

A Rapid Situational Analysis of Barriers and Enablers to Equitable Access to COVID-19 Health Technologies in South Africa

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Conducted by Catherine Tomlinson on behalf of the People's Health Movement

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Overview and objectives

This rapid situational analysis was conducted during October 2020 to gain insight into the current situation with respect to access to quality health technologies (PPE, diagnostic tests, ventilators) for COVID-19 in South Africa, as well as potential barriers and enablers to access to health technologies currently under development (vaccines, treatments). The situational analysis further sought to understand how regulatory frameworks, health financing, local manufacturing capacity and domestic research activities impact/may impact health technology access in the country.

Data for the situational analysis was collected through in-depth interviews with key informants, stakeholder engagement, and an extensive review of grey literature related to health technology development and access in South Africa. Five in-depth interviews were conducted with key informants actively involved with or leading government's efforts to respond to COVID-19 and deliver needed health technologies (this input is referred to in the report as interviewee input). Input was also sourced from stakeholders (civil society members and PHM partners and colleagues) through phone and email communication (this input is referred to in the report as stakeholder input).

All inputs from key informants and stakeholders are anonymised in the report.

The purpose of this situational analysis is to inform and strengthen civil society's engagement towards ensuring that health technologies for COVID-19 are broadly and equitably accessible in South Africa, including for marginalised and vulnerable groups.

The report is organised in two sections:

1. The first section gives an overview of the current situation with regards to access to health technologies (and key services) for COVID-19 in South Africa
2. The second section explores how South Africa's research, development, and manufacturing capacity, as well as legal frameworks and process for protecting intellectual property and regulating health technologies impact/may impact access to COVID-19 health technologies in the country.

Health technology access barriers identified and described in the report are summarised in Table 1 (see page 6). The table also identifies potential areas for community monitoring or advocacy towards improving equitable access to COVID-19 health technologies in South Africa.

Executive summary

Since the appearance of SARS-CoV-2 in late 2019, the novel virus has rapidly spread across the globe and caused a staggering toll in terms of loss of life and health impairment. By end-October 2020, more than 43 million cases of COVID-19 were confirmed and over a million deaths were reported.¹

COVID-19 and its responses have also significantly disrupted routine health care services—including childhood vaccinations, HIV, and TB services—and upended economic systems—severely increasing economic vulnerability and food insecurity. Morbidity and mortality due to increased economic hardship and disruption of regular health services may surpass and outlast morbidity and mortality due to COVID-19.²

Effective health responses and access to health technologies for COVID-19 are critical to reduce COVID-19 illness and death, enable broader health service functioning, and repair damaged industries and economies. While country responses to COVID-19 have significantly varied, access to health technologies have fallen into long entrenched patterns of inequality both between and within countries.

High-income countries (HICs) have pushed aside the needs of low- and middle-income countries (LMICs) in seeking to secure health technologies for their own populations. In the early months of the pandemic, wealthy countries used their financial and political strength to secure and hoard critical personal protective equipment (PPE) and diagnostics for their populations.³ As the development of vaccine candidates has progressed, wealthy countries have pre-bought vaccine supply at-risk—impeding efforts by the World Health Organisation (WHO) to facilitate equitable distribution of vaccines (once available) across all countries.

Within South Africa, access to COVID-19 health technologies has also been stratified across income levels, due to existing inequities in the distribution of critical resources between the public and private health sectors. The private health sector which serves around 15 percent of South Africa's population and consumes around 50 percent of health spending in the country is significantly better resourced than the public sector to respond to COVID-19. At the start of the pandemic, two-thirds of the country's ventilators and over 80 percent of the critical care bed capacity was located in the private sector.^{4,5}

Significant work has been undertaken by government agencies to prepare and enable South Africa's public health sector to respond to the pandemic, with support from local industry and other stakeholders. The public sector brokered a deal to procure critical care beds from the private sector, supported the 'National Ventilator Project' which developed and distributed 20,000 CPAP machines⁶

1 World Health Organization. WHO Coronavirus Disease (COVID -19) Dashboard. <https://covid19.who.int/>.

2 Khan M, et al. Mitigating the impact of COVID-19 on tuberculosis and HIV services: a cross-sectional survey of 669 health professionals in 64 low and middle-income countries. medRxiv Preprint. 13 October 2020. <https://doi.org/10.1101/2020.10.08.20207969>.

3 Bradley J, In Scramble for Coronavirus Supplies, Rich Countries Push Poor Aside. New York Times. 9 April 2020. <https://www.nytimes.com/2020/04/09/world/coronavirus-equipment-rich-poor.html>.

4 Cowan K, Evans S. Just 207 critical care beds and 350 ventilators added to public hospitals during lockdown. News24. 7 June 2020. <https://www.news24.com/news24/southafrica/investigations/exclusive-just-207-critical-care-beds-and-350-ventilators-added-to-public-hospitals-during-lockdown-20200607>.

5 van den Heever A. South Africa sets aside more money for COVID-19 but lacks a spending strategy. The Conversation. 29 June 2020. <https://theconversation.com/south-africa-sets-aside-more-money-for-covid-19-but-lacks-a-spending-strategy-141619>.

6 CPAP (or continuous positive airway pressure) machines use air pressure to keep airways open and can be used to deliver supplemental oxygen to patients. Unlike ventilators, CPAP machines do not require intubation (inserting a tube through the mouth into the airways).

across the country, and is supporting local development and commercialisation of COVID-19 tests and test materials. Government is also supporting local trialling of COVID-19 treatments and vaccines, which will provide important evidence on their effectiveness in local populations.

South Africa has also been an international leader in seeking to ensure that commercial monopolies and barriers to knowledge do not impede the development of and access to health technologies for COVID-19. In this vein, South Africa (together with India) has asked the World Trade Organisation (WTO) to grant a waiver to allow countries to not grant or enforce patents on COVID-19 health technologies throughout the pandemic, stating that *“The waiver should continue until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity”*.⁷

On 16 October, South Africa told the TRIPS Council that *“the COVID-19 pandemic is a clarion call for us to answer to the better angels of our nature”, adding “Given this present context of global emergency, it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products...to combat COVID-19”*.⁸

Yet, despite South Africa’s leadership in seeking to address intellectual property (IP) access barriers at an international level, domestic reform of the country’s patent laws to improve health technology access, which has been the subject of a sustained campaign by civil society organisations⁹, remains overdue and sluggish. The country’s response to COVID-19 has also faltered in other critical areas. Procurement of PPE has been mired in corruption and shortages and poor-quality PPE have placed health care workers’ lives at risk. Further, despite massive efforts by the South African Health Products Regulatory Authority (SAHPRA)¹⁰ to rapidly establish and enforce systems to ensure the safety and efficacy of COVID-19 health technologies, slow regulatory processes have impeded the introduction of and access to critical health technologies—the National Ventilator Project reportedly ‘missed the peak’ due to slow regulatory guidance and approval of CPAP machines.¹¹

Lessons from experiences to date can help South Africa prepare for a potential second and any subsequent surges in infections, strengthen its ongoing response to COVID-19, and prepare for the mammoth task of procuring and delivering COVID-19 vaccines in the face of significant and daunting unknowns.

Civil society has a critical role to play in ensuring that lessons are learnt from responses to date and that shortcomings are addressed, including through: challenging legal barriers to health technology access; highlighting incoherence between South Africa’s statements regarding IP at an international level and domestic laws and policies; engaging with the rapidly changing regulatory environment for medical devices and demanding greater transparency from the regulator; challenging procurement processes that enable corruption; and holding corrupt officials to account. Civil society is already making important contributions in these areas through the Fix the Patent Laws Coalition, the Moral Call Collective, #orangemaskfridays, the C19 Peoples Coalition and other community initiatives.

⁷ Knowledge Ecology International. WTO TRIPS Council (October 2020): South Africa issues clarion call urging support for TRIPS Waiver Proposal. 16 October 2020. <https://www.keionline.org/34235>.

⁸ Knowledge Ecology International. WTO TRIPS Council (October 2020): South Africa issues clarion call urging support for TRIPS Waiver Proposal. 16 October 2020. <https://www.keionline.org/34235>.

⁹ Fix the Patent Laws. A Timeline of Intellectual Property Reform in South Africa. 2017.

<https://www.fixthepatentlaws.org/wp-content/uploads/2017/10/IP-reform-timeline-2017-continuous.pdf>

¹⁰ SAHPRA, or the South African Health Products Regulatory Authority is the national regulatory body responsible for ensuring the safety and efficacy of medicines and medical devices used in South Africa.

¹¹ Stakeholder interview

Civil society also has a role to play in monitoring health technology access and raising awareness of shortages and quality challenges. While this report is focused on access to medical technologies, the availability of running water and soap at health facilities is also critical to prevent the spread of COVID-19 and other pathogens.

Fear of contracting COVID-19 has impeded access to and reduced uptake of other critical health services such as TB and HIV services, and childhood vaccines.¹² Civil society can play an important role in mitigating these disruptions through engaging communities on the science of COVID-19 and monitoring and reporting health facilities not implementing proper precaution and hygiene measures—as done by the Treatment Action Campaign in the Eastern Cape.¹³

Finally, as government grapples with difficult decisions about who will get first access to vaccines, civil society must ensure that community voices and preferences are heard and accounted for in the rollout plan, and that the most marginalised and vulnerable members of community are protected.

Table 1. Barriers to health technology access and potential monitoring and advocacy areas for civil society to promote equitable access

Issue	Impediments to equitable access identified in the rapid situational analysis	Potential areas for community monitoring and advocacy towards improving equitable access
Diagnostics	<ul style="list-style-type: none"> - Unequal buying power between wealthy and poor countries - Inequitable division of resources and capacity between the public and private health sectors - Test material shortages, exacerbated by monopoly positions impeding competition - IP barriers/trade secrets - Overly ambitious/ill-advised early testing campaign - Regulatory delays 	<ul style="list-style-type: none"> - Monitor access to diagnostics - Highlight access challenges - Identify and highlight barriers to local manufacturing/ manufacturing scale-up of needed test materials – i.e. patent barriers, trade secrets, no/ inadequate tech transfer, and non-transparency of R&D financing (incl. public contributions) and production costs - Amplify messaging regarding the need for equal distribution of health resources in the country, including through nationalisation and the NHI
PPE	<ul style="list-style-type: none"> - Unequal buying power between wealthy and poor countries - Procurement corruption - Shifting regulatory rules - Procurement of substandard products - Supply shortages - Hierarchical hoarding 	<ul style="list-style-type: none"> - Monitor access to PPE - Highlight access challenges - Advocate against procurement practises that enable corruption - Amplify messaging and efforts to combat corruption
Ventilators, CPAP machines, critical care beds and oxygen	<ul style="list-style-type: none"> - Inequitable division of resources and capacity between the public and private sector - Inadequate hospital infrastructure, esp. in rural areas 	<ul style="list-style-type: none"> - Monitor access to critical care beds, oxygen, ventilators and CPAP machines - Highlight access challenges, including those that are specific to rural areas - Amplify messaging regarding the need for equal distribution of health resources in the

12 Khan M, et al. Mitigating the impact of COVID-19 on tuberculosis and HIV services: a cross-sectional survey of 669 health professionals in 64 low and middle-income countries. medRxiv Preprint. 13 October 2020. <https://doi.org/10.1101/2020.10.08.20207969>.

13 Mbovane T. Dire conditions in Eastern Cape clinics made worse by pandemic. GroundUp. 24 August 2020. <https://allafrica.com/stories/202008240941.html>.

	<ul style="list-style-type: none"> - Poor roads, long distances between health facilities, and lack of emergency transportation in rural areas 	<ul style="list-style-type: none"> country, including through nationalisation and the NHI
Medicines	<ul style="list-style-type: none"> - Lack of treatments with demonstrated efficacy (apart from corticosteroids) - Patent barriers and related licensing agreements impeding broad competition and price-reductions 	<ul style="list-style-type: none"> - Monitor access to COVID-19 treatments - Highlight access challenges - Identify and highlight barriers to local manufacturing/ manufacturing scale-up of affordable treatments – i.e. patent barriers, restrictive licensing agreements, and non-transparency of R&D financing contributions (incl. public contributions), production costs, and licensing and commercialisation arrangements
Vaccines	<ul style="list-style-type: none"> - Unequal buying power between wealthy and poor countries - Lack of solidarity in countries' procurement approaches (vaccine nationalism) - Cost barriers - Inadequate manufacturing capacity (globally and locally) to meet demand - Critical gaps in knowledge and data needed to guide and inform the rollout - Intellectual property barriers to competition and technology transfer - Lack of transparency/understanding of regulatory pathways for introducing new vaccines - High levels of distrust of vaccines - Lack of existing pathways for vaccine delivery and logistical supply chain challenges - Decision making power related to vaccine access (incl. for COVAX) overly concentrated among large funders and pharmaceutical companies, without adequate transparency or community/country engagement 	<ul style="list-style-type: none"> - Engage government on its rollout strategy, and input on efforts to identify priority populations that will receive first access to vaccines - Engage communities on the vaccine rollout and ensure community voices and perspectives are heard and considered by government in developing a rollout plan - Raise attention to price barriers to access and opportunities to improve affordability - Advocate for a People's vaccine that is free of IP and other artificial restrictions to manufacturing - Combat anti-vax messaging, and amplify messaging regarding the benefits of trialling vaccines locally - Seek greater transparency from large funders (philanthropic and government) and pharmaceutical companies on negotiations/deals impacting IP ownership, licensing, tech transfer, pricing, and access - Seek meaningful country and community representation and engagement in decision-making spaces and forums
Intellectual property law	<ul style="list-style-type: none"> - Problematic domestic patent laws that do not contain critical TRIPS health safeguards - Ongoing delays in instituting examination procedures to meaningfully assess patent applications, more than two years after patent examiners hired by CIPC and a new national IP policy committed to the introduction of substantive patent examination - International (WTO) requirements for protection of IP (waiver not granted to date) - Wealthy countries that are home to multinational pharmaceutical companies (EU countries, U.S., Japan) actively opposing the TRIPS waiver proposed by South Africa and India - Lack of transparency regarding patents on health technologies, and licensing and commercialisation arrangements 	<ul style="list-style-type: none"> - Advocate for pro-public health reform of South Africa's patent laws in line with policy commitments - Promote the adoption of the TRIPS waiver at the WTO - Advocate for a moratorium on the granting of patents on COVID-19 health technologies in South Africa - Advocate for improved transparency of IP, commercialisation and licensing arrangements - Advocate for improved transparency of R&D financing and public contributions - Consider how South Africa's position and power as a public R&D funder (relative to other global funders) impacts its ability to demand contract transparency, and engage stakeholders on challenges and opportunities to secure greater transparency requirements - Request details on the CIPC analysis of COVID-19 health technology patents, and

		assess whether further analysis is needed (i.e. on diagnostic tools?)
Regulation of medical devices and medicines	<ul style="list-style-type: none"> - Lack of clarity regarding pathways for registration of vaccines - Lack of transparency from the regulator - Shifting rules for regulation of medical devices - Slow regulatory decision making - Delays by the regulator, combined with lack of knowledge among companies regarding regulatory requirements for medical devices, contributing to slow approval and introduction of medical devices for COVID-19 	<ul style="list-style-type: none"> - Monitor shifting regulatory requirements for medical devices - Demand greater transparency from the regulator - Advocate for reform legal impediments to transparency in the Medicines Act - Engage the regulator on pathways and plans for registration of COVID-19 vaccines
Local capacity for research, development, and manufacturing	<ul style="list-style-type: none"> - Limited local manufacturing capacity - Business as usual patent, licensing and technology transfer approaches many impede growth of local manufacturing capacity - Limited funds for COVID-19 research - Diversion of funds away from R&D for other critical health issues for COVID-19 	<ul style="list-style-type: none"> - Support mechanisms that overcome IP and other barriers to local manufacturing. i.e. TRIPS waiver, C-TAP and the People's Vaccine - Advocate for licensing (voluntary and/or compulsory) to overcome barriers to local manufacturing - Advocate for investment towards building local manufacturing capacity - Advocate for expanded investment into health and COVID-19 R&D and against the diversion of funds from other health areas (i.e. TB, HIV, NCDs) for COVID-19 research and responses

SECTION 1: Barriers and enablers to access to COVID-19 health technologies

South Africa's government responded swiftly to COVID-19, implementing a stringent lockdown on 26 March—21 days after the first case was reported in the country and one day before the country's first reported COVID-19 death.^{14,15} The 'late' arrival of COVID-19 in the country and the rapid shutdown afforded time to the health system and government to prepare its epidemic response, including through identifying and securing needed health technologies and capacity.

This section explores efforts, challenges, and successes faced in the country in securing access to critical health technologies to date, as well as what is being done to secure access to future health technologies under development. This section is divided into seven parts, with each part exploring the access situation for a critical health technology: (1) diagnostic tests, (2) ventilators, (3) critical care beds, (4) oxygen, (5) personal protective equipment, (6) treatments, and (7) vaccines.

Diagnostic tests

COVID-19 is typically diagnosed using molecular PCR tests conducted at a laboratory level. These tests require specific reagents and materials to prepare and test sputum samples for COVID-19 using PCR testing platforms. At the start of the epidemic, the National Health Laboratory Services (NHLS) highlighted the country's preparedness to rapidly scale-up COVID-19 testing given its existing investments into Cepheid and Roche's diagnostic platforms which (with adequate test materials from Cepheid and Roche) would have enabled the NHLS to perform 36,000 tests per day.¹⁶

During March, NHLS CEO Dr Kammy Chetty stressed that South Africa had "*adequate testing capacity and infrastructure to meet demand*" and noted that its investment into Roche's Cobas and Cepheid's GeneXpert high-throughput diagnostic platforms would "*dramatically improve the volumes that can be done as well as the turnaround time*".¹⁷ Dr Sibongiseni Dhlomo, chair of Parliament's Portfolio Committee for Health, confidently stressed that South Africa's investment in Cepheid's GeneXpert diagnostic platforms "*would prove a masterstroke a few years later*" when the company received approval for its COVID-19 test cartridges.¹⁸

Yet, initial high hopes proved misplaced after South Africa found itself unable to procure adequate test materials (reagents, cartridges, consumables) from Roche and Cepheid to scale-up COVID-19 testing in line with the need, as wealthy countries cannibalised available supply, and the proprietary nature of Roche and Cepheid's platforms prevented South Africa from sourcing test materials for use on their platforms from other suppliers.

14 Pillay-van Wyk V, et al. COVID deaths in South Africa: 99 days since South Africa's first death. *S Afr Med J*. Published online 30 September 2020. <https://doi.org/10.7196/SAMJ.2020.v110i11.15249>.

15 Stiegler N, Bouchard JP. South Africa: Challenges and successes of the COVID-19 lockdown. *Ann Med Psychol (Paris)*. Published online 2020 May 27. doi: 10.1016/j.amp.2020.05.006.

16 National Health Laboratory Service. NHLS preparedness for testing to meet COVID-19 demands. 25 March 2020. <https://www.nhls.ac.za/nhls-preparedness-for-testing-to-meet-covid-19-demands/>.

17 National Health Laboratory Service. NHLS preparedness for testing to meet COVID-19 demands. 25 March 2020. <https://www.nhls.ac.za/nhls-preparedness-for-testing-to-meet-covid-19-demands/>.

18 Dhlomo S. South Africa's investments into health innovation prove important in the COVID-19 response. 9 April 2020. <https://bhekisisa.org/advertorial/2020-04-09-south-africas-investments-into-health-innovation-prove-important-in-the-covid-19-response/>.

Spotlight reported in May that Cepheid and Roche's proprietary platforms are designed in a way that "prevents laboratories from making their own test materials or procuring test materials from sources other than the diagnostic machine's manufacturer".¹⁹ Adding that despite being "the first country to roll out GeneXpert diagnostics at scale after GeneXpert tests were shown to be effective in diagnosing tuberculosis [and] a crucial site for the trialling of the diagnostic machines", South Africa was struggling to secure cartridges for diagnosing COVID-19 on GeneXpert diagnostic platforms from Cepheid.²⁰

One stakeholder explained the trade-off of investing in closed/proprietary systems, such as Cepheid and Roche's platforms, versus procuring open/non-proprietary systems: "Closed systems are usually highly controlled and the manufacturer takes over much of quality assurance etc., at a (hefty) price. If anything goes wrong or runs out, that is it. Open systems are more flexible but require a lot more operator input at a high level, which stands in the way of efficient high-throughput testing. Finding and retaining those scarce staff is often a huge challenge in many settings including ours". The stakeholder added "My biggest disappointments during the pandemic were the dire shortages of both GeneXpert cartridges and Roche Cobas kits. One the ideal tool for near-patient rapid testing and the other one ideal for centralised labs."

The shortages of test materials faced in South Africa were exacerbated by an overly ambitious screening and testing campaign early in the pandemic, which some experts urged was unnecessary, wasteful, and contributing to the large testing backlog.²¹

During May 2020, the mean turnaround time for a COVID-19 test in the public sector was over nine days.²² A turnaround time of nine days for a result effectively nullifies the purpose of testing, since the person has likely recovered (or died or developed severe disease) by the time the test result is back, or is nearing the end of any quarantine. It is an effective waste of resources to test with such long delays.

Yet the private sector, which also faced international shortages of test materials, was able to largely avoid diagnostic delays. Spotlight reported in June that in "South Africa's private healthcare sector, COVID-19 tests are typically processed within a day or two. Tests are also relatively easy to get, provided you or your medical scheme are willing to pay the R900 plus that it costs. Even if you don't want a COVID-19 test, many private hospitals require you to have one should you plan to be admitted for even a relatively minor elective procedure unrelated to COVID-19. In stark contrast, healthcare workers and patients in the public sector often have to wait a week, or even weeks, for test results".²³

Peter Benjamin et al. argued in the Daily Maverick in July that private sector diagnostic resources should be nationalised to address the public sector testing backlog and ensure equitable access to diagnostics, stating "The public and private health services must be brought together coherently. The

19 Tomlinson C. COVID-19: Behind SA's shortage of test materials. Spotlight. 5 May 2020.

<https://www.spotlightnsp.co.za/2020/05/05/covid-19-behind-sas-shortages-of-test-materials/>.

20 Tomlinson C. COVID-19: Behind SA's shortage of test materials. Spotlight. 5 May 2020.

<https://www.spotlightnsp.co.za/2020/05/05/covid-19-behind-sas-shortages-of-test-materials/>.

21 Medical Brief. Experts urge: Stop random COVID-19 testing and sort out the backlog. 3 June 2020.

<https://www.medicalbrief.co.za/archives/experts-urge-stop-random-covid-19-testing-and-sort-out-the-backlog/>.

22 National Institute for Communicable Diseases. Covid-19 testing summary: Week 22. 2020.

https://www.nicd.ac.za/wp-content/uploads/2020/06/NICD-COVID-19-Testing-Summary_-Week-22-2020.pdf.

23 Green A. Covid-19: Stark differences between public and private sector testing. Spotlight. 24 June 2020.

<https://www.spotlightnsp.co.za/2020/06/24/covid-19-stark-differences-between-public-and-private-sector-testing/>.

Covid-19 testing strategy should have started with the nationalisation of private laboratories, one testing protocol, and free access for all who need a test”.²⁴

Efforts to address test material shortages

In seeking to address the public sector testing backlog, South Africa has (1) adopted stricter criteria for COVID-19 testing, (2) taken steps to diversify its test materials and platforms²⁵, (3) supported R&D to enable local manufacture of test materials, and (4) participated in the African Medical Supplies Platform to combine the demand and buying power of African Union member countries.

As part of efforts to diversify test materials and platforms, South Africa has expanded its procurement of test materials that can be used on non-proprietary systems and invested in expanding non-proprietary infrastructure. During July, the NHLS reported that it had *“upscaled its capacity on a national level and diversified the testing platforms to remove dependency on a few suppliers”*.²⁶

South Africa has also invested in the local development and commercialisation of test materials for COVID-19. To date, the Department of Science and Innovation (DSI) and the Technology Innovation Agency (TIA), through the South African Medical Research Council (SAMRC) have awarded R14 million to local companies, universities and science councils to develop COVID-19 test reagents and novel tests. This funding has included support for the CSIR to develop “open source” reagents that can be used on all non-proprietary platforms for diagnosis of COVID-19.²⁷

South Africa has also engaged Cepheid and Roche regarding securing licensing and technology transfer agreements to enable local manufacture of test materials for use of their proprietary platforms, but these efforts have not progressed—reportedly due to a lack of interest/willingness from Cepheid and Roche.²⁸

One stakeholder noted that civil society can play a critical role in pressuring Cepheid and Roche to grant licenses, transfer technology and share know-how necessary to enable local production of test materials. Although another questioned local capacity to develop test materials stating: *“I think the problem is actually skill and local infrastructure. To make these reagents, especially at scale, we (as a country) need years if not decades of investment. We are reasonable researchers by global standards, but in my opinion, do not have the sort of capital and skill-based economy to support local diagnostic test manufacturing”*.

Finally, South Africa has worked with other African countries to develop mechanisms to enable better access to COVID-19 health technologies (including diagnostics) through combining countries’ buying power. John Nkengasong, head of the Africa CDC, highlighted challenges faced across the region in securing COVID-19 test materials during April, stating *“The collapse of global cooperation and a failure of international solidarity have shoved Africa out of the diagnostics market...Lack of access to*

24 Benjamin P et al. What a people centred response to COVID-19 would look like. Daily Maverick. 14 July 2020. <https://www.dailymaverick.co.za/article/2020-07-14-what-a-peoplecentred-response-to-covid-19-would-look-like/>

25 Tomlinson C. COVID-19: NHLS reducing its dependency on “a few suppliers”. Spotlight. 22 July 2020. <https://www.spotlightnsp.co.za/2020/07/22/covid-19-nhls-reducing-its-dependence-on-a-few-suppliers/>.

26 Tomlinson C. COVID-19: NHLS reducing its dependency on “a few suppliers”. Spotlight. 22 July 2020. <https://www.spotlightnsp.co.za/2020/07/22/covid-19-nhls-reducing-its-dependence-on-a-few-suppliers/>.

²⁷ Stakeholder interviews.

²⁸ Key informant interviews.

diagnostics is Africa's Achilles heel... This is not a question of demanding charity. African countries have funds to pay for reagents but cannot buy them".²⁹

To improve access to test materials across the region, South African President and African Union Chair, Cyril Ramaphosa, launched the African Medical Supplies Platform (AMSP) on 19 July. The AMSP is an online platform from which African Union member countries can buy COVID-19 health technologies (including diagnostics) from 'vetted suppliers' at set prices and volumes secured through combining countries' demand and buying power.³⁰

Ventilators

South Africa's response to ventilator shortages provides a strong example of how public sector funding, open access knowledge, local manufacturing and private sector support and engagement can be galvanised for public benefit. Yet regulatory challenges and delays ultimately tripped up timely delivery of this critical health technology.

South Africa quickly identified that shortages of ventilators would seriously impede its ability to respond to COVID-19. The Department of Health (DoH) estimated that South Africa had 3,216 ventilators in the country at the start of the epidemic, of which two-thirds (2,105) were located in the private sector, but could need up to 20,000 during the pandemic peak.^{31,32}

In April 2020, the DTIC launched the national ventilator project (NVP) to address the anticipated shortages of ventilators needed for the country's COVID-19 response. One interviewee explained that, at the time, evidence coming from Europe and China indicated that full ventilation wasn't necessary and that Continuous Positive Airway Pressure (CPAP) "*was a very good solution*"—adding that at the time there were "*a number of open source CPAP designs with no IP constraints*". The Department of Trade Industry and Competition (DTIC) invited bids for development of "*a non-invasive pre-intubation ventilator solution*" during April.³³

The DTIC mandated the South African Radio Astronomy Organisation (SARAO), 'a business unit of the National Research Foundation', to manage the process of developing (including developing and testing a spec) and commercialising ventilators.³⁴

DTIC/SARAO reportedly received five bids that met its spec and awarded contracts for the manufacture of CPAP machines to CSIR and Save-P. CSIR was contracted to locally manufacture and supply 18,000 CPAP devices and Save-P was contracted to supply 2,000 devices. One interviewee noted that because "*state procurement was a mess*" at the time, the Solidarity Fund was identified as a buyer for the devices.

29 Nkengasong J. Let Africa into the market for COVID-19 diagnostics. *Nature* 580:565; 2020.

<https://www.nature.com/articles/d41586-020-01265-0>.

30 African Medical Supplies Platform: <https://amsp.africa/>.

31 Cowan K, Evans S. Just 207 critical care beds and 350 ventilators added to public hospitals during lockdown. *News24*. 7 June 2020. <https://www.news24.com/news24/southafrica/investigations/exclusive-just-207-critical-care-beds-and-350-ventilators-added-to-public-hospitals-during-lockdown-20200607>.

32 Cowan K, Evans S. Just 207 critical care beds and 350 ventilators added to public hospitals during lockdown. *News24*. 7 June 2020. <https://www.news24.com/news24/southafrica/investigations/exclusive-just-207-critical-care-beds-and-350-ventilators-added-to-public-hospitals-during-lockdown-20200607>.

33 Department of Trade, Industry and Competition. National Ventilator Project Call for Proposals. April 2020. http://www.thedti.gov.za/news2020/CFP_NVP.pdf

34 <https://www.sarao.ac.za/wp-content/uploads/2020/04/SSA4003-0009-002-Rev-1-CFP-for-NVP-signed.pdf>

While the national ventilator project has been criticised in the media for late delivery of CPAP devices^{35,36}, all 20,000 devices have reportedly now been manufactured and delivered.

SAHPRA's regulatory process were highlighted as an impediment to timeous delivery of the devices. One interviewee noted that *"SAHPRA had no way of licensing this thing, so they had to figure it out quite quickly. The NVP project was held up by effectively six weeks, between the Solidarity Fund's due diligence and SAHPRA figuring out how to do the licensing, we were six weeks later than we would have liked in getting into full swing of production, which actually meant that we missed the peak by a couple of weeks"*.

The CPAP devices procured from CSIR cost R1,250 for the CPAP unit and R1,700 for the single use patient circuit (composed of masks, tubes and valves). In comparison, a traditional ventilator typically costs over R100,000.

Critical care beds

The stark inequalities between health care services available to private versus public sector users were brought to the fore in discussions regarding critical care beds. Dr Tom Boyles wrote in the Daily Maverick in March that *"In developed countries, the strongest predictors of dying from Covid-19 are advanced age and pre-existing health conditions. If there is a major outbreak affecting all communities in South Africa, the strongest predictor of survival will be something quite different – access to medical insurance and therefore an ICU bed. This is a chilling fact, which will expose the current inequalities in the health system in terms of life and death"*.³⁷

Alex van den Heever wrote in the Conversation in June that *"South Africa only has critical care bed capacity for the remainder of the financial year of around 468,433 bed days... of which 90,400 bed days (16.3%) are in the public sector. However, if the epidemic trajectory continues as at present, COVID-specific critical care bed need may be as high as 2.9 million bed days over the period July to December 2020"*.³⁸

Adri Kotze explained in Bhekisisa in July that *"critical care beds, which are the type of beds that the government is most in need of, do not traditionally exist in South Africa's private sector. Nicholas Crisp added that "The beds that the government needs are a hybrid between [high care] HCU and [intensive care] ICU beds in the private sector"*.³⁹

35 Wicks J. Slow start to national ventilator project as infection surge looms. TimesLive. 24 May 2020. <https://www.timeslive.co.za/sunday-times/news/2020-05-24-slow-start-to-national-ventilator-project-as-infection-surge-looms/>.

36 de Villiers J. What happened to the project to build 10,000 ventilators in South Africa by end June? News24. 9 July 2020. <https://www.news24.com/news24/analysis/explainer-what-happened-to-the-project-to-build-10-000-ventilators-in-sa-by-end-of-june-20200709>.

37 Boyles T. COVID-19 brings inequality and the NHI into sharp focus. Daily Maverick. 9 March 2020. <https://www.dailymaverick.co.za/article/2020-03-09-covid-19-brings-inequality-and-the-nhi-into-sharp-focus/>

38 van den Heever A. South Africa sets aside more money for COVID-19 but lacks a spending strategy. The Conversation. 29 June 2020. <https://theconversation.com/south-africa-sets-aside-more-money-for-covid-19-but-lacks-a-spending-strategy-141619>.

39 Kotze A. Q&A: State patients in private hospitals: What's the deal? Bhekisisa. 15 July 2020. <https://bhekisisa.org/health-news-south-africa/2020-07-15-qa-state-patients-in-private-hospitals-whats-the-deal/>.

To mitigate the public sector shortage, the Department of Health worked to negotiate a deal to enable provinces to procure beds for public sector patients from private health facilities at set prices. The negotiations, which were drawn out and reportedly complex, only concluded in July when it was reported that private sector parties had agreed to 'sell' critical care beds to the public sector at a rate of R16,156 per day.⁴⁰ (The fees also include the cost of specialists caring for patients).⁴¹

Spotlight reported that *"paying for these beds will be up to each province, but it's unclear where the money will come from in provincial health budgets to make such purchases. There are also concerns over the possibility of provincial budget constraints negatively affecting patient care"*.⁴²

South Africa was criticised by some stakeholders for not taking a similar approach to that of Spain and Ireland; countries that reportedly temporarily nationalised private hospitals and healthcare worker capacity for their COVID-19 responses.

Nimi Hoffman wrote in the Mail & Guardian that Spain *"nationalised private hospitals overnight, reversing post-2008 privatisation reforms. As thousands died in Spain, the government was forced to recognise that doctors and nurses were right to oppose privatisation as unsustainable and ineffective. But unlike Spain, we actually have a plan in place. This plan is called the National Health Insurance"*. She added *"if Spain can do it, then maybe we can too. And we can finally join the list of many other countries with a universal national health service"*.⁴³

However, one interviewee questioned the feasibility of nationalisation as an approach to secure beds for public sector users, stating *"the public sector has very little capacity to even run the public sector, I can't even imagine how they would have capacity to run the private sector"*.

Several stakeholders further criticised the approaches used in Spain and Ireland, noting that while they were hailed in the media as 'nationalisation', in reality they involved the procurement of services from the private sector for public sector users, as has been done in South Africa.

One stakeholder explained that in Ireland *"there was no takeover in the sense of a nationalisation (whether formally or informally) and no takeover in the sense of the services optioned by the state actually being called upon to any very significant degree... The government negotiated with the 18 different private hospitals and reached heads of agreement that were acceptable to them. In effect, this was equivalent to a Service Level Agreement"*.

Another stakeholder said that *"Despite some sensationalistic headlines, there has been little contribution from the private sector [in Spain] ... In fact, some private companies even cut down staff and closed facilities during the first wave of the pandemic... Nonetheless, private companies demanded hefty compensations for the contribution they made."*

40 Cleary K. The deals that will see public sector patients in private hospitals. Spotlight 22 June 2020. <https://www.spotlightnsp.co.za/2020/06/22/in-depth-the-deals-that-will-see-public-sector-patients-in-private-hospitals/>.

41 Winning A. Treating COVID-19 patients in private hospitals could cost government up to R16,000 a day. IOL. 7 June 2020. <https://www.iol.co.za/news/politics/treating-covid-19-patients-in-private-hospitals-could-cost-government-up-to-r16-000-a-day-49085179>.

42 Cleary K. The deals that will see public sector patients in private hospitals. Spotlight 22 June 2020. <https://www.spotlightnsp.co.za/2020/06/22/in-depth-the-deals-that-will-see-public-sector-patients-in-private-hospitals/>.

43 Hoffman N. Spain did it, so why can't South Africa nationalise healthcare to save lives? Mail & Guardian. 12 April 2020. <https://mg.co.za/article/2020-04-12-spain-did-it-so-why-cant-south-africa-nationalise-healthcare-to-save-lives/>.

Finally, despite the extended and complex negotiation involved in procuring private sector beds for public sector patients in South Africa, few private beds were actually 'bought' in the end. One stakeholder noted that only one of South Africa's nine provinces (the Western Cape) has signed a service level agreement to buy beds from private health facilities for public sector patients under the negotiated deal to date and, on 29 September, Katharine Childs tweeted that only six state patients had been treated at private Netcare hospitals during the country's COVID-19 peak.⁴⁴

Oxygen

The availability of a steady supply of oxygen supply to critical care beds has also arisen as a potential barrier to COVID-19 care in the country.

On 13 July, Minister Mkhize highlighted potential looming shortages of medical oxygen and noted that government had held urgent meetings with oxygen suppliers regarding increasing oxygen supply and capacity. Mkhize stated *"we have also, in the modelling, noticed that the country doesn't right now have the same level of oxygen for medical usage, and therefore we have now been involved in these discussions to divert some of the oxygen for industrial use into the healthcare [system] and also looking at how the production must be increased"*.⁴⁵

During July, the Daily Maverick reported that *"as Covid-19 surges, Gauteng hospitals and clinics are running out of oxygen. Nasrec field hospital, the province's biggest, only has 8 beds supplied with piped oxygen"*⁴⁶ In the same month, the Washington Post reported that *"the coronavirus storm has arrived in South Africa, but...medical oxygen is already low in hospitals at the new epicenter of the outbreak, Gauteng province, home to the power centers of Johannesburg and the capital, Pretoria"*.⁴⁷

Afrox, the sole supplier of medical oxygen to the public sector quickly denied reports of supply shortages, stating in July *"as the sole supplier of medical oxygen to the state hospitals and clinics as well as to a number of privately owned hospitals and clinics, Afrox affirms that there is no shortage of medical oxygen in South Africa"*.⁴⁸ In October, Afrox's Managing Director added *"Even at the peak in South Africa we never had any challenges on oxygen supply. So, I don't foresee a shortage of medical oxygen at all... At the peak of certain provinces, we experienced about twice the normal demand and we could supply up to five times. We are very well covered in terms of capacity"*.⁴⁹

An ongoing challenge, however, in ensuring oxygen availability and accessibility is inadequate infrastructure within health facilities to deliver oxygen to patients—particularly in rural areas.

44 See twitter post at:

https://twitter.com/katjanechild?ref_src=twsrc%5Egoogle%7Ctwcamp%5Eserp%7Ctwgr%5Eauthor

45 Polity. Concerns over medical oxygen as govt embarks on plan to increase supply. 14 July 2020.

<https://www.polity.org.za/article/concern-over-medical-oxygen-as-govt-embarks-on-plan-to-increase-supply-2020-07-14>

46 Haffajee F. Gauteng's oxygen shortages raise questions about lockdown planning. Daily Maverick. 9 July 2020. <https://www.dailymaverick.co.za/article/2020-07-09-gautengs-oxygen-shortages-raise-questions-about-lockdown-planning/>

47 Magome M. Oxygen already low in South Africa as COVID-19 surges in South Africa. The Washington Post. 10 July 2020. https://www.washingtonpost.com/world/africa/oxygen-already-runs-low-as-covid-19-surges-in-south-africa/2020/07/10/c9b1bb5e-c293-11ea-8908-68a2b9eae9e0_story.html.

48 Afrox. Oxygen shortages holding statement. 6 July 2020.

http://www.afrox.co.za/en/news_and_media/press_releases/oxygen_shortages.html.

49 Sampson J. Afrox: No shortage of medical oxygen in South Africa. Gas World. 15 October 2020.

<https://www.gasworld.com/afrox-no-shortage-of-medical-oxygen-in-south-africa/2019955.article>

One interviewee explained that *“the big constraint if we had really been hit hard by the peak would not have been the devices, it would have been the oxygen supply. Not the availability of the oxygen, but the actual infrastructure in hospitals”*. He explained that oxygen sockets run in a series in the wall and beds were set up in a line along the wall, adding that if all beds were full then the first two beds would get enough oxygen, but thereafter supply would be insufficient. He added that it took weeks to get in appropriate engineers to resolve this infrastructure problem after it was identified in hospitals. DoH spokesperson, Popo Maja stated in July that government had experienced engineering challenges and had to make modification in a number of hospitals to deliver stable oxygen supply.⁵⁰

RuDaSA highlighted in July that *“Oxygen Therapy is vital to save the lives of these patients in rural hospitals, that are without ICU facilities, and have long transit times to tertiary hospitals. Some of our rural hospitals say they are running out of oxygen, or have failed oxygen points or insufficient oxygen masks even during these early stages leading up to the epidemic ‘peak’ in rural areas”*.⁵¹

Doctors Without Borders further stressed in September that rural hospitals must be capacitated to treat COVID-19 patients and provide oxygen therapy on-site, as poor roads and long distances between health facilities impedes timeous access to life-saving oxygen treatment in rural areas.⁵²

Personal protective equipment

Personal protective equipment (PPE) for COVID-19 includes respirators, medical/surgical masks, gloves, gowns, face shields, and eye wear. The rapid global spread of COVID-19 coupled with a lack of global cooperation set off a mad scramble and bidding wars between countries seeking to secure adequate PPE for frontline workers.

On 3 March, the WHO warned that *“that severe and mounting disruption to the global supply of personal protective equipment (PPE) – caused by rising demand, panic buying, hoarding and misuse – is putting lives at risk from the new coronavirus and other infectious diseases. Healthcare workers rely on personal protective equipment to protect themselves and their patients from being infected and infecting others”*.⁵³

In April, the New York Times reported that between-country inequality was contributing to PPE shortages in developing countries noting that *“as the United States and European Union countries compete to acquire scarce medical equipment to combat the*

During the early months of the epidemic, Business for South Africa (B4SA) and other industry, government and non-government groups sourced and donated significant numbers of PPE for the country's health response. *“The Business for South Africa (B4SA) portal was able to acquire 41 million pieces of PPE, while myriad small and medium-sized enterprises have donated PPE stock and offered to assist with manufacturing. Various corporates also made significant PPE donations, along with the People's Republic of China, the WHO and the Solidarity Fund”*. (Quality issues and concerns have been raised in relation to PPE donations from China).

50 Medical Brief. Afrox denies reports of medical oxygen shortages. 15 July 2020.

<https://www.medicalbrief.co.za/archives/afrox-denies-reports-of-medical-oxygen-shortages/>.

51 RuDaSa. Press Release: Oxygen Supplies Vital for Rural Hospitals COVID-19 Response. 22 July 2020.

<http://rhap.org.za/press-release-oxygen-supplies-vital-for-rural-hospitals-covid-19-response/>

52 Doctors Without Borders. COVID-19 and rural South Africa: The good, the bad and the ugly. 15 September 2020. <https://www.msf.org.za/news-and-resources/latest-news/covid-19-and-rural-south-africa-good-bad-and-ugly>

53 World Health Organization. Shortage of personal protective equipment endangering health workers worldwide. 3 March 2020. <https://www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>.

*coronavirus, another troubling divide is also emerging, with poorer countries losing out to wealthier ones in the global scrum for masks and testing materials”.*⁵⁴

In addition to facing global shortages of PPE, South Africa has faced a myriad of domestic challenges in securing and providing quality PPE to frontline workers – including widespread corruption in tenders for PPE, procurement of substandard and unapproved products, and shifting regulatory rules for PPE manufacturing, import and marketing. (These challenges are discussed in greater detail in later sections of the report).

The decentralised nature of procurement has been highlighted as a key factor enabling corruption. KZN Premier Sihle Zikalala explained to the media on 21 July that National Treasury Instruction Note 3 (issued on 15 April) initially required centralised procurement of PPE, but this was quickly overturned by National Treasury Instruction Note 5 which “*effectively decentralised the procurement of PPE products, prescribed the procurement procedures and set the maximum prices to be paid by institutions for selected COVID-19 PPE items and cloth masks*”.⁵⁵ (Spotlight reported in September that Note 5 also undermined efforts by SAHPRA to communicate and uphold newly adopted regulatory requirements for PPE, by failing to clarify that importers, manufacturers and marketers must be licensed by SAHPRA.⁵⁶)

One interviewee noted that South Africa decentralised the procurement processes for PPE after an outcry against central procurement by local businesses and entrepreneurs, adding that “*Treasury completely switched its approach and sent out a new set of circulars which undid the central procurement mechanism and allowed the provinces to procure PPE.*”

Member of Parliament, Ms Maida Dorothy Mabiletsa, stated that “*Decentralised procurement was intended to facilitate the economy in poor and rural provinces. It facilitated localisation*”.⁵⁷

Yet, one interviewee stressed that rather than supporting local PPE manufacturers “*the corrupt tenders were going to middle-men who were sourcing PPE from outside the country*”, adding that delays by

Community, labour, and faith-based groups have mobilised in response to allegations and evidence of corrupt spending under government’s COVID-19 stimulus budget and on PPE.

During August, the South African Council of Churches (SACC), together with the Ahmed Kathrada Foundation, Council for the Advancement of the South African Constitution, Desmond & Leah Tutu Legacy Foundation, Foundation for Human Rights, and Nelson Mandela Foundation created the Moral Call Collective against COVID-19 corruption. The Moral Call Collective has called for accountable, transparent and ethical governance, as well as accountability and consequences for corruption and crime. The South African Council of Churches has also organised silent prayers across the country in protest of corruption.

Union groups, have also mobilised against COVID-19 corruption and on 7 October, the South African Federation of Trade Unions (Safu) and Congress of South African Trade Unions (Cosatu) held protests across the country against corruption, state capture and gender based violence.

Multiple civil society groups and collectives, including the C19 Peoples Coalition, Corruption Watch and Active Citizens Movement (ACM) have highlighted and condemned PPE corruption and the ACM has organised #orangemaskfridays during which individuals and communities can show solidarity in protesting corruption through wearing orange masks.

54 Bradley J, In Scramble for Coronavirus Supplies, Rich Countries Push Poor Aside. New York Times. 9 April 2020. <https://www.nytimes.com/2020/04/09/world/coronavirus-equipment-rich-poor.html>.

55 South African Government. Premier Sihle Zikalala: Forensic investigations into alleged irregular procurement of Personal Protective Equipment and blankets. 21 July 2020. <https://www.gov.za/speeches/premier-sihle-zikalala-forensic-investigations-alleged-irregular-procurement-personal>.

56 Tomlinson C. The tangled web of medical device regulation in SA. Spotlight. 3 September 2020. <https://www.spotlightnsp.co.za/2020/09/03/in-depth-the-tangled-web-of-medical-device-regulation-in-sa/>.

57 Parliamentary Monitoring Group. National Treasury on procurement of PPE for COVID-19. 5 August 2020. <https://pmg.org.za/page/NationalTreasuryonprocurementofPPEforCOVID19>.

SAHPRA in developing and instituting regulatory standards, and licensing local suppliers enabled the corruption. *“If SAHPRA hadn’t been so obstructive and difficult in licensing local manufacturers, the windows and the doors for corruption from bringing in non-compliant PPE from China would have not been there”*.

One interviewee argued that medical device procurement (including PPE procurement) should be centralised as it is for medicine, noting that as South Africa moves towards implementing the National Health Insurance (NHI) *“central contracting is the way to go”*. The NHI Bill, which is currently under review by Parliament, seeks to establish an Office of Health Product Procurement (OHPP) that *“is responsible for the centralised facilitation and coordination of functions related to the public procurement of health related products, including but not limited to medicines, medical devices and equipment”*.⁵⁸

In addition to decentralised procurement, the declaration of a state of disaster was highlighted as a factor that enabled corrupt procurement of PPE as it allowed provinces to procure PPE without going through regular procurement mechanisms (such as securing multiple bids before issuing tenders). One interviewee explained *“in an environment of emergency, provinces could just take a single bid”*.

Shortages of PPE and poor-quality PPE have negatively impacted health services delivery, led to service go-slows and strikes, and placed the lives of health care workers at risk.^{59,60,61} As of 4 August, there have been 27,360 diagnosed COVID-19 cases and 230 COVID-19 deaths among healthcare workers in South Africa.⁶²

According to one stakeholder, the PPE shortages were exacerbated by ‘hierarchical hoarding’ *“where managers and doctors hoarded supplies for themselves, leaving nurses without”*. During May, the Daily Maverick reported that *“Managers at hospitals and clinics in Nelson Mandela Bay are hoarding personal protective equipment for when the outbreak comes”*, while nurses struggle to access PPE.⁶³

Treatments

Multiple treatments are undergoing/have undergone evaluation for treatment of COVID-19 globally. The National Department of Health (NDoH) has undertaken rapid reviews of available evidence of 14 treatments under investigation for COVID-19, which are all available on the NDoH website.⁶⁴

58 Republic of South Africa. National Health Insurance Bill. B11-2019.

59 Cleary K. Desperate pleas as protective gear runs low. Spotlight. 30 March 2020.

<https://www.spotlightnsp.co.za/2020/03/30/covid-19-desperate-pleas-as-protective-gear-runs-low/>.

60 Portia Jonas S. Eastern Cape healthcare woes worsen. New Frame. 23 June 2020.

<https://www.newframe.com/eastern-cape-healthcare-woes-worsen/>.

61 Hlati O. Khayelitsha EMS crew goes on strike over ‘inadequate’ personal protection equipment. IOL. 4 May 2020. <https://www.iol.co.za/capetimes/news/khayelitsha-ems-crews-go-on-strike-over-inadequate-personal-protection-equipment-47499847>

62 Medical Brief. Covid-19’s impact on SA healthcare workers: 230 dead. 19 August 2020.

<https://www.medicalbrief.co.za/archives/covid-19s-impact-on-sa-healthcare-workers-230-dead/>.

63 Ellis E. Health workers infected as managers withhold PPE for “when the outbreak comes”. Daily Maverick. 13 May 2020. <https://www.dailymaverick.co.za/article/2020-05-13-health-workers-infected-as-managers-withhold-ppe-for-when-the-outbreak-comes/>.

64 National Department of Health. COVID-19 rapid reviews. <http://www.health.gov.za/index.php/national-essential-medicine-list-committee-nemlc/category/633-covid-19-rapid-reviews>.

Corticosteroids, such as dexamethasone, are the only specific product currently recommended for treatment of COVID-19 in the public sector—although additional treatments are used for treatment of COVID-19 symptoms such as headaches, fever and body aches.⁶⁵

Dexamethasone was locally registered, locally manufactured, off-patent, and widely available and affordable prior to the emergence of SARS-CoV-2, which has enabled the public sector to provide this medicine for COVID-19 with relative ease. The DoH is procuring locally manufactured, generic dexamethasone from Fresenius Kabi and Pharma-Q. Multiple additional generic dexamethasone products are available for use in the private sector.⁶⁶

Remdesivir, another treatment seen as promising until evidence released by the WHO on 15 October showed no mortality benefit⁶⁷, was available to private sector patients through Section 21 authorisations—but not recommended for use or provided in the public sector.⁶⁸ One interviewee explained (before new WHO evidence was released) that *“the NEMC is not convinced that cost justifies the use of remdesivir, given the paucity of evidence around use of the product”* but added that *“if mortality benefit is shown, its use in the public sector will be reconsidered”*. The price considered by the DoH in judging the cost-effectiveness of remdesivir was the price offered by Cipla.

Tamar Kahn reported in the Business Day that *“Cipla plans to sell the drug at \$55 a shot, or \$330 (R5,600) for a five-day course”* in South Africa, which is *“considerably lower”* than the \$3,120 price tag charged by Gilead for a full-course of remdesivir treatment in the U.S.^{69,70} While generic products offer a 90% cost reduction when compared to the cost of Gilead’s patented product, they remain prohibitively expensive and unrelated to the cost of production. Andrew Hill recently estimated that a full-course of remdesivir treatment can be produced for less than \$10 per person.⁷¹

While remdesivir remains under patent in South Africa until 2035⁷², multiple generic companies have been licensed by Gilead to market generic remdesivir in the country. Gilead licensed nine generic companies to manufacture and market generic remdesivir in 127 countries (mainly LMICs) in May. However, Gilead’s licensing approach has been criticised for limiting access to remdesivir:

65 National Department of Health. Corticosteroids for COVID-19: Evidence review of the clinical benefit and harm. 6 August 2020.

file:///C:/Users/crtom/Downloads/rapid%20review%20of%20corticosteroids%20for%20covid-19%20update%206%20august%202020%20(1).pdf.

66 <https://medicineprices.org.za/#search:dexamethasone>

67 World Health Organization. “Solidarity” clinical trials for COVID-19 treatments. 16 October 2020 Update. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>

68 National Department of Health. Remdesivir for COVID-19: Evidence review of the clinical benefit and harm. 29 September 2020. file:///C:/Users/crtom/Downloads/rapid%20review%20of%20remdesivir%20for%20covid-19%20update_29sept2020.pdf.

69 Kahn T. Cipla’s generic COVID-19 drug lands in SA but the state isn’t buying it. 3 August 2020.

<https://www.businesslive.co.za/bd/national/health/2020-08-03-ciplas-generic-covid-19-drug-lands-in-sa-but-the-state-isnt-buying-it/>.

70 Pharmaceutical Technology. Gilead sets COVID-19 drug candidate remdesivir price at \$390 per vial. 29 June 2020. <https://www.pharmaceutical-technology.com/news/gilead-remdesivir-price/>

71 Clayden P. Potential treatments for COVID-19 could be manufactured for \$1 a day or less. i-base. 17 April 2020. <https://i-base.info/htb/37606>

72 MedsPal.org

- Health Gap stated in May that Gilead’s licensing approach denies competitive access to remdesivir in the 73 countries not included in the license, which are home to half of the global population.⁷³
- South Africa stated in the 16 October TRIPS Council Meeting that “*despite receiving significant public funding of at least US\$70.5 million, Gilead has signed secretive bilateral licenses for Remdesivir... with a few generic companies of its choosing that excludes nearly half of the world’s population from its licensed territories. Much of Gilead’s supply has also been reserved for very rich nations. As a result, to date, most developing countries have barely received any supply of Remdesivir. The prices of Remdesivir are also prohibitively high*”.⁷⁴

Vaccines

Global supply shortages and vaccine nationalism

Over 100 vaccine candidates are under development for COVID-19 globally, of which 11 are in large-scale, phase 3 clinical trials.⁷⁵ Ultimately most of these vaccine candidates will fail to demonstrate safety and efficacy against COVID-19. Oxfam has warned that no companies have the capacity to manufacture vaccines for all people that need them and explained that “*even in the extremely unlikely event that all five [leading] vaccines succeed, nearly two thirds (61 percent) of the world’s population will not have a vaccine until at least 2022*”.⁷⁶

In response to anticipated supply scarcity, several high-income countries have entered at-risk deals with pharmaceutical companies developing COVID-19 vaccines in order to secure first access to the vaccines once they become available. The deals are at-risk because many of the pre-bought vaccines will fail phase 3 trials. According to research by Oxfam, “*wealthy nations representing just 13 percent of the world’s population have already cornered more than half (51 percent) of the promised doses of leading COVID-19 vaccine candidates*”.⁷⁷

Most developing countries are unable to make at-risk deals, as they do not have the fiscal space and flexibility to pay enormous sums to secure vaccines that may fail ongoing safety and efficacy tests. Although India has been able to secure significant stock commitments, based on its position as a leading global manufacturer of vaccines. The Serum Institute of India (the world’s largest vaccine manufacturer) has said that it will keep half of the vaccines that it produces for the people of India, while supplying the other half to the rest of the world.⁷⁸

73 HealthGap. Gilead Remdesivir Licenses: Half Measures Are Not Nearly Good Enough. 13 May 2020.

<https://healthgap.org/gilead-remdesivir-licenses-half-measures-are-not-nearly-good-enough/>

74 Knowledge Ecology International. WTO TRIPS Council (October 2020): South Africa issues clarion call urging support for TRIPS Waiver Proposal. 16 October 2020. <https://www.keionline.org/34235>.

75 Corum J, et al. Coronavirus Vaccine Tracker. New York Times. 27 October 2020 Update/
<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>.

76 Oxfam. Small group of rich nations have bought more than half of the future supply of leading COVID-19 vaccine contenders. 16 September 2020. <https://www.oxfam.ca/news/small-group-of-rich-nations-have-bought-up-more-than-half-the-future-supply-of-leading-covid-19-vaccine-contenders/>.

77 Oxfam. Small group of rich nations have bought more than half of the future supply of leading COVID-19 vaccine contenders. 16 September 2020. <https://www.oxfam.ca/news/small-group-of-rich-nations-have-bought-up-more-than-half-the-future-supply-of-leading-covid-19-vaccine-contenders/>.

78 Gettleman J. Indian Billionaires Bet Big on Head Start in Coronavirus Vaccine Race. New York Times. 15 October 2020. <https://www.nytimes.com/2020/08/01/world/asia/coronavirus-vaccine-india.html>.

The head of the WHO, Tedros Adhanom Ghebreyesus, has urged countries not to pursue ‘vaccine nationalism’—placing the needs of their populations ahead of global needs, but rather to participate in COVAX which is seeking to pool advanced marketing commitments from countries to advance the development of promising vaccine candidates to be equitably distributed across countries.⁷⁹

COVAX

COVAX or ‘The COVID-19 Vaccines Global Access Facility’ is the vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator. The Act Accelerator is a global collaboration seeking to advance the development of health technologies for COVID-19.

COVAX, which is led by GAVI⁸⁰, CEPI⁸¹ and the WHO, is seeking to secure and pool advanced marketing commitments from countries to support the manufacture and delivery of two billion COVID-19 vaccines by the end of 2021 that will be distributed to countries participating in COVAX. Vaccines will be delivered to countries according to their population size. Participating countries will receive enough stock to vaccinate *up to* 20 percent of their population—depending on the number of doses required and the final cost of vaccines delivered. Low-income countries (but not middle-income countries, such as South Africa) participating in the scheme will be subsidised by higher income countries.

South Africa is currently deliberating over whether to participate in COVAX. The Mail & Guardian reported on 14 October that “*South Africa has submitted a non-binding confirmation of intent to participate*” in COVAX, adding that “*aside from solely relying on COVAX, the South African government is trying to secure direct deals with pharmaceutical companies*”.⁸²

Key considerations regarding joining COVAX

While interviewees raised several concerns about COVAX, they largely agreed that South Africa should join the mechanism. It was also noted that, while South Africa was exploring options to secure more affordable vaccines than those offered by COVAX through bilateral deals with pharmaceutical companies, it would be fiscally challenging (and potentially unfeasible) for South Africa to enter at-risk deals as done by high-income countries.

One interviewee noted that South Africa is being asked to pay R2 billion as a down payment to secure vaccines for 5 million people through COVAX. Another interviewee explained that this funding could procure vaccines for between 10 and 20 percent of the population— depending on the final cost of the vaccine and number of doses needed.

Interviewees raised concerns about outstanding uncertainties regarding the final/total costs of procuring vaccines through COVAX will be, or what will ultimately be delivered:

79 UN News. WHO Chief warns against ‘vaccine nationalism’, urges support for fair access. 18 August 2020. <https://news.un.org/en/story/2020/08/1070422>

80 GAVI is an international public-private-philanthropic partnership seeking to advance access to vaccines in LMICs through (among other activities) pooling country demand and procurement. <https://www.gavi.org/>.

81 CEPI, or the Coalition for Epidemic Preparedness Innovations, is an international public-private-philanthropic partnership, that is seeking to advance the development of vaccines against emerging infectious diseases. <https://cepi.net/>.

82 Abdool Karim A. The world could see a COVID-19 vaccine by next year – here’s who will get it and how. Bhekisisa. 14 October 2020. <https://bhekisisa.org/health-news-south-africa/2020-10-14-the-world-could-see-a-covid-19-vaccine-by-next-year-heres-who-will-get-it-and-how/>

- *“COVAX has said it will cost between \$10 and \$22 per dose. If its \$10 we could potentially look at vaccinating 20% of the population, if its \$22 it really limits our ability to buy the vaccine... It is unlikely that we will be able to buy a vaccine for the entire population, we are just not in a position to do that”.*
- *“What it ultimately will cost, well that is our problem, we don't know! People have not costed what will it cost to transport the vaccine from Geneva, we haven't been told what we have to pay for that. What will the cost of the new delivery system be to deliver the vaccine?”*
- *“The lack of information on cost also extends to the COVAX contract, which is virtually silent and non-committal on price. Also, South Africa may ultimately want a much higher level of vaccination coverage, which potentially implies much higher cost - potentially exceeding R10 billion or more”.*
- *“The current contract you have to guarantee several billion rand but there is no guarantee that you get anything back. You have to make a down payment that goes to pharmaceutical companies to help them to start manufacturing even before their product is found effective. Is the location of the risk correct?”*

Interviewees also criticised the lack of tiered-pricing arrangements for middle-income countries offered by COVAX, and queried why the forecasted prices are so high:

- *“The pricing regime is not explicitly tiered. So effectively we are being asked to contribute as much as say Japan or UK, there is no explicit provision for middle income countries, and there have been some questions as to whether we should be negotiating a better arrangement for middle income countries”.*
- *“Pharmaceutical companies will say the R&D cost is what drives the cost of a product especially when it is new. You have so many investors in this R&D, so why is the price still so high? I can't get my head around what is driving the cost of the vaccine to be so high.”*

Another challenge raised by interviewees was that South Africa's procurement laws and processes are not designed to enable advanced market commitments or pooled procurement with other countries:

- *“In general, I think South Africa's procurement approach and law to some extent undermines global equity. Our procurement mechanisms are very country focused and undermine these kind of global procurement efforts. That is partly why we haven't procured from GAVI before... it might require legislative change to change this”.*
- *The Public Finance Management Act (PFMA) “says you can't pay in advance, but when you read it more carefully it says you can't pay in advance unless there is a contractual requirement to do so, so that might address that?”*

One interviewee noted that South Africa had queried options to include some conditionalities in its contract with COVAX (such as building local manufacturing requirements into its contract), but that there has been resistance against this:

- *“Even though we like COVAX very much and are very committed to pooled procurement and international solidarity and don't like the idea of these secret bilateral deals by countries, there is a sense that we are being bullied here a bit because we have sought to negotiate some amendments to the contract with COVAX and they have been very reluctant. They basically say everyone is signing up to the same thing, if it doesn't suit you don't sign up”.*

While interviewees stressed concerns regarding COVAX, they felt that not signing up to COVAX could impede access to vaccines in South Africa after they become available, which would be politically embarrassing:

- *“We are seeing vaccine nationalism where the wealthy countries have already got deals. We are not in position to make those deals just yet, and it is something we would have to do at-risk.*

That's why we have to consider the COVAX option because the COVAX option gives us access that is equitable, so we don't have to stand at back of queue".

- *"I think government would be very embarrassed not to sign up for COVAX unless there was a very good reason for it... it would be seen as the government being very uncaring and remiss if it had not negotiated access to vaccines. There is huge political pressure to say look we really care about our people, we care about our health workers, we are doing everything we can to get early access, to get first in the queue for these things".*

Although one interviewee expressed doubts as to whether not signing up for COVAX would really disadvantage South Africa stating *"I am not convinced that if we go the COVAX route we are going to get a huge supply early and if we don't go the COVAX route we are going to get nothing".*

Vaccine delivery and cold storage

In addition to procurement approaches for COVID-19 vaccines, interviewees highlighted concerns regarding how vaccines would be delivered, and what this would cost. Aisha Abdool Karim recently explained in the Mail & Guardian that *"South Africa would need to devise an entirely new vaccine delivery system — one aimed at immunising adults as opposed to the current setup that focuses on vaccinating children"* in order to deliver the COVID-19 vaccine.⁸³

One interviewee explained that *"When HPV was put in place it required an entirely new delivery system to schools, and school health nurses had to be available in some places to administer the vaccine. This vaccine might have to be done with industries, it might require special storage facilities, what is the cost of that? No one has done that work".*

Another interviewee stressed concerns about cold storage requirements for transporting and delivering vaccines to patients, stating that if the vaccine candidate that is ultimately successful is one of the products under development *"that requires storage at minus 70 or minus 80 degrees Celsius it is not something that we will be able to consider in South Africa. The cold chain is a very big problem, even with Eskom, fridges go down, you don't have a generator, you are in trouble".*

Rationing vaccines/ Identifying priority populations

A further challenge that will be faced in delivering the vaccine will be identifying who will be eligible to receive it, as South Africa may be unable to source or procure adequate vaccine supply for its entire population. The WHO has developed a framework to assist countries in identifying priority groups and work is reportedly underway to identify who will be given the first rounds of vaccines in South Africa.

Aisha Abdool Karim clarified in Bhekisisa that the rollout plan will need to be 'adjustable' as it is not yet known how many vaccines doses will be required per person, which will impact how many people can be vaccinated.⁸⁴

⁸³ Abdool Karim A. The world could see a COVID-19 vaccine by next year – here's who will get it and how. Bhekisisa. 14 October 2020. <https://bhekisisa.org/health-news-south-africa/2020-10-14-the-world-could-see-a-covid-19-vaccine-by-next-year-heres-who-will-get-it-and-how/>.

⁸⁴ Abdool Karim A. The world could see a COVID-19 vaccine by next year – here's who will get it and how. Bhekisisa. 14 October 2020. <https://bhekisisa.org/health-news-south-africa/2020-10-14-the-world-could-see-a-covid-19-vaccine-by-next-year-heres-who-will-get-it-and-how/>.

One interviewee explained *“It is important that we source vaccines for most vulnerable groups and priority groups, but we even need more data to identify these groups”*, adding *“The MAC will make a recommendation to the Minister of Health on how the vaccine should be rationed and distributed and based on other criteria the Minister may or may not take forward the MAC’s recommendation”*.

The SAMRC is reportedly currently *“working on translating Western approaches to fair allocation into our local context”*.⁸⁵ SAMRC Bioethics Advisory Committee Ames Dhai told Bhekisisa that *“it’s not just putting together a framework, but involving communities and being transparent right from the outset”*. *“We must make sure that our communities actually understand why only certain parts of the populations are going to get the vaccine first because this will promote legitimacy, trust, and also a sense of ownership of such decisions.”*⁸⁶

One interviewee noted that civil society can play a role in communicating to the public why the vaccine needs to be given to vulnerable and priority groups first— adding that *“the flu shot flew off the shelves when it arrived in South Africa and it wasn’t the people who needed it the most who got it”*.

It was also noted that civil society could play a role in combating anti-vaccination messaging that may impede uptake of the vaccine. In a recent survey conducted on behalf of the World Economic Forum, only 64 percent of South African indicated that they would accept a vaccine for COVID-19 when and if it becomes available—while only 82 percent indicated that they believed vaccines are safe.⁸⁷

SECTION 27, the public interest law firm, is currently exploring how a human rights frameworks and lens can be applied in South Africa to identify populations that are eligible to receive the vaccine.⁸⁸

Public versus private sector distribution/allocation

In response to queries regarding public versus private distribution of the vaccine, it was noted that during the initial phase, COVAX will only allocate supply to governments – although the private sector may enter into agreements with pharmaceutical companies to buy vaccines once they are registered in the country.

One interviewee noted that *“We see it more as working in collaboration with the private sector, rather than in competition with the private sector. A lot of the private sector patients when they access a vaccine, it’s a state vaccine”*. *“The conversation is not them versus us, but rather how do we include them to ensure that priority groups are vaccinated. For example, if we talk about vaccinating health care workers, we are not just looking at public sector health care workers, we are looking at healthcare workers in South Africa”*.

Another interviewee asked *“should government just give the vaccines free of charge to the private sector like everybody else or should they charge the private sector, and then should they charge the*

85 Abdool Karim A. The world could see a COVID-19 vaccine by next year – here’s who will get it and how. Bhekisisa. 14 October 2020. <https://bhekisisa.org/health-news-south-africa/2020-10-14-the-world-could-see-a-covid-19-vaccine-by-next-year-heres-who-will-get-it-and-how/>.

86 Abdool Karim A. The world could see a COVID-19 vaccine by next year – here’s who will get it and how. Bhekisisa. 14 October 2020. <https://bhekisisa.org/health-news-south-africa/2020-10-14-the-world-could-see-a-covid-19-vaccine-by-next-year-heres-who-will-get-it-and-how/>.

87 Baleta A. What we know about vaccine hesitancy in South Africa. Spotlight. 7 October 2020. <https://www.spotlightnsp.co.za/2020/10/07/what-we-know-about-vaccine-hesitancy-in-south-africa/>

⁸⁸ Stakeholder input.

private sector at cost, or at a premium which would help to finance the public sector to buy more doses?”

SECTION 2: Budgets, regulatory frameworks, and local capacity for research, development and manufacturing

Budgets for COVID-19 responses in South Africa

President Cyril Ramaphosa announced a stimulus package of R500 billion in April 2020 to mitigate the social and economic consequences of COVID-19 and support the country's COVID-19 response. The Mail & Guardian reported that *“of the R500-billion proposed economic stimulus, R130-billion will come from a reprioritisation of the current budget, with the rest of the funds to be raised from local sources, including the UIF, as well as from global partners and international finance institutions that have worked on financing packages to assist countries to address the effects of the coronavirus. The biggest part of the R500-billion would be a R200-billion loan guarantee scheme, in partnership with major banks, the treasury and the South African Reserve Bank”*.⁸⁹

While the stimulus package aims to support and expand social and economic relief services in the country, spending under the package, including on PPE, food relief and unemployment insurance, has been plagued by allegations of corruption⁹⁰ and has been woefully inadequate—not reaching significant parts of the population⁹¹. One interviewee further noted that the stimulus package has largely had to plug holes in the existing budget, as revenue dropped by R300 billion this year, which has impeded government's ability to expand social services to mitigate the impact of COVID-19. The interviewee added however that *“The revenue drop is not just this year (2020/21), but over the three-year MTEF, and likely to lead to reductions in health budgets”*.

While conducting a full review of COVID-19 spending on health services was beyond the scope of this project, budgets figures identified from grey literature and in the course of stakeholder interviews are shared below:

- R500 billion: South Africa's COVID-19 social support and economic relief package
- R21,5 billion: Supplementary budget split between the national and provincial departments of health to support their COVID-19 responses⁹²
- R2 billion: The advanced market commitment that South Africa is required to pay to participate in COVAX⁹³
- R80 million: Funding repurposed by the SAMRC from previous financial year, other budget allocations (including DSI funds) and savings (e.g. on travel) to support COVID-19 R&D.⁹⁴

89 Tromp B. Ramaphosa announces R500 billion COVID-19 package for South Africa. Mail & Guardian. 21 April 2020. <https://mg.co.za/article/2020-04-21-ramaphosa-announces-r500-billion-covid-19-package-for-south-africa/>.

90 Chutel L. South Africa's Big Coronavirus Aid Effort Tainted by Corruption. 19 August 2020. <https://www.nytimes.com/2020/08/19/world/africa/coronavirus-south-africa-aid-corruption.html>.

⁹¹ Stakeholder input.

92 van den Heever A. South Africa sets aside more money for COVID-19 but lacks a spending strategy. The Conversation. 29 June 2020. <https://theconversation.com/south-africa-sets-aside-more-money-for-covid-19-but-lacks-a-spending-strategy-141619>.

93 Key informant interview

94 Key informant interview

- The SAMRC has an annual budget of around R1 billion which includes base line grants and donor funds.⁹⁵ The SAMRC has therefore allocated around 8% (R80 mill) of its annual budget for COVID-19 R&D. The repurposing of existing funds for COVID-19 R&D is concerning as it means that R&D financing is likely being diverted away from other health conditions for which R&D remains urgent (i.e., TB, HIV, NCDs).
- R25 million: Funding provided to Biovac from the DSI to support the vaccine manufacturer in expanding its capacity to ‘fill and finish’ COVID-19 vaccines⁹⁶
- R14 million: The value of seven funding awards made by DSI, TIA and the SAMRC to support local companies in developing COVID-19 test materials and tests.⁹⁷

Legal frameworks governing intellectual property

South Africa’s Patents Act 57 of 1978 outlines legal requirements for protecting intellectual property (IP) in the country. As a member of the World Trade Organisation (WTO), South Africa is required to provide protections for IP in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While TRIPS requires that WTO member countries provide 20-year periods of patent monopoly protection, it also contains safeguards that countries can use to protect the right to health and combat abusive patenting practises (i.e. patenting minor modifications of existing products). However, in order to use these safeguards, countries must first incorporate them into their national laws.

While South Africa’s Patents Act provides for 20-year monopoly periods, it does not contain many of the safeguards to protect health or combat abusive patenting provided under TRIPS. As a result, South Africa routinely grants patents that are rejected, withdrawn or overturned in other parts of the world.⁹⁸ The granting and upholding of patents rejected elsewhere often prevents people living in South Africa from accessing more affordable generic and biosimilar versions of medicines long after they are available on the global market.⁹⁹

Research demonstrates that the vast majority of patents granted in South Africa don’t even meet the country’s own patentability criteria, as South Africa grants patents without examining the substantive merits of patent applications (i.e., whether patentability criteria are met).¹⁰⁰

Recognising the harmful impact of South Africa’s patent laws and processes on access to medicines, the Treatment Action Campaign, SECTION27, and Doctors Without Borders launched the Fix the Patent Laws coalition in 2011 to advocate for pro-public reform of the country’s patent laws. The coalition has subsequently grown to include more than 40 patient groups.

⁹⁵ South African Medical Research Council. Annual Performance Plan for 2019/20. https://static.pmg.org.za/SAMRC_APP_2019_2020.pdf

⁹⁶ Key informant interview

⁹⁷ Key informant interview

⁹⁸ Fix the Patent Laws. Why IP reform in South Africa will help not hurt economic development and innovation. 2019. <https://www.fixthepatentlaws.org/resources/why-ip-reform-in-sa-will-help-not-hurt-economic-development-innovation-2019/>

⁹⁹ Fix the Patent Laws. Why IP reform in South Africa will help not hurt economic development and innovation. 2019. <https://www.fixthepatentlaws.org/resources/why-ip-reform-in-sa-will-help-not-hurt-economic-development-innovation-2019/>

¹⁰⁰ Fix the Patent Laws. Why IP reform in South Africa will help not hurt economic development and innovation. 2019. <https://www.fixthepatentlaws.org/resources/why-ip-reform-in-sa-will-help-not-hurt-economic-development-innovation-2019/>.

In response to ongoing pressure from civil society, as well as evidence demonstrating the harmful impact of South Africa's patent laws, government committed to reform the country's patent laws. In 2018, South Africa adopted phase 1 of a new national intellectual property policy. The Intellectual Property Policy of the Republic of South Africa: Phase 1 deals with issues related to IP and health and commits to (among other reforms) introduce examination procedures to assess the merits of patent applications prior to their granting, strengthen the country's patentability criteria to encourage genuine innovation, and simplify procedures for granting compulsory licenses when patents impede health rights.

Yet, while South Africa committed to pro-public health reform of its patent laws in 2018, a Bill to reform the country's patent laws in line with policy commitments has still not been introduced to Parliament.

During May 2020, Fix the Patent Laws together with over 80 academics, researchers and teachers sent a letter to President Ramaphosa calling on government to take urgent steps to reform the country's laws. The letter stated *"we are writing because of the urgency of completing the process of amending South Africa's Patent Law to strengthen patentability criteria, to provide for substantive examination of patent applications, and to adopt lawful flexibilities under the WTO TRIPS Agreement to ensure access to medicines for all. That long-delayed imperative is even clearer now as we face high prices and limited supplies of vitally needed COVID-19 health products"*.

Adding *"It is therefore imperative that the draft legislation is tabled, through the relevant Minister, as a matter of urgency, subjected to a short period of public comment, processed expeditiously through our legislature, and assented to by the President"*.¹⁰¹

One interviewee noted that *"draft legislation to reform South Africa's Patent Laws is currently undergoing an internal government review process. When this technical work is finished there will be a bureaucratic process to take legislation through Cabinet and introduce it to Parliament"*. While there is not a set timeline to introduce the Bill to Parliament, and many previous deadlines have been missed, it was noted that the Bill was expected to be introduced during 2020. *"The presidency has given a directive that no legislation will be considered this year if it is not directly related to COVID. This legislation is able to move forward because it is very important in the context of COVID-19"*.

Although one stakeholder said it is very unlikely that a Bill to reform the Patents Act will be introduced to Parliament this year, as it is not reflected on the legislative calendar.

In addition to highlighting the urgency of domestic law reform, Fix the Patent Laws have called for the adoption of *"a temporary moratorium on the issuance of any patents on COVID-19-related health products for the duration of the pandemic emergency"*.¹⁰²

101 Fix the Patent Laws. More than 80 academics, researchers and teachers call on President Ramaphosa to fix the patent laws. 20 May 2020. <https://www.fixthepatentlaws.org/more-than-80-academics-researchers-and-teachers-call-on-president-ramaphosa-to-fix-the-patent-laws/>.

102 Fix the Patent Laws. More than 80 academics, researchers and teachers call on President Ramaphosa to fix the patent laws. 20 May 2020. <https://www.fixthepatentlaws.org/more-than-80-academics-researchers-and-teachers-call-on-president-ramaphosa-to-fix-the-patent-laws/>.

The extent to which patents will impact access to COVID-19 health technologies was however contested by interviewees—echoing international debates and discussions regarding the role of IP in impeding access to COVID-19 health technologies.¹⁰³

One interviewee noted that in seeking to proactively identify potential barriers to health technology access for COVID-19, a search was undertaken of COVID-19-related patents by the Companies and Intellectual Property Commission (CIPC) and that no pending applications or granted patents were identified. Although one stakeholder contradicted this, saying that patents held by Cepheid in South Africa are an impediment to local production of COVID-19 diagnostic cartridges for use on GeneXpert platforms.

Two interviewees said that they did not expect patents would impede COVID-19 health technology access in South Africa, as they had seen an ‘unprecedented’ willingness to share knowledge, data, resources, and materials. One interviewee said *“Everyone that we have dealt with appears to have nothing but good intentions when it comes to providing affordable access”*, adding *“Any company that has a product for COVID and is not prepared to provide affordable access to it is going to be hammered in the press and face reputational damage and I don’t think anyone is going to risk that”*.

Despite doubts raised about the impact that patents will have on access to COVID-19 health technologies in South Africa, the country has taken a leading role globally in advocating against the granting of patents on COVID-19 health technologies.

Request for TRIPS waiver

On 2 October, South Africa, together with India, asked the WTO to waive its rules governing patents and other intellectual property protection to allow countries to choose to neither grant nor enforce patents on COVID-19 health technologies for the duration of the pandemic, until global herd immunity is achieved. This issue was debated during the 16 October TRIPS Council meeting, below is a summary of the meeting’s outcomes copied from keionline.org:

On Friday, 16 October 2020, members of the World Trade Organization’s (WTO) TRIPS Council held a three hour debate on the proposal (IP/C/W/669) first tabled by India and South Africa for a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. By Friday, Eswatini and Kenya emerged as co-sponsors of the TRIPS waiver proposal.

From informed sources, three blocs emerged from the discussions:

- WTO Members who supported the proposal, the vast majority of which were least developed and developing countries (Tanzania on behalf of the African Group, Chad on behalf of the LDC members, Bangladesh, Sri Lanka, Pakistan, Venezuela, Honduras, Nepal, Nicaragua, Egypt, Indonesia, Argentina, Tunisia, Mali, Mauritius and Mozambique);
- WTO Members who expressed their rejection of the text, the vast majority of which were developed countries (European Union, United States of America, Switzerland, Norway, Australia, Canada, Japan and the United Kingdom), joined by Brazil;
- WTO members who welcomed the proposal but asked for further clarification on some points, particularly with regards the possible economic impact of the waiver and said they were consulting with capital in order to make a more informed decision (Nigeria, Philippines, Turkey, Ecuador, China, Thailand, Senegal, Jamaica, Colombia, Costa Rica, Chile and El Salvador).

At the end of Friday’s deliberations, South Africa made the following procedural request:

¹⁰³ Malpani et al. Corporate Charity – Is the Gates Foundation Addressing or Reinforcing Systemic Problems Raised by COVID-19? Health Policy Watch. 31 October 2020. <https://healthpolicy-watch.news/gates-foundation-address-systemic-covid-19/>

- It is clear that Members have different opinions regarding the waiver proposal introduced at today's TRIPS Council meeting, there is a need to discuss this proposal further. According to Article IX.3(b) a request for a waiver shall be submitted to the relevant Council for consideration during a period which shall not exceed 90 days. We request that this item remain open for discussion for the intervening period. This can be done on the basis suspending this item and reconvening the TRIPS Council formally or informally or through consultations that may be convened by you or a combination of both modalities.

Excerpts from South Africa's statements at the 16 October TRIPS Council meeting are also provided below:

- Never has there been a weaker case for the granting of monopolies. Governments have been funding the development of COVID drugs and vaccines, and no company is able to meet the global demand. In the context of COVID-19, despite the billions of tax payer dollars invested in R&D, and announcements that COVID-19 vaccines should be considered a public good, no government has openly stated committed to this undertaking.
- In 2004 the highly pathogenic avian influenza H5N1 re-emerged, developed countries had priority access, while affected developing countries did not. Within 5 years another pandemic flu (H1N1) emerged and once again rich countries placed large pre-orders of a vaccine buying almost all doses that could possibly be manufactured. Many countries promised to donate vaccines, most of them reneged and moved to secure their own countries' supply. With COVID-19 history is repeating itself.
- The "case by case" or "product by product" approach required when using flexibilities to address IP barriers at the national level could be limiting during the pandemic. Some countries also face limitations with respect to their national laws, pressures from their trading partners, or lack the practical and institutional capacity required to exercise TRIPS flexibilities during the pandemic quickly and effectively. The existing mechanisms for compulsory licenses under Article 31 and Article 31bis of the TRIPS Agreement contain territorial and procedural restrictions that make the practice of issuing product-by-product compulsory licenses a complex process, making it difficult for countries to collaborate. Article 31 requires that compulsory licenses are issued on a case-by-case basis and used predominantly to supply domestic markets, thereby limiting the ability of manufacturing countries to export to countries in need.
- Governments and public funding agencies around the world have poured billions of US dollars of public money to support COVID-19 R&D, especially for drugs and vaccines. However, by and large no conditions for access or affordability have been included as a precondition to any of that funding. Governments must attach strings to any public money given for COVID-19 medical tools to guarantee that, if they prove safe and effective, they are available to everyone. Today some Members have admitted that some conditions had been set on companies, but none of it goes far enough to ensure that IP rights assigned to companies benefiting from taxpayer money do not abuse such rights down the line.
- It is the pandemic – not IP – that has mobilized collaboration of multiple stakeholders. It is knowledge and skills held by scientists, researchers, public health experts and universities that have enabled the cross-country collaborations – not IP! It is public funding, again, facilitated these collaborations – not IP!

In addition to calling for a waiver to enable countries to not grant or enforce COVID-19 patents, South Africa has supported and signed up for the COVID-19 Technology Access Pool (C-TAP), launched by the WHO and Costa Rica to encourage and enable the voluntary sharing of patents, know-how, data and other resources needed for local manufacture of COVID-19 health technologies. Yet, C-TAP has struggled to secure support from wealthy countries and, according to South Africa's statements during the 16 October TRIPS Council meeting *"to date not a single company has committed to the voluntary Covid-19 Technology Access Pool of WHO"*.¹⁰⁴

Ellen T'Hoen wrote in The Wire on 14 October that the lack of political support for C-TAP from wealthy countries and industry necessitates the TRIPS waiver requested by South Africa and India. T'Hoen stated that *"despite the lofty promises of the vaccine as a global public good, wealthy nations are not making such demands. It is therefore understandable that developing countries are also looking at non-*

¹⁰⁴ Knowledge Ecology International. WTO TRIPS Council (October 2020): South Africa issues clarion call urging support for TRIPS Waiver Proposal. 16 October 2020. <https://www.keionline.org/34235>.

*voluntary measures such as the proposal for a temporary waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. No doubt this will be met with opposition from wealthy countries and drug companies. But those countries and companies who refuse to make the WHO C-TAP a success while telling developing countries they are not entitled to take measures to protect public health in the midst of a global health crisis are not credible”.*¹⁰⁵

Wealthy countries (incl., the U.S., EU countries, and Japan) that are home to large international pharmaceutical companies (incl. those developing leading COVID-19 vaccine candidates) are opposing South Africa and India’s request for a waiver from the requirements of TRIPS during the pandemic..

Publicly funded R&D

The South African Medical Research Council (SAMRC) is supporting multiple research projects towards the development of COVID-19 health technologies, together with other partners such as the DSI and TIA.

The SAMRC has provided funding of around R1 million each to two of the global COVID-19 treatment and prevention clinical trials that have sites in South Africa: the Solidarity Trial and the Crown Coronation Trial. The R1 million contribution provided by the SAMRC to each trial has gone towards supporting local sites participating in the two international trials.

1. The Solidarity Trial is an international trial launched by the WHO comparing the effectiveness of different treatments against COVID-19. On 16 October, the WHO reported that interim results *“found that all 4 treatments evaluated (remdesivir, hydroxychloroquine, lopinavir/ritonavir and interferon) had little or no effect on overall mortality, initiation of ventilation and duration of hospital stay in hospitalized patients. The Solidarity Trial is considering evaluating other treatments, to continue the search for effective COVID-19 therapeutics. So far, only corticosteroids have been proven effective against severe and critical COVID-19”*.¹⁰⁶
2. The COVID-19 Research Outcomes Worldwide Network for CORONAVIRUS mitigation (CROWN) Coronation Trial is a Gates foundation supported trial. The trial is evaluating the effectiveness of a repurposed MMR vaccine in protecting healthcare workers from COVID-19.¹⁰⁷

In addition to the two international COVID-19 treatment trials underway in South Africa, South Africa is participating in multi-country trials of three COVID-19 vaccines: the Oxford/AstraZeneca vaccine; the Johnson & Johnson vaccine; and the Novavax vaccine. The AstraZeneca/Oxford and the Novavax vaccines are two of the nine “CEPI-supported candidate vaccines [and] are part of the COVAX initiative”. In addition to the nine vaccine candidates currently receiving support from CEPI, another

105 t’Hoen E. COVID-19 Crisis and WTO: Why India and South Africa’s Proposal on Intellectual Property is Important. The Wire. 12 October 2020. <https://thewire.in/law/covid-19-crisis-wto-intellectual-property-vaccine-public-health>.

106 World Health Organization. “Solidarity” clinical trials for COVID-19 treatments. 16 October 2020 Update. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>

107 News24. Repurposed vaccine trials to fight COVID-19 set to kick off in SA – report. 21 September 2020. <https://www.news24.com/news24/southafrica/news/repurposed-measles-vaccine-trials-to-fight-covid-19-set-to-kick-off-in-sa-report-20200921>

nine candidates are being evaluated for inclusion in COVAX.¹⁰⁸ (The Cape Town-based medical trials centre, TASK, is also investigating whether re-vaccination of healthcare workers with the BCG vaccine reduces their risk of COVID-19 infection and/or severity of symptoms.¹⁰⁹)

South Africa has reportedly taken a decision not to fund new vaccine development for COVID-19, given the extensive number of candidates already in development globally, and rather focus resources on getting promising vaccine candidates trialled and manufactured in South Africa. It was further noted that, given the pressure on limited funding resources, South Africa is not in a position to fund vaccine trials on its own, is therefore unable to trial vaccine candidates without funding support from industry and other donors. One interviewee noted that *“our expectation is that the actual owner or developer of the vaccine would largely pay or raise funding for the trial, and we would make a contribution to the sites that are in SA”*.

The SAMRC is also funding R&D towards the development and commercialisation of COVID-19 test reagents and rapid tests, together with the DSI and TIA. One interviewee reported that the SAMRC has made three funding awards to support the local development of reagents for PCR diagnostics, and four funding awards towards the development of point-of-care rapid diagnostic tests. While none of the publicly funded COVID-19 tests or test reagents are yet available on the market, some are close to the stage of regulatory review.¹¹⁰

Public financing has also been provided to support surveillance, epidemiology, genomics research, as well as the collection of good quality convalescent plasma for use in further trials.

Ownership and commercialisation of publicly funded health technologies

Intellectual property developed from public financing is governed under the Intellectual Property Rights from Publicly Financed Research and Development Act (the IPR Act)¹¹¹. Tomlinson and Low explain that *“The IPR Act introduced obligations for management of IP resulting from research supported through public financing in South Africa, regardless of the proportion of public financing to overall R&D expenditure. For institutions listed in the Act, the only research excluded from the Act’s obligations is research that is paid for at least at the deemed full-cost from non-public sources. Full-cost must include all direct and indirect costs incurred during the research, including staff and overhead costs at institutions undertaking research”*.¹¹²

One interviewee explained that the IPR Act applies to all research supported with government funds including where public funds contribute towards vaccine trials; but noted that the Act it is unlikely to come into play in relation to vaccines that are being trialled in South Africa with partial public support as it is not expected that new IP related to the vaccine will be developed at the trial sites. *“A clinical trial aims to look at the effect of giving a product to a patient and typically does not involve improving that product or changing its properties. So, I think it is very unlikely that new IP will be developed”*. *“However, if IP is developed specifically with the use of public funds then the IPR Act would apply”*.

¹⁰⁸ It is unclear whether the Johnson & Johnsons vaccine is being evaluated for inclusion in COVAX.

¹⁰⁹ <https://task.org.za/2020/05/04/covid-19-bcg-vaccine-trial/>

¹¹⁰ Interviewee input

¹¹¹ REGULATIONS MADE IN TERMS SECTION 17 OF THE INTELLECTUAL PROPERTY RIGHTS FROM PUBLICLY FINANCED RESEARCH AND DEVELOPMENT ACT, 2008 (ACT NO. 51 OF 2008). 2 August 2010.

https://www.gov.za/sites/default/files/gcis_document/201409/33433675.pdf

¹¹² Tomlinson C, Low M. Tuberculosis innovation approaches in SA and strategies to secure public returns. 2019. Fix the Patent Laws. <https://www.fixthepatentlaws.org/wp-content/uploads/2020/05/Tuberculosis-Innovation-Approaches-in-SA-Strategies-to-Secure-Public>Returns-Tomlinson-Low.pdf>

Domestic public funders of health R&D, such as the SAMRC, typically include standard clauses in all funding contracts requiring that the commercialisation of resultant innovations is undertaken in a way that provides affordable access in South Africa and other developing countries.¹¹³

The IPR Act also encourages, but does not require, that holders of publicly funded IP use non-exclusive licensing approaches for commercialisation. In response to queries regarding the number of companies that would be licensed to commercialise publicly funded tests and test materials, it was explained that *“initially it might just be one company because we don’t have a lot to choose from, there are very few companies in South Africa that can make lateral flow devices... or that have the required certifications to produce test materials. The idea would be to diversify to include other suppliers if the demand is there”*.

Transparency of IP, licensing and commercialisation arrangements

South Africa recently expressed concern about non-transparency of licensing and commercialisation agreements for COVID-19 health technologies globally, telling the TRIPS Council that *“in cases where companies have made such commitments to issue voluntary licenses, the lack of transparency of license agreements for products to treat COVID-19 is substantial”*.¹¹⁴

Medicine access advocates have long called for improved transparency of patent landscapes, licensing and commercialisation arrangements, R&D financing (including public contributions), and health technology production costs to improve medicine affordability and access.¹¹⁵ One interviewee, commented on the challenges faced in requiring that contracts relating to IP ownership, licensing and commercialisation are transparent—noting that South Africa *“was not in the best bargaining position”* to demand transparency, particularly from large international companies, as its investments are typically dwarfed by those of more wealthy countries and investors not requiring transparency.

Regulation of medical products

The South African Health Products Regulatory Authority (SAHPRA) is responsible for the regulation of medicines, medical devices, clinical trials, and radiation emitting devices in South Africa. SAHPRA replaced South Africa’s former regulator, the Medicines Control Council (MCC) in February 2018, after the 2008 and 2015 Amendments Acts to the Medicines and Related Substances Act [101 of 1965] came into force. In addition to establishing SAHPRA, the Amendment Acts introduced requirements for the registration of medical devices in South Africa—which were previously unregulated under the MCC.

The term medical devices encompasses a broad range of products used for COVID-19, including PPE, ventilators and invitro diagnostics (IVDs). While regulations for the registration of medical devices and

¹¹³ Interviewee input

¹¹⁴ Knowledge Ecology International. WTO TRIPS Council (October 2020): South Africa issues clarion call urging support for TRIPS Waiver Proposal. 16 October 2020. <https://www.keionline.org/34235>.

¹¹⁵ Malpani et al. Corporate Charity – Is the Gates Foundation Addressing or Reinforcing Systemic Problems Raised by COVID-19? Health Policy Watch. 31 October 2020. <https://healthpolicy-watch.news/gates-foundation-address-systemic-covid-19/>

IVDs have been published¹¹⁶, no medical devices have yet been ‘called-up’ and therefore no medical devices currently require registration in South Africa.¹¹⁷

In the absence of medical device registration, SAHPRA has released a flurry of communications outlining the requirements that medical device companies marketing, manufacturing, or importing COVID-19 health technologies must meet. Since the start of the pandemic, SAHPRA has issued 25 communications to stakeholders providing detailed guidance on the standards and requirements for COVID-19 health technologies.¹¹⁸ All COVID-19 tests and test materials, for example, must be validated by the National Health Laboratory Service prior to being marketed in the country.

SAHPRA is also using Section 21 authorisations as a mechanism to control the marketing of COVID-19 diagnostic tests and ventilators in South Africa. Some stakeholders have criticised the use of Section 21 authorisation processes by SAHPRA as inappropriate noting that the legal provision is only relevant for registerable products—which medical devices are not. Yet, despite legal ambiguity, the use of Section 21 authorisations has enabled SAHPRA to oversee and regulate the sale of medical devices for COVID-19 in South Africa without undergoing the time-consuming legal processes that are required for a product call-up.¹¹⁹

In addition to requiring Section 21 authorisations for the marketing of some COVID-19 products, as of March 2020, all establishments manufacturing, distributing and marketing medical devices in South Africa (excluding non-sterile Class A medical devices without a measuring function) must be licensed by SAHPRA. As part of its establishment licensing processes, SAHPRA requires that establishments provide proof of registration or marketing authorisation by a recognised regulatory authority for all devices defined as moderate or high risk.¹²⁰

Several interviewees noted that SAHPRA’s regulatory process have delayed access to COVID-19 health technologies:

- Regulatory pathways for locally produced test materials have *“been a nightmare because SAHPRA is not set up to provide licensing pathways for any medical devices or test kits, they have not developed this because they are so dependent on reliance models”*.
- *“SAHPRA tried its best, they were not focussing on the problem, but on covering their backs”*.
- One interviewee criticised SAHPRA’s approach to regulating medical devices, stating *“they are just taking what they do with medicines and applying it to medical devices. SAHPRA is regulating in ways that are not fit for purpose. They are just not set up to handle it. They must go back to drawing board”*.
- *“The regulators are all under-funded and under-resourced. It is not just SAHPRA, but the labs and groups that test. SANAS was not even sending inspectors out during COVID”*.

Another interviewee explained that delays in registering medical devices were also due to a lack of understanding among industry members regarding what is required for SAHPRA approval, which has led to the submitting of incomplete applications. *“In some cases, it is not that products are not getting registered because of SAHPRA, it is because something is missing in the application, for example not*

116 Medicines and Related Substances Act, as well as Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices (IVDs)

117 Tomlinson C. The tangled web of medical device regulation in SA. Spotlight. 3 September 2020.

<https://www.spotlightnsp.co.za/2020/09/03/in-depth-the-tangled-web-of-medical-device-regulation-in-sa/>.

118 <https://www.sahpra.org.za/medical-devices/> See communications MD001 to MD025

119 Tomlinson C. The tangled web of medical device regulation in SA. Spotlight. 3 September 2020.

<https://www.spotlightnsp.co.za/2020/09/03/in-depth-the-tangled-web-of-medical-device-regulation-in-sa/>.

¹²⁰ Ibid.

all of the required data is available, or the application is incomplete. SAHPRA's expert committees on medical devices are meeting twice a week to evaluate applications, so that should not be a bottleneck".

Lack of transparency regarding SAHPRA's processes was noted as a challenge. *"SAHPRA, they've got this notion about conflict of interest they operate secretly. I think it is completely wrong. I think their technical evaluation teams must be known to the public, their minutes should be published, we need transparency in that process".* Vawda and Gray have previously highlighted that secrecy provisions contained in section 34 of the Medicine and Related Substances Act create legal impediments to transparency by SAHPRA and have proposed reforms to address the problematic provisions. Vawda and Gray state *"It is accordingly submitted that section 34 of the Medicines Act is unconstitutional, to the extent that it violates the right to access to information in section 32 of the Constitution of SA, and should be amended in an appropriate manner to accommodate the fundamental right to access to information".*¹²¹

Regulation of vaccines

As the body responsible for the regulation of medicines, SAHPRA will have to register vaccines or provide Section 21 authorisations to enable the use of unregistered products in the country prior to the rollout of vaccines. This raises questions about how the regulatory process may impact the rollout of vaccines, once they are available from COVAX or alternate sources.

One interviewee stressed the importance of SAHPRA's regulatory processes to ensure the safety and efficacy of COVID-19 vaccines, stating *"we want our regulator to give us assurance that the safety, quality, efficacy is there, because we are concerned, we have seen the articles talking about other regulators cutting corners, especially in the USA".*

What remains unclear is what regulatory pathway SAHPRA will use for registration of COVID-19 vaccines. Outstanding questions include:

- Will SAHPRA utilise reliance pathways to approve products locally that have been approved by a recognised regulatory authority or through WHO pre-qualification processes?
- Will there be additional research and data requirements for the registration of vaccines that have not been trialled in South Africa (or another similar context)?
- Will Section 21 authorisations be used for rollout of vaccines in the absence of regulatory approval?

One interviewee said *"just because a vaccine works in other populations doesn't mean it is going to work in ours, so I think it is important to trial those products here to see whether they work in our population, but I personally don't think it's a barrier to registration if they are not trialled here if sufficient data from other jurisdictions is available for review. They may, however, at least require some kind of bridging study to see if one can find the same correlates of protection in a smaller study in our populations".*

While South Africa's regulatory body utilises reliance models that enable SAHPRA to rely on work done and decisions made by other recognised regulatory bodies in evaluating applications for domestic registration, SAHPRA's current regulatory guidelines do not allow for the use of reliance pathways in

¹²¹ Vawda Y, Gray A. Transparency in medicines regulatory affairs – reclaiming missed opportunities. S Afr J Bioethics Law 2017;10(2):70-74. DOI:10.7196/SAJBL.2017.v10i2.607

evaluating applications for “products containing chemical entities/active moieties that are not registered in South Africa”.¹²²

In August 2020, SAHPRA’s spokesperson, Yuven Gounden told Spotlight (in response to queries about SAHPRA’s regulatory pathways and their impact on HCV medicine access) that SAHPRA is revising its clinical reliance framework to “achieve maximum value from work already done elsewhere” and “accommodate the use of reliance pathways in reviewing applications for new chemical entities”.¹²³

Manufacturing capacity for COVID-19 health technologies

On 15 May, government and labour, together with Business for South Africa (B4SA) developed the ‘local manufacturing partnership’ which put together eight workstreams “committed to supporting local manufacturers through the various accreditation, testing and funding processes and aim to get these manufacturers procurement ready”.¹²⁴ The eight workstreams included: face shields, gloves, testing, FFP2 masks, textile PPE, sanitiser, medical device consumables, and Black Enterprise Development.

These efforts have resulted in substantial growth in South Africa’s capacity to locally manufacture PPE. One interviewee noted that “we have learnt from this experience about how much easier localisation is than we think it is”.

- “At the start of the pandemic, we were barely manufacturing any gowns or aprons, but the textile industry was ready and waiting to pivot. For aprons and gowns we are probably now 75% self-sufficient”
- “For visors/face shields we are 100% self-sufficient now. We worked very closely with auto industry sector on this”
- “At the start of the pandemic, we could manufacture around 4 million FFP2 masks a month, but epi models told us we would need 15 million. We can now produce 13,5 million FFP2 a month”
- “Gloves remains a big problem, we are still predominately reliant on imports”.

It was noted that growth of local manufacturing capacity for PPE was driven primarily by private sector purchases, as well as procurement through the Motsepe Foundation and Solidarity Fund, as provincial departments of health were largely procuring products through ‘middle-men’ importing products into the country. However, it was added that following efforts to educate provinces about locally produced goods meeting regulatory standards, provincial health departments were starting to procure products from local producers.

South Africa is also manufacturing dexamethasone locally, the only medicine currently recommended by the WHO for treating COVID-19. Although it was noted that the country would probably be unlikely to locally produce COVID-19 treatments that were not already registered locally. “If there is an existing dossier then it is an easy thing to do, if there isn’t an existing dossier then you have a problem... our [registration] process is so difficult that it immediately disadvantages anyone unless the drugs that get approved have applicability beyond COVID”.

122 Tomlinson C. Hepatitis C medicines remain in regulatory limbo. Spotlight. 4 August 2020.

<https://www.spotlightnsp.co.za/2020/08/04/breakthrough-hepatitis-c-medicines-remain-in-regulatory-limbo/>

123 Tomlinson C. Hepatitis C medicines remain in regulatory limbo. Spotlight. 4 August 2020.

<https://www.spotlightnsp.co.za/2020/08/04/breakthrough-hepatitis-c-medicines-remain-in-regulatory-limbo/>

124 Business for SA. The Local Manufacturing Partnership success stories. August 2020.

https://www.businessforrsa.org/wp-content/uploads/2020/09/Bloomberg-Interview_B4SA-Success-stories_20200821_v0.6-1.pdf.

Local manufacturing of vaccines

While South Africa does not have the capacity to produce the active vaccine, it can play a role in the ‘fill and finish’ of vaccines, which involves transferring bulk vaccines into ‘vials, plastic tubes, ampoules or syringes’.¹²⁵ On 14 October, Reuters reported that Biovac is in discussions with CEPI to secure an agreement to fill and finish vaccines produced under COVAX, adding that Biovac could produce up to 30 million COVID-19 vaccines a year.¹²⁶ On 2 November, it was reported that Aspen Pharmacare had signed a provisional agreement with Johnson & Johnson (J&J) to the fill and finish J&J vaccines locally.¹²⁷

Biovac

Biovac, the partially state-owned vaccine manufacturer, has received R25 million from the DSI to “procure equipment to upgrade their facility” to expand their capacity to fill and finish vaccines and prepare for a possible tech transfer. Biovac’s facility upgrade will reportedly enable the company to produce an additional 30 million vaccines a year—beyond its existing capacity to produce 40–50 million doses.¹²⁸

During September, Minister of Higher Education, Science and Innovation, Dr Blade Nzimande, told reporters that “current operations of Biovac, a company established in 2003 as a public-private partnership to produce local vaccines in South Africa, would be expanded. The upscaling of Biovac’s manufacturing capabilities is important to ensure that COVID-19 vaccines can be manufactured for African use by an African company”. “The upscaling of the manufacturing pipeline for hundreds of millions, or even billions, of doses will require intense collaboration and needs to be done in such a way that it will not compromise the production of other essential vaccines”.¹²⁹

A challenge in scaling-up manufacturing capacity at this stage is that different vaccines will have different manufacturing and finishing processes and it remains unclear which vaccines candidates will ultimately succeed. Biovac CEO, Morena Makhoana told Reuters in October “We need to look at who is likely to get to the finishing line and who has the technological fit”.

Aspen Pharmacare

Aspen has signed a provisional agreement with Johnson & Johnson to “formulate, fill and provide secondary packaging of the vaccine for Johnson & Johnson” at its facility in Port Elizabeth, “with the agreement still subject to the successful completion of relevant technology transfers, and the finalisation of commercial manufacturing terms.”¹³⁰

125 UNIDO. White Paper: Establishing Manufacturing Capabilities for Human Vaccines. 2017.

<https://www.unido.org/sites/default/files/files/2017-12/Establishing-Manufacturing-Capabilities-for-Human-Vaccines-ebook.pdf>.

126 Roelf W, Winning A. South Africa’s Biovac in talks to manufacture COVID-19 vaccines. Reuters. 14 October 2020. <https://www.reuters.com/article/health-coronavirus-safrica-vaccines/south-africas-biovac-in-talks-to-manufacture-covid-19-vaccines-idINL8N2H32FN>

127 Tamar K. Aspen bags COVID-19 vaccine deal with J&J. Business Day. 2 November 2020.

128 Stakeholder input

129 <https://www.dst.gov.za/index.php/media-room/latest-news/3168-sa-working-on-a-plan-to-achieve-population-immunity-to-covid-19>.

130 Planting S. Aspen may make COVID-19 vaccine in SA. Daily Maverick. 2 November 2020. <https://www.dailymaverick.co.za/article/2020-11-02-covid-19-vaccine-could-be-made-in-sa/>

Sasha Planting reported in Daily Maverick in November that Aspen has invested R3.5 billion into its sterile manufacturing capacity over the last decade, adding *“It has invested in a high containment facility in Port Elizabeth which allows it to produce state-of-the-art sterile drugs and vaccines, packaged into vials, ampoules and pre-filled syringes. While the facility will be fully operational by 2023, it already has the capacity to produce more than 300 million doses of the Covid-19 vaccine candidate a year”*.¹³¹

One stakeholder recently noted on Druginfo-digest that reporting on the deal to date has offered *“few details on the nature of the technology transfer, or any changes that would need to be made to the existing plant to handle a biological product such as an adenovirus-vectored vaccine”*. Further while it has been reported that the deal should boost regional vaccine supply¹³², there are little details as to how Aspen produced vaccines will be allocated and whether the J&J/Aspen deal allocates or requires supply for South African and the region. Aspen’s press statement announcing the deal states that Aspen will supply the domestically produced vaccines to J&J, adding *“We are particularly pleased to be given the opportunity of providing assistance for patients in need across the world from our South African base”*.¹³³

IP and local manufacturing capacity

Globally, powerful stakeholders (wealthy countries, pharmaceutical companies, the Gates Foundation) have argued that limited local/regional manufacturing capacity (particularly in poor countries)—not intellectual property—will impede access to COVID-19 health technologies. They have argued that because capacity does not exist to scale-up manufacturing beyond a limited set of partners within contracted arrangements, IP is not a barrier that needs to be overcome to advance access.¹³⁴

While limited manufacturing capacity is certainly a barrier to medicine access, these capacity challenges may be exacerbated by intellectual property and licensing barriers to domestic manufacturing. For example, while Medicine Patent Pool (MPP) licenses have significantly improved access to affordable generic HIV treatment in region, the MPP’s licensing approaches may have hindered growth of local/regional manufacturing capacity—as very few licenses have been granted to generic manufacturers based Africa.¹³⁵

Rohit Malpani et al. recently wrote that pursuing a business-as-usual approach that gives large funders and pharmaceutical companies discretion over licensing and pricing reinforces systemic inequalities—impeding both access to medicines and growth of local manufacturing capacity.¹³⁶

131 Planting S. Aspen may make COVID-19 vaccine in SA. Daily Maverick. 2 November 2020.

<https://www.dailymaverick.co.za/article/2020-11-02-covid-19-vaccine-could-be-made-in-sa/>

¹³² Kew J, Sguazzin A. Next Africa: Aspen’s Vaccine Deal Eases Regional Fears. Bloomberg. 6 November 2020.

<https://www.bloomberg.com/news/newsletters/2020-11-06/next-africa-aspen-s-vaccine-deal-eases-regional-fears>

¹³³ Aspen Pharmacare (Press Statement). Aspen Announces Agreement With Johnson & Johnson to Manufacture Investigational COVID-19 Vaccine Candidate. <https://www.aspenpharma.com/2020/11/02/aspen-announces-agreement-with-johnson-johnson-to-manufacture-investigational-covid-19-vaccine-candidate/>

¹³⁴ Malpani et al. Corporate Charity – Is the Gates Foundation Addressing or Reinforcing Systemic Problems Raised by COVID-19? Health Policy Watch. 31 October 2020. <https://healthpolicy-watch.news/gates-foundation-address-systemic-covid-19/>

¹³⁵ AUDA-NEPAD. Africa Pharma Conference 2019: Post Conference Report. Johannesburg, South Africa. 4–5 June 2019.

¹³⁶ Malpani et al. Corporate Charity – Is the Gates Foundation Addressing or Reinforcing Systemic Problems Raised by COVID-19? Health Policy Watch. 31 October 2020. <https://healthpolicy-watch.news/gates-foundation-address-systemic-covid-19/>

Oxfam, UNAIDS and other groups have created the People's Vaccine Alliance to advocate for a People's Vaccine that is free of IP and licensing arrangements that create artificial restrictions to manufacturing.

The People's Health Movement have highlighted that, in addition to overcoming IP barriers to manufacturing, "*Establishing new production lines will also need access to tacit technical knowhow and to formulae and trial data*". In this vein, PHM have called for expanded international cooperation around technology transfer and scaling up manufacturing capacity in LMICs, coupled with the adoption of the TRIPS waiver as proposed by India and South Africa.¹³⁷

[END]

137 Peoples Health Movement. Urgent call for action on COVID-19 health technologies: Statement by People's Health Movement. 14 October 2020.