CHAPTER 2

Broken Supply Chains and Local Manufacturing Innovation: Responses to Covid-19 and Their Implications for Policy

Geoffrey Banda, Cecilia Wanjala, Veronica Manduku, Julius Mugwagwa, and Dinar Kale

Introduction: Warnings Become Reality

For decades, industrialists, industry associations, supranational organisations such as AU (African Union) and AUDA/NEPAD (African Union Development Agency/New Partnership for Africa's Development), development agents such as GIZ and UNIDO (United Nations

G. Banda (✉)
University of Edinburgh, Edinburgh, UK
e-mail: Geoffrey.Banda@ed.ac.uk

C. Wanjala · V. Manduku
Kenya Medical Research Institute (KEMRI), Nairobi, Kenya

J. Mugwagwa
University College London, London, UK

G. Banda et al. (eds.), *Cancer Care in Pandemic Times: Building Inclusive Local Health Security in Africa and India*, International Political Economy Series,
https://doi.org/10.1007/978-3-031-44123-3_2

Industrial Development Organisation) and academic researchers have been advocating localisation of medicines production in Sub-Saharan African countries. However, governments had responded that they were juggling multiple intractable development problems. Consequently, the local health industries have struggled to gain attention and policy priority.

Then Covid-19 laid bare Africa's state of unpreparedness for pandemics. Faced with an impatient public, governments that had traditionally not prioritised support for local health industries suddenly turned to them for urgent help. Covid-19 changed the policy and innovation dynamics. Faced with an existential threat, African governments suddenly paid attention to local medicines production. The results, discussed in this chapter, have been striking. The pandemic crisis opened up innovation spaces and scope for collaborations among local agents, some of whom, such as local entrepreneurs, had been ignored for a long time. Governments facilitated collaborative innovation.

What caused this sudden volte-face? Covid-19 caused African policymakers to wake up to the implications of broken supply chains for medicines and other key health-related commodities, both for Covid-19 and for the wider health system (Banda et al., 2021a). Crises typically have these effects, discrediting conventional ways of doing things: the bigger the crisis, the bigger the policy and practice impact (Nohrstedt & Weible, 2010, p. 3). African health stakeholders had been well aware before the pandemic of the risks implied by extreme import dependence and the imperative on governments to protect their own populations first. Hence, their central expressed concern when asked about pandemic preparedness was to build local scientific competence and production capacity (Mackintosh et al., 2018a, p. 603). The pandemic demonstrated the relevance of these concerns and forced a re-evaluation of accepted wisdom, norms, policies and institutions.

This chapter surveys these experiences and argues that they hold important lessons for building stronger health security in Africa and even in the much stronger industrial context of India. The rest of the book builds on this understanding of the pandemic achievements of coordination and collaboration across multiple policy and industrial sectors, and the agency, urgency and legitimacy of action achieved in that period. It

D. Kale
The Open University, Milton Keynes, UK

argues that the cancer care crisis requires and enables a similar response. Themes identified here that run through the book include: the importance of demand for health inputs and how that structures supply and industrial capabilities; the interconnections between local production and local health security; and how local capabilities imbue health systemic resilience against sudden exogenous shocks. We thus use the impact of the Covid-19 pandemic on health-related manufacturing in India and African countries to understand the induced scale of shift in thinking and re-evaluation of public policy required.

Covid-19: An Immediate Crisis that Triggered a Wakeup Call for Africa

Covid-19 started in China, Europe and Africa at different times; however, public health policy responses on lockdowns, clinical approaches and dependence on local industrial capabilities were largely similar. What was different was the extremely inequitable access to vaccines, drugs and Personal Protective Equipment (PPE) for medical personnel and the public. African populations lost out because of weak local industrial capabilities. In addition, African countries with low purchasing power failed to benefit from global supply chains that served Europe and North America first.

In order to understand how Covid-19 generated an immediate crisis for Africa, we briefly describe the sequence of events to show how global supply chains were broken and Africa was left vulnerable.

On 31st December 2019, the WHO Country Office in China was notified of the incidence of viral pneumonia in Wuhan, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The genomic sequence of this new coronavirus was released shortly afterwards on 10th January 2020, and the WHO announced on 11 February 2020 that the new disease would be called Covid-19.[1] In about a month, on 14th February 2020, the first case of Covid-19 on the African continent was confirmed in Egypt. In Sub-Saharan Africa, the first country to confirm the disease was Nigeria at the end of February 2020. Two years later, by 28th February 2022, the African Centres for Disease Control (CDC) had reported 249 000 deaths, 11.2 million total cases and total recoveries of 10.4 million. Tests administered to 28th February 2022 totalled 99.6 million.[2]

From early in the pandemic, major producing countries for vaccines, drugs, medical devices and diagnostics prioritised their own populations, and governments imposed export controls. Elsewhere, imports of essential finished items dried up, and supplies of key inputs to local manufacturing were cut off by competition from large-scale buyers with deeper pockets. The sharp financial squeeze on firms was aggravated by other sources of financial loss: private debtors and governments were slower to pay, while input suppliers required pre-payment. This collapse in supply chains caused serious shortages of raw materials and finished goods in African countries. At a webinar organised in October 2020, a Southern African industrialist crystallised the impact of total dependence on pharmaceutical imports as follows: "Africa found itself inevitably at the back of the queue for *all* product supplies" (Banda et al., 2021a).

Flight cancellations and shortage of cargo carriers caused freight charges to skyrocket and historical orders' prices were revised upwards. A facemask-producing company in Ghana saw their key input prices—for meltblown fabric—rise 20-fold. An East African pharmaceutical manufacturer who was waiting for a delivery of bulk chloroquine, ordered from an Indian company before the pandemic and delayed in delivery for months, saw an 800% price increase from USD 32 per Kg to USD 260 per Kg. The company had no option but to cancel the already delayed order (Banda et al., 2021a). These broken input supply chains reduced local manufacturers' capacity utilisation just at the moment when local demand was rising and local buyers turned to local suppliers. Those manufacturers without large stocks in their warehouses had to grapple with lower quality and more expensive inputs, especially for the production of diagnostics and PPE products.

This local production crisis was worsened by shortages of APIs and excipients. There is an absence of API producers in Sub-Saharan Africa except for South Africa where a few APIs are produced. South Africa is making efforts through the Department of Trade, Industry and Competition (DTI) to localise API production. In Ghana, La Gray Pharmaceuticals had progressed through the API development phases for the antibiotic azithromycin, however after working with a technical partner and due to other challenges, this highly innovative company is currently closed. The behaviour by leading producers of medicines, medical devices and diagnostics caused Africa's policymakers to stop and revaluate their reliance on global supply chains, which at a time of crisis had failed them. Suddenly local medicine production became a national security issue.

Similar but Unequal Response to Crisis: Proximity and Positionality

African industrialists, scholars and promoters of local medicines production have long sounded the alarm that in the event of a pandemic or epidemic, African countries would be left extremely vulnerable. This occurred when African countries could not import Covid-19 medicines or place orders for vaccines when they became available. The vaccine nationalism that gripped high-income countries and dominated access to early vaccine supplies, with devastating destructiveness elsewhere, reflected purchasing power, technological capabilities and willingness to use these assets for national benefit to the detriment of others.

While the severely detrimental impact of monopolising behaviour by high income countries was rightly excoriated, a focus by national governments on their own populations was a general pandemic response. Global collaborations and global supply chains rapidly disintegrated, while responses to the crisis were strongly structured by proximity and accountability to local populations.

Prior to the pandemic, we predicted, reflecting the widespread views of African stakeholders, that in the event of a medical disaster, Africa would be left in a lurch as all countries would look after their own citizens first (Mackintosh et al., 2017, p. 6). We argued for close attention to the implications of proximity and positionality in understanding the importance of local health industries in Africa and their direct link to local health security (Mackintosh et al., 2018a). Proximity, we argued, has several facets. Geographical proximity can generate benefits of shared knowledge, resource pools and short supply lines. Relational proximity recognises shared culture and economic spillovers of knowledge. The values assigned to proximity reflect the scope for mutual understanding, legitimation and trust. These benefits of co-location, however riven by other sources of division, can be economic and social assets in times of crisis. Meanwhile positionality, defined by the extent of local power, agency and responsibility, generates distinctive local priorities and sharply differentiated capabilities to use these assets for national benefit.

The interconnected pressures of proximity and positionality played out strongly in the pandemic. They structured the form and shape of responses to the pandemic. Countries with strong industrial capabilities and deep pockets exploited the strengths of proximity to secure the health of their citizens first, using forward contracts on vaccines, and

export bans of APIs and finished products. Other countries benefitting from local manufacturing close to local populations could also generate greater health security in the face of the pandemic. Geographic proximity of manufacturing and technological capability to local populations was shown to be critical in building agile responses to medical health emergencies (Banda et al., 2021a; Mackintosh et al., 2018a). As we show below, the confluence of geographic and public policy proximity allowed a rapid re-purposing of industrial capabilities in some countries, including India, to meet public health policy objectives. An inability to use strong local manufacturing capabilities to support public health objectives drove the crisis for African policymakers elsewhere.

Sources of Supply Chain Crisis: Cascading Import Dependencies

The Indian domestic pharmaceutical sector has 3000 companies and 10,500 manufacturing units. It is the largest global supplier of generic medicines. It met approximately 60% of global demand for vaccines as of 2021, over 40% of generic demand in the USA and 25% of all medicines in the UK (India Brand Equity Foundation, 2022). The pharmaceutical industry is expected to be valued at USD 130 billion by 2030, and is currently ranked third by volume and 14th by value globally (*ibid.*). Sub-Saharan African countries are particularly highly dependent on India for imports of essential medicines (Chaudhuri, 2016). Chaudhuri et al. (2010) had earlier warned that the African reliance on Indian suppliers was based on the unexamined assumption that provision of low-cost generics from Indian manufacturers was sustainable. Reviewing Indian firms' strategies, the authors warned of the risk that African countries faced a reduction in reliable low-cost Indian suppliers, identifying the risk that a change in market strategy would see the Indian suppliers targeting more lucrative higher margin products, and markets in higher-income countries. Shifting from low margin generics to higher margin products could be an astute business strategy for Indian companies, since businesses are driven by profit motives and not philanthropy. Thus, a large-scale strategy shift to wealthier markets would have huge implications for African health systems. Hence, they argued, that it was important to enhance African local manufacturing capabilities to improve access to local populations (ibid).

Africa however was not the only area that had built up supply chain risks. Not only India and Africa but the whole world is highly dependent on China for APIs and other technologies. India, renowned for its generic medicines production capabilities over the last two decades has become highly dependent on China for APIs. According to the Trade Promotion Councils India imports about 85% of its APIs from China.[3] When in the pandemic China imposed lockdowns that led to factory closures, it triggered a domino effect and cascaded global supply shortages. First China then India imposed exports controls on PPE, medical devices and APIs, reserving what they had in stock for their countries. As the pandemic rolled out, a number of potential antiretroviral and anti-inflammatory agents were trialled for effectiveness against Covid-19 (Carvalho et al., 2021). However, shortages of these medicines, and of oxygen, quickly became common (Stein et al., 2020) and these gaps were exacerbated by disruptions to global cargo movement. The African continent then bore the brunt of these logistics and export controls.

The dominance of China in medical health technology production results from national initiative. China has over the last five decades rapidly built up technological capabilities through reverse engineering, and at the same time making in-roads in creating new-to-the-world technologies. As a result, China overtook India to become the world's largest API and excipient producer, covering 40% of global APIs production. Its pharmaceutical market value grew from USD 158 billion in 2016 to a projected USD 315 billion in 2020 (Medicines and Healthcare products Regulatory Agency, 2017). In addition, China has become an important medical device exporter, including into Africa. This context shows the scale of the impact of China's 1st April 2020 imposition of export controls on five classes of Covid-19-related products namely "Covid-19 detection reagents, medical masks, medical protective clothing, ventilators and infrared thermometers".[4] Reuters reported that the move was triggered by highly publicised reports from some governments and hospitals who alleged they had received faulty goods.[5] However, in a time of crisis, this fuelled export embargoes by producers, and panic and price increases for import dependent countries.

Export controls that started in China spread to Asia, Europe and the Middle East as well as the USA (Federation of German Industries, 2020). India on the 3rd of March 2020, imposed export restrictions on some vitamins and APIs, and medicines which included paracetamol, antiviral agents and antibiotics (*ibid.*). In March 2021, facing a devastating second

Covid-19 wave, India imposed a de facto export ban on Covid vaccines produced by the Serum Institute of India (SII), diverting the vaccines to local needs. The SII is the largest manufacturer of vaccines in the world and was at the time the biggest supplier to the international Covax programme on which many African countries relied for vaccine access.[6] In June 2021 the Indian Finance Minister allocated USD 26.578 billion to the pharmaceutical Production Linked Incentive Scheme (PLI scheme)[7] covering 13 sectors that include APIs and excipients, drug intermediaries and starting materials (India Brand Equity Foundation, 2022). The PLI scheme targeted the enhancement of India's manufacturing capabilities and investment in the productive sector to enable diversification and transition to high-value pharmaceutical goods. Another key target for the scheme was to develop global champions out of India that would participate in cutting-edge technology value chains (Ministry of Chemicals and Fertilizers, 2021). The PLI Schemes also covered domestic manufacturing of medical devices, and there were other schemes to promote bulk drug and medical device parks.

In September 2021, India restarted vaccine deliveries from SII to Covax.[8] At the same time, access to the highly innovative and more expensive mRNA vaccine BNT162 (Carvalho et al., 2021) was difficult for African nations to achieve. The African continent therefore had by far the lowest vaccine rates. By late August/September 2022, Tunisia and Morocco had the highest percentage of the population having received at least one dose, at 72.5% and 68%. In Sub-Saharan Africa, rates remained low: countries where at least 30% of the population had received one dose included South Africa, Uganda, Ghana and Tanzania; large countries with very poor vaccination rates included the Democratic Republic of Congo (DRC) (4.4%) and Nigeria (19%)[9] (see also [Mathieu et al., 2021]). By contrast the figures for India and China, both with vaccine industrial capability, were 73% and 91%.

Pandemic Impacts in India

In India, the first Covid-19 case was reported in Kerala on 27th of January 2020. This patient zero had returned from Wuhan city on 23rd of January 2020, because of the outbreak in that city (Andrews et al., 2020). Early treatment in India consisted of azithromycin (500mg), cetirizine (10mg) and saline gargle. On referral to the Government Medical College, patient zero was put on oseltamivir (brand name Tamiflu), an antiviral used to

treat influenza A and B, viruses that cause flu. The patient recovered and was released on 20th of February 2020 (ibid.). All the drugs used to treat patient zero are manufactured in India as generics, thus India leveraged its deep industrial capabilities in responding to the pandemic. India used its broad pharmaceutical and biopharmaceutical capabilities to achieve a higher vaccination rate compared to African countries with limited industrial capabilities. India's Serum Institute of India produced the Covishield (Astra Zeneca) vaccine for worldwide low-cost distribution. In addition, Bharat Biotech, an Indian company, developed and produced Covaxin (BBV152) a whole inactivated vaccine.

Nevertheless, India suffered from supply chain problems during the pandemic. Chinese factory closures in the first quarter of 2020 had a ripple effect in India. Ordinarily, the raw material stockholding capacity for many producers is two to three months, as companies try to avoid holding costs by locking-in money in raw materials. Order lead times after factory closures in China rose to as much as three months which disrupted the continuity of raw material supplies for local producers (UNAIDS, 2022). In a webinar discussion (Banda et al., 2021a), Indian industrialists and academics acknowledged that India had made a mistake in allowing such a high API concentration risk arising from reliance on Chinese suppliers. They reported that Covid-19 served as a warning to reconsider the wisdom of off-shoring such an important production activity.

Shortages of packaging in India were also acute as producers generally keep low stock levels. The lockdowns, border closures, export controls and bans triggered by Covid-19 restrictions did not only affect Covid-19 medicines but included other lifesaving drugs such as ARVs for HIV/AIDS. In a press release in June 2020, UNAIDS highlighted lockdowns negatively affecting supply and distribution chains for HIV medicines as manufacturers faced logistical challenges that could last for months (UNAIDS, 2022). Eight Indian generic manufacturers that collectively supply 80% of generic ARVs globally faced these logistical challenges. India exports generic ARV drugs valued between USD 850 million and USD 900 million per annum. The other affected countries with domestic ARV producers were Brazil, Indonesia, Kenya, South Africa and Thailand.

Compounding these input challenges was operating capacity. Local companies in India were forced to operate at 50% of normal workforce levels, because of movement restrictions. In addition, finished goods piled up at factories, as they could not be transferred to ports. Indian manufacturers' sea freight of finished products faced three logistical issues. Goods

movements at ports significantly slowed down due to customs workforce shortages. The shortage extended to the cargo handling staff, and third, road distribution links were disrupted because of lack of road transport, which made transporting goods to and from the port problematic. Air freight also faced three challenges: it suddenly had to undergo multiple customs and clearance processes; only a few cargo planes were flying; and even passenger planes that handle a significant amount of cargo were cancelled (UNAIDS, 2022).

The impact on India therefore created coordination challenges for both productive activities and logistics that policymakers may not have thought through clearly at the beginning of the pandemic. As inputs for production including APIs and packaging ran low, local small stockpiles were rapidly used up. Temporary halts on exports of vaccines and other products were compounded by the huge logistics challenges. However, because of the broad industrial and technology bases of India, the country bounced back fast, and even at the height of the pandemic the local industry quickly adapted, for example to produce needed oxygen supplies for the hospitals.

Sociotechnical Imaginaries: Imaging and Designing the Future

These glaring concentration and technology risks have exposed the need for more proximate manufacturing of generic medicines in Africa. Local production needs to cover a wider range of off-patent drugs as well as gradually moving to include more innovative drugs, APIs, excipients, vaccines and other biologicals (see Chapters 7–9). This shift requires concerted efforts to support industrial development and transition. The science and technologies required are not new. However, the shift calls for investment and technology transfer as well as incentives that cover issues such as upstream inputs, waste treatment plants, logistics and affordable energy. We use the notion of sociotechnical imaginaries to explore how envisaged technological futures can be created and at the same time have the legitimacy critical for such long-term projects.

Sociotechnical imaginaries and proximity are useful notions to frame what generates government agency, urgency and provides legitimacy with the public. We combine science, technology and society (STS) and innovation systems literature in this chapter. There is merit in using theory as a sense-making tool, no matter how sub-optimal, to solve time-sensitive

problems. Sociotechnical imaginaries have been defined as "collectively held, institutionally stabilised, and publicly performed visions of a desirable future, animated and shared understandings of forms of social life and social order attainable through, and supportive of, advances in science and technology" (Jasanoff & Kim, 2015, p. 6). Critical to the argument in this chapter, these authors assert that sociotechnical imaginaries are important in shaping technological design and hence technological futures, as well as legitimating the channelling of public resources to projects based on the deemed benefits that will accrue to society from the technological advancement.

The attraction of the sociotechnical imaginaries concept is that it helps to make sense of how political actors, innovators and the public can generate shared "visions of desirable technological futures" emanating from science and technology advances. Covid-19 demonstrated the urgent need for Africa to leverage science and technology to prepare for not only pandemics but economic development as well. Investment in pharmaceutical sector development and upgrading is critical for enhancing local health security.

However, because sociotechnical imaginaries arise from deliberate choices, they can be contested. In addition, multiple sociotechnical imaginaries can exist, depending on the actors driving them. These could be private or institutional actors (Mager & Katzenbach, 2021). Thus, conflict or contestations can arise on which particular sociotechnical imaginary to pursue. This could be more problematic in resource-constrained settings with multiple intractable development objectives. Conflict arises if for example, the sociotechnical imaginaries driven by the private sector differ from those held by the state. On the other hand, different sociotechnical imaginaries can co-exist (Mager & Katzenbach, 2021). For resource-constrained settings, collaborative approaches are preferable that support aligned visions of the future and efficiently use available public resources.

The notion of sociotechnical imaginaries has been applied in emerging sectors such as new energy systems (Jasanoff & Kim, 2013) governance of digital technologies (Mager & Katzenbach, 2021), public security (Gerhold & Brandes, 2021) and the defence industry (Martins & Mawdsley, 2021). Sociotechnical imaginaries are particularly applicable to new or emerging technologies because they are potent "cultural resources that help shape social responses to innovation" (Jasanoff & Kim, 2013, p. 190). These cultural responses are inherently linked to politics, public mood and scarce resource allocation, the remit of the political economy

of technological development and advances. Covid-19 changed the public mood and shaped pro-technology intervention public policy responses in African countries. This drove sudden political imagination, agency and urgency to prepare the continent for future pandemic threats. This crisis-driven shift and questioning of conventional wisdom still requires shared sociotechnical imaginaries co-generated and sustained by not only technocrats, but also political leaders and the public.

These visions of the future entail science, technology, innovation and social transitions/change. Thus, who creates and sustains sociotechnical imaginaries matters a great deal. Over the last twelve years development agents such as UNIDO, GIZ, WHO and UNCTAD, supranational organisations such as (AUDA/NEPAD), and local industry associations have been driving the sociotechnical imaginary of a future vibrant innovative African pharmaceutical sector. The Pharmaceutical Manufacturing Plan for Africa (PMPA) is one encapsulation of this imaginary. However, national governments, except for a few and even the public have not engaged in shaping these technological futures. Covid-19 placed governments under siege from an impatient public, which demanded government do something about the pandemic, and news about investments in vaccine manufacturing plants was met with public approval. The success of such projects depends on patient investment and support for the local health industries. Covid-19 forced disparate but geographically proximate African private and public professional networks and actors to stop, regroup and collaborate, and this momentum needs to be sustained. India on the other hand, which has developed technological capabilities and skills still faced challenges during Covid-19 with collaboration, multidisciplinary working and coordination between health and industry (see Chapter 6).

Historically promoters of African local manufacturing and roadmaps lacked sufficient patient capital, political reach, urgency and agency to successfully execute what are essentially politico-technological projects. Shaping new technological trajectories and industrial transitions generates commercial and political resistance from incumbents whose economic competitiveness or market dominance is threatened. Mager and Katzenbach (2021, p. 1) while focusing on digital technologies highlighted that sociotechnical imaginaries have elements of "function, power and performativity" which can be used to shape and govern new technologies. Consequently, the state is a key actor because of its political power and reach, legitimacy, access to resources and latitude to use public policy

to shape technological transitions of the magnitude required for this sector—hence our calling them politico-technical projects.

However, the state cannot do it on its own. It has to work with both the private and public sectors and other organisations important for the sector. Our argument is that localisation of the medical health technology industry requires sustained technological skills development, value chain upgrading and development of new business models. The only actor possessing the legitimacy to galvanise the development of technological futures is the state. In addition, through policy and incentive structures, the state can reward good behaviour and punish errant behaviour through penalties.

The state similarly played an important role in restructuring the pharmaceutical sector in India and Bangladesh (Chaudhuri, 2021; Lall & Bibile, 1978) and these examples clearly show that it was a socio-political process that drove technological transitions observed in these countries today. We briefly describe below how India developed its pharmaceutical sector. When India and Bangladesh changed public policy and incumbents felt threated, those incumbents resisted the change and even roped in health professionals to discredit local manufacturing, claiming quality would be compromised. Thus, significant reforms depend on political conditions within and outside the country (Reich, 1994). However, Covid-19 has generated a window for African governments to cite vaccine nationalism as a significant threat to their local health security. We argue that this window should be used to shift public policy and generate local medical health technology production sociotechnical imaginaries that improve the local health outcomes for local populations, and in particular for this book for cancer care.

India's Pharmaceutical Industry: Technological and Political Projects

The Indian pharmaceutical industry's journey from importers in 1947 to imitators by 1990 and finally innovators represents a story of technological upgrading and self-reliant development influenced by protective public policy instruments, processes of contestation and local entrepreneurship (Kale, 2019a; Watkins et al., 2015). The Indian pharmaceutical industry developed in several stages across different political administrations that adopted and sustained industrial policies to address three key objectives/sociotechnical imaginaries: achieving self-reliance in

the supply of medical products; improving the local healthcare sector and securing access to the industry's global research and development (R&D) knowledge through selective compliance with international intellectual property rights (IPR) laws. These were national politico-technical projects that developed because of purposive political support in policy design and execution in addition to incentives to support the growth of the nascent sector.

At independence, the Indian industry and market was dominated by European-based MNC subsidiaries that focused on sales with little local R&D or manufacturing. Post-independence, the Indian government, led by Nehru, adopted state intervention economic policies and set up public sector units to encourage the domestic development and manufacturing of pharmaceuticals. However, the real boost to the development of the Indian pharmaceutical industry happened under the leadership of the Indira Gandhi government. It initiated effective industrial protection policies such as the Patents Act 1970, the Foreign Exchange Regulation Act (FERA) 1973 and New Drug Policy (NDP) 1978 that helped the Indian industry to achieve remarkable success from the 1970s.

Economic liberalisation initiated in 1991 by the Rao government later brought significant changes to the operation of the Indian pharmaceutical industry, by abolishing industrial licensing and encouraging foreign capital. Economic liberalisation proved a contentious issue among industry associations, political groups, civil society organisations and industry leaders (Kale et al., 2015). However, the Indian pharmaceutical industry responded positively by performing well in export markets. For example, the export of bulk drugs increased by 14% and formulations by 18% from 1991 to 2000 (James et al., 2021). The Vajpayee government further extended the era of economic liberalisation by negotiating and signing the TRIPS (Trade-Related Intellectual Property Rights) agreement that made all pharmaceutical products and processes eligible for 20-year patent protection aligning with international IPR laws. This government disinvested from most Public Sector Units and further amended domestic investment and FDI regulations (James et al., 2021).

The Indian government, led by different political leaders with roots in diverse ideologies, managed to transform the country from an economic laggard to one of the most dynamic economies in the world (Srinivas, 2012). The Indian economic and industrial policies adopted under different political administrations helped build solid technological capabilities in local healthcare technology industries. Comparably, in very

different political contexts, China also provided manufacturing incentives, and over 20 years built API manufacturing capabilities. Using the incentives of building waste treatment plants, industrial parks and subsidised energy costs, China wooed partners for joint ventures and successfully transferred the technology for API production (WHO, 2017). What are the lessons for industrialisation leadership in the expanding markets of large African countries and regions?

African Pandemic Innovation

African countries' responses to being locked out of global health supply chains caused a re-thinking of innovators' roles. Scarcity-induced innovation was triggered. Local industries, universities and research institutes which had operated in the background and in the words of a respondent, were "denied the opportunity, space and latitude to innovate" all of a sudden were thrust into urgently producing ventilators, diagnostic kits and reagents, among others. For a moment public policy was sharpened to focus on supporting local innovation ecosystems (Banda et al., 2021a, 2021b). African governments, like others across the world, focused on their own populations.

Some of the innovations included local production of sanitisers, face shields, medical scrubs, and PPE and there was also an acceleration of local production of Covid-related medicines such as dexamethasone, paracetamol and azithromycin. Kenya provides a number of examples of innovative African responses to the pandemic emergency. The Kenyan Medical Research Institute (KEMRI) worked closely with government ministries and local manufacturers, to scale up existing products, including hand sanitiser and viral transport medium, switching to local input suppliers where possible. KEMRI collaborated with local manufacturers to design and produce swabs for Covid-19 testing and redesign and scale up production of appropriate bottles for sanitiser when inputs such as pump caps from China were blocked. These responses leveraged the technological capabilities that had been developed and sustained in KEMRI for years. They also tested both the depth and limitations of Kenya's local industry. A key challenge raised was the dearth of local testing laboratories and notified bodies for medical devices among the local Standards Bodies (Banda et al., 2021a).

It remains to be seen if the reliance on the local innovative capabilities will be sustained. A test case may be Kenya's vaccine manufacturing ambitions. Kenya had announced plans to construct a vaccine manufacturing plant before Covid-19. Work by a multidisciplinary team on plans for Biovax started in 2015, reviewing the feasibility of vaccine manufacture in Kenya; in 2019, attention focused on human vaccines. Again, the progenitor institution was the KEMRI Production Unit. The 2015 concept note proposed the establishment of a biomedical manufacturing facility in Kenya through a public–private partnership. The pandemic accelerated the plans, and it became a government project. At the time of writing, an appointed CEO has begun global recruitment for staff. The shortages of vaccines and urgency of the situation have forced nationalisation of the project.

The initial focus was the production of childhood vaccines targeting primary vaccination programmes in the East African Community market. Kenya was exiting the GAVI vaccine procurement programme, hence the supply concern. Covid-19 broadened the scope and ambition, with participation in African Union vaccination meetings. A key consideration was whether it was cheaper for Kenya to continue relying on importing vaccines, or should they bite the bullet now and set up manufacturing capacity for the longer run? In line with our discussion on sociotechnical imaginaries Kenya has a "big four" policy agenda for economic development and local manufacturing features in that agenda (see Chapter 7). Biovax is using the resources allocation from government and political goodwill to progress the setting up of the manufacturing plant.

Procurement will be key for vaccines as for other local production initiatives in Africa. Manufacturers repeatedly identify procurement commitments as a key signal for investment and a key determinant of survival. In Kenya, the longstanding animal vaccine manufacturing is a commercial enterprise, since farmers pay for the vaccines. Human vaccines on the other hand are more of a public good, largely procured through public health programmes to ensure wide uptake. Hence, investors require government procurement commitment that had not been assured in Kenya at the time of writing. The industrial capabilities development in vaccines will also need to be accompanied by commensurate local vaccine and biological regulatory skills development.

Covid-19-induced Policy Shifts and Need for Long-term Policy Sustainability

Covid-19 triggered a huge shift in public policy towards the development of local health industries. However, internationally, there was a biased focus on vaccine production at the expense of APIs, drugs, medical devices and diagnostics. The WHO backed a technology transfer hub in South Africa to manufacture an mRNA vaccine (see Chapter 10); South Africa and Senegal, with existing vaccine manufacturing capabilities, were nominated as centres of excellence for technology transfer, while Ghana, Kenya and Uganda announced plans to set up new vaccine production facilities.

These plans for increased local manufacture are commendable, since state policy for domestic manufacturing and technology sectors is critical for technological transitions (Lall & Bibile, 1978). However, planners and development coordinators must carefully think through the right policy mixes required to meet the short, medium and long-term industrial structure, health systems funding, procurement and localisation policies. In particular, the pandemic has demonstrated the importance of industrial depth and breadth as well as scientific and research capability, in generating innovation under pressure. Important considerations for achieving sustained localisation of medicines manufacture include the following. What should the government, public, innovators and the private sector envision as the science and technology futures they want? What type of industrial policy should come out of the Covid-19 pandemic? What type of collaborations and linkages within and outside the country are required? How can pragmatic industrial policy seek to learn from those doing well, create new opportunities for technological upgrading and connect with health policy?

Regulation

Covid-19 demonstrated the need for policy shifts in regulation and regulatory capabilities. Regulatory capabilities are an important component of local industrial mix of sociotechnical imaginaries, in the quest to mend broken supply chains and develop and sustain manufacturing innovation for health. Colleagues have argued in allied work that health sector regulatory authorities in African countries not only face challenges regarding

their own capabilities, but have to grapple with heterogeneous levels of technological and innovation capabilities within firms (Mkwashi & Brass, 2022). The rapid pace of change in technologies and other regulatory requirements necessitated by the Covid-19 pandemic presents both challenges and opportunities for African regulators.

In Kenya, pandemic innovators in a university and a manufacturing company encountered a regulatory maze. A private firm and a university had designed ventilators. University students after designing their ventilators had no knowledge of what to do next to get regulatory approval. The private company that developed a ventilator had no idea of the science and rigour that goes into governing medical devices. In addition, both needed to comply with regulations overseen by the Pharmacy and Poisons Boards as well as the Kenya Bureau of Standards. These challenges led to the ministry setting up a sectoral task force composed of different regulators to resolve these regulatory traffic jams during the pandemic. What was apparent was although innovators could produce technologies rapidly, there were no attendant regulatory, funding and production support mechanisms.

The advent of many new manufacturers, including those traditionally not involved in manufacturing for health is both a challenge and an opportunity to stress-test the systems and mechanisms of national drug regulatory agencies, medicines control agencies and other regulators. It is also both a challenge and an opportunity to put to test some of the aspirations of some supranational activities, such as AUDA/NEPAD's African Medicines Regulatory Harmonisation. The pandemic gave traction to arguments we made in earlier work on standards (Banda et al., 2016a) making a case for mutability in some of the standards as a way of removing some of the bottlenecks in the progression to high levels of manufacturing capability for African countries. The pandemic opened up the space for using appropriate, adaptive and agile governance systems that balanced safety and supply security needs. Some of the sub-optimal responses seen not just in Africa but globally in regulating technologies during the pandemic are a result of working in silos and a lack of cross-sectoral coordination. Co-evolution of technological and regulatory capabilities, including close collaboration between researchers, industrialists and regulators will be important in building new institutions for regulation on the continent.

Industry Policy

Establishing and sustaining a future vibrant local pharmaceutical industry can take up to twenty-five years. It takes time to set up local, regional and international value chains, create backward and forward linkages and establish relationships of trust. Training personnel and generating institutional memory as well as passing on tacit knowledge gained through learning by doing and through making mistakes also takes time. Covid-19-induced industrial policy shifts need to take into consideration these and other factors, such as bridging value chain gaps, absence of critical actors and institutions as well as the business environment.

At industry level, we have found serious disjunctures in sectoral policies. The pharmaceutical industry is linked to other industrial sectors such as plastics and packaging, engineering, energy, water reticulation and treatment and transport and logistics for example. Inter-sectoral policies need to be aligned to support the co-evolution of mutually reinforcing capabilities and innovations.

Covid-19 demonstrated that those countries that were quick to repurpose local industrial capabilities to supply drugs and other commodities were those with these deep and broad industrial capabilities (Banda et al., 2021a). Local pharmaceutical industrial policy needs to support the development of these deep and broad industrial capabilities and linkages across different sectors. This calls for a broad systemic industrial capabilities development approach, which entails identifying existing and future collaborative industrial structures critical for the medical health technologies sector emergence and upgrading.

Evidence of this scope for collaboration can be seen in the medical devices manufacturing sector where an emerging medical devices company in South Africa collaborated with a plastics manufacturing company to start producing medical grade products (Banda et al., 2022). The medical devices company approached the local plastic manufacturing company and they agreed on risk sharing with the medical devices company incurring the development costs for a new to that country medical device. However, for a set time the medical devices company would enjoy a preferential price from the plastic company because they had been involved in the development work with the plastics company thereby giving it additional revenue streams. There was recognition that

once the plastics company had developed medical grade plastics manufacturing they could expand their portfolio of products. The development of these local company collaborations that broaden and deepen local manufacturing capabilities and expand product portfolios and markets are critical planning and coordination roles that industrial policy needs drive.

Crises act as pivotal points for questioning conventional wisdom and generally accepted principles and policies. Covid-19 amply demonstrated that public policy and active state intervention for emerging or fledgling industries is a legitimate exercise. Building institutions of technological capabilities learning, regulation and governance, as well as acting as an innovation brokers, are functions that the state is best placed to take. From our discussion, it is evident that the state is currently the only institution with the agency, legitimacy, reach and resources to lead local industry development, technological capabilities upgrading, entrepreneurial activity, knowledge development, knowledge diffusion, resource mobilisation, market formation and legitimation. Crises such as Covid-19 generate the urgency and legitimacy needed to create new sociotechnical imaginaries.

Conclusion

Covid-19 amply demonstrated productive and logistics coordination problems, the consequences of API, raw material and component concentration risk, and the sharp limitations of not having a broad industrial and technological base. The current status of technological and industrial unpreparedness for future epidemics and pandemics is not sustainable for African countries. One of the lessons learnt from the Covid-19 crisis is that global health systems literature that sees medical health technologies as easily accessible commodities available from global health value chains is problematic. The system is vulnerable and will be subverted by governments with money and those proximate to technology producers focusing on their own citizens. African governments need to generate new sociotechnical imaginaries that place their citizens at the centre of their preparedness for pandemics and epidemics by having geographically proximate industrial and technological capabilities.

The story of India developing pharmaceutical capabilities demonstrates how such projects are politico-technical projects that require continuity across different political regimes. China demonstrated that with the right incentives given by the state and through joint ventures, it is feasible to come from behind and overtake the leaders in API production to the extent of the forerunners becoming dependent on the latecomer. When the right actor with legitimacy, access to resources, agency and urgency is placed at the right locus for designing sociotechnical imaginaries, legitimating political decisions and resource allocation, then huge politico-technical projects can be achieved. Our discussion points to the importance of generating political currency and sustaining sociotechnical imaginaries across different political administrations. The actors in government with longevity and permanency to be able to carry these projects are the permanent secretaries in ministries. Industrial and health policies can be harnessed to produce successful sectoral policies if astute collaboration and coordination are achieved. Urgency plus agency are drivers of change that need to be reflected on and used as a springboard for urgent policy shifts for future pandemic preparedness to avoid broken supply chains that expose African countries to the scale of risk that occurred during Covid-19.

Notes

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