Task Force 1
Global Health and COVID-19

Policy brief

BOOSTING EQUITABLE ACCESS AND PRODUCTION OF DIAGNOSTICS, THERAPEUTICS AND VACCINES TO CONFRONT COVID-19 ON A GLOBAL FOOTING

SEPTEMBER 2021

Lieve Fransen European Policy Centre; and Wits University
John Nkengason African Centers for Disease Control and Prevention
Smita Srinivas Co-Chair T20 Italy Task Force on Global Health and Covid-19; Open University; National Centre for Biological Sciences TIFR-NCBS; and University College London
Stefano Vella Co-Chair T20 Italy Task Force on Global Health and Covid-19; and Università Cattolica del Sacro Cuore

T20 NATIONAL COORDINATOR AND CHAIR
ISPI

T20 CO-CHAIR
IAI

T20 SUMMIT CO-CHAIR
Università Bocconi MILANO

THINK20 ITALY 2021

G20 ITALIA 2021

ABSTRACT

The COVID-19 pandemic has demonstrated the devastating impact of a large-scale disease on global health and wellbeing, security and economies. It has also shown the importance of reliable preparedness systems, and international collaboration and co-ordination among diverse stakeholders. G20 leaders are actively encouraged to build on the lessons learned from the pandemic. These include: ensuring worldwide equitable access to tests, vaccines and treatments for COVID-19 and beyond; the importance of not leaving low and middle income countries (LMICs) behind; and ensuring resilient supply chains through new and more robust manufacturing policies and capacities.

THE CHALLENGES

The COVID-19 pandemic brought longstanding healthcare issues into sharp focus, putting global crisis preparedness under extreme pressure and testing the solidarity of nations. Indeed, protectionist "beggar-thy-neighbour" policies have limited stock availability, sidelined discussions about a multilateral architecture to boost access, and endangered lives across the world.

As well described by the report of the I**ndependent Panel on Pandemic Preparedness ad Response (IPPPR)** which has been presented to the 2021 World Health Assembly, the international system intended for health security did not work effectively, there has been major gaps in preparedness and response, and lessons from previous epidemics have not been learned.

Despite the World Health Organization (WHO) warning on the risk of COVID-19 spreading beyond Asia, many countries adopted slow preparations for an outbreak. This included a failure to quickly enact effective control measures such as testing and contact tracing, as well as different and poorly co-ordinated mitigation measures, increased the difficulties involved in tracking and monitoring the outbreak.

In many countries, the procurement and supply of COVID-19 health products was led by panic and fear. As a consequence, many countries acted at the expense of the principles of global solidarity and collaboration, hampering the efficient delivery of essential goods to people in need.

Other countries have performed better at working together and have shared the supply of vaccines, medicines and equipment. Many lower income countries have managed the pandemic better than higher income countries. While data has been gathered primarily at country level, experiences across the world have revealed institutional innovations at lower levels of government; these have allowed countries to better anticipate and manage scarce resources including personnel and supplies. Lessons can be learned from analysing the evidence suggesting that countries and regions had specific differences in their preparedness and response despite often being poorer and with reduced access to critical products. Several East and South Asian and African countries, for example, have generated testing kits, generic and patented medicines, and vaccines, and used public health measures such as track and trace early, despite their lower income status. Preparedness of countries clearly differed significantly.

PRODUCTION CAPACITY LACKING GLOBALLY, A MAJOR GAP IN AFRICA, AND EXPORT BANS

In the absence of sufficient manufacturing capacities, and an enforceable covenant on how scientific, supply chain and manufacturing capacities can be shared equitably in global health, special attention for boosting manufacturing investments should be given to countries and regions with the highest public health needs and the most limited health inno-

vation or industrial production capabilities. Existing global health approaches and national priorities have emphasized aid and imports rather than distributed production or strategic industrial policies, and have rarely required explicit attention to local policy-setting capabilities needed for attending to local health challenges.

Emerging innovation systems - driven by local concerns and facilitated by better integrated economies, which are creating large regional markets - can foster innovation and direct investments.[1] The sole dependency on manufacturing of health products by private sector companies in recent decades, despite large public sector investments in fundamental and clinical research to develop products such as medicines and vaccines, requires revisiting the business models involved.

In the last 20 years, while a number of initiatives have emerged to address some of the access challenges in LMICs, little attention has been given to developing own capacities-in planning as well as execution, which should be a fundamental focus in development efforts. Initiatives such as advance market commitments, product development partnerships and medicines patent pooling mechanisms have mainly been concerned with creating incentives for innovation for the developed country's concerns.

Export bans on essential health products in 80 countries, ranging from personal protective equipment (PPE) to ventilators, have not helped the situation. In the absence of clear global guidance, up to 130 countries have imposed an uneven patchwork of travel restrictions in an attempt to keep more contagious variants of the virus at bay, mostly to no avail.

EQUITABLE SUPPLY OF RAW MATERIALS

The COVID-19 pandemic demonstrated how supply chains are globalized and depend on certain raw materials sourced from a handful of producers. Several G20 members are now developing Action Plans on Critical Raw Materials focusing on their resilience and autonomy while avoiding protectionist measures. These raw materials are needed in the production of medicines and vaccines and not only access is required but also exemption of import taxes, clear importation and exportation rules, substitute materials lists, stockpiling and price ceilings, especially in preparation for and during a crisis.

EXISTING INITIATIVES ARE NOT ENOUGH

While well-intentioned, global responses to the pandemic have been largely defined by WHO, the Coalition for Epidemic Preparedness Innovation (CEPI), charities and intermediary organizations mainly based in a limited group of G20 member countries. Meanwhile, despite significant public funding for COVID-19 vaccines and in principle support for wider access, there has not been a systematic concerted response in terms of geographic and market priorities, and intellectual property strategies.

On current averages, one in four people in high income countries have received a vaccine, compared with only one in more than five hunderd people in low income countries (DATE?). This shocking and expanding disparity requires an urgent and long-term response.

This imbalance triggered calls to waive intellectual property rights for COVID-19 vaccines and treatments, initiated by India and South Africa in WTO in October 2020. Today, more than 100 countries,including the US back a WTO waiver, but the G7 has no shared statement on this. Members now will have to engage in detailed negotiations on the scope and duration of the waiver at the World Trade Organization, whose 164 members have to unanimously agree to such a change after which implementation will have to be speeded up as much as possible.

The temporary waiver of certain provisions of the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) could indeed enable faster knowledge sharing and technology transfer to increase pharmaceutical production capacity and possibly mobilize additional manufacturers but some will still continue to argue that the waiver would dissuade additional manufacturing investments and undermine long-run medicines and vaccine development, including those to address emerging COVID-19 variants.

This is valuable evolution being pursued and resolved by the WTO, taking health emergencies into account and considering that research and development of COVID 19 vaccines is heavily supported by public funds and we are facing a pandemie raging across the world.

The recent African Continental Free Trade Agreement (AfCFTA) and other regional trade agreements are critically important, and could also strengthen the region's ability to ensure the flexibilities offered by TRIPS can be exploited fully to enable more local production and access to pharmaceutical products.

However, the authors of this paper argue that the current imperative is to scale existing pharmaceutical products as quickly as possible while maintaining strict safety and quality standards.

SCALING PRODUCTION NOW

Innovative companies and manufacturers came under commercial and geopolitical pressure to scale as quickly as possible to meet unprecedented immediate demand, to increase production and supply. To do so, some started co-operating with competitors and generic

manufacturers, including via voluntary licenses, contracted production and proactive technology transfer. We argue that the pressure on these companies and manufacturers should be increased for them to pursue the voluntary horizontal collaborations and new organizational models that have started driving scale more rapidly.

At this stage, it is not clear that any additional generic manufacturers are "standing by" ready to produce; under TRIPS flexibilities, countries can issue compulsory licenses to produce vaccines without permission from the patent-holder if they so wish.

Claims that technology transfer is too hard or takes too long are exaggerated, as shown by the several manufacturing, outsourcing,and production sharing agreements already implemented, such as between BioNTech and Pfizer, between Oxford/AstraZeneca and between Novavax and the Serum Institute, between Bharat Biotech's Covaxin and state-led Haffkine Institute and Novavax and the Canadian government. The remain mutual recognition challenges for existing vaccines, voluntary licensing and technology transfer from originator companies can help to increase long-term manufacturing capacity, especially if paired with public investment, non-profit, or public sector manufacturing which can generate competition and new models with access in mind. Originators-whether private or public- also have an interest in enforcing safety and quality control standards while doing this, which is especially important in the context of dealing with widespread vaccine hesitancy. Their co-operation is important for both speed and quality, and so far some seem willing to do this.

At the same time, developing local production capacity for COVID-19 vaccines requires scientific knowledge, technology platforms, financial outlays, and personnel contributions, among others, from multiple actors. Increasing manufacturing capacity needs risk-tolerant capital and a partnership platform to enable technology transfer to new manufacturing sites around the world. Such a platform will mainly succeed if both parties in the technology transfer equation - recipient company and originator company - trust and have confidence in the platform. The future health scenarios that countries are entering may also require renewed attention to the degree of public investment or ownership in clinical trials and the subsequent manufacturing process or indemnity in order to manage overall costs of R&D and considered profits.

ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR AND COVAX

The ACT Accelerator including the Covax facility is a global collaboration to speed up development and equitable access to COVID-19 tests, treatments and vaccines for every country. It remains underfunded some 12 months after its April 2020 launch, although it received a USD 4.3 billion boost from G7 leaders in February 2021. While very important, investment in local production capabilities is not within the scope of this initiative.

COALITION FOR EPIDEMIC PREPAREDNESS INNOVATION (CEPI)

CEPI is a global partnership with a mandate and expertise to develop vaccines to deal with future epidemics. CEPI has been highly instrumental in successfully developing COVID-19 vaccines and invested in enlarging the production capacities in many regions - but has not

focused on boosting manufacturing in Africa until now. The partnership recently concluded a memorandum of understanding with the African Union (AU)/Africa Centres for Disease Control (ACDC) that could help to change this landscape in Africa.

LOCAL AND REGIONAL MANUFACTURING INITIATIVES

Attempts to understand the relationship between markets and manufacturing require pinpointing major conceptual and pragmatic gaps between industrial policies and health policies of countries.[2] For example, better procurement design including oversight and upgrading, can be critical to simultaneously assisting governments, firms, and patients. The lack of attention to the connections between health and wider industrial policies and their goals requires open debate, some of which are exacerbated by inconsistencies between global and national priorities for aid and trade. Autonomy at national, local and regional levels in defining economic and industrial priorities can help offer new pathways for shaping technological change.[3] This affects not only vaccines, but availability of all diagnostics and therapeutics, inclusing skilled personnel and integrated perspectives on long-term and preventative strategies.

Beyond industrial autonomy, distributed manufacturing is helpful for more rapid pandemic mitigation, Some vaccine makers have made strides in advancing more local production. For example, Russia's Sputnik V vaccine is already being produced in India, South Korea, Brazil and China. Production is set to begin in Kazakhstan and Belarus, and other countries including Turkey and Iran, although it has yet to receive formal regulatory approval from a western regulatory agency or the WHO.

India's Serum Institute is manufacturing a local version of the Oxford/AstraZeneca vaccine, which was approved by the European Medicines Agency in March 2021. The vaccine is locally branded as Covishield, India exported 23 million doses of the locally-produced "Covishield" vaccine to low and middle income countries but stopped export recently to give priority for the domestic needs.

EXTENDING LICENCES AND TECHNICAL TRANSFER - MEDICINES PATENT POOL (MPP)

With several companies engaging in limited licencing agreements, those initiatives are ready to be expanded bilaterally or via the MPP. Created a decade ago, the MPP resulted in access to more than 14 billion doses of treatment for diseases including HIV and tuberculosis, and their voluntary licensing expertise can be used. For some products, like biologic medicines or vaccines, licences should be complemented by initiatives aimed at scaling up manufacturing capacity through technology transfer.

However, while many pharmaceutical companies have given HIV and hepatitis C licences to MPP, not a single licence for COVID-19 technology has yet been offered. There are many reasons but perhaps the most important is the lack of strong political support for voluntary licensing clearly articulated to pharmaceutical company CEOs for COVID-19 products.

In the absence of voluntary licensing, alternative, realistic and binding incentives for firms based on market access or other arrangements are being explored. Innovative production arrangements are already effective in many countries such as South Korea and India.

Bharat Biotech's Covaxin in technology transfer to India's state-led Haffkine Institute, will commence manufacturing of Covaxin through Haffkine Bio-Pharmaceutical Corporation.[4]

GENERICS AVAILABILITY AND PRICE REGULATION

The availability of generic medicines has been crucial, alongside supply chain robustness and just-in-time production of oxygen to hospitals, point of care, warehousing, freight and cold storage facilities. Indeed, the pandemic showcased the essential role that off-patent medicines (generic, biosimilar and value-added medicines) play in a major public health crisis, as the majority of medicine needs are covered by such medicines. For example, in Germany, 97% of the medicines needed for COVID-19 had a generic medicine option available on the market. Between 70% and 90% of medicines used during the first wave in ICU were off-patent medicines. Repurposing of medicines was essential in securing treatment options in a crisis. In India's first wave, price caps on tests and medicines, vaccines and new insurance have played an important role.

The pivotal role played by off-patent medicines and price regulation in healthcare was, of course, already clear and well-known before the latest pandemic.[5] Off-patent medicines are the greatest key drivers of equitable access to medicines, and the backbone of public health by contributing massively to providing equitable access to medicines while making healthcare systems sustainable.

OFF-PATENT MEDICINES ROLE IN DELIVERING EQUITABLE ACCESS GLOBALLY

The current pandemic showcased the essential role that generic, biosimilar and value added (including repurposed) medicines play in a large public health crisis, as the majority of medicine needs were covered by those medicines during the first wave in the intensive care units (ICU). The pivotal role that off-patent medicines play in the healthcare systems was already crystal clear before the pandemic worldwide.

To concretely deliver equitable access to medicines global leaders should support policies that promote the uptake of off-patent medicines as well as remove of all barriers to access and anti-competitive marketing strategies that delay the entrance of off-patent medicines after expiry of the patents, to leverage the opportunities of these medicines (for example by tackling intellectual property evergreening strategies).

At the same time, the pandemic had a dramatic impact on demand surges that in some cases doubled or tripled relative to the normal annual consumption, therefore scale up production and the movement of medicines are key to ensure their availability where they are needed the most. This can be done by allowing regulatory flexibility measures, introducing

manufacturing measures that encourage stronger global cooperation on supply chain security and resilience and by promoting deep regulatory convergence for affordable medicines to stimulate cost-effective off-patent medicines development.

Local health responses in Central and Latin America, Taiwan, Japan and Vietnam demonstrated the importance of co-ordinating clinical and industrial knowledge and public health messaging by trusted persons. Some African countries have demonstrated the value of community workers, while Indian states in the first wave showed the critical importance of police and civic personnel (rather than public health workers alone) in testing, tracking and contact tracing when co-ordinated with a fast turnaround time for results and triaging.

UNITAID AND FIND

Unitaid is a global health initiative that identifies and implements solutions to increase access to health products, in particular for HIV, tuberculosis and malaria - which can be also used for COVID-19 and other pandemics.

FIND is a global health initiative that identifies and implement solutions to identify and scale access to diagnostics.

Unitaid closes the gap between late-stage development of health products and scaling for access and applies expertise to advance new life-saving therapies and diagnostics for the COVID-19 pandemic. It is an important member of the Access to COVID-19 Tools (ACT) Accelerator and leads the ACT-A Therapeutics Pillar. Unitaid works with FIND to accelerate the availability and manufacturing scale-up of rapid diagnostic tests to detect SARS-CoV-2 antigens (Ag RDTs) and has worked to make Ag RDTs available at an affordable price in LMICs (just over EUR 2 each).

Unitaid has also been scanning the pipeline of promising COVID-19 treatments. Together with Unicef, it made an advance purchase of almost three million doses of the corticosteroid dexamethasone for LMICs in July 2020 as soon as it was proven to significantly reduce mortality in hospitalized patients.

GLOBAL CO-OPERATION AND SOLIDARITY FOR EQUITABLE ACCESS

Co-operation at a local, regional and global level is critical to deal with the COVID-19 crisis effectively, including a colossal surge in demand for tests, vaccines and therapeutics. Certain responses, including those in Africa and Asia, have been innovative and successful. These responses must be catalogued and built into future pandemic preparedness responses. New geopolitical relations have also been forged in supply chain arrangements.

G20 leaders now have an opportunity to strengthen global health synergies and so ensure equitable access, affordability and availability in the production and supply of tests, therapeutics and vaccines to urgently deal with COVID-19 today while going way beyond the current crisis.

THE PROPOSAL: TOWARDS EQUITABLE ACCESS TO DIAGNOSTICS, MEDICINES AND VACCINES FOR COVID-19 FOR ALL

The pandemic demonstrated that supply and production capacities are wholly insufficient to deliver large quantities of health products quickly, and that generic production, patent pools and voluntary licensing mechanisms have not enabled the huge supplies of products required to confront COVID-19. Low and middle income countries are poorly served, and the African region in particular has few production capabilities able to provide for their own citizens.

Under the auspices of the G20, the world's major economies have a once-in-a-generation opportunity to transform this unequal situation by launching new initiatives that deliver more robust public health, healthcare and industrial production systems. Such initiatives and systems would ensure:

- A people centered approach worldwide
- Enhanced prepradeness and preventative action to limit transmission sooner and deal with new viruses and variants rapidly and equitably
- Worldwide equitable access for all people to diagnostics, vaccines and off-patent medicines.
- New arrangements to accelerate access for all people to on-patent medicines, vaccines and equipment - including price controls, licensing, enhanced public and private sector production, limited time approvals.
- Enhanced production capacity in LMICs and especially Africa where present capacities and investments are unacceptably limited.
- Clarity on role played to improve access through strategic use of public, non-profit, or public-private arrangements in regional R&D, trials, and manufacturing plans.
- Globally resilient supply chains achieved through robust manufacturing networks and access to raw materials.

1. WE CALL ON G20 LEADERS TO SUPPORT MANUFACTURING INITIATIVES REGIONALLY WITH A SPECIAL FOCUS ON AFRICA

This will boost capabilities to produce diagnostics, therapeutics and vaccines for COVID-19 and create a global network of public and private manufacturing to enable a faster response to COVID-19 and future pandemics, enhancing global preparedness and long-term supply chain resilience for health-related products and the raw materials required.

Resilient supply chains need to be built globally via more robust manufacturing: the pandemic had a dramatic impact on demand surges that in some cases doubled or tripled rela-

tive to normal annual consumption. Demand is also expected to increase for new medicines being developed and vaccines for new variants. A central lesson from this crisis is the need to build trust in the security of global and regional supply chains by removing trade barriers while encouraging regional diversification with permanent solutions that look beyond COVID-19.

The smarter and more sustainable way to speed up testing, vaccines and treatments everywhere in the world, today and beyond COVID-19, is to expand and diversify manufacturing regionally, and to ensure the supply chains of essential raw material and finished dosage forms. G20 leaders should therefore focus on short, medium and long term robust industrial and trade policy measures to address vulnerabilities in manufacturing value chains while enhancing manufacturing resilience.

Moving fast is essential. Existing infrastructure should be upscaled and new infrastructure built. Technology and knowledge transfer needs to be accelerated and better targeted to boost innovation and production in public and private entities. This activity needs to emphasize commercial opportunities to ensure sustainability and resilience. Closer proximity between purchasers and suppliers will reduce transport needs and shorten lead times, reducing carbon impacts and lowering transaction costs, while creating new jobs and promoting economic growth.

Public and private investments should therefore be facilitated in companies in Africa as well as other regions when they have some capabilities, political will and readiness to act as regional providers. This will bring essential supplies closer to the point-of-need in faster and lower cost ways, through diversified and scaled-up production and supply chains.

2 *WE CALL ON G20 LEADERS TO INVEST IN SCALING UP MANUFACTURING CAPACITIES AND IN COLLABORATIVE NETWORKS BY ADOPTING SUPPORTIVE INDUSTRIAL AND HEALTH POLICIES AND INVESTMENTS*

We are calling on global leaders to:

- Facilitate technology transfer and sharing technical know-how to build the capacities where they are most needed, throughvoluntary and compulsory licencing agreements and the full use of the flexibilities under TRIPS, and consider waiving protection of IP rights when and where it is useful. This includes speeding the transfer to generic drug status and limited patent timelines for critical clinical areas.
- Provide foresight and planning for decentralized industrial capabilities: to speed up processes and co-ordinate updated mapping of production sites, supply channels of raw materials, finished dosage form, and other measures needed to make access to tests, therapeutics and vaccines rapidly available and affordable.
- Review and update business models, market authorizations and pricing conditionalities when large amounts of taxpayer and philanthropic funds are utilized for clinical research, and advanced purchasing agreements of diagnostics, medicines and vaccines.

- Promote measures that enhance the security of medicines supply, such as reciprocal commitments to limit export restrictions.
- Adopt regulatory flexibilities and increase collaboration initiatives, to ensure the harmonization of medical regulation throughout the African Union (AU) and the implementation of international standards for medicines in line with the Pan-AU creations such as the African Medicines Regulatory Harmonization (AMRH) initiative and African Vaccines Regulatory Forum (AVAREF) - until the African Medicines Agency Treaty is ratified and the agency is operational.
- Set up a global co-operation network for raw materials and vaccine manufacturing to help diversify the supply of essential raw materials.

RECOMMENDATION

Urge G20 to give highest priority to boosting local health capacity toward long-term autonomy and self-reliance in technology and distributed manufacturing wherever most needed, including in Africa. Regionally responsive offices working closely with national and sub-national governments can form the basis and accountability of a strengthened multilateral system to exert full use of policy instruments.

- Recommendation 1: Technology development and transfer with long-term distributed manufacturing: this includes supporting local autonomy and ownership in agenda-setting for health plans, building capacity in technical know-how, and expanding public investment and ownership of clinical trial data.
- Recommendation 2: G20 should commit to supporting ad hoc and standing technical capacity to full use of existing policy instruments. This includes full use of TRIPS flexibilities where voluntary licensing is insufficient; the speeding to generic drug status; and limited patent timelines for critical health areas.
- Recommendation 3: The regional offices can assist the integration of long-term health and industrial plans: these may include building policy capacity for review, including access to ad hoc or standing expert groups to ensure harmonisation and reciprocal commitments, conditionalities for purchasing and pooling, a global co-operation network for raw materials supply, mutual accreditations and inspection systems for approving GMP sites, products and services, and limited export restrictions.

NOTES

[1] Health innovation in sub-Saharan Africa in the BMC International health and human rights Calestous Juma -13 December 2010. PLEASE CHECK THIS – title, capitalisation, details etc.

[2] Srinivas (2012) on technological advance and differentiating supplier countries from other 'developing' countries; Macktinosh et al (2016) on R&D and manufacturing in Africa; Greenhalgh and Papoutsi (2018) on the importance of expanding public health and clinical methodologies; Srinivas, Prasad, and Rao (2020) on the importance of uncertainities generated from both industrial and clinical imperatives.

[3] Banda et al (2021) on broad-based manufacturing in Africa; Also handbook for local diagnostics manufacturers from wide consultations of the Subgroup of the Technology Access Partnership (TAP) of the UN Technology Bank for the Least Developed Countries.

[4] https://www.livemint.com/news/india/haffkine-gets-centre-s-nod-to-manufacture-bharat-biotech-s-covaxin-11618558996343.html.

[5] In India, 95% of prescribed medicines are generics, which contributes substantially to patient access and expenditure savings. In Australia, the genericized medicine market accounts for just over 84% of the volume of subsidized medicines but only 28.7% of the cost. During the period 2016 to 2019, the reimbursed script rate by volume increased by 7%, the cost fell by 12%. This demonstrates the significant savings that generics have provided to the Pharmaceutical Benefit Scheme. In Europe, off-patent medicines account almost 70% of prescribed medicines by contributing only for 2-3% of the total healthcare budget. They doubled access to therapy for hypertension, diabetes, cardiovascular, epilepsy and mental health over 10 years in Europe (2007-2017).

REFERENCES

The Independent Panel for Pandemic Preparedness & Response, established by the Director-General of WHO in response to World Health Assembly resolution WHA73.1. - COVID-19: Make it the Last Pandemic

G20 Leaders' Statement on COVID-19, March 2020, including the commitment to "expand manufacturing capacity to meet the increasing needs for medical supplies and ensure these are made widely available, at an affordable price, on an equitable basis, where they are most needed and as quickly as possible"

Risking further COVID-19 waves despite vaccination, The Lancet Infectious Diseases, March 18, 2021 https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00167-5/fulltext - See Online/Articles https://doi.org/10.1016/S1473-3099(21)00143-2

Expanding production of biopharmaceutical products through an African-European partnership. Policy document for The Africa-EU Partnership, Lieve Fransen, March 2020

Roundtable webinar on *Investments in bio-infrastructure and raw materials stockpiling, a special focus on Europe and Africa*. With Dr. Richard J. Hachett, CEO of CEPI; Dr Anissa Boumlic-Courtade, Director, Head of Global Vaccine & Plasma Bioprocessing Segments, Merck Life Sciences; Dr. John Nkengaso, Director of the African Centre of Disease Control; and Ms. Laura Piovesan, Director Innovation and Competitiveness, European Investment Bank (Luxembourg). 29/09/2020

African Union's *Pharmaceutical Plan for Africa* and an agreed MoU with WHO (2019) that prioritizes local production

Africa needs a New Public Health Order to tackle infectious disease threats. John N. Nkengasong and Sofoais K. Tessema. Africa Centre of Disease Control and Prevention, Addis Ababa, Ethiopia. Cellpress Lasker October 15, 2020, Elsevier

Statement of Director-General Elect Dr. Ngozi Okonjo-Iweala to the Special Session of the WTO General Council

Editorial/volume 397, issue 10283, p1419, April 17, 2021. The ACT Accelerator: heading in the right direction?

Banda, G., D. Kale, M. Mackintosh and J. Mugwagwa (2021) *Local manufacturing for health in Africa in the time of Covid-19: experience and lessons for policy*. Growth Research Programme. Webinar Report https://www.open.ac.uk/researchprojects/innovation-cancer-care-africa/publications/local-manufacturing-health-africa-time-covid-19-experience-and-lessons-policy

Greenhalgh, T., Papoutsi, C. (2018) Studying complexity in health services research: desperately seeking an overdue paradigm shift. BMC Med 16, 95. https://doi.org/10.1186/s12916-018-1089-4

Maureen Mackintosh et al. (2016) Making Medicines in Africa, The Political Economy of Industrializing for Local Health, Palgrave Macmillan

Smita Srinivas (2012) Market Menagerie: Health and Development in Late Industrial States, Palo Alto: Stanford University Press. https://www.sup.org/books/title/?id=21146

Smita Srinivas, Ramakrishna Prasad and Pritika Rao *The clinical foreground and industrial background: Customizing national strategy for COVID-19 testing*, IKD Working Paper No. 87 October2020; https://www.

open.ac.uk/ikd/publications/working-papers/87

The erosion of public sector vaccine production: the case of the Netherlands, Stuart Blume, Manchester University press - The politics of vaccination,31 march 2017

A global history Editors: Christine Holmberg, Stuart Blume, and Paul Greenough, eISBN:9781526110916 Publisher: Manchester University Press

See Wouters, O.J. et al. Challenges in ensuring global access toCOVID-19 vaccines: production, affordability, allocation, and deployment in: The Lancet, Health Policy| Volume 397, ISSUE 10278, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00306-8/fulltext, March 13, 2021

ABOUT THE AUTHORS

Lieve Fransen European Policy Centre; and Wits University

Fransen is a senior social and health policy advisor with a range of different institutions, businesses and think thanks. She is medical doctor specialized in global public health and social policies worldwide. She has a PhD in social policies. Dr Fransen has a considerable and recognised experience in development policies and European policies and institutions. She worked extensively on formulating evidence based policies on social investment and innovation, pensions, health and health care and gender, HIv and Population. She worked as a Medical Doctor and clinical and public health researcher and international public health in the developing world and in Europe.

John Nkengason African Centers for Disease Control and Prevention

Nkengason currently serves as Director of the Africa Centres for Disease Control and Prevention, a specialized technical institution of the African Union. In early 2020, he was appointed as one of the WHO Director-General's Special Envoys on COVID-19 Preparedness and Response. Dr Nkengasong has received numerous awards for his work including the Bill and Melinda Gates Foundation's 2020 Global Goalkeeper Award for his contributions to the continental response in fighting the COVID-19 pandemic in Africa. He is an adjunct professor at the Emory School of Public Health, Emory University, Atlanta, GA. He serves on several international advisory boards and has authored over 250 publications.

Smita Srinivas Co-Chair T20 Italy Task Force on Global Health and Covid-19; Open University; National Centre for Biological Sciences TIFR-NCBS; and University College London

Srinivas is an academic and advisor on technological change and economic development (Technological Change Lab TC-Lab). Her research centres on the economics of technological learning and innovation, industrial policy, and the variable growth of knowledge systems in economic development. Her current research looks at the institutional, evolutionary economics of heuristics toward multi-technology and cross-industry problems. She currently leads the India research team of a 4-country project Innovation for Cancer Care in Africa (ICCA) at India's National Centre for Biological Sciences, Tata Institute of Fundamental Research (NCBS-TIFR).

Stefano Vella Co-Chair T20 Italy Task Force on Global Health and Covid-19; and Università Cattolica del Sacro Cuore

Vella received his degree in Medicine from the University of Rome. He subsequently achieved specialty degree in both Infectious Diseases and Internal Medicine. Medical staff at the Institute of Internal Medicine of the University "La Sapienza" Hospital, he developed an extensive experience in the clinical management of internal medicine and infectious diseases. Specific research has been conducted by Dr Vella on major pandemics, specifically on HIV/AIDS and Tuberculosis. Former President of the International AIDS Society [IAS], he served as the Italian Board Member of the Global Fund to Fight Tuberculosis, AIDS and Malaria. Director of Department of Pharmacology of the Italian National Institute of Health [ISS] (2003-2017), he was appointed, in January 2017, Director of the Italian National Center for Global Health. Dr Vella has been the President of the Italian Medicines Agency from 2017 till 2018. He is currently Adjunct Professor of Global Health at the Catholic University of Rome, and is a member of the Program Committee of Horizon Europe - Health Cluster, the Research Program of the European Commission (2021-2027).