to strengthen future pandemic preparedness and truly enhance global health security," Thomas Cueni, IFPMA Director-General told *Health Policy Watch.* "But for now, the most important thing to do is to knuckle down and tackle what is potentially one of the biggest public health, social and economic crisis we have faced in 100 years.

"Coordinated, inclusive, and multi-stakeholder action is the only possible solution to mitigate the impact of this unprecedented global health emergency. Multilateral organizations such as the World Health Organization (WHO) have an important role to play in these global efforts and in supporting the most vulnerable populations. International cooperation is critical to maintain global supply chains, to avoid shortages and to ensure effective surveillance mechanisms."

In terms of the mechanics of response, the key debate here for medicines access advocates is whether the resolution can really ensure more equitable distribution of COVID-19 treatments. For that to happen, they argue that there needs to be an explicit reference to existing "TRIPS flexibilities" – the legal World Trade Organization framework that allows countries to legally override patent laws when a clear national health interest is at stake. Right now, the text makes only general reference to this: "using fully the provisions of international legal treaties."

However, there could be new blocs of allies and opponents forming around the access issue – which traditionally divided roughly along lines of global north and south.

Recently, for instance, the United States moved to issue an emergency use authorization for remdesivir, the drug produced by Gilead Sciences that has shown some initial efficacy against the SARS-CoV-2 virus that causes COVID-19. That has led to worries in European circles that an "America-first" approach could cut off access to the drug – including in other high-income European countries that have also been at the virus epidemic. As for the ins- and outs of the debate, *Health Policy Watch* interviewed half a dozen observers of the negotiations; to see what else they had to say.

Explicit Reference To IP "Flexibilities" In WHA Draft Resolution: A Hot Topic For Debate

The May 4 draft resolution has called for "equitable access to and fair distribution to all countries" to COVID-19 technologies, "including through using fully the provisions of international treaties…. Required in the response to the COVID-19 pandemic."

However, these drafts, and even alternative language so far proposed, makes no specific reference to the foundational World Trade Organization treaty and agreements enabling intellectual property barriers to be temporarily lifted under emergency conditions. The **Trade-Related Aspects of Intellectual Property Rights** (TRIPS) saw IP flexibilities for public health needs further affirmed by the 2001 **Doha Declaration** on the TRIPS Agreement and Public Health.

Lack of reference to TRIPS flexibilities is "strange" because "it ignores a great deal of history and the global efforts that were needed to facilitate equitable access to health technologies, products and services" like vaccines or PPE, said Frederick Abbott, Professor of International Law at Florida State University.

The draft resolution's silence is a "double standard" given that some EU members have already taken steps to make use of TRIPS flexibilities, said Legal Advisor for the **Third World Network** (TWN) K.M Gopakumar.

He referred to recent instances when the European Commission reportedly pressured Roche Pharmaceuticals to disclose the critical recipe for a reagent in a patented diagnostic. Germany has meanwhile amended its patent law to fast-track the issuing of compulsory licenses to override patents on health products, should there be a need. **Other countries** to have taken similar steps include Israel, Canada, Indonesia, Chile, Colombia and Ecuador.

K.M. Gopakumar, Legal Advisor for the Third World Network (TWN).

The silence of the EU-sponsored resolution could nonetheless be explained by the region's strong pharma industry base, he added.

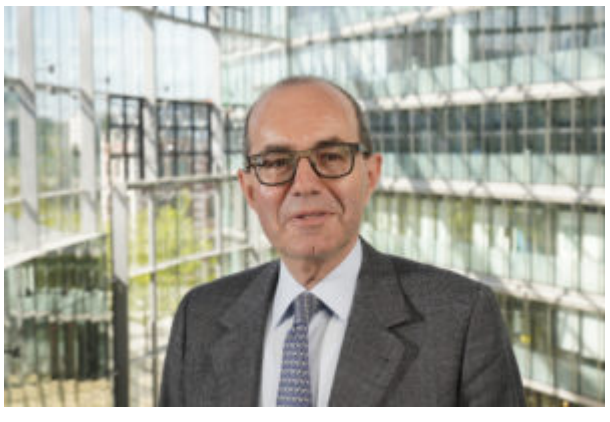
Some advocates have pointed their finger squarely at the Member State diplomats engaged in the WHA negotiations as failing to pick up the gauntlet – despite the fact that the international community affirmed the use of such measures through the WTO Doha agreement nearly two decades ago.

"Member state diplomats who are negotiating at the WHA need to step up to the plate," said Thiru Balasubramaniam, Knowledge Ecology International's Geneva representative.

"19 years later after Doha, it is disheartening that WHO delegates tasked with the mandate to protect public health cannot muster the courage to make explicit references [in the draft resolution] to TRIPS public health safeguards amidst a pandemic."

Even so, negotiations are still ongoing – and a reference to TRIPS may yet appear in later drafts, said Jaume Vidal, Senior Policy Advisor of Health Action International.

Intellectual Property Rights May Not Be The Issue – Compulsory Licences Could Be Innovation Barrier



Thomas Cueni, director general of the IFPMA

There are also concerns, however, that opening the floodgates to a practice of very widespread compulsory licensing could upend the status quo of patent-driven R&D, at a critical moment when private investment in research is needed now, more than ever – alongside the public sector grants and donations.

In an interview with *Health Policy Watch*, Francis Gurry, Director General of The World Intellectual Property Organization (WIPO) pointedly noted that **patent rights is not the main barrier** accessing treatments right now; in fact the main barrier is the lack of treatments, for which private sector investment is important.

Those sentiments are echoed by IFPMA's Cueni, who has been highly supportive of recent UN and global moves to expand public funding for drug development and ensure broad access; "IP is not a hindrance to developing COVID-19 treatments or vaccines, indeed quite the opposite," Cueni said. "The main policy challenge is to encourage the innovation that may lead to COVID-19 vaccines, treatments and cures, as well as innovation that assists in managing the coronavirus crisis."

Added Cueni, "There is no evidence that IP has been or will be an impediment to the research, development and testing of potential COVID-19 treatments and vaccines or to the many research partnerships underway between companies and institutions around the world.

"We can only overcome this through a coordinated, inclusive, and multi-stakeholder response," he added. Referring to a recent UN General Assembly resolution on COVID-19 response, which received broad industry blessing, he said, "We hope WHO member states will be able to build on this momentum and approve a truly inclusive text that recognizes that the expertise of the private sector is central in fighting this pandemic."

Lifting intellectual property protections could have long-term repercussions on innovation, warns Duane Schulthess, a health consultant and Managing Director of the Belgium-based consultancy firm, Vital Transformation.

Compulsory licenses will make it "hugely expensive and risky to produce at scale for any commercial enterprise," said Shutlthess, who works with both public and private sectors in Europe.

Managing Director of Vital Transformation, Duane Schulthess

"As an investor and consultant to many international biotech firms and biopharma supporting governments, I think that a compulsory license is a REALLY bad idea in this case."

Issuing compulsory licenses for new therapies that are typically more costly to development, such as vaccines or monoclonal antibody treatments "may seem like a good idea in the short-term", but would become "a huge barrier against anyone taking on risk for vaccine or monoclonal antibody development."

Given the high safety standards required for vaccines, as well as debate over the actual fatality rate for COVID-19, any company willing to invest "multiples of billions of Euros" to develop and manufacture a vaccine or monoclonal antidote at scale will be "extremely concerned."

"The up-front costs of development will be astronomical due to the need to simultaneously invest in manufacturing capacity", as well as the need for high safety standards, he said.

Voluntary Patent Pools Offer A Third Way – But Some Not So Sure It will Work

There has been widespread support by countries, as well as by WHO, for a voluntary "patent pool" – whereby industry would offer licenses to other countries to manufacture their products.

This would build upon the successful model of the Medicines Patents Pool, which has succeeded in bringing affordable treatments for HIV/AIDS and Hepatitis C to billions in Africa and elsewhere.

Indeed, the most recent drafts of the EU resolution call for member states to "work collaboratively at all levels, including through existing mechanisms, for voluntary pooling of patents, and licensing of medicines and vaccines to facilitate equitable and affordable access (OP 7.2)."

But not everyone is convinced such schemes will really work for the challenges posed by COVID-19.

Michelle Childs, Head of Policy Advocacy for Drugs for Neglected Diseases Initiative (DNDI)

"We need to hope for the best and prepare for the worst," said Head of Policy Advocacy for Drugs for Neglected Diseases Initiative (DNDi) Michelle Childs.

"Everyone would prefer if there were no intellectual property barriers and for innovators to waive their rights through a voluntary patent pool, but we need to have all tools in our toolbox just in case that doesn't happen. Countries should have all options available to them, such as compulsory licensing."

Said Vidal, "the patent pool is a unique mechanism to operationalise voluntary licensing. Within its constraints, it is an effective instrument to improve access conditions. It is not, and was not, designed to be a remedy for the anticompetitive practices of patent holders, nor can it compensate the excesses of monopolies worldwide. Support for the Medicines Patent Pool does not invalidate the need to promote a widespread and intensive use of Compulsory Licensing, beyond COVID-19."

Already during the COVID-19 pandemic, the world has observed some countries halting export of certain drugs or personal protective equipment (PPE) so as to insure domestic supplies, other observers note.

The irony is that while past outbreaks or pandemics have seen northern countries pitted against the south, here the fault lines may shape up around the Atlantic – between the United States and European countries nervous that they might not

"We need to deal with equitable access issues in advance – when push comes to shove, people end up panicking, and we've seen countries hoard things like PPE," said one source.

Prioritizing Access – Will Health Workers, Older People & Those With Pre-existing Conditions Really Come First?

Iranian healthcare workers in personal protective equipment

Presuming that some international mechanism is created, voluntary or compulsory, to ensure widespread access to new treatments or vaccines – agreement on what groups might be prioritized will be another minefield in any process. Most experts would agree that in the case of COVID-19, healthcare workers, older people and those with pre-existing conditions are those most in need of any forthcoming treatments and vaccines.

But while the preamble (PP11) of the draft resolution emphasizes the need to protect key populations like 'people with pre-existing conditions…older persons and healthcare professionals," there is no explicit reference to those groups as priorities for being the first to receive new drugs or interventions in the operative sections of the draft.

Rather, there is a general call for governments to: "Put in place…measures across government sectors against COVID-19; ensuring respect for human rights and fundamental freedoms, and paying particular attention to the needs of vulnerable groups and people in vulnerable situations; promoting social cohesion, taking necessary measures to ensure social protection and prevent discrimination and marginalization."

Even that language may somehow become tied up in traditional disputes over a) sanctions, such as those currently applied by the US against Iran and b) language that refers to **sexual and reproductive rights** in the healthcare context – something that has been hotly opposed by the US administration in recent years due to fears that it could be somehow interpreted as legitimizing abortion.

And…. Even if a Resolution is Passed – Enforcement Will Be A Challenge

A United Nations Solidarity Flight lands in Brazzaville, Republic of the Congo with PPE and diagnostics supplies

Even if widespread access to treatment by the groups most in need was enshrined in the final WHA resolution – enforcing such provisions would be another matter altogether.

International agreements are critical, but they are insufficient if they are not enforced, sources underlined to *Health Policy Watch*.

"It's not just about intellectual property… we need international agreements about how drugs and other technologies will be used," said the source.

"We've seen very good statements about what countries want to achieve but they need to follow that…They're trying to outsource some of [access] questions to initiatives like WHO's Access to COVID-19 Tools (ACT) Accelerator (ACT). There are no easy answers…

"We cannot leave this to the [international] agencies. Countries have to do this work themselves and follow what they have publicly committed to do."

Equitable access will also depend on a range of other factors, as well, including scaling up manufacturing capabilities and securing supply mechanisms within health systems, said Vidal.

An Investigation of The WHO's Handling of COVID-19 Is Important – But Not Right Now

Regarding the independent examination of investigation of COVID-19 management, there appears to be agreement across the classic fault lines of industry, academia and civil society that the timing is not right for this now.

Says Abbott: "Conducting a review as soon as possible is likely to be a drain on internal WHO resources that are vitally needed to coordinate the global response. There are external political pressures underlying the demand for immediate

Frederick Abbott, Professor of International Law at Florida State University.

It will also be vital to assure the objective integrity of the review process and not to succumb to external politics that have pressured the review to be undertaken as soon as possible, said Abott.

A review of the WHO's efforts will be important *after* we emerge from this global crisis, underlines Cueni, which has also publicly backed the WHO co-sponsored Access to Covid-19 Tools Accelerator that just raised nearly **US$ 7.4 billion** this week for drug research, manufacture and distribution. However, the "most important thing to do" right know is is to "knuckle down and tackle" the crisis.

While accountability is good for transparency and governance within international organisations, the WHO 'cannot be a chip in a power game' between certain Member States, says Vidal. And he adds, suggestively, that WHO is not the only entity that should be examined:

"When we scrutinise WHO handling of the pandemic we should also look into the actions (or indeed inaction) of some Member States, experts and political figures."

Senior Policy Advisor of Health Action International Jaume Vidal

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