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The South African Pharmaceutical Industry: Can Digital Innovation Drive Localisation?

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Digital innovation, capabilities and localisation of manufacturing

This policy brief discusses the analysis and reports on the findings and policy recommendations of our background study on digital innovation in the South African pharmaceutical industry. It is part of a broader UJ project on *"Productive Skills in the 4th Industrial Revolution"*, aimed at analysing how the actual adoption of 4IR technologies and digital innovations at sectoral level affect firm dynamics, productive trends and employment composition. Acknowledging the potentially groundbreaking effects of adopting advanced digital technologies, but also warning against actual obstacles and risks associated with the process, we explore the state-of-the-art in terms of technology acquisition, possible trends with regard to employment re-composition and both obstacles to and possibilities for further localisation of pharmaceutical production.

Engaging with debates on digital transition and on a possible 4th industrial revolution, we advocate for the need to acknowledge the radical changes brought about by the improvement of existing and the introduction of new, automated and digital technologies, together with the need to critically assess the impact of such technologies on manufacturing, work and society. We also build on the concept of technological capabilities and on the idea of industrial development as accumulation of

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productive capabilities.[1] The process of capabilities accumulation entails risks and potential failures, whereby learning and adapting depend on a range of factors, including initial technological endowment, complexity of the introduced technology, skills and capital availability, and a series of structural features that affect the access to such technologies. Such analytical lenses allow us to assess the level of technological preparedness, the competitiveness and the constraints that a selected sample of local manufacturers[2] face. In addition, we explore the potential for further localisation of production, building on structural limits reported by the interviewed firms but also on successful cases of local collaborations and technology transfers.

The South African pharmaceutical industry in a global context

Understanding the dynamics of advanced technology adoption in the South African pharmaceutical industry is of utmost importance in the particular context of post-COVID-19 recovery, given the debates on developing autonomous productive capabilities in the wake of vaccine supply shortages experienced by many developing countries (WHO, 2021a; 2021b). Globally, the pharma industry is one of the most innovative sectors as it invests more resources in R&D and brings more new products to the market than any other industry every year (International Federation of Pharmaceutical Manufacturers and Associations, 2023). Because of the crucial role that medicines play in ensuring public health outcomes, and the multiplicity of compounds that need to be developed to find the right candidate, it is also one of the largest producers of intellectual properties. This of course has significant implications in terms of access to innovative drugs and technology transfers, across companies and countries (Abrams and Sampat, 2017; Gurgula, 2017; Gurgula, 2020).

Since the 1990s, the global pharmaceutical industry underwent a major restructuring, following two main lines. On the one hand, it saw the migration of investments and manufacturing operations away from traditional industrial hubs and towards identified 'centres of excellence', development poles expressly chosen for a combination of market advantages, industrial capabilities and competitive costs. New manufacturing locations were specifically selected for having the right combination of skills, a beneficial geographic location in the world market and the provision of government incentives and benefits aimed at attracting foreign investment. Cause and consequence of such a shift has been a consolidation of global pharmaceutical production, where big pharmaceutical companies have moved with the intent of maximising economies of scale, optimise production efficiencies and harmonise quality standards of produced drugs (Naudé and Luiz, 2013). In recent years, this has led to the emergence of excellence centres like Puerto Rico or Singapore, and to the progressive consolidation of giant hubs like India (IPASA interview, 2022).

The other major change in the global pharmaceutical industry, already started in the 1970s, has been the increasing shift of generic drug manufacturing to the developing world, especially to China and India. This has been characterised by both relocations and the

[1] See Lall, 1992; 2003; Cimoli et al., 2009; Fagerberg and Srholec, 2017.

[2] The present study entailed in-depth interviews with both firms and business associations operating in the South African pharmaceutical industry. In terms of sectoral associations or research centres, the research involved Medicines For Europe; the South African Council for Scientific and Industrial Research (CSIR), Pharmaceuticals Made in South Africa (PharmiSA) and the Innovative Pharmaceutical Association of South Africa (IPASA). Firm-wise, our sample included both foreign and South African-owned firms but with the condition that they had manufacturing operations in South Africa, for a total of eleven firms.

establishment of partnerships across the global pharmaceutical value chain, more and more often involving manufacturing companies based in the Global South and R&D, innovation centres located in the developed regions. Most often, this has allowed big pharma companies headquartered in the Global North to secure skilled labour but also low-cost research facilities, contract manufacturing sites and low-cost sales and distribution within growing markets (Naudé and Luiz, 2013).

Within this global scenario, the South African pharmaceutical industry remains a potentially relevant and reliable industrial centre, also relatively advanced on the African continent, yet very small and secondary compared to international competitors and global excellence hubs. Today, the South African pharmaceutical industry has a market size valued at $4.6 billion (2021), with main productive segments being generics, biologics, biosimilars and over-the-counter (OTC) drugs. The main big pharma companies are Pfizer, La Roche, Novartis, Sanofi and Aspen Pharmacare Holdings Ltd. One of the main structural weaknesses of the industry remains its extensive reliance on imported products, that account for over two-thirds of pharmaceutical sales (GlobalData, 2022). In 2017, the SA Department of Trade and Industry (DTI) outlined a market size of approximately R45 billion (2015), of which 84% dominated by the private sector and 16% covered by the public sector. Joint estimates produced by the Department of Health (DoH) and the DTI counted up to 276 companies licensed by the DoH and the MCC[3] to import, manufacture, distribute or export pharmaceuticals. Overall, domestic manufacturing is almost exclusively focused on generic drugs, with local companies largely depending on the import of active pharmaceutical ingredients (APIs). In 2013, generics accounted for 63% of the private pharmaceutical market and 80% market share in government's pharmaceutical use. In terms of ownership and structure, alongside large foreign companies like Pfizer, Sanofi and Novartis, there are also a few South African-owned multinational companies that dominate the market, like Aspen and Adcock Ingram. These dominating, international players are vertically integrated across the pharmaceutical value chain, but their vertical integration does not necessarily occur in South Africa, where local linkages are relatively poor (DTI, 2017).

Technological innovation and employment re-composition

If we look at the South African industry as a whole, we can observe that automation and digitalisation are advancing, but at different paces and according to different patterns depending on type of product, production volumes and type of manufacturing process (ex. differences in weighing, packaging, testing).

Overall, while small/medium sized firms still often operate on manual, labour-intensive operations and outdated technologies, some high-tech niches are also visible. Within our analysed sample, for example, we witnessed a good level of integrated systems, connecting ordering, production planning, manufacturing and sales operations. Another segment that is particularly advanced is that of packaging and distribution, thanks to automated weighing and barcode reading. The use of advanced infrared technology has also been tested and implemented in the companies we interviewed: here, the upgrade from NIR technology to Fourier-transform infrared spectroscopy (FTIR) allowed for a much more sophisticated qualitative and quantitative test of ingredients and formulations. Automated samplers (similar to robots), doing calculations and feeding them into HPLC or GC machines are also used. Digital control of machines and digital storage of data are quite common.

[3] Medicines Control Council.

Software controlled HVAC machines and fridges have also been introduced: the first allow to keep air clean within a production cell, the second have highly improved temperature regulation, crucial for many vital medicines like vaccines. We were also reported about sophisticated SD and digital camera technologies, that allow for much more precise automated inspections Finally, filling processes are also pretty sophisticated, having been largely automated and digitalised compared to the past (field interviews, 2022).

Advanced cleanroom design: software-controlled HVAC Source: web

Further digital innovation, however, is challenged by issues related to data integrity and process validation. In this regard, while interviewed firms acknowledge the huge improvements that fully digitalised data collection would bring about, the frequent lack of quality data still forces many small/medium companies to manual collection and verification (field interviews, 2022).

For what concerns robotisation, this is very limited or almost absent, especially in smaller local producers or contract manufacturers, as financially not viable in most cases. Finally, the use of artificial intelligence and machine learning is recognised as potentially ground-breaking, but their adoption still remains an aspirational goal (fieldwork interviews, 2021; 2022).

Overall, digital technology adoption in the South African pharmaceutical industry is still challenged by several factors: these include capital availability, often insufficient to support a business case for investment; the local availability of skills and the cost of labour; the strong trade-off between increasing automation and the existing, dramatic levels of unemployment/ under-employment; the SA currency volatility that frequently affects investment profitability; finally, the cost and the accessibility of production equipment/ machinery, often prohibitive for local manufacturers (fieldwork interviews, 2021; 2022).

Skills and employment

Given the ongoing digital transformation, and the aspirations to further adoption of innovative digital technologies, how will the 'workforce of the future' look like? Here, our sample of firms highlighted several factors and predicted the following trends. First and foremost, all South African firms (both larger and smaller) reveal considerable fear towards the undeniable labour-displacing effect that might be linked to increasing automation. Considering South Africa's dramatic unemployment levels, this remains a crucial trade-off.

As for the current workforce composition and the possible changes that could be observed in

the near future, our interviews confirmed the following trends. First, that while unskilled operators will likely be less needed, highly skilled profiles may be expanding. In this regard, significant shortages are currently reported in terms of qualified pharmacists, data analysts, industrial engineers and middle managers. On the other hand, quality control and quality management experts, IT maintenance technicians, operators with advanced digital skills and millwrights will be increasingly needed. Overall, our interviews also reveal how South Africa owns a good pool of experts (ex. biologists, data scientists) and has managed to develop cutting-edge R&D in specific institutions and universities/technical schools, but unfortunately, these seem to be rarely aligned to the actual needs of the industry (interview, IPASA, 2021).

Obstacles to Localisation

In line with other manufacturing sectors, the firms and associations we interviewed highlighted several factors among the main obstacles to expanding local manufacturing of pharmaceutical products. A crucial issue is undoubtedly linked to low economies of scale and production volumes, that would not make investments in more sophisticated technologies sufficiently profitable. Another issue concerns the quality and availability of inputs used, especially in terms of active pharmaceutical ingredients (APIs). Here, even in cases where firms intend to locally source inputs, the trial procedure, the approval by the competent regulatory authority (ex. SAHPRA) and the stability test may require a process lasting up to two years, making the switch too burdensome and complicated for the local buyer (field interview, 2022). In terms of inputs quality, a telling example is that of human plasma that once fractionated serves to produce albumin and immunoglobulin for cancer treatments: only the African continents dumps over 9 million litres a year as they do not meet the quality standards to be processed (field interview, 2022).

A third constraint is identified in the lack of adequate institutional support, of different kinds (ex. protective measures, public procurement, incentives provided). Institutional support is crucial for the development of local manufacturing capacity as stressed by Lall (1992). For the pharmaceutical industry dominated by strong research capacity and a strong fortress of intellectual property rights, a more flexible approach to IPR can play a key role in providing institutional support for domestic producer as exemplified by India's experience (Asianometry, 2023). An important market-related factor that particularly hampers local manufacturing is the heavy foreign competition, especially in the generic drugs segment. Here, an unsurmountable competitor appears to be India, the 'pharmacy of the Global South'. In addition, the compliance with regulatory standards and procedures is seen as a difficult wall to climb, especially for smaller firms. Finally, the several crises linked to local infrastructure, in particular water and electricity, certainly discourage local investment, representing a significant risk for the correct functioning of machines and the quality and continuity of manufacturing processes (fieldwork interviews, 2021; 2022).

Some positive stories

Despite the limitations in the acquisition of advanced technologies by smaller, local firms, and the evident obstacles to further localisation, South Africa must also be highlighted as a location of interesting collaborations and positive stories. For example, CSIR works through different partnerships with WITS University: in the study of genomics, the two have developed a fruitful collaborative learning process, where CSIR contributes with biotechnology expertise, and WITS supports with data analytics, providing skills that are extremely critical on the South African territory (CSIR, Interview, 2022). Other positive collaborations to report are those

between Siemens and Aspen, where Siemens provided digital devices to monitor temperature during vaccine production, and the advanced partnerships around the manufacturing and distribution of the Covid-19 vaccine: both the first collaboration between Pfizer and Biovac, and the recent project for the creation of a mRNA vaccine hub in South Africa (Pharmisa Interview, 2022).

The collaboration between Siemens and Aspen South Africa, supported by the German Deutsche Investitions- und Entwicklungsgesellschaft (DEG), was based on an agreement meant to enable the acquisition of digital technologies and make the production of the Covid-19 vaccine more efficient. From their side, Siemens provided digital technologies to enhance the current manufacturing processes at the Aspen's plant in Gqeberha (Eastern Cape) and ultimately improve production execution, energy efficiency, product tracking, central management of the entire production network and introduce additional energy monitoring devices, flow instruments and temperature sensors. Crucially, the project also included training and skills development for the effective maintenance of Aspen's production facility (Siemens, press release, 2022). The recent plan to establish an mRNA vaccine hub in South Africa was welcomed with much clamour, presented as a glorious initiative to increase ownership on vaccine production and reduce dependency on foreign suppliers that had such dramatic effects during the pandemic (Mazzucato and Songwe, 2022). Launched and sponsored by the World Health Organisation and the SA Government, with the support of the South African Medical Research Council (SAMRC), the hub involves Afrigen Biologics as vaccine technology provider, SAMRC as research developer, and the local Biovac as first manufacturing spoke. According to the WHO (2023a and b), the mRNA Vaccine Technology Transfer Programme has an enormous potential to collectively drive innovation, finance and capacity together, for the common good, along the lines of an unprecedented South-South cooperation. Ideally based on an innovative platform that should allow for technology transfers and for the decentralisation and the diversification of mRNA vaccine manufacturing capacity across 15 production sites spread in different low- and middle-income countries, the model is also intended for future vaccine production beyond the Covid-19 vaccine (WHO, 2023b). The project is still in the making – while initial production facilities have been established and limited manufacturing has been launched but needs to be scaled up, several regulatory and demand bottlenecks are still under discussion, with the future objective of actually guaranteeing sustainable and accessible vaccines (WHO, 2023a).

Conclusions and policy implications

From our empirical analysis, we obtained a picture of a small but dynamic industry, with structural impediments that constrain further expansion and competitiveness, but also positive stories and examples of excellence and innovative collaborations with a strong potential for the future.

In terms of 4IR/ automated and digital technologies adoption, we certainly found cases of implementation of sophisticated technologies – more in terms of digitalisation and automation than with reference to robotisation and AI, and concentrated in those products or segments that allow for higher economies of scale or that offer a sounder business case for investment. In this regard, high costs and low volumes – as in other manufacturing segments, represent a significant barrier to further technological change.

Regarding employment and skills, our investigation suggested projections on the skills and job profiles that could be at highest risk of displacement or strongly needed to fill the technical needs of new machines and production processes.

With reference to manufacturing localisation, the pharma case confirmed obstacles that are common to other sectors in South Africa, with the difference that increasing localisation of drug production would not only bring about economic benefits at domestic level, but strongly contribute to common good objectives of wider access to healthcare and vital medicines, reducing inequalities and the current overreliance on foreign supply. In terms of overall obstacles to localisation, production volumes, inputs availability, lack of adequate institutional support, foreign competition and regulations emerged as main hindrances to improve local competitiveness and build stronger domestic capabilities. However, our investigation also highlighted some positive stories and cases of promising collaborations, both between institutions and firms, that could represent successful examples to potentially expand or replicate.

Ultimately, the synthesis of our analysis gave us a picture of a small industry, struggling to grow and expand, but also characterised by poles of technological excellence and innovative collaborations, despite the difficult global environment and the harsh foreign competition. In terms of skills and workforce composition, it seems clear that skills shortage may hamper the digital transition and the sustainability of the process: this highlights the strong need to invest in skills formation and to align education and training to the needs expressed by the industry. In addition, serious challenges may continue coming from the current state of local infrastructure: in this regard, strong management of the water and electricity crises will be crucial. Finally, our discussions related to the policy environment underline the need for much stronger support to localisation initiatives and institutional coordination, especially between the DTIC, the DST and the DH.

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