Webinar Summaries

Please note that the statistics shared were all relevant as of the time of the webinar as reported by the panellists and do not necessarily reflect the current situation. The SingHealth Duke-NUS Global Health Institute (SDGHI) does not bear responsibility for their accuracy.

WEBINAR 1

Challenges to equitable access: a look at legal and equity considerations related to ensuring access to essential vaccines and therapeutics in low and middle income countries (LMICs)

MS LEENA MENGHANEY, Regional Head, South Asia Access Campaign, Médecins Sans Frontières (MSF)
DR CHRIS VINDURAMPULLE, Senior Associate, Patent and Trade Mark Attorney, K&L Gates
PROFESSOR MARK FINDLAY, Director, Centre for AI and Data Governance, Singapore Management University
MS AMINA MAHMOOD, Deputy Director, Programme Development & Business Administration, SingHealth Duke-NUS Global Health Institute (SDGHI) (moderator)

SDGHI hosted the first webinar in the series on 2 December 2020 with three experienced lawyers from around the world leading the discussion. The webinar explored key issues related to legal factors and examined the role of major international agreements and Intellectual Property (IP) rights on equitable access to essential medications, vaccines and healthcare products. The three panellists shared a common background in law but approached the topic from different perspectives, offering a rich and dynamic discussion.

Ms Leena Menghaney opened the webinar and presented her insights on some of the main legal issues, The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver proposal and the need for IP rights reform. Leena also detailed the problems faced specifically by organisations like MSF as a treatment provider. Leena offered a strong and interesting 'treatment activist' perspective throughout the webinar.

Leena explained the details of the TRIPS waiver proposed by South Africa and India. "We think a global automatic expedited solution which allows a waiver of IP obligations is very critical at this point to unlock the capacity of the developing world, allowing scale up of lifesaving essential tools for COVID-19", said Leena. She also outlined some of the policies and regulations in the past that were used to obstruct the application of compulsory licensing and highlighted the irony in using compulsory licensing as an argument for not considering the TRIPS waiver proposal.

> *"These problems are not independent and unrelated but are a result of the fundamental nature of the IP system and pharmaceutical market"*
>
> *– Leena Menghaney*

Leena underlined the need to break the myth that protection of IP rights, in order to re-coup Research and Development (R&D) costs, is what is needed to drive innovation. She pointed out that most often the riskiest aspects of R&D are subsidised by public funds. When a large part of R&D are collectively funded by tax payers then it must not be under proprietary control, said Leena. She stressed that the international IP structure is particularly constraining in the context of the current COVID-19 pandemic.

Dr Chris Vindurampulle took one step back to provide an overview of IP rights and patents, enabling the audience to make connections between IP rights, patents, vaccines and the issue of equitable access. Chris helped to answer a fundamental question – Why do we have patents? He stated that patents exist to encourage investment in R&D and drive innovation, while at the same time allowing the information necessary to use an invention to be publicly shared.

Chris shared his insights on the big question: "Will patents prevent access?"

- A patent system per se should not prevent access – patents are a tool to protect products and should be used for social good
- Pre-existing economic and social problems contribute to inequality that may impact equitable distribution of vaccines

- The TRIPS/Doha agreement provides a framework for protection and recognition of IP rights and includes mechanisms to assist poorer countries through the use of compulsory licenses
- Other options may be used such as - voluntary licensing, pledges of non-enforcement, etc.

"It is hard to dismiss the value in having a monopoly right, it is a two-edged sword and no single solution"

-Chris Vindurampulle

Chris encouraged the audience to use the insights gained from this webinar as food for thought and to utilise the information presented to ask important questions to both themselves and to relevant higher authorities. He stressed the point that this is a complex problem with competing interests and no single solution.

Ms Amina Mahmood asked the speakers if the there is scope for the patent system and patent timelines to be reformed or adjusted in the context of COVID-19. Leena highlighted that countries are not asking to scrap the patent system but to bring reform and accountability. Better patent examination, better implementation of compulsory licencing and the right to challenge poor quality patents were suggested as key aspects to improve accountability.

Offering a different perspective, Chris mentioned that the patent system and monopoly rights have their own place. However, they may not provide a complete solution and governments need to still devise strategies to deliver drugs and vaccines to people in need through other mechanisms such as compulsory licencing.

Professor Mark Findlay highlighted how fundamentally *patents* do not prevent access but instead *price* prevents access. He shared his insights on what he calls the "Vaccine Olympics" where vaccines are promoted as a global solution to combatting the pandemic, but in reality it is a race amongst nations to secure the vaccine for their own populations. He further explained how various externalities impact how vaccines are accessed and regulated; he stressed that it is not vaccines per se but rather vaccination that will help curb the global spread of the virus. He further drew attention to four key questions that summarised the current complexities:

- **Vaccines for what?** For health and safety or more to reopen economies, global travel, trade, getting back to 'normal'
- **Vaccines for who?** – The main problematic question in terms of access and distribution challenges
- **Vaccines for when?** – The rush to develop vaccines might increase safety concerns and tighten regulatory mechanisms for approval
- **And vaccines for where?** – Should not be limited to only benefiting the North world

Mark ended with two important points addressed to two different groups. He posed the first question to a general audience – "Should protection of the world from dangers to health and safety depend on politics and wealth?" In his second point he specifically targeted lawyers to think about the concept of law as a community resource as well as something that can support the wealth of the world.

"Push it forward and make it equal or hold it back make it pricey, interesting questions that regulators will face."

- Mark Findlay

On the whole, this webinar presented three distinct and strong voices, enabling the audience to rethink the issue of access to COVID-19 health products against the backdrop of legal considerations. The complete recording of webinar 1 is available on SDGHI's YouTube channel, please click the link to access it: https://www.youtube.com/watch?v=hPZgs3XKotI

WEBINAR 2

Operational challenges and the ground realities of enabling access to essential vaccines and therapeutics in the ASEAN region

MS SUSAN BROWN, Director of Public Policy Engagement, Gavi, the Vaccine Alliance (Gavi)
MR LUC DEBRUYNE, Former CEO, Global Vaccines, GSK Strategy Advisor to CEO, Coalition for Epidemic Preparedness Innovations (CEPI)
ASSOCIATE PROFESSOR KRISHNA UDAYAKUMAR, Founding Director, Duke Global Health Innovation Center and Associate Professor, Global Health and Medicine, Duke University
ASSOCIATE PROFESSOR REN EE CHEE, Senior Principal Investigator, Singapore Immunology Network and Associate Professor, Department of Microbiology, National University of Singapore
DR NAKORN PREMSRI, Director, National Vaccine Institute (NVI), Thailand
DR ERLINA BURHAN, Department of Pulmonology and Respiratory Medicine Faculty of Medicine, University of Indonesia
PROFESSOR MICHAEL MERSON, Founding Director, SingHealth Duke-NUS Global Health Institute, Wolfgang Joklik Professor of Global Health, Duke University (moderator)

SDGHI hosted its second webinar in the series on 9 December 2020. The panellists who participated in the webinar represented a wide range of organisations from many different parts of the world. The main topic of discussion was the challenges of ensuring equitable access to vaccines. The session was sectioned into two parts with speakers from international organisations providing a global perspective, followed by speakers from the ASEAN region providing country level responses to vaccine access.

Ms Susan Brown opened this webinar by presenting the COVAX facility and pointed out the importance of centring the dialogue on the ASEAN region. Susan mentioned the collaborative efforts of Gavi, CEPI and The World Health Organization (WHO) in forming a core group with other partners to design and create the largest operationalisation of vaccines in the current time frame. Susan underlined the vision of COVAX is to end the acute phase of the pandemic by December 2021 - with approximately 2 billion doses required to meet this goal.

> *"We have seen that it has been more and more difficult for global solidarity efforts in the last decade or so. It has been tricky in the multilateral space but this initiative has a huge amount of goodwill and recognition that it is a difficult task but it is in everybody's interest."*
>
> - *Susan Brown*

Susan emphasised that COVAX is working towards ensuring that the cost of the vaccine is not a barrier to access. She stated that Gavi is also working with countries to ensure access for their most vulnerable sub-populations within each country and tailor their vaccine response and efforts in collaboration with The United Nations Children's Fund (UNICEF), WHO and other civil society organisations. She also spoke about the impact of COVID-19 on routine immunisations and highlighted the need to work on catch up campaigns and tackle missed routine vaccinations in parallel, to avoid any other disease outbreak amidst the pandemic.

Mr Luc Debruyne focused his presentation on the need for better pandemic preparedness and delved further into Susan's point on how the next pandemic is inevitable. Luc presented the difference between a 'vaccine' and 'vaccination', underlining a key message on how a vaccine is only a solution when a population has been vaccinated.

Luc proposed three key suggestions for better preparedness:

- Engaging key national, regional and global organisations for better pandemic preparedness
- Collaborating with national research institutes for improved science and technology
- Bridging what we have with what we need through systematic capacity building

"For the scale that is required across the world, we need to allow for the first half of 2021 to get things right."
- *Luc Debruyne*

Luc offered an interesting perspective on important factors to consider or what he calls 'the 4 buckets' to activate for better pandemic preparedness: 1) science, 2) sustainable financing, 3) political leadership and 4) citizen engagement. He emphasised that any national, regional or global response must consider and activate all of these categories for effective pandemic response and preparedness.

Associate Professor Krishna Udayakumar provided detailed insights on the Launch and Scale Speedometer initiative. He described the objective of the initiative to collect and analyse data on the development, testing and scale of COVID-19 innovations - including vaccines, therapeutics and other interventions - with a global access and equity lens. Specific to vaccines, the launch and scale speedometer analyses global data on advance purchase commitments and manufacturing deals, as well as country-level distribution plans for COVID-19 vaccine candidates, in order to better understand allocation and distribution challenges.

Krishna recognised the importance of and enormous effort by the COVAX facility to address issues of equitable access; he pointed out the need for continued strengthening of such multilateral platforms in terms of governance and financing. From the perspective of a LMIC ASEAN country, a single multilateral platform might not be the answer. LMICs, and even some high income countries (HICs), which are largely relying only on their supply of vaccines through the COVAX facility are not going to have enough vaccines to effectively cover their populations for the next couple of years. This calls for heightened regional cooperation and capacity-building to ensure wider and more equitable access.

"I do think regional cooperation is a really important aspect of creating strength and solidarity combined with both supply and demand side effectiveness for COVID-19."
- *Dr Krishna Udayakumar*

"For ASEAN to move ahead on the pandemic vaccine issue, it would be good to establish a coordinated roadmap for the next 2-3 years. This will help to strategise a realistic schedule to cover vaccinating 670 million people."
- *Dr Ren Ee Chee*

In the second part of the webinar, Professor Michael Merson directed specific questions to the three panellists from the ASEAN region. Presenting a regional perspective, Dr Ren Ee Chee described four major roadblocks to equitable access in the ASEAN region:

- **Timing**: Amidst the race for COVID-19 vaccines there is a challenge that not all countries in ASEAN will secure access at the same time
- **Volume**: Across ASEAN there are 670 million people (twice that of USA) to be vaccinated
- **Quality of vaccines**: With many different vaccines and candidate vaccines in the portfolio, their safety and efficacy are key concerns
- **Price of vaccines:** Prices of vaccines may not be uniform across the region and high prices may act as barrier to access

Dr Nakorn Premsri shared information on Thailand's vaccine production and distribution plans. Siam Bioscience, a Bangkok based pharmaceutical company, is re-purposing its facility to manufacture the Oxford-AstraZeneca vaccine. Thailand is preparing to manufacture 200 million doses per year. This partnership between the Ministry of Health, Thailand, Siam Bioscience, Astra Zeneca and Oxford University will produce vaccines for both Thailand and the rest of ASEAN. Out of the 200 million doses per year, Thailand would require 24 million, with the remainder for ASEAN. He further stated the importance of ASEAN vaccine security and self-reliance. He also shared that the Thai government has provided USD20 million to support Siam Bioscience to increase their manufacturing capacity and enable technology transfer through the Oxford-AstraZeneca collaboration.

"I think this collaboration will be a good start and we can work more on vaccine supply with the region for our ASEAN member states."

- *Dr Nakorn Premsri*

Dr Erlina Burhan shared her concerns on the deteriorating COVID-19 situation in Indonesia, with 6000-8000 cases per day. She provided a ground reality perspective by taking the speakers and audience through all the serious concerns she had for her country. She described the supply side impact on the health system that resulted from an overflow of patients in hospitals. She shared her worries on the vaccine safety, drawing particular attention to the lack of timely information with respect to clinical trials data. Erlina also raised a point on the religious sentiments of the population and the need for a halal vaccine. On a final note, Erlina stated that research efforts for Indonesia's own in-country vaccine development is planned to be completed by 2022.

"When you make a consideration for vaccine distribution is the country with very high incidence is included in one of your priorities or only those countries that can pay in advance?"
– asks Dr Erlina Burhan

In closing, webinar 2 offered an interesting combination of global and regional perspectives on the current emerging operational challenges to vaccine access. The discussion explored ASEAN's unique characteristics and recent developments in managing COVID-19 and preparing for vaccine distribution within the context of the global efforts to tackle the pandemic. To watch the complete recording of the webinar on SDGHI's YouTube channel, please click the link below to access it:
https://www.youtube.com/watch?v=dJALIFwAi24

Unanswered questions from Webinar 1

Please find below a series of questions submitted for the Webinar 1 speakers which have been answered post-hoc due to event time constraints.

If pharma companies delay registering drugs in developing countries, does that mean that other people could copy the drug and bring it to the developing country market (and even register it there) during the time of delay?

Not normally. Patent rights include the right to manufacture and export. However, compulsory licensing could provide an opportunity for third parties to manufacture and export to poor countries.

- Answered by Dr Vindurampulle

Can one patent mRNA vaccine constructs which are naturally occurring?

A vaccine construct implies human intervention, so in theory there would not be one that exists in nature as such. To be patentable, a claimed vaccine must meet patentability hurdles such as novelty and inventiveness. A known construct would not be new.

- Answered by Dr Vindurampulle

For Mark's question of why equity should depend on philanthropy, and not a global consensus to realise that equity is better for global health: From any one nation-state's POV, is equitable access really better? It seems to me that it might actually be better for a country (in terms of long-term recovery) to vaccinate its own people first. On a larger scale, North World countries (between which there is much travel) might deem it better to vaccinate themselves to get some level of herd immunity first, as opposed to having a diluted level of immunity in the larger world.

The pandemic is a global problem and its control requires a global solution. For countries where they have not the market attractiveness to be seen by vaccine distributors as a profitable first option there will be difficulties of access. For those states without the resources for preferential stockpiles, there will be access problems. In countries where domestic vaccine development is not of sufficient capacity, there will be access problems. The WHO is encouraging global vaccination as the best approach to control. For those countries that are disadvantaged they will have to rely on the assistance of richer and more privileged nations (and MNC's and philanthropic organisations) to create a global fund for widespread vaccination. This needs to be happening at least in parallel with vaccine roll-out in privileged nation states, otherwise the protection of immunisation will be sectoral and as such the pandemic will not be under control (even if a small number of people may have protection). The idea of immunising citizens first reflects the nation-state control approaches which have so far stood in the way of a global response. While the political imperatives for this approach are clear, these do not address the essential priority of global COVID 19 eradication, rather than privileged and sectoral immunisation.

- Answered by Professor Findlay

Can granting non-exclusive licences provide innovation while ensuring competition to drive prices down?

I think the intention was to use the word 'access' instead of 'innovation'. This is a difficult question to answer and depends on whether there is voluntary licensing or compulsory licensing or crown use. A licence is a negotiated agreement, where the licensor receives a royalty fee. A licensor will typically avoid licensing if it introduces competition. However, if circumstances permitted compulsory licensing or crown use, there may be an opportunity to reduce the ultimate cost to the consumer/purchaser. Government subsidy may further reduce cost.

- Answered by Dr Vindurampulle

FURTHER READINGS AND RESOURCES

- NY times COVID-19 tracker: https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html?auth=login-google
- Moderna patents: https://www.modernatx.com/patents
- Oxfam report: https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19
- COVID-19 vaccine patents: https://pursuit.unimelb.edu.au/articles/why-we-should-grant-patents-on-covid-19-vaccines
- COVID-19 drugs and vaccines patents:https://theconversation.com/covid-19-drug-and-vaccine-patents-are-putting-profit-before-people-149270
- COVID-19 related resources from Centre for AI data and Governance, Singapore Management University: https://caidg.smu.edu.sg/covid-resources?category=All
- WTO Waiver: COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020_LM.pdf
- TRIPS waiver myths and realities: MSF-AC-COVID-IP-TRIPSWaiverMythsRealities-Dec2020 (1).pdf
- IP Basics: K&L Gates - IP Basics Brochure_CV.pdf
- HICs vs LMICs: https://www.theguardian.com/society/2020/dec/09/nine-out-of-10-in-poor-nations-to-miss-out-on-inoculation-as-west-buys-up-covid-vaccines
- TRIPS waiver myths and realities: MSF-AC-COVID-IP-TRIPSWaiverMythsRealities-Dec2020 (1).pdf
- A Moment of Truth in the Pandemic – Seth Berkley, Richard Hatchett, Soumya Swaminathan: https://www.project-syndicate.org/commentary/covax-vaccine-global-access-binding-commitments-by-seth-berkley-et-al-2020-09?barrier=accesspaylog
- COVAX Explained: https://www.gavi.org/vaccineswork/covax-explained
- The Gavi COVAX AMC Explained: https://www.gavi.org/vaccineswork/gavi-covax-amc-explained
- Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility – Final working version – 9 September 2020: https://www.gavi.org/sites/default/files/covid/covax/who-covid19-vaccine-allocation-final-working-version-9sept.pdf
- COVAX AMC application guidance: https://www.gavi.org/sites/default/files/covid/covax/covax-amc/COVAX-AMC-APPLICATION-GUIDANCE.pdf
- Launch and Scale speedometer: https://launchandscalefaster.org/COVID-19