Digital Innovation, Localisation and Productive Capabilities in the South African Pharmaceutical Industry

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SARChI Industrial Development Working Paper Series
WP 2024-04
February 2024

science & innovation
Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA

National Research Foundation

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Industrial Development

UNIVERSITY OF JOHANNESBURG

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ISBN 978-1-7764501-9-0

February 2024

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Funding acknowledgement

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Recommended citation

Monaco, L. and Habiyaremye, A. (2024). Digital Innovation, Localisation and Productive Capabilities in the South African Pharmaceutical Industry. SARChI Industrial Development Working Paper Series WP 2024-04. SARChI Industrial Development, University of Johannesburg.

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Abstract

The pharmaceutical industry is one of the most innovative sectors in terms of R&D investment and new products brought to the market every year. Pharmaceutical innovation, with its complexity and public health implications, is associated with one of the largest numbers of patents and intellectual property rights, which in turn have a significant effect on access to medicines and technology transfer across firms and countries. As part of a broader research on "Productive Skills in the 4th Industrial Revolution", this study of the South African pharmaceutical industry aims to assess its current state in terms of the acquisition of advanced technologies, their effect on manufacturing and employment, and the actual obstacles to the further localisation of production. Together with limits and constraints to further expansion, the paper also highlights positive cases of local innovation and institutional collaboration that could potentially be replicated. Ultimately, the study provides a picture of a small but dynamic industry, with structural weakness and constraints, but also poles of excellence and successful cases of collaborative innovation.

Keywords: Innovation, digital technologies, localisation, manufacturing capabilities, South Africa, pharmaceuticals

JEL codes: O14, O25, O32, O33.

About the Authors

Lorenza Monaco is a Research Fellow in the Economics of Innovation and Industrial Policy at the Institute for Innovation and Public Purpose, University College London, and a Senior Research Associate at the DSI/NRF South African Research Chair (SARChI) in Industrial Development, University of Johannesburg. E-mail: l.monaco@ucl.ac.uk

Alexis Habiyaremye is the Senior Researcher in the DSI/NRF South African Research Chair in Industrial Development, College of Business and Economics, University of Johannesburg. E-mail: alexish@uj.ac.za

Acknowledgements

Support for this research was received under the project ‘Community of Practice in Industrialisation and Innovation’ (grant number 110691), hosted by the DSI/NRF South African Research Chair in Industrial Development (grant number 98627), University of Johannesburg.

This paper is part of the study on “Productive Skills in the 4th Industrial Revolution”, one of the activities taking place under the Community of Practice (CoP) in ‘Innovation and Inclusive Industrialisation’ hosted by the SARChI in Industrial Development at the University of Johannesburg. We wish to thank the Research Chair for organisational and financial support, and Ms Gillian Scott and Mr Thulani Zulu for practical assistance in arranging fieldwork interviews. We want to express our gratitude to the various individuals, organisations and firms that welcomed us during fieldwork and shared their valuable perspectives and insights. All mistakes are our own.

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List of Abbreviations

4IR	Fourth Industrial Revolution
AI	Artificial intelligence
APIs	Active pharmaceutical ingredients
ASCCI	Automotive Supply Chain Competitiveness Initiative
BMZ	German Federal Ministry for Economic Cooperation and Development
CSIR	Council for Scientific and Industrial Research
DEG	Deutsche Investitions- und Entwicklungsgesellschaft
DOH	South African Department of Health
DST	South African Department of Science and Technology
DTIC (Former DTI)	South African Department of Trade, Industry and Competition
GMP	Good manufacturing practices
IOT	Internet of things
IPASA	Innovative Pharmaceutical Association of South Africa
ISPE	International Society for Pharmaceutical Engineering
NRF	National Research Foundation
PHARMISA	Pharmaceutical Made in South Africa
SAHPRA	South African Health Products Regulatory Authority
SAMRC	South African Medical Research Council
TIPS	Trade and Industrial Policy Strategies
WHO	World Health Organization

1. Introduction

The present study aims to provide an empirical assessment of the adoption and diffusion of advanced production technology in the South African pharmaceutical industry, and to contribute to a broader debate on the potential advantages, obstacles and effects of the adoption of 4IR technologies in the Global South. It acknowledges the potentially revolutionary effects of adopting advanced digital technologies and the ideal benefits arising from closer connection with and integration into the global space thanks to such technological advances, but also warns against actual obstacles and potential risks associated with the process.

The debate on the fourth industrial revolution has been explored extensively, but it still triggers both theoretical and empirical studies. Besides a global fascination with the potential technological innovations involved in the new paradigm (Schwab 2016; World Economic Forum 2016), it has gathered both fervent supporters and passionate critics, highlighting revolutionary promises on the one hand, and hypes and potential risks on the other (Pardi et al. 2020).

Overall, transformative innovations in the sphere of production are seen as radically transforming both the manufacturing and the labour process, ultimately improving productivity and efficiency, reducing faults and waste, boosting firm competitiveness and creating new markets (Monaco et al. 2019). Such transformations are achieved due to the increasing use of automation, of “cyber-physical systems” (World Economic Forum 2016), and of optimised machine connectivity, together with the progressive adoption of a wide range of digital technologies like artificial intelligence, virtual reality, machine learning, advanced robotics and biotechnology, 3D printing and the internet of things (IoT).

By contrast, critical studies point to the need to go beyond technological determinism and linear trajectories (Garibaldo and Rinaldini 2021; Pardi et al. 2020), and to look at actual gains and risks embodied in the process of technological change. This also implies assessing winners and losers in the technology adoption process and analysing the specific effect of applied technological innovations on key socioeconomic outcomes, such as skills intensification, employment dynamics and social inclusion.

This study can be inscribed in such a trend, having the objective of analysing how the actual adoption of 4IR technologies and digital innovations at the sectoral level affect firm dynamics, productive trends and employment composition in the adopting technology follower. It also aims to reflect on the diffusion patterns of technological adoption and the trajectory of digital transition, on the challenges faced by the adopters, and on the actual influence of applied technologies in terms of labour market and structural transformation.

Drawing on a wider study promoted by the South African Research Chair in Industrial Development at the University of Johannesburg with the support of the DST/NRF, and aimed at investigating “Productive Skills in the 4th Industrial Revolution”, this paper fits into the idea that the changes occurring in advanced manufacturing and related services are best understood by closely examining specific technological innovations implemented in different productive sectors, and their influence on specific production processes and on different skills levels/layers of the workforce. Ultimately, by comparing the technological transition taking place (or not) in different sectors, we will be able to draw more general conclusions on the level of preparedness for technological innovation, for the challenges faced in implementing new technologies, and for potential benefits and risks associated with the application of such technologies to manufacturing equipment and labour processes.

Following studies of the South African automotive, airlines, logistics, mining equipment, textiles and business services, the present paper reports the findings of field research conducted in the South African pharmaceutical industry in 2021 and 2022.

Understanding the dynamics of advanced technology adoption in the South African pharmaceutical industry is of the utmost importance in the particular context of post-COVID-19 recovery, given the debates on developing autonomous productive capabilities in the wake of the vaccine supply shortages experienced by many developing countries (United Nations 2021; World Health Organization [WHO] 2021). 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 [IFPMA] 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 property. This, of course, has significant implications in terms of access to innovative drugs and technology transfer across companies and countries (Abrams and Sampat 2017; Gurgula 2017, 2020).[1] Overall, critical 4IR technologies for the pharma industry include advances in biotechnology and nanotechnology, as well as automation and robotisation in smart manufacturing processes.

Based on a systematic analysis of interviews conducted with both foreign-owned and domestic South African pharmaceutical firms, the present study seeks to highlight the opportunities for local manufacturing strategies in a sector dominated by gigantic foreign corporations, the challenges domestic players face on their journey to advanced technology adoption, and their potential effect on manufacturing processes and workforce composition. Inspired by some interesting success stories identified during interviews with local industry players (reported in the last section of the paper), the study also aims to shed light on positive local collaborations and corporate strategies that may serve as an example to further strengthen local productive capabilities and increase local competitiveness within the global

[1] On average, approximately five to ten thousand compounds that are developed are screened in the pre-clinical development for the discovery of one candidate that leads to a medicine or a vaccine. Extensive testing in clinical trials is necessary to ensure the safety and medical efficacy of the compound.

rush to a digital transition. Overall, our study's findings point to a slow and constrained adoption rate and enable us to warn against possible structural hindrances and increasing inequalities emerging from uneven access to technologies and the difficult accumulation of adequate technological and productive capabilities.

The paper is organised as follows. This section introduces the study and outlines the context in which it emerged. The next section sets out the theoretical background underpinning its methodological approach and analysis. Section 3 describes the sample, methodology and guiding questions that structured the field research and informed the research findings collated in the present report. Section 4 provides a brief description of the South African pharmaceutical industry and places it in a global context, providing discussion thrusts of the main challenges that affect its global competitiveness and hamper its digital transition. Section 5 reports the main research findings in terms of technological innovation, localisation of manufacturing operations and productive skills, as they emerged from the interviews that were conducted. In section 6 we report some success stories that either represent positive examples of inter-firm collaboration, or successful corporate strategies that have led to competitive local ownership or to the creation of a local manufacturing niche that potentially could resist foreign competition and help expand local capabilities in the country/across the continent. Throughout sections 5 and 6, we also illustrate the most advanced instances of technology adoption we encountered during our field interviews, briefly describing their technical features and the potential improvements they can generate in the manufacturing process. Finally, we draw conclusions in the final section on the structural issues that affect the digital transition of the South African pharmaceutical industry and derive some policy implications.

2. Theoretical Background: Digital Innovation, Capabilities and Localisation of Manufacturing

The debate on a possible transition to the fourth industrial revolution points to the revolutionary effects of sophisticated automation and digital innovation on manufacturing, industrial organisation and work. In his pioneering work on the fourth industrial revolution, Schwab (2016) describes a scenario of groundbreaking technological innovations that are changing the way we produce, consume and communicate. Enthusiastic about the radical transformative power of combined technological advancements in multiple fields, ranging from artificial intelligence (AI) and advanced robotics to quantum computing, high-tech biotechnology, the internet of things (IoT) and autonomous vehicles, Schwab predicts unprecedented, revolutionary changes in manufacturing and work organisation, communication, transport and logistics, business models and so forth (Effoduh 2017; Monaco et al. 2019; Schwab 2016; World Economic Forum 2016).

Overall, transformative innovations in the sphere of production are seen as radically changing both the manufacturing and the labour process, ultimately improving productivity and efficiency, reducing faults and waste, boosting firm competitiveness and creating new markets (Monaco et al. 2019). Such transformations are achieved through the increasing use of automation, of "cyber-physical systems" (World Economic Forum 2016), and of optimised machine connectivity, together with the progressive adoption of a wide range of cutting-edge technologies such as artificial intelligence, virtual reality, machine learning, advanced robotics, biotechnology, 3D printing and the IoT.

In response to Schwab's optimistic view of the scope, speed and diffusion of the benefits of radical technological change, two points have been raised within the debate. On the one hand is the realistic interpretation of what is actually new versus what represents an extension or a perfection of previously introduced technologies. In this regard, automation, robotics and internet connectivity have been in place for some decades, and have mostly advanced, in recent years, to higher levels of sophistication. More than a revolutionary change, we can speak of increasing progress on a continuum scale of technological improvements. On the other hand, there is a critical side of the debate that warns against technological determinism (Garibaldo and Rinaldini 2022), with possible hype that inflates the scope and the benefits of technological changes hiding the real political projects behind supposed revolutions (Pardi et al. 2020). It invites people to look at the concrete impact of 4IR technologies and digital innovations on labour market dynamics, or more generally on those that will be excluded from the real benefits of such technological revolutions (e.g., Ngwane and Tshoaedi 2021).

In this paper, we take a rather intermediate position, advocating 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 effect of such technologies on manufacturing, work and society. This is done by closely analysing the process of adoption of technological innovations and their actual influence – in terms of productivity and global competitiveness, but also in terms of productive asset deployment and labour organisation. Ideally, the analysis should entail a look at specific firms, sectors and countries, and include a particular focus on lower-tech firms and countries in the Global South, with the ultimate objective of identifying policies and practices that lead to reducing technological disparities, while remaining on a balanced and sustainable growth trajectory. Overall, this paper is part of a broader study, but aims to contribute to a grounded investigation of concrete practices of technological change in order to question some generalised narratives that fail to embrace the multiplicity of real experiences. In addition to engaging with the debate on 4IR technology adoption, the paper builds on the concept of technological capabilities, and on the idea of industrial development as the accumulation of productive capabilities (see Cimoli et al. 2009; Fagerberg and Srholec 2017; Lall 1992, 2003).

The concept of technological capabilities rests upon a broad literature, mostly empirical and firm-oriented, that looks at how enterprises master, manage, adapt to and improve on new or existing technologies (Bell and Pavitt 1995; Fagerberg et al. 2010; Kim 1997; Lall 2003). The process 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 on a series of structural features (e.g. the structure of the value chain) (see Monaco et al. 2019; Bell and Monaco 2021). These factors affect access to such technologies. Whilst generally looking at specific firms or sectors, and not frequently engaging with the structural and political economic factors that explain real inequalities between industries and countries, this literature is certainly useful to provide technical illustrations of the process of technology acquisition and innovation. It also gives useful indications in terms of policy interventions that may be needed to protect or support firms or sectors aiming to develop or upgrade. A broader definition of capabilities that influence the process of industrial development is given by Cimoli et al. (2009). In their view, technological learning alone is not a magic bullet, while industrial development involves a wider base of learning, knowledge acquisition and capability accumulation, both at the individual and organisational level. Embracing a more comprehensive political economy view, this approach includes a wider range of institutional, scientific, political and cultural factors in the explanation of different industrial development paths. Overall, Cimoli et al.'s (2009) understanding of capabilities accumulation is extremely helpful in analysing how the global and local contexts affect technology adoption, innovation patterns and learning processes at the firm or sectoral level.

The last debate that this paper engages with is the discussion of whether, and to what extent, the localisation of manufacturing is possible in today's late industrialisers. Set as one of South Africa's policy priorities, localisation, along with the discussion on it, is related to a broader reflection on industrial policy tools available today within globalised production and in a world dominated by established World Trade Organization (WTO) regulations. While the protective measures associated with local content policies may not be easy to apply and implement, especially in a context where liberalisation has already occurred and foreign firms have been granted generous incentives designed to attract foreign direct investment (FDI), it is useful to set localisation in context and to adopt a comprehensive view of what it would entail. In this regard, the excellent work conducted by TIPS in South Africa provides a good outline of the complexity of the problem. Makgetla (2023) clearly illustrates both theoretical and implementation issues behind localisation. Theoretically, localisation is largely dismissed as associated with import-substitution industrialisation, which is seen as a failure and as an outdated strategy that is no longer feasible in our globalised and interconnected world. However, she explains that the theoretical opposition between import-substitution and export-oriented industrialisation is mostly anchored in very simplified, dualistic terms – in reality, all industrial strategies include mixed elements, and localisation itself embodies ingredients coming from both. Rooted in the infant industry argument, the localisation approach still aims at "using local and domestic demand to incubate infant industries into competitive producers" (Makgetla 2023:3). This assumes that not only can local producers become nationally or even internationally competitive, to the point of owning a solid exporting capacity, but rests on the idea that local production can be advantageous in terms of transaction costs, delivery times and suitability in relation to domestic demand. In theory, localisation builds on import-substitution strategies to the extent that it seeks to identify the most viable opportunities for local production, but also attempts to overcome their limitations with regard to overreliance on tariffs and the production of final consumer goods for domestic consumers (Makgetla 2023).

In practice, localisation requires a careful assessment of local manufacturing opportunities for single products and segments, including a thorough evaluation of business cases, the availability of inputs, infrastructure, international competition, etc.[2] In terms of policy tools, the localisation approach aims for the effective use of local procurement, seen as potentially boosting production, investment, technological capacity and employment. In reality, several obstacles may hamper local sourcing and manufacturing – like preferential contracts already established with foreign suppliers, asymmetric information that does not allow reaching or selecting the most capable local suppliers, restrictive regulations or technical specifications that exclude local manufacturers, etc. (Makgetla 2023). Ultimately, effective localisation policies need not only entail in-depth assessments of opportunities and potential blockages, but also a patient and forward-looking attitude, whereby initial regulatory or financial support will not be enough without allowing local producers sufficient time to develop sound manufacturing and export capabilities. In relation to the South African pharmaceutical industry analysed in this paper, we aimed to partly engage with these three main debates to develop a) a realistic assessment of the level of adoption of 4IR/advanced digital technologies in the sector, based on our sample and field research; b) a broad understanding of the current level of local capabilities and the main gaps to fill; and c) an engagement with the case for further localisation of pharma manufacturing in South Africa. The paper eventually presents some policy implications and overall conclusions.

3. Overview of the Project: Sample, Methodology and Key Questions

The present study took the form of a deep dive, i.e. it 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 a representative of Medicines for Europe, who provided an overview of the global pharmaceutical industry, of

[2] For example, in the South African automotive case, ASCCI (the Automotive Supply Chain Competitiveness Initiative) conducted many localisation studies for single auto components, while TIPS is engaged in the evaluation of local minerals/metals to be used in batteries or the production of sustainable energy.

innovation and regulation processes in the sector, and of manufacturing distribution across the Global North and the Global South; a representative of the South African Council for Scientific and Industrial Research (CSIR); of Pharmaceuticals Made in South Africa (PharmiSA); and of the Innovative Pharmaceutical Association of South Africa (IPASA). The South African CSIR is a statutory research council devoted to industrial research, strongly representing the connection between public scientific research and the industry, and engaged in the commercialisation of public R&D. It has several divisions and runs multiple projects: we interviewed a research group leader from the bioengineering and integrative genomics research group who is directly involved in projects focused on digital precision medicines and collaborates closely with the 4IR division of the CSIR (CSIR interview August 2022). PharmiSA and IPASA are the two main sectoral associations of South Africa. The first represents South African-owned pharmaceutical manufacturers, placing particular emphasis on promoting local production and BEE/economic empowerment opportunities for local firms. IPASA specifically supports innovation-led health care, and represents global pharmaceutical companies operating in South Africa: it works on issues related to pricing, market access and intellectual property rights, making sure that international and South African regulations align and that global companies and technologies can penetrate the SA market (field interviews 2022).

In relation to firms, our sample included both South African-owned and foreign firms, on condition that they had manufacturing operations in South Africa. Given the already limited number of firms manufacturing pharmaceutical products in South Africa, and some difficulties in securing access for field interviews, our sample eventually was based on in-depth interviews conducted with eleven firms, including three foreign-owned, multinational companies, two large South African companies with an established international presence, and six smaller, South African firms.

Our interviews were based on a common structure exploring the following key aspects:

- Perceived or actual costs and benefits of investing in 4IR technologies (including robotics, internet of things, big data and AI).
- Obstacles to the adoption of 4IR technologies.
- Compatible technologies adopted by infrastructure providers and constraints imposed by the regulatory authorities.
- Re-organisation/changes in manufacturing and work organisation as a result of 4IR technologies: effects on labour productivity, employment, organisational structure.
- Perceived skills gaps and skills bridging training requirements to prepare the industry for the technologies it needs/would need to adopt in order to stay competitive.

The above structure was employed across firms and different sectors analysed as part of the overarching research project on “Productive Skills in the 4th Industrial Revolution” in order to facilitate comparability and to extract recurring patterns of technology adoption.

4. The South African Pharmaceutical Industry in a Global Context

Since the 1990s, the global pharmaceutical industry has undergone major restructuring following two main lines. On the one hand, it involved 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 geographical location in the world market, and the provision of government incentives and benefits aimed at attracting foreign investment. The cause and consequence of this shift have been a consolidation of global pharmaceutical production, where big pharmaceutical companies have moved with the intent of maximising economies of scale, optimising production efficiencies and standardising the quality standards of the drugs produced (Naudé and Luiz 2013). In recent years, this had led to the emergence of centres of excellence like Puerto Rico and 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 establishment of partnerships across the global pharmaceutical value chain, increasingly involving manufacturing companies based in the Global South, and R&D and innovation centres located in the developed regions. Most often, this has allowed big pharma companies headquartered in the Global North to secure skilled labour and also low-cost research facilities, and to contract manufacturing sites and low-cost sales and distribution in growing markets (Naudé and Luiz 2013).

Within this global scenario, the South African pharmaceutical industry remains a potentially relevant and reliable industrial centre, although relatively advanced on the African continent, yet very small and secondary compared to international competitors and global excellence hubs.

Following a trajectory somewhat similar to other industrial sectors in the country (e.g. automotive), the industry flourished during the 1960s and 1970s, experienced a halt because of the apartheid sanctions, and then saw a decline in the liberalisation era, despite significant government support and policy attention. Before 1994, the South African pharmaceutical industry was able to develop in terms of skills and infrastructure, despite a marked skewedness in the provision of health care, in the distribution of medical facilities, and in access to medicine. In the period following the 1994 elections, the double push to democratise the accessibility of basic services and increase the affordability of health care, together with the desire to compensate for the economic delay accumulated because of sanctions and isolation, led to a progressive liberalisation of the sector. Domestic manufacturers, often operating through plants involving outdated technologies and limited volume capacity, were severely hit by the exposure to external competition and often did not survive the impact of market opening. The industry thus experienced a significant contraction, seeing both a decline in manufacturing GDP and a substantial reduction in the number of firms operating in the country. Overall, several foreign firms (mostly European and North American) have 'functionally downgraded' their South African operations since the post-apartheid era; in addition, it is estimated that more than 30 pharmaceutical manufacturing plants closed, with a loss of at least 6 500 jobs (Horner 2021).[3] Of the companies that moved out of South Africa, most relocated their manufacturing operations around the newly established 'centres of excellence' in other parts of the globe, especially where they could find lower-cost units benefitting from economies of scale and serving larger international markets. Many of the companies that remained, on the other hand, operate below their full capacity (Horner 2021).

Today, the South African pharmaceutical industry has a market size valued at $4.6 billion (2021), with the 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, which account for over two-thirds of pharmaceutical sales (GlobalData 2022).

In 2017, the SA Department of Trade and Industry (DTI) estimated a market size of approximately R45 billion (2015), of which 84% was dominated by the private sector and 16% covered by the public sector. Joint estimates by the Department of Health (DoH) and the DTI counted up to 276 companies licensed by the DoH and the Medicines Control Council (MCC) to import, manufacture, distribute or export pharmaceuticals. Figure 1 provides an overview of the main players across the industry value chain, from research and development to marketing of the finished products. Overall, domestic manufacturing is focused almost exclusively 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 an 80% market share in the government's pharmaceutical use. In terms of ownership and structure, there are also a few South African-owned multinational companies that dominate the market, like Aspen and Adcock Ingram, alongside large foreign companies like Pfizer, Sanofi and Novartis. 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).

[3] Maloney and Segal (2007, in Naudé and Luiz 2013) report that employment in the industry declined from 18 000 in 1999 to barely 11 000 in 2007.

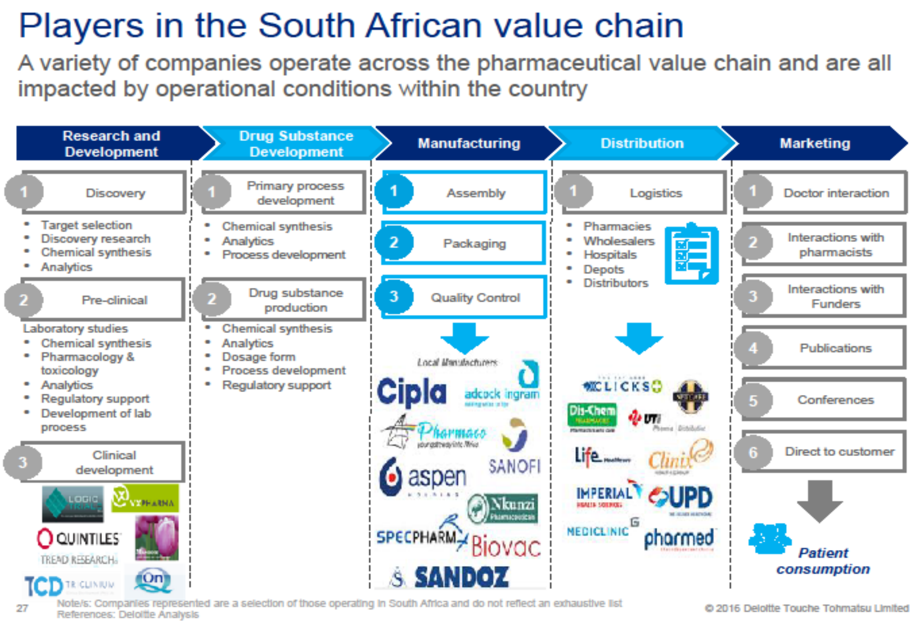

Figure 1: Players in the South African value chain

Source: Deloitte 2016, in DTI 2017.

As highlighted by the DTI, the South African pharmaceutical industry undoubtedly offers opportunities for investment and growth. There have been numerous initiatives to increase the localisation of manufacturing production, as this is high on the policy agenda and attracts significant attention from the government. In 2020, the DTI and InvestSA underlined predictions of robust market growth, with forecasts of +40% growth in sales; the privileged position in the SADC region, where SA acts as a gateway, being the only country that meets the WHO Good Manufacturing Practice standards; the overall good manufacturing capabilities, including biotechnology manufacturing facilities; the large potential in relation to antiretroviral (ARV) treatment programmes; and the wide market share for generic drugs (above 40%) (DTI/InvestSA, 2020).

Indeed, investment opportunities do exist, and the rationale for supporting further localisation of manufacturing is strong. Overall, strengthening the local manufacturing of pharmaceutical products is seen as a much needed commitment towards achieving the double objective of guaranteeing wider and cheaper access to health care, while promoting local industrial development (Mackintosh et al. 2015, 2017). Boosting local manufacturing may also mean enhancing the productive capabilities of domestic firms and reducing drug prices, while lowering the dependence on external producers (Amara and Aljunid 2012). So far, the extreme dependence on imported products has not only represented a financial burden, but has often caused interruptions in the supply of vital medicines, further threatening populations already at risk of contracting dangerous or endemic diseases (Dong and Mirza 2015; Steele et al. 2020). In this regard, the Covid-19 pandemic has dramatically exposed the need for self-reliance, along with the dangers of excessive dependence on imported drugs, and this exploding particularly around the issue of vaccine production (Boschiero 2021; Steele et al. 2020). Furthermore, support for local manufacturing is seen as a means to create employment, trigger virtuous dynamics of economic development, and make production more sustainable overall (Fisher et al. 2022; Steele et al. 2020).

However, increasing localisation and bolstering local productive capabilities also entails overcoming a series of economic challenges and structural obstacles. While building a business case to attract investment to small markets may not be easy, the compliance with global regulations in terms of intellectual property rights (TRIPS), quality standards and good manufacturing practices (GMP) may represent a significant barrier (Amara and Aljunid 2012; Bate 2008; Boschiero 2021; Habiyaremye 2022; Steele et al. 2020). In South Africa, and in developing countries more broadly, structural weaknesses may also emerge because of inadequate institutional support, a lack of sound infrastructure, insufficiency of specialised skills and limited financial resources (Fisher et al. 2022; Ussai et al. 2022). With specific reference to South Africa, Naudé and Luiz (2013) also discuss the outdated technologies and manufacturing facilities, which increase production costs, the lack of a comprehensive plan for drugs testing and evaluation, a system of procurement and distribution that can effectively cater for rural areas, and specific skills shortages, especially with regard to qualified pharmacists.

Some of these challenges and constraints are discussed in the next section in relation to the possibility of strengthening local competitiveness and manufacturing capabilities by facilitating technological innovation and the adoption of 4IR/advanced digital technologies in South Africa's pharmaceutical production.

5. Overall Findings: Technological Innovation, Localisation and Skills

5.1 Pharma 4.0

The global pharmaceutical industry is driving towards 4.0 innovation at full speed. According to the International Society for Pharmaceutical Engineering (ISPE 2023), at the forefront of the promotion of the Pharma 4.0 model is that "Pharma 4.0™ is not a must, but a competitive advantage. Missing Pharma 4.0™ might be a business risk". Adopting 4.0 technologies and innovative processes is thus seen as a necessary condition to remain competitive and to avoid lagging behind in the new digital world. Firms are not compelled to embrace it, but are warned they will risk economic exclusion and increasing disadvantage if they do not. In ISPE's (2023) words, Pharma 4.0

> emphasizes on building a single virtual network that connects human, data and machines. It gives a vision to improve quality, productivity and lead times through interconnectivity and automation by gathering real-time data with the help of Internet

of Things (IoT) and big data analytics. It provides real-time monitoring of manufacturing process to predict any error or glitch that may occur in the near future, so that necessary measures can be taken to fix it.

The model is thus seen as a platform to optimise the digitalisation of resources to prepare the workforce of the future, to connect machines and processes in a holistic control strategy, and to improve data integrity (Figure 2). From a firm perspective, companies interviewed in South Africa underlined how higher compliance with Pharma 4.0 guidelines might facilitate WHO accreditation, thus making products sales easier and possibly opening up new markets (field interviews 2022).

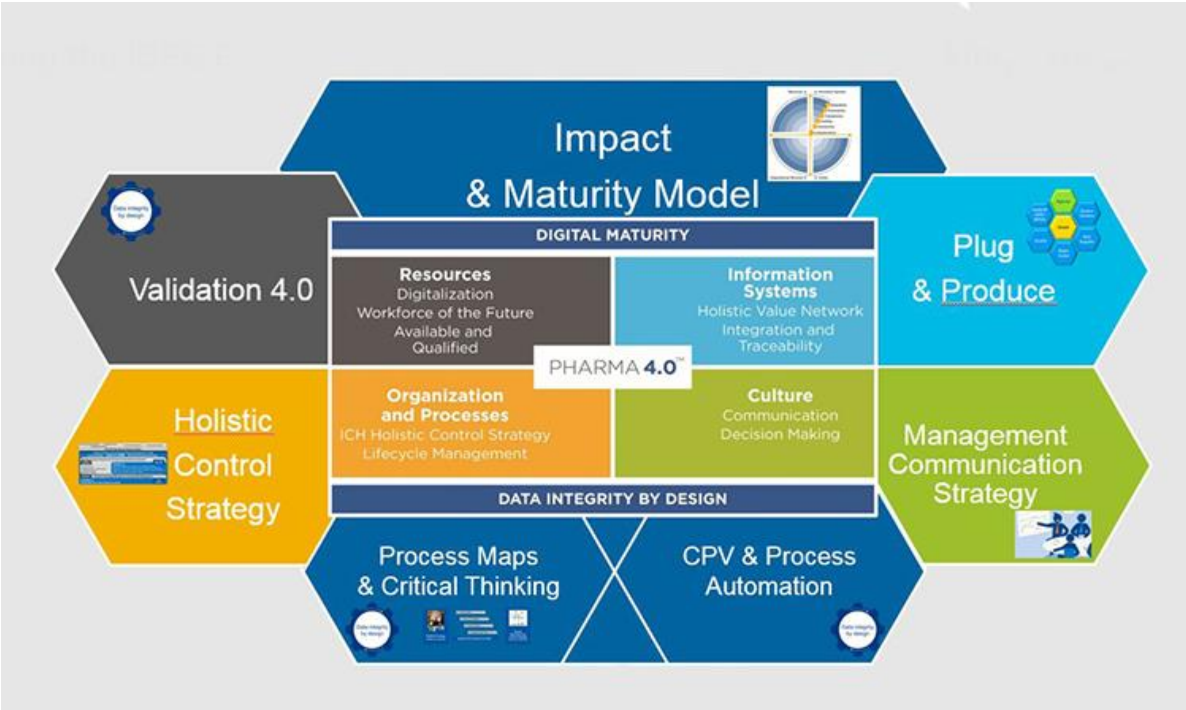

Figure 2: Impact and maturity model

Source: ispe.org

Taking Pharma 4.0 as a reference roadmap, the question is – which companies are actually complying with the proposed models, and how are different countries and industrial sectors placed along the digital transition path? Building on a qualitative assessment of the adoption of 4IR technologies and their influence on work and productive organisation, the present study represents an explorative investigation of the preparedness and competitiveness of the South African pharmaceutical industry in this regard. Here, we group our findings around three main issues. Based on our sample of interviewed firms and sectoral associations, we first seek to assess the level of technological innovation and adoption of digital technologies. We then connect the level of technological competitiveness to the issue of manufacturing localisation: to what extent might the adoption of new technologies favour the competitiveness of the local industry and even facilitate the further localisation of manufacturing activities? What are the obstacles and the constraints to such a process? Thirdly, we explore the effects of technological adoption on the workforce and on work organisation: what will be the skills and the competencies at risk, and what are the gaps that should be filled in order to prepare the workforce for future changes? These and other questions are addressed in the sections below.

5.2 Technological Innovation: State of the Art

At the global level, some production processes have registered enormous advancements thanks to the application of digital/sophisticated technologies. For example, assay tests, allowing for the determination of the contents and quantities of the ingredients needed for a specific drug, have shifted from high-performance liquid chromatography (HPLC) to advanced infrared technologies: the former required extraction, dissolution of ingredients and a lengthy test overnight, while the latest technologies permit the assay to be conducted on the spot. Another significant improvement has been achieved thanks to the introduction of continuous and integrated manufacturing processes: firms implementing them can now go beyond production in batches, and processes like granulation and compression can be connected. Finally, highly automated machines like those now employed for compression allow for speedy and reliable controls and weight checks, also adjusting for the hardness, thickness and diameter of a production unit (e.g., a tablet) (IPASA interview 2022). Figure 3 provides an illustrative example of a high-performance integrated machine used for granulation.

Figure 3: GEA Machine for integrated granulation

Source: web

Looking at the South African industry as a whole, we can observe that automation and digitalisation are advancing, but the observed technological progress takes place different paces and according to different patterns. These differences depend on the type of product, production volumes and type of manufacturing process (e.g., differences in weighing, packaging, testing). While small/medium-sized firms often still operate on manual, labour-intensive operations and outdated technologies, some high-tech niches are also visible. All visited production facilities operate within highly protected cleanroom environment, comparable to the one illustrated in Figure 4. Within our analysed sample, for example, we observed 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 near infrared spectroscopy (NIR) technology to Fourier-transform infrared spectroscopy (FTIR) has 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 gas chromatography (GC) machines, are also used. Digital control of machines and digital storage of data are quite common. Software-controlled heating, ventilation and air conditioning (HVAC) machines and fridges have also been introduced: the first allow air to be kept clean within a production cell, the second have highly improved temperature regulation, which is crucial for many vital medicines like vaccines. In our *in situ* observation, our respondents also provided the demonstration of the use of sophisticated standard definition (SD) and digital camera technologies, which allow for much more precise automated inspections. Finally, filling processes are also highly sophisticated, having largely been automated and digitalised compared to the past (field interviews 2022).

Figure 4: 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 the interviewed firms acknowledged the huge improvements that fully digitalised data collection would bring about, the frequent lack of quality data still forces many small/medium companies to undertake manual collection and verification (field interviews 2022).

As far as robotisation is concerned, this is very limited or almost absent, especially in smaller local producers or contract manufacturers, as in most cases it is not financially viable. As stressed by one local manufacturer, the low viability of investing in the acquisition of industrial robots also depends on the vast product line of many pharmaceutical manufacturers. In their case, despite the middle size of their operations, they manufacture over 600 products, making the type of business and production process too diverse to really apply robots (field interview 2022). 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 volatility of the SA currency, which frequently affects investment profitability; and finally, the cost and accessibility of production equipment/machinery, which are often prohibitive for local manufacturers (fieldwork interviews 2021, 2022).

5.3 Localisation

Confirming the conclusions of previous studies, 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, which 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 source inputs locally, the trial procedure, the approval by the competent regulatory authority (i.e. 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. Once fractionated, it serves to produce albumin and immunoglobulin for cancer treatments, although the African continents dumps over nine 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 (e.g., protective measures, public procurement, incentives provided). As stressed by Lall

(1992), institutional support is crucial for the development of local manufacturing capacity. For the pharmaceutical industry, which is dominated by strong research capacity and a strong fortress of intellectual property rights (IPR), a flexible approach to IPR can play a key role in providing institutional support for domestic producers, 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, compliance with regulatory standards and procedures is seen as a difficult obstacle to overcome, 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).

However, as we will see in the next section, the South African pharmaceutical industry was also the terrain of some recent success stories and positive, local collaborations, like the partnerships developed between the CSIR and IPASA, Pfizer and Biovac, Siemens and Aspen, etc. Here, a thorough assessment of the possible expansion or replicability of such experiences would be particularly interesting and helpful to eventually explore new avenues for localisation.

5.4 Skills and Workforce

Given the ongoing digital transformation, and the aspirations to further the adoption of innovative digital technologies, what 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 of 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 a representative of a large, international company declared:

> The easiest and the best way for us to become more competitive is just to automate. But then, look at where SA is sitting, with 35/40% unemployment, it's just sad. Then you know, I don't want to become more competitive (field interview 2022).

Regarding what concerns the current workforce composition and the possible changes that could be observed in the near future, our interviews confirmed the following trends. First, while unskilled operators will likely be needed less, 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, there will be an increasing need for quality control and quality management experts, IT maintenance technicians, operators with advanced digital skills and millwrights. Overall, our interviews also revealed how South Africa owns a good pool of experts (e.g., biologists, data scientists) and has managed to develop cutting-edge R&D in specific institutions and universities/technical schools, but these unfortunately rarely seem to be aligned with the actual needs of the industry (IPASA interview 2021).

6. Some Success Stories: How Sustainable and Replicable?

Despite the limitations to 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, the CSIR works through different partnerships with Wits University: in the study of genomics, the two have developed a fruitful collaborative learning process, where the CSIR contributes biotechnology expertise and Wits supports with data analytics, providing skills that are extremely critical for South Africa (CSIR interview 2022). Other positive collaborations to report are those between Siemens and Aspen, where Siemens provides digital devices to monitor temperatures 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 an 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),[4] 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 plant in Gqeberha (Eastern Cape), and ultimately to improve production execution, energy efficiency, product tracking and central management of the entire production network, and to introduce additional energy-monitoring devices, flow instruments and temperature sensors. Crucially, the project also includes 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 enthusiasm and presented as a glorious initiative to increase ownership of vaccine production and reduce dependence on foreign suppliers – something that had dramatic effects during the pandemic (Mazzucato and Songwe 2022). Launched and sponsored by the World Health Organization 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 the research developer, and the local Biovac as first manufacturing spoke. The project, launched in July 2021 and involving six hubs on the African continent,

> will share technology and technical know-how with local producers. WHO and partners will bring training and financial support to build the necessary human capital

[4] Commissioned by the German Federal Ministry for Economic Cooperation and Development (BMZ).

for production know-how, quality control and product regulation, and will assist where needed with the necessary licenses (WHO 2021).

According to the WHO (2023) and the WHO Council on the Economics of Health for All (2023), the mRNA vaccine technology transfer programme has enormous potential to drive innovation, finance and capacity together, for the common good, along the lines of unprecedented South-South cooperation. Ideally based on an innovative platform that should allow for technology transfers and for the decentralisation and diversification of mRNA vaccine manufacturing capacity, the model is also intended for future vaccine production beyond the Covid-19 vaccine (WHO Council on the Economics of Health for All 2023). The project, which will introduce 15 production sites spread in different low- and middle-income countries, 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 2023). In April 2003, after the formal inauguration of the mRNA technology hub facility at Afrigen, the partners, European funders and both the SA Ministry of Health (DoH, Minister Phaahla) and of Trade, Industry and Competition (DTIC, Minister Patel) gathered in Cape Town to discuss the way forward. While financial constraints and regulatory bottlenecks remain on the agenda, the project is an undeniably positive step, with a high potential to boost collaboration and technology transfers across South Africa and the Global South.

7. Conclusions: Structural Issues and Policy Implications

The present deep dive into the South African pharmaceutical industry, part of the overarching study of "Productive Skills in the 4th Industrial Revolution", served two objectives and proved useful for two main reasons. On the one hand, it provided us with an outline of the main characteristics of the South African pharma sector today, allowing its main strengths and weaknesses to emerge. On the other hand, it enhanced our comparative overview of the adoption of advanced technologies in South African manufacturing, confirming the main trends in and obstacles to technological innovation, and the key gaps to fill.

From a theoretical perspective, this paper aimed to engage with three main discussions. Firstly, it aimed to contribute to empirical analyses of 4IR technology adoption and digital transitions in the Global South, with the intention to highlight context specificities and potential bottlenecks, and to deconstruct unhelpful generalisations and easy inflations of the ideal benefits of technological progress. Secondly, the paper aimed to connect to the idea of industrial development as a process of accumulation of productive capabilities. This was connected to an analysis of obstacles to further the localisation of pharma manufacturing in South Africa. Ultimately, connecting the two allowed us to shed light on locally available know-how and even pools of expertise, together with barriers to further technological advancement, increasing competitiveness and strengthening of domestic capabilities.

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 strong potential for the future. We grouped our findings along three main lines, analysing technology adoption, obstacles to further localisation, and the overall (or potential) impact of technology adoption on skills and workforce. In terms of the adoption of 4IR/automated and digital technologies, we certainly found cases of implementation of sophisticated technologies – more in terms of digitalisation and automation than with reference to robotisation and AI, concentrated in those products or segments that allow for higher economies of scale or that offer a sounder business case for investment. This stands in contrast to the intensive pace of innovation and sophisticated manufacturing processes observed in the large pharmaceutical R&D and production hubs in advanced countries. In this regard, high costs and low volumes – as in other manufacturing segments – represent a significant barrier to further technological change. With reference to manufacturing localisation, the pharma case confirmed obstacles that are common to other sectors in South Africa, with the difference being that increasing the localisation of drug production would not only bring about economic benefits at the domestic level, but contribute strongly to the common-good objectives of wider access to health care and vital medicines, thereby reducing inequalities and the current overreliance on foreign supply. In terms of overall obstacles to localisation, production volumes, the availability of inputs, a lack of adequate institutional support, foreign competition and regulations emerged as the main hindrances to improve local competitiveness and build stronger domestic capabilities. Finally, our investigation also offered projections of 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.

Besides these main findings, the paper also reports some positive stories and cases of promising collaborations, between both institutions and firms, that could represent successful examples to potentially expand on or replicate.

Ultimately, we gained a picture of a small industry, struggling to grow and expand, but also characterised by poles of technological excellence and innovative collaboration, despite the difficult global environment and the harsh foreign competition. In terms of skills and workforce composition, it seems clear that skills shortages 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 with 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 for localisation initiatives and institutional coordination, especially between the DTIC, the DST and the Department of Health.

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DSI/NRF South African Research Chair in
Industrial Development (SARChI-ID)
31 Henley Road, Auckland Park,
Johannesburg, South Africa

General enquiries:
Koketso Manyane-Dlangamandla
Email: koketsom@uj.ac.za
Tel: +27 011 559 7454