

C-19 CONVERSATIONS' VACCINE EQUITY AND ACCESS

IMAGE CREDITS:
PEOPLE'S VACCINE, FREE THE VACCINE, MSF, DAILY MAVERICK





C-19 Inequality and impact

- COVID-19 and lock-down measures have severe impact on global health and economic systems
 - Africa: More than 2.3 million cases, 53 000 deaths
 - SA: On-going second wave exposing fault lines of our **2-tiered** health system; 2.7% fatality rate and collapse of health systems in some provinces
- Global state relief insufficient
 - Job losses, hunger crisis and ill-health as well as severe interruption of health prevention and treatment services (esp. SRHR, HIV/AIDS, TB and harm reduction)
- Vulnerable groups and communities
 - Disproportionate socio-economic impact esp. for women, and workers not ordinarily covered by worker protection systems due to criminalization of their occupation/work
- So far, no widespread treatment options but vaccine options now possible hence focus is on vaccines, for now
 - Accelerated and unprecedented vaccine investment and research for Covid-19 since January 2020
 - Over 200 candidates (38/Ph1; 17/Ph 2; 12/Ph 3)
 - High efficacy of vaccine needed for herd immunity and this means we need high vaccination coverage
 - EUA: last week UK, now US, and Russia, China and Cuba
 - Alongside, anti-vaccine movement spreading ...

The People's Vaccine

 Everyone, everywhere, who needs it, must get a safe and effective vaccine Peoples Vaccine - http://peoplesvaccine.org/

COVID-19 diagnostic tools, treatments, and vaccines must be available to everyone everywhere, free at the point-of-delivery.

UAEM – Free the Vaccine
https://freethevaccine.org/

Ordinarily - Medicine System Pathway

- Investment
- Research
- Patent
- Regulatory
- Suppliers
- Delivery
- Access

*With Covid-19 - compressed

Understanding IP



- HJI Podcast ACCESS: Episode 1 Discusses Intellectual Property (IP) and focuses on Patents https://www.volume.africa/access
- What is IP?
 - Refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce
 - IP is protected through **patents, copyright and trademarks**, which enable people to earn recognition or financial benefit from what they invent or create, to reward true innovation
 - A patent is an exclusive right granted for an invention and 'provides the patent owner with the right to decide how or whether the invention can be used by others. In exchange for this right, the patent owner makes technical information about the invention publicly available in the published patent document' (WIPO)
 - Trade secrets are IP rights on confidential information which may be sold or licensed. The unauthorized acquisition, use or disclosure of such secret information in a manner contrary to honest commercial practices by others is regarded as an unfair practice and a violation of the trade secret protection
 - Copyright is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings

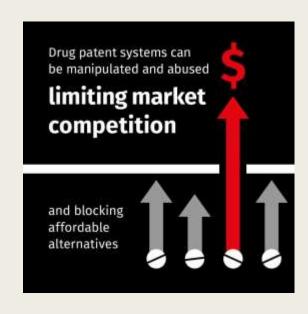
TRIPS as part of the WTO Rules

- The Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') sets the 'standards' for intellectual property protection in the world today, including patents, which governs medicines
 - 1 January 1995
 - Binding on all members of the World Trade Organization (WTO)
 - Member states of the WTO (150 + countries) agree to certain common standards in the way they enact and implement their patent laws
 - Patents be given for a minimum of 20 years; given both for products and processes; and that pharmaceutical test data be protected against 'unfair commercial use'
 - What 'deserves' to be patented is left for countries to determine
 - Implementation of the TRIPS Agreement's intellectual property standards limits competition and local manufacturing, affecting access to medicines
- The pressure to enact or implement even tougher or more restrictive measures and laws are known as 'TRIPS plus' provisions and bi-lateral trade pressure often influences countries adopting such negative measures
- In SA- TRIPS plus provisions are yet to be remedied and the Fix Patents Law (FPL) Campaign is leading on this issue

How do patent monopolies work?

- Patent protection enables exclusive monopolies or oligopolies, limiting the number of companies that can make or distribute a generic equivalent
- Data exclusivity' is a backdoor way of preventing competition, so that even when a medicine is not protected by a patent, a pharmaceutical company will receive a minimum period of market monopoly when artificially high prices can be charged
- Patent monopolies held by pharmaceutical corporations and a lack of price-lowering competition means that high drug prices can be charged for life-saving medicines, like they were / are for ARVs and cancer medicines

How does market exclusivity undermine health rights and medicine access?





Phrma - Myths

- "IP is not a barrier
- Private investment should be rewarded
- Voluntary and bi-lateral agreements are sufficient
- TRIPS is flexible
- COVAX is sufficient
- Donations are sufficient
- Africa cannot manufacture safe and effective products"

Civil Society - Responses & Realities

- Access cannot hinge on benevolence and charity and no transparency
- Billions in public investment including for vaccine research for Covid-19
 - See Public Citizen, KEI online, Peoples Vaccine Alliance, UAEM, MSF Access Campaign
- Voluntary licenses are limited, even if helpful
- COVAX has several limitations
- Rich countries have pre-bought supplies in advanced purchase agreements, bilaterally
- TRIPS flexibilities are difficult to use in practice
- Domestic fix the patent laws
- Safe manufacturing can be ramped up with proper investment and data sharing

'Vaccine Nationalism'

- Vaccines and IP More than just about Patent monopolies and rights / claims also:
 - Background technologies (platforms); Foreground technologies (vaccine products)
 - Manufacturing know how and clinical data (trade secrets)
 - Bi-lateral technology transfer and licensing
- Recent Reports Rich countries have bought up more than half the world's supply (Some 3 times needed, some 5 times needed)
 - Bi-lateral negotiations and advanced purchase agreements (APPs)
 - Price and geography / API source limitations or restrictions

COVAX limitations

- Voluntary pooling mechanism; 'Tiered pricing; Self-financing for MICs; Alongside bi-lateral agreements; Not all
 governments and companies entered pool; Own deadlines, no pricing transparency, no pricing data shared,
 unclear governance frameworks- GAVI; Relies on charity for LICs not yet raised target
- Phrma refuses to grant multiple non-exclusive, reasonable terms, global licenses in a pandemic
- African Governments not yet committed to compulsory licenses because hoping for access through donations, goodwill, bi-lateral agreements or COVAX and deference to volunteerism (explains TRIPS Waiver request)
- WHO- C-TAP lack of participation

'TRIPS WAIVER' Request



- SA Government Submission to WTO: July 2020 ('TRIPs flexibilities are difficult to use, rarely invoked by Global South')
- AU Communique on IP Barriers for Vaccine Access: July 2020
- SA and Indian Government Joint Proposal for TRIPS Waiver: October 2020
 - India and South Africa on 2 October 2020 asked the World Trade Organization (WTO) to allow all countries to choose to neither grant nor enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics and other technologies for the duration of the pandemic, until global herd immunity is achieved (not just for patents, but for trade secrets and copyrights, industrial design)
 - Now supported by many developing world countries
 - Opposed by Brazil, Australia, EU, UK, US, Canada
- While waiver request is important, again, limitations and domestic constraints, including local laws not being passed
- See also: https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies

Calls





- 'A People's Vaccine' / 'Free the Vaccine'
- An Equitable Plan for Access and Allocation in South Africa (HJI correspondence) that deals with 2-tiered health system, equity in allocation and access #1COuntry1Plan no detailed response yet
- Geography everyone, everywhere
- Stop opposing the waiver (US, EU, UK, Canada, Brazil, Australia)
- Price at cost, not at profit, for a longer period of time
- Transparency Require pharma corporations and university research institutions to open their books and show the public all research & development and production costs
- Companies cannot unilaterally decide supplies, pricing and when pandemic ends
- Community involvement to encourage democratic participation, build community trust and avoid vaccine hesitancy as well as growing anti-vaccine movement
- Share technology and treat as 'global public good'

South Africa – impact locally

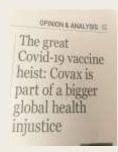
- 4 vaccine clinical trials
 - AstraZeneca/Oxford Group; Johnson and Johnson; Novavax; Pfizer/BioNtech
- The South African government has spent public funds on vaccine clinical research (approximately R10-million) and has committed to "sign up" to COVAX with a ZAR 250 million contribution from the Solidarity Fund
- MSF reports that vaccine candidates are benefiting from more than \$4.4-billion of public and philanthropic funding:
 - nearly \$1-billion from the US Biomedical Advanced Research and Development Authority (BARDA) to just two companies, Johnson & Johnson and Moderna
 - BioNTech received \$445-million from the German government
 - Moderna was also given \$1-million by the Coalition for Epidemic Preparedness Innovations (CEPI)
 - The AstraZeneca-Oxford Group- Oxford University vaccine research has been reported to have received more than £1-billion (about \$1.3-billion) of public funding
- 2 possible SA based 'manufacturing agreements' 'unclear and secret talks'
 - Biovac Institute SA CEPI has identified Biovac as a potential drug product manufacturer but has not signed an agreement yet, unclear for which vaccine pricing and geography conditions unclear
 - Aspen SA Johnson and Johnson Vaccine details unclear, pricing and geography terms or restrictions / conditions also unclear

Africa and SA - AU Vaccine Roadmap

- Global shortages, high prices, limited supplies as well as lack of commitment to share technology, coupled with lack of commitment to force phrma's hand and refusal to accept waiver means we will have to RATION
- Africa Framework AU leaders accepts now that Africa will require rationing who will decide who gets limited supplies (maybe 10-20% of worlds supplies)?
 - How will 'at risk populations and communities' and 'vulnerable groups' and front line workers be defined?
 - Will African countries pass laws that require a central supply framework for each country to avoid domestic vaccine apartheid (rich and poor- as we had with ARVS)?
- What are the ethical and procedural principles for allocating limited supplies?
 - Some principles include: Equal concern; Co-morbidities and ill health; Mitigate inequality; Engage communities in allocation planning; Use best evidence; Prevent severe cases; Protect exposed persons first HCWs, front line workers (essential) elderly, patients with co-morbidities, prioritise dense informal settlements, students, youth

Reading and Materials





- SA Government Submission July 2020
- SA Government Statement on TRIPS / WTO Negotiations ('TRIPS Waiver') and Submissions https://www.Keionline.org
- MSF TRIPS Waiver Briefing Document; MSF Report on Patents and Vaccines https://msfaccess.org/fair-shot-vaccine-affordability
- 'Whoever Finds the Vaccine Must Share It Strengthening Human Rights and Transparency Around Covid-19 Vaccines' – HRW
- '9 out of 10 people in poor countries are set to miss out on COVID-19 vaccine next year' –
 Amnesty International, Oxfam +
- The Great COVID-19 Vaccine Heist; Patents, Politics and Power HJI, Daily Maverick

Contact and questions

