



## East Central and Southern Africa Health community (ECSA HC)<sup>1</sup> and Regional network for Equity in health in east and southern Africa (EQUINET)<sup>2</sup>



### **Brief: Securing COVID-19 related diagnostics, health technology, medicines and vaccines for African public health, May 2020**

#### **Introduction:**

The ability of African countries to mount effective and equitable responses to COVID-19 reflects in part the access that countries have to reliable, sustained, distributed supplies of diagnostics (antigen and antibody test kits and equipment for decentralised laboratories) and health technologies (personal protective equipment (PPEs), oxygen and constant positive airway pressure (CPAP) equipment). As medicines and vaccines are developed and approved for COVID-19 they too need to be available at mass scale and locally distributed. Currently, African countries, like many others, face shortfalls in all of these essential commodities relative to need. For example, report that orders for test kits placed in March have still not been delivered to African countries indicates a deficit that is undermining public health interventions. High income countries affected by the pandemic have a self-interest in securing their own access, undermining solidarity-based international health co-operation, notwithstanding WHO's clear message about the global nature of the pandemic and efforts towards collaborative responses.

This is not a matter that can be dealt with through aid. For African countries, COVID-19 has exposed the weaknesses in being dependent on R&D capabilities and production systems located outside the continent for commodities that need to be made available in good time and in widely distributed systems to communities and services across the continent. This not only relates to current demands like test kits. It also forewarns of African countries being last in the queue when medicines and vaccines are approved.

The pandemic is projected to be sustained and it will not be the last. The level of global impact is opening new arrangements and within this the possibility for African countries to support and widen initiatives on distributed local production and joint procurement systems for the diagnostics, health technologies, medicines and vaccines needed to mount an equitable and predictable sustained public health response. This depends on addressing the intellectual property regimes, R&D and global funding arrangements for this, including through clear representation of African positions in global and other international negotiations and initiatives underway and in south-south partnerships.

Various global, multilateral and bilateral arrangements have been proposed, including a submission to the WHO from Costa Rica on the sharing of intellectual property and R&D; a resolution tabled at the May 2020 World Health Assembly (WHA#73) and the Access to COVID-19 Tools Accelerator ("ACT Accelerator"), launched April 2020. This brief shares information on initiatives related to diagnostics, health technologies, medicines and vaccines, the issues for African countries and options for addressing them in the dialogue and negotiations at global fora. *Please click on the hyperlinks for references and sources.*

The brief does not cover what African countries would need to do *within countries and within the region* to secure these interests, such as through national patent laws, using and preparing protocols to apply the TRIPS flexibilities for use of compulsory licensing, or registering as legitimate importers with the World Trade Organization (WTO) and promoting joint regional procurement.

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## International measures for COVID-19 related diagnostics, health technologies, medicines and vaccines

There have been a series of international resolutions and initiatives that are pertinent for access to diagnostics, health technologies, medicines and vaccines for COVID-19.

**Equitable access:** The UN General Assembly (UNGASS) adopted Resolution 74/247 on 8 April 2020 'International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19' requesting the UN Secretary General in collaboration with WHO and other relevant UN agencies "*to identify and recommend options, including approaches to rapidly scaling manufacturing and strengthening supply chains that promote and ensure fair, transparent, equitable, efficient and timely access to and distribution of preventive tools, laboratory testing, reagents and supporting materials, essential medical supplies, new diagnostics, drugs and future COVID-19 vaccines, with a view to making them available to all those in need, in particular in developing countries*". WHO and WTO have also called on governments to provide targeted investment, open access to clinical test results and shared relevant intellectual property rights to increase manufacturing capacity and open and transparent procurement regimes.

**Pooled rights to technology:** The Government of Costa Rica approached the WHO at the end of March 2020 to '*undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic*'. The proposal was for WHO to prepare a memorandum of understanding where states, non-profit institutions, industry and others could volunteer to sign a commitment to share rights in technologies and for a database of R&D activity related to COVID-19, including estimates of the costs of clinical trials and subsidies provided by governments and charities. This proposal would establish a technology pool with voluntary assignment of intellectual property rights over patented inventions and designs, regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It would prevent exclusive rights being a barrier to local production of products for COVID-19 and facilitate their manufacture on the basis of free or affordable licensing. The WHO Director General endorsed this proposal on 6 April. However as noted in the discussion on the ACT Accelerator below, key global actors have counter-proposed a mechanism that does not require this level of sharing. The Costa Rica proposal has potential to improve access to and local production of COVID-19 technologies. Pharmaceutical companies may, however, not sign up to it given their resistance to use the flexibilities in the WTO's Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement on access to medicines.

**The ACT Accelerator:** On 24 April WHO issued what it called a "landmark collaboration" for "equitable global access to innovative tools for COVID-19 for all", the Access to COVID-19 Tools Accelerator ("ACT Accelerator"). It involved WHO, the World Bank, vaccine and pharmaceutical industry groups, and external funders, including the Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Wellcome Trust and others. The ACT Accelerator is a global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies. A target of EUR 7.4 billion was pledged for it. Various issues have already been raised on it. As it is "time bound", it suggests that commitments and collaborations will cease when the global *pandemic* is declared over by WHO, even if it remains an endemic issue for African countries. There is a divergence of views on what it actually covers: while South Africa and France both described it as encompassing diagnostics, antiviral drugs and vaccines at the launch, Germany and UK saw it as limited to vaccines. The general legal counsel of the CEPI said that the Costa Rica proposal above was 'not effective and not necessary', that pharmaceutical companies, biotech firms and academic labs will refuse to share their vaccine technologies and scientific processes and there is '*simply no time now*' to do anything different to the usual. Although WHO is part of the ACT Accelerator, its leadership is not clearly stated and there are concerns on its positioning and capacity to co-ordinate private pharmaceutical companies and foundations that have significantly larger budgets.

**A resolution endorsed by countries at the May 18 World Health Assembly** session calls for a multilateral co-ordinated response, under the leadership of the WHO working with other UN organisations . It includes, among other things:

- a. in para 4 *the universal, timely and equitable access to, and fair distribution of, all quality, safe, efficacious and affordable essential health technologies and products, including their components and precursors, that are required in the response to the COVID-19 pandemic as a global priority, and the urgent removal of unjustified obstacles thereto, consistent with the provisions of relevant international treaties, including the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health; and*
- b. In para 7(12) for member states to *collaborate to promote both private sector and government-funded research and development, including open innovation, across all relevant domains, on measures necessary to contain and end the COVID-19 pandemic, in particular on vaccines, diagnostics, and therapeutics, and to share relevant information with WHO.*
- c. In para 9 (8), noting the UNGASS resolution 74/274 (outlined above) for the WHO Director General in consultation with countries, relevant international organizations, civil society, and the private sector, *to identify and provide options that respect the provisions of relevant international treaties, including the provisions of the TRIPS Agreement and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health, to be used in scaling up development, manufacturing and distribution capacities needed for transparent equitable and timely access to quality, safe, affordable and efficacious diagnostics, therapeutics, medicines, and vaccines for the COVID-19 response, taking into account existing mechanisms, tools, and initiatives, such as the Access to COVID-19 Tools (ACT) Accelerator, and relevant pledging appeals, such as the Coronavirus Global Response pledging campaign.*

These statements and initiatives move in the direction of enabling the distributed local production, joint procurement and access to diagnostics, health technologies, medicines and vaccines that are critical for the response in African countries. However, there is need to avoid ambiguities, address gaps, ensure implementation of measures indicated, including to ensure that African countries access what is needed to protect public health. Notwithstanding these measures, and the establishment by the Africa Centre for Disease Control and Prevention (ACDC) of a digital purchasing platform to let African governments bulk order test supplies and protective equipment to improve the continent's negotiating position when bidding for supplies, the ACDC director, Dr John Nkengasong, said last month that "a collapse of global cooperation and a failure of international solidarity have shoved Africa out of the diagnostics market".

### **Issues in advancing African interests in global negotiations on diagnostics, health technology, medicines and vaccines**

As observed above, African countries face specific concerns in relation to the diagnostics, technologies, medicines and vaccines, with challenges in:

- Fair, equitable, transparent, efficient and timely access to relevant products.
- The level, timeliness, distribution and costs of supply relative to demand.
- Accessing technologies that provide for distributed provision, given situations of remote services and limited communication and transport, such as rapid diagnostic tests with high turnover and short processing times in decentralised laboratories.<sup>3</sup>
- The concentration of production in few large producers, mostly outside the continent implying use of foreign currency– or aid- to procure, with limited local manufacture in African countries or regions to reduce transport and supply chain issues.
- Disruptions to supply chains, where national preference results in export bans, seizures of health products, queues or delays in shipments as higher paying countries 'jump the queue'.

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<sup>3</sup> A specialized facility in Dakar, Senegal, a joint investment of the Institut Pasteur de Dakar and the UK government and private sector is developing "point of need" test kits that can diagnose Covid-19 in 10 minutes, with prototype test kits validated by specialists from UK, China, Malaysia and Brazil

- Tariff reductions and reduced protections for domestic industry that have suited a global strategy of ‘lowest-cost-production’ but have led to a fall in ‘uncompetitive’ domestic production in the region, leaving ESA countries vulnerable in the global competition for products, limiting options for switching production lines or amplifying methods for scaling up local production of key technologies, such as medical visors for PPE, CPAP equipment for ventilation assembled from locally available equipment as is being done in Uganda and South Africa, for example. A UN Economic Commission for Africa (UNECA) report notes that Africa is critically dependent on imported medicinal and pharmaceutical products. Every single African country is a net importer of these products and as much as 94% of Africa’s total stock of pharmaceuticals are imported. With at least 71 countries having imposed limitations or outright bans on exports of certain COVID-19 essential supplies, UNECA observe that this *puts access to these supplies in Africa in a perilous position.*

Many of these challenges stem from the lack of distributed production and weaknesses in health system distribution channels within the continent. Yet the capacity for local production does exist in low income countries. In the three months after the outbreak Vietnam, a lower-middle income country, created through its local hospitals, research institutes and universities reliable platforms to track cases and produced vital commodities including low-cost test kits. There are already south-south partnerships on medicine production in the region, such as the joint pharmaceutical production venture between Quality Chemicals Uganda and CIPLA Limited India or the Brazil-Mozambique co-operation on antiretroviral production and UNECA has mapped potential production capacities on the continent (*Table 1*). A number of initiatives are underway to expand health technology production on the continent. For example, WHO AFRO’s first virtual ‘hackathon’ involved 100 leading innovators from across Africa yielded innovations for self-diagnosis using smartphones, fever screening, mapping tools and low-cost methods for health technologies. UNIDO in a joint initiative with WHO AFRO is also contributing technical expertise to retool factories to switch from traditional production lines and diversify into products needed for the response to COVID-19.

Table.1 UNECA report of Africa’s capacity for domestic production of essential medical products by area of manufacturing and country. (UNECA, 2020:25)

	Medicine	Medicine and PPE	PPE (incl. equipment and device producers)	Other (hygiene, oxygen, textile)	Total
<b>Western subregion</b>					<b>234</b>
Nigeria	37	7	63	39	146
Ghana	20	3	4	1	28
Burkina Faso	4	7	7		18
Senegal	10				10
Mali		8		2	10
Sierra Leone				2	2
Benin				4	4
Guinea				4	4
Liberia				4	4
Côte d'Ivoire	1		1	6	8
<b>Central subregion</b>					<b>15</b>
Gabon	2	0	4	5	11
Congo			2	2	4
<b>Southern subregion</b>					<b>74</b>
South Africa	15		18	28	61
Malawi	2				2
Mozambique	1				1
Zimbabwe	2	1			3
Zambia	0	0	1	6	7
<b>Eastern subregion</b>					<b>89</b>
Kenya	16	11	1	12	40
Ethiopia	15		10		25
Uganda	15			5	20
Sudan	1				1
UR of Tanzania	3				3
<b>Northern subregion</b>					<b>119</b>
Egypt	15		21	10	46
Morocco	11		10	10	31
Algeria	8		7		15
Tunisia	10		7	10	27
<b>Total</b>	<b>188</b>	<b>37</b>	<b>156</b>	<b>150</b>	<b>531</b>

Source: ECA and Afreximbank compilation.

*While there are short term interests in securing solidarity-based bilateral and multilateral resource streams to fund the import of all of these products in the interest of global health security, this cannot be at the cost of or substitute the current and longer term interest in building distributed domestic production capacities in the continent for diagnostics, health technologies, medicines and vaccines, not only to address health needs and have greater control over supply chains, but also as an economic asset, to generate employment, value addition and income in the continent.* Health development cannot be framed as an unaffordable cost for the continent, dependent on foreign aid. For sustainable development it must be configured as an investment and source of value. COVID-19 offers an opportunity to advance this, with clear evidence from successful examples in Asian countries<sup>4</sup> of the benefit of doing so for management of both the health and economic implications of COVID-19.

For African countries this thus raises key interests in global diplomacy and international co-operation that have short-, medium- and long-term implications for responses to COVID-19, future pandemics and indeed the promotion of health and wellbeing in the continent more generally. This section articulates these and how they are, are not, and could be addressed in the key global negotiations underway.

### **1. Securing solidarity-based bilateral and multilateral resource streams:**

There will be bilateral and multilateral aid flows for COVID-19. The questions they raise for African countries relate to whether they:

- a. Set problematic conditionalities, such as for purchase of non-generic commodities; constraints to use of TRIPS flexibilities, etc;
- b. support a distributed and co-ordinated systems response;
- c. facilitate investment in or state procurement of locally-produced technologies;
- d. facilitate regional joint procurement and distribution strategies;
- e. co-invest in management of public sector supply chain management.

Generally, however, African countries have an interest in not relying on aid flows for a public health emergency like COVID-19. The UN Economic Commission for Africa has indicated that almost half of the funds needed for prevention, health services and safety net measures could come from waiving interest payments to multilateral institutions. African finance ministers have thus called for the suspension of debt interest payments, and for waiving the principal debt for fragile states. An immediate emergency economic stimulus of US\$100 billion could in part be met by a waiver of all interest payments on public debt and sovereign bonds, estimated at US\$44 billion for 2020. African countries have rejected free market conditionalities being associated with any debt relief, fiscal or aid packages, especially given that this demand is in direct contrast to the protectionism and sharp rise in state intervention taking place in high income countries, despite their prior opposition to these measures in global forums. On 14 April the IMF Executive board approved immediate debt service relief for 25 of the IMF's member countries under its Catastrophe Containment and Relief Trust to cover their IMF debt obligations for the next six months. This came in the form of US\$500 million in grant-based debt service relief, supported by contributions from the U.K, Japan, China, the Netherlands and others. Of the 25 countries, 18 are in Africa, so this does not cover all African countries that need this fiscal relief. Further, it only covers 6 months when the financial recovery and public health demands will go well into 2022 and it only allocates 10% of the estimated US\$100bn raised for African countries. African countries have thus called for a new significant allocation of between \$500 bn to \$1 trillion of Special Drawing Rights, the IMF's reserve asset that, importantly, carry no policy conditions. Yet here too there is a disadvantage as Sub-Saharan African countries currently collectively only receive about 5% of this allocation because the rights are allocated according to country's IMF quotas (voting rights). UNCTAD has thus called for high income countries to contribute the unneeded portion of their share of special drawing rights to a fund to support low income countries. South Africa's Institute for Economic Justice have also indicated that more predictable and meaningful forms of development aid need to be sourced through solidarity taxation and greater contribution from wealthy enterprises.

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<sup>4</sup> Such as China, South Korea, Vietnam

The [WHA#73 Resolution on COVID-19](#) endorsed the WHO's Strategic Preparedness and Response Plan and called for the WHO DG to report on funding allocated and gaps and results achieved, particularly in relation to support given to countries, noting that WHO itself needs sustainable funding from its member states. African countries will, however, also need to take up the resourcing of public health needs in other forums (UN, IMF and the development banks) given the significantly greater domestic resources identified above that are needed to manage the impacts of COVID-19 and the longer term costs to health, food security and the SDG commitments if these are not addressed.

## **2. Using existing TRIPS flexibilities**

Member states have the authority to use TRIPS flexibilities when this is necessary to protect public health and to promote access to medicines and African countries have declared COVID-19 a public health emergency. The last time these were considered for this purpose was to accelerate the production of anti-retrovirals (ARVs) for HIV and AIDS.

The [TRIPS provision for compulsory licencing](#) can be provided for and exercised as a mandatory provision in national laws and multilateral agreements, in contrast to some of the more voluntary options proposed in the pooled patent proposal from the EU and the ACT Accelerator, and [compulsory licenses have already been used in Chile, Ecuador and Israel for COVID-19 related medicines](#). A [South Centre guide](#) provides information on how to use these flexibilities for procurement and production of patent-protected diagnostics, health technologies, medicines and vaccines. The [World Intellectual Property Organisation \(WIPO\)](#) has set up a [COVID-19 tracker](#) to monitor the use of intellectual property flexibilities and policies in all countries.

The [WHA#73 Resolution on COVID-19](#) in para 8(2) includes provision for existing mechanisms for voluntary pooling and licensing of patents to facilitate timely, equitable and affordable access to diagnostics, medicines and vaccines, *consistent with the provisions of relevant international treaties, including the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health*. Notably [the United States disassociated](#) itself from operative paragraphs 4, 8.2 and 9.8 that referred to the TRIPS Agreement and the 2001 Doha Declaration on the TRIPS Agreement and Public Health, arguing that the wording of these paragraphs "send the wrong message to innovators who will be essential to the solutions the whole world needs". It further provided its interpretation of the reference in operative paragraph 8.2 to "existing mechanisms for voluntary pooling ... of patents" limiting it to voluntary mechanisms existing before the COVID-19 pandemic, not new or proposed "patent pooling" mechanisms created in response to the pandemic. This forewarns of potential conflict over these interpretations at the WTO Ministerial, postponed to a future date.

## **3. Enabling open innovation and sharing of intellectual property (IP)**

There is a need to make a distinction between what is needed to produce existing products for COVID-19, discussed in the next subsection, and what is needed for products which are anticipated and in development, such as vaccines and some therapeutics. This subsection discusses the latter. The current regime for R&D and innovation is not appropriate for the enormity of the challenge COVID-19 poses. It links R&D efforts to the ability of innovators to charge high prices for their products and acts as a barrier to the scale of public health response needed for the pandemic, especially for African and other low-income countries and communities globally. With the widest possible efforts on innovation needed, it cannot be "business as usual".

The Costa Rica proposal to WHO noted earlier explicitly calls for the *voluntary* assignment of intellectual property rights over patented inventions and designs, regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines in a voluntary emergency Technology Intellectual Property Pool [TIPP] that will accelerate scientific discovery, technology development, proof of safety/efficacy/quality, and broad sharing of the benefits of scientific advancement and its applications in furtherance of the right to health. Even where African countries are not the primary R&D developers of diagnostics, vaccines or

medicines, a TIPP enables accelerated access, distributed manufacture and onward context relevant innovations to accelerate the response and save lives. There are already open science measures underway in sharing viral genomes, sharing early research data, in joint clinical trials such as the WHO Solidarity trial of treatments, particularly that funded by public sectors. The ACT Accelerator initiative is silent on the issue of intellectual property. Such sharing would enable others to collaborate and solve the problems or take forward innovations.

Participation in these technology pools is voluntary, with technology owners expected to share their technology and know-how within the pool by choice. However, some technology holders, especially from the private sector, may place restrictions on the use of their technologies, such as to exclude some countries or certain R&D activities. Some of these conditions may also influence manufacturing with a view to restrict competition in the marketplace. Such restrictions may be contrary to the purpose of the pool. Therefore, the participation should be based on *ex-ante* (prior) conditions and should not be based on negotiated contracts. Patent holders may patent small improvements as part of the original strategy of obtaining maximum patents on a single molecule or technology, hindering both innovation and manufacturing. While these patents might not be valid in all WHO member states, donating these or pending applications to the pool is insufficient for the full scope of what is needed for innovation and access.

While what vaccines or medicines receive regulatory approval is not yet clear, unless the ACT Accelerator addresses intellectual property and national-level export prohibitions, ESA countries may not access the vaccines that they need, notwithstanding promises of equitable access in the WHA#73 resolution. Furthermore, the provisions should cover the full scope of diagnostics, health technologies, medicines and vaccines. Over 260 civil society organizations have thus written to the UN Secretary-General and WHO Director-General to operationalize fair and equitable benefit sharing for COVID-19-related medical products, as intended in the UN Convention on Biological Diversity and the Nagoya Protocol. The gains made in ensuring access to R&D effort, for the production of vaccines or other technologies will not only be relevant for COVID-19 but for preparedness for the next pandemics that will surely occur.

#### **4. Enabling open manufacturing and distributed production**

The evidence is clear that for COVID-19, as for other epidemics, the effectiveness of the public health response depends on access to health products that are made available, affordable and equitably and timeously distributed to where they are needed. African countries face challenges in all these respects related primarily to manufacturing, production infrastructure, skills and know-how. The global supply chains for medicines, reagents, health technologies are integrated and a few locations in high income countries have gained primacy, with a decline in distributed local production. COVID-19 has revealed this situation to be a major weakness. It has shown that in relation to vital health commodities, decisions based on lowest cost, prices, cost/benefit or return on investment analyses that lead to importation rather than local or regional production in Africa can leave the continent without adequate and affordable access to health technologies and that in a pandemic the key issue is rapid scale up of availability of the products. Yet in the early responses to COVID-19 when it mattered most, supply chains were broken by national preference preventing exports or access to African countries and impediments in scaling up production due to gaps in supply chains such as for APIs and reagents.

A number of issues raised in the previous discussion on intellectual property apply to enabling open manufacture. Patents can pose barriers during the commercial manufacturing stage. While research exceptions available in national laws may allow R&D activities to be carried out without the permission of patent holders, it is when countries move to manufacture that the patent rights discussed earlier may be invoked. Any mechanism should function therefore as a platform to promote both open innovation and open manufacturing and participation in these open platforms should be based on certain norms to promote both open innovation and open manufacturing. The participants, both the provider of technology and the user, should agree to an open innovation policy which should include obligations to share further improvements back to the open platform along with enhancing access to technologies, whether diagnostics,

health technologies, medicines or vaccines at affordable price to people and governments, in line with the recommendations of the WHO Consultative Expert Working Group on Research and Development.

Such sharing needs an agency to coordinate and prioritize innovation or to hand-hold the manufacturing, and to prequalify manufacture and verify quality of products. This role needs to lie in multilateral public control in the WHO and not be subject to interests of particular private enterprises or specific countries. There have been challenges in WHO implementing this but in the current context of COVID-19 as a global pandemic, WHO has the legitimacy, representation and transparency to play this role. A civil society initiative to monitor the R&D into vaccines to support accountability and transparency in this area also needs to be strengthened and supported. There is thus some concern on whether WHO indeed has this central, coordinating/leading role in the ACT Accelerator, considering its presence as just one of multiple stakeholders, including private pharmaceutical bodies, in its governance, and the expansion of other funding initiatives not under the WHO. This raises concerns previously identified by African countries on the low level of member contributions to WHO relative to funding from non-state institutions, exacerbated now by the withholding of funds by the USA.

### **Proposals and options for global health engagement**

The issues raised in this brief indicate areas of progress and barriers in current global platforms and proposals for advancing African interests on effective access to diagnostics, health technologies, medicines or vaccines, in relation to resource streams, using existing TRIPS flexibilities for national and regional procurement and production, and on measures for open innovation and open manufacturing, particularly for the latter to support local or regional production for the distributed response needed. The issues point to the need for public agency-driven multilateralism to enable this and raise concerns on whether this is being eroded.

This section makes proposals for African countries to secure regional and global collective interests in responding to COVID-19 and pandemics generally, within the four areas above.

#### **1. Securing solidarity-based bilateral and multilateral resource streams:**

The COVID-19 pandemic calls for international solidarity, for application of the public health precautionary principles and for equity in national and global resources to be directed to need and to protect life in all countries. The public health response to COVID-19 needs to be planned, distributed and sustained. For this to happen there is need for resources to be locally and nationally available, without conditionalities for interests that have no relationship to the effective public health response.

In the dialogue within the UN and international finance institutions support, solidarity and self-determination call for support for the African government calls for appropriate and unconditional finance; debt cancellation and moratoria on repayments of interest and capital to free up domestic resources for public health needs; a fairer distribution of IMF Special Drawing Rights for African countries; and stimulus packages that addresses the challenges without causing harm to production systems and capacities in African countries. While these measures are not the responsibility of health sectors, there is need for health sectors to play a role in showing the immediate public health need, but also the longer-term health need generated by economic impacts, and to show the effective use of these resources for public health.

In inputs to the draft WHA#73 resolution, Zambia and Tanzania called for debt relief. Cameroon, on behalf of the Africa Group of diplomats in Geneva called for debt relief or forgiveness to help countries cope with the impact of COVID-19, for African countries to channel more limited financial resources towards the emergency response and to invest in health system strengthening to prevent future outbreaks and safeguard livelihoods of millions of vulnerable people. The final WHA#73 resolution did not make a direct call for debt relief, despite recognising the repercussions for poverty and development gains, and *the impact of high debt levels on countries' ability to withstand the impact of the COVID-19 shock*. The call for debt relief thus remains directed at the IMF, World Bank

and development banks, and at the G8 countries. Chinese President Xi Jinping announced at the WHA China's readiness to implement the Debt Service Suspension Initiative of G20 for the poorest countries. There is scope for others to follow suit.

African countries and health sectors can also negotiate for financial measures to:

- a. not include problematic conditionalities, such as for purchase of non-generic commodities; constraints to use of TRIPS flexibilities;
- b. enable public sector support for a distributed and co-ordinated systems response;
- c. include binding commitments to measures and to the supply of diagnostics, health technologies, medicines and vaccines products for COVID-19, ensure that any flexibilities provided to countries include African countries and that measures are included to deal with any practical impediments to this;
- d. facilitate investment in or state procurement of locally-produced technologies and regional joint procurement and distribution strategies;
- e. co-invest in management of public sector supply chain management, specifically geared to resource poor settings;
- f. involve civil society and other non-state actors nationally and multilateralism with WHO as the lead global health institution in these wider platforms; and,
- g. report on the distribution and use of global funds, their allocation relative to health need; and their use in building national capacities to produce and distribute products at affordable cost and to where they are most needed.

## **2. Using existing TRIPS flexibilities**

African countries need to ensure that their legal rights to access patents and other flexibilities related to intellectual property under the TRIPs agreement are safeguarded and available, including by having enabling legislation to use them.

Countries have had difficulty in the past in using their legal rights. WHO already has a resolution on use of these flexibilities in Resolution WHA67.6 of 24 May 2014 for viral hepatitis. This has been restated for COVID-19 in the WHA#73 resolution in para 8(2) noted earlier, notwithstanding the weaknesses in the implementation of Resolution WHA67.6..

Furthermore, given the scale of challenge posed by COVID-19, African countries could strengthen these proposals by including commitments that countries must not be prevented in any way from exercising the TRIPS flexibilities in any other agreement or platform, and that where needed, these flexibilities be operationalised to facilitate joint procurement. The African Union should support when its member states use these flexibilities in production or R&D for the use of protected knowledge (IP) or information.

As noted above, given the US objections to the measures included in the WHA#73 Resolution on COVID-19, African countries and others will need to ensure that in any bilateral and multilateral negotiations, including at the WTO, their right is protected to fully apply and remove obstacles to the application of the provisions of international treaties that provide flexibilities in relation procurement and production of diagnostics, health technologies, medicines and vaccines required for the response to the COVID-19 pandemic, including without reservation the inclusion and use as necessary of national legislative mechanisms to use of the flexibilities contained in the TRIPS Agreement. Further, there should be technical assistance in the use of these flexibilities when needed, in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

## **3. Enabling open innovation and sharing of intellectual property**

Countries have already taken extraordinary measures in their responses to epidemics, particularly to COVID-19. The principles driving innovation and sharing of innovation for diagnostics, health technologies, medicines and vaccines for COVID-19 cannot be based on the existing model linking research effort with high monopoly prices for novel health products. Open innovation and open production offer an alternative more supportive of the public health response. It maximises effort, with participants all operating with the highest knowledge and technical evidence possible. This implies in particular that publicly

funded R&D be treated as a global public good and that all publicly funded innovation, whether in whole or part, be freely and openly available to the global community.

Various ways have been recommended for this for diagnostics, health technologies, medicines and vaccines that may resonate with African interests. They include for:

- a. WHO to create an open innovation platform on these products for COVID-19.
- b. WHO to develop an online panel of experts to review these inputs, refine the research findings and facilitate the filling in of knowledge and research gaps.
- c. WHO to convert its R&D Blue Print into a dynamic online platform, allowing public and private institutions, academics, individual researchers to publicly share their R&D research, data, related to virus, epidemiological studies, epidemic prevention control, health products such as vaccines and medicines, accompanied by measures for and sharing of rigorous evaluation and peer review.
- d. Any such open innovation platform aggregate existing knowledge, be dynamic and interactive allowing for sharing of COVID-19- related R&D outcomes and for peer review and wider input in the scientific community.
- e. Participation in open innovation or patent pooling initiatives be explicitly based on *ex-ante* conditions and not on negotiated contracts.
- f. WHO to take the leading role of co-ordinating agency in such an open innovation platform at global/ multilateral level, including in the platform for the ACT Accelerator.

The silence on these matters in the WHA#73 resolution implies that the intention of the UNGASS Resolution 74/274 noted earlier still needs to be addressed in relation to:

- Sharing COVID-19 related knowledge, technology and know-how, research and development outcomes, lessons learned, data, materials and commodities globally and across countries;
- Promoting R&D models that delink the cost of new R&D from the prices of diagnostics, medicines and vaccines across all relevant domains, ensuring that publicly funded research and development outcomes are considered global public goods that are accessible, available and affordable to all states; and
- Working collaboratively at all levels to develop, test, scale-up production and ensure timely equitable distribution of safe, effective, quality diagnostics, medicines and vaccines for the COVID-19 through non-exclusive worldwide competitive licensing.

#### **4. Enabling open manufacturing and distributed production**

A distributed supply of diagnostics, health technologies, medicines and vaccines needs to be supported by a level of local or regional production, to avoid the supply chain problems noted in *Section 3*. Every crisis is a threat for some and an opportunity for others. A lens for scrutiny of measures proposed in global platforms is whether they will leave African countries more or less advanced in terms of a self-determined local/ regional production capacity for these essential health products, the terms on which access is granted to protected technologies and to support adequate and affordable distributed and timely access.

This calls for an open manufacturing model for production of a list of essential products, sharing the technical specifications, designs and other necessary inputs for production. Immediate priorities could be PPE, diagnostics, CPAP equipment and oxygen and other relevant therapeutics and medicines, reagents and medical devices. At the global level, WHO has a role in identifying the list of essential products, creating a platform for open manufacturing to promote public and private sector and research institutions sharing of specifications, designs and related information to facilitate open manufacturing. The platform may also provide pharmacopeia standards, analytical methods, appropriate limits for testing and assessing the active pharmaceutical ingredients, excipients and finished products.

For African countries it implies:

- a. Including the extent to which measures/proposals increase and build on manufacturing and manufacturing capabilities distributed around the continent.
- b. How finance is made available locally, nationally and regionally and blended with international resources and various forms of international collaboration to enable manufacture and public national and regional procurement of health technologies.

- c. Co-operation in sub-regions to:
  - identify capacities for preparing or switching production to key technologies and products, sharing expertise where needed;
  - ensure quality production, prequalification of plants, and to organise forward and backward linkages and address upstream and downstream bottlenecks;
  - identification of current vaccine production capabilities to negotiate investment (such as by Gates Foundation) in factory retooling for this in African countries in the different regions; and
  - dialogue between governments, pharmaceutical companies and training institutions on human resource requirements for supporting manufacturing and distribution of COVID-19 health related technologies and products.
- d. Continental level coordination of the R&D and regional manufacturing efforts under the African Union and regional bodies with capability to provide such support online panel of experts should be available to facilitate innovation and implementation.

The WHA#73 Resolution on COVID in para (4) shown earlier states it to be a global priority to ensure the universal, timely and equitable access to, and fair distribution of essential health technologies and products, including their components and precursors, to respond to COVID-19. This needs further measures to realise the intention, including establishment of a technology platform for the open sharing of existing and future technologies and know-how including blueprints, designs, specifications and provision of technical and financial support to facilitate local manufacturing of medical products required for COVID -19 response.

## **5. Vaccines, diagnostics, tests and medicines for COVID-19 as global public goods to ensure equitable, universal access**

The measures described above to expand open innovation, open manufacturing, distributed production, to protect TRIPS flexibility and to secure resources for the response locate as a practical means for African countries to take from words to practice the intention stated in the UNGASS Resolution 74/247 noted earlier to make vaccines, diagnostics, tests and treatments for COVID-19 *available to all those in need, in particular in developing countries.*

The WHA#73 Resolution on COVID-19 recognised diagnostics, vaccines, medicines and other health products such as personal protective equipment as ‘global public goods’ needed to bring the pandemic to an end that should be made universally and adequately available and affordable to all. This was equally stated in a letter signed by 140 individuals, including current and former heads of government, international civil servants, Nobel laureates and other prominent individuals that identified vaccines, diagnostics, tests and treatments for COVID as a public good, to be provided free of charge to everyone, everywhere. Achieving this was understood to call for mandatory worldwide sharing of all COVID-19 related knowledge, data and technologies with a pool of COVID-19 licenses freely available to all countries, and a global and equitable rapid manufacturing and distribution plan —fully-funded by rich nations — for the vaccine and all COVID-19 products and technologies that guarantees transparent ‘at true cost-prices’ and supplies according to need, and that guarantees COVID-19 vaccines, diagnostics, tests and treatments are provided free of charge to everyone, everywhere. This concept of a people’s vaccine was endorsed by the Executive-Director of UNAIDS, while the understanding that it be a global public good was supported by Chinese President Xi Jinping, who indicated that any vaccine developed in China will be made on this basis.

The pressure is thus growing for all COVID-19 related drugs, diagnostics, vaccines and health products, existing or future, to be considered global public goods, as expressed by the UN Secretary General on 24 April. At the same time, African countries need to be clear that the way to make these products available to everyone, everywhere, at the same time must, as argued in this brief, be by structurally linking open innovation and open manufacture to distributed production and access. As the experience recounted in the introduction on the bottlenecks in accessing test kits indicates, any other approach may fall short on delivering timely and equitably distributed access for African countries.