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Factors, challenges and opportunities for the South African pharmaceutical manufacturing sector

Introduction

The South African pharmaceutical space showed resilience and opportunity during the disruption of the COVID-19 pandemic (Fitch Solutions Group, 2023). South Africa is represented as the largest pharmaceutical market in Sub-Saharan Africa, defined in particular by its region-leading expenditure on pharmaceuticals (Fitch Solutions Group, 2023). Recognisable local and international investment has been present and consistent with added opportunitiesfor both the local and regional terrain.

An understanding of the factors that govern the local manufacturing value-chain and its accompanying challenges is pivotal for manufacturers. In the South African pharmaceutical manufacturing context, generic medications find increased utilisation when contrasted to originator drugs. The local pharmaceutical manufacturing does however face challenges in capacity, cost and ensuring robust regulation, access and quality. Capacity challenges manifest in that, even though between 60-70% of pharmaceutical products are produced locally, almost 98% (R15bn) of active pharmaceutical ingredients (API) are imported (WhoOwnsWhom, 2020), (Ntsele, 2023).

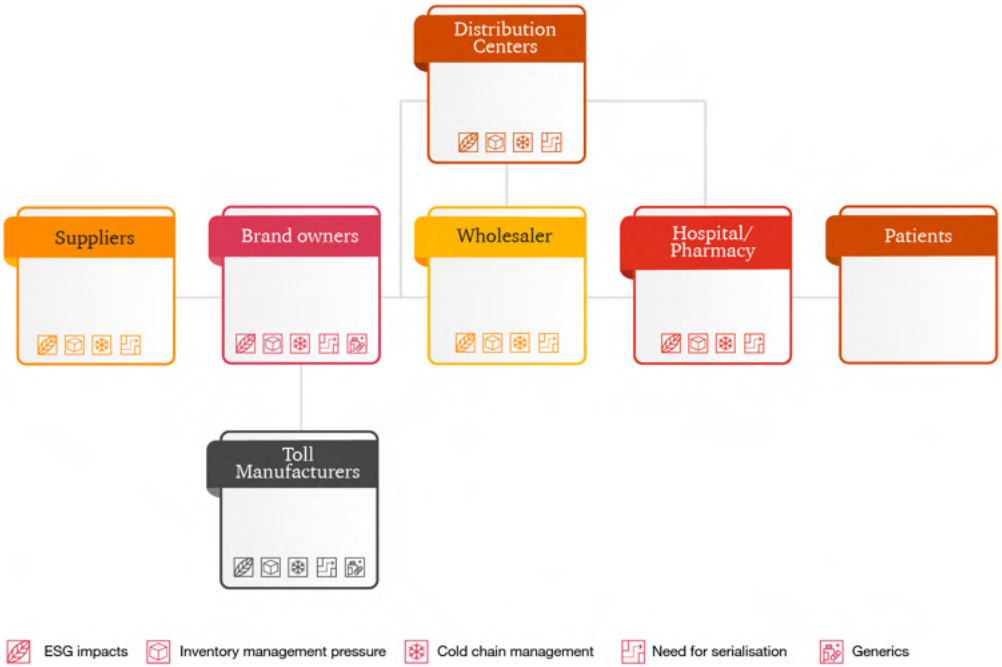
The COVID-19 pandemic was a wake-up call for local manufacturers. Export bans on pharmaceutical products by Asian producers manifested in medicine shortages across the African continent - further emphasising the need for increased investment in local manufacturing (Thomas & Dasgupta, 2020). Cost challenges mean that the ability to spend is limited by the demand for cheaper generic alternatives sourced from international markets. The cheaper options speak to purchasing power of the population and policy-influenced, cost-conscious governments (Fitch Solutions Group, 2023). Increased imports realise challenges in quality control as there are concerns around international manufacturing standards, substandard pharmaceutical products, counterfeiting and quality regulation (Ntsele, 2023).

Global supply chain disruptions bring additional challenges with logistics disruptions, workforce and labour shortages as well as production delays and increased consumer lead times because of the limited supply of important raw materials (WhoOwnsWhom, 2020). The South African contextual concerns extend into intellectual property and single-exit price (SEP) based pricing control systems.

For local manufacturing organisations to get, and stay, ahead amidst the aforementioned operational environment, the opportunity is now to invest in digitisation and operational excellence as a response to these challenges. An organisation’s commitment towards operational excellence will be far reaching in where they localise in the market as well as how they realise continued growth. Pivotal to achieving this is awareness of the variables that an organisation can control to allow it to drive decisions aimed at building operational resiliance and drive efficiency.

This document serves in part to articulate the intricate meeting place between the challenges currently faced in the South African pharmaceutical manufacturing space and the value of operational excellence as a response.

Key challenges across the value chain



Pharmaceutical companies face multiple challenges across operations in their supply chains, however the most pertinent challenges (as depicted in the above figure) will be discussed herein.

Cold chain manufacturing

Modernisation, urban migration and lifestyle changes mean an increased demand for the cold chain across products across several industries in South Africa, including pharmaceutical manufacturing (The International Trade Administration, 2022).
An increased demand for pharmaceutical products means an increased demand for cold chain reliability, especially in local pharmaceutical manufacturing.

Cold chain maintenance impacts on the quality of certain pharmaceutical products manufactured for consumption. If the quality is compromised, it may result in spoilage, loss of therapeutic efficacy and negatively impact patient safety (The international Trade Administration, 2022). Vaccines, various biologics, selected diabetic products and, crucially, APIs are some examples of pharmaceutical products reliant on a reliable cold chain. Manufacturers need to be sure that the inbound raw materials have been reliably transported, the production process maintains the cold chain demands and outbound logistics do not break the cold chain (van Berkel, 2023). For local manufacturers the demand to ensure the production process maintains the cold chain is increasingly constrained by electricity blackouts (Crouth, 2023). With rolling blackouts, manufacturers are faced with challenges to manage increased production costs related to time loss and disruptions. Furthermore, there are heightened requirements for worker safety and maintaining the quality of products.

Regardless of the energy crisis, manufacturers must still maintain operational excellence and resilience. For this to be achieved, manufacturers require an understanding of the factors within their control. Good energy management is vital for sustained maintenance of pharmaceutical manufacturing cold chains (Manufacturing Chemist, 2022) and good cold-chain management encompasses real-time facility monitoring and management. additionally, awareness and management of refrigeration operational and maintenance costs is essential when assessing the total plant energy costs. Finally, effective data collection, analysis and reporting that enables proactive intervention to disruptions and continued improvement is crucial. An increased visualisation of the plant that is driven by data will ensure continued improvement in problem solving time and is important for the preservation of the integrity of the products.

Manufacturing plants should have adequate surveillance and a comprehensive understanding of their management data to drive operational efficiency through relevant activities and upscaling. Adopting technology for the plant building management systems, automation and drones will improve inventory control and realise operational excellence (The International Trade Administration, 2022).

Inventory SLOB (Slow-moving and obsolete inventory) and disposal management of pharmaceuticals

The importance of inventory management and optimisation is a well understood function in manufacturing, with its accompanying demand for coordination across the supply chain. In pharmaceutical manufacturing, there are nuances that result in the generally accepted knowledge and practices having to be amended to suit the context (The Inventory Challenge for the Pharmaceutical Industry, 2023). The shortage, waste and cost reduction goals still persist. However, the production precision demands, regulation across the value chain, lengthened manufacturing lead times and limited supply options lead to real challenges in inventory optimisation.

The ever-present uncertainty in demand means that there will always be uncertainty in inventory management. Forecasting accuracy has been and still remains a big challenge in the pharmaceutical industry (Merkuryeva et al., 2018). The high margins from sales of original products result in a reduced effort to reduce supply chain costs. The cost of shortages does not only affect margins but presents real health risks for consumers. The compounded risk in avoiding out-of-stock products leads to subsequent high inventory levels (Merkuryeva et al., 2018).

The reduction of forecast error is crucial in reducing the cost of holding inventory. This forms part of improved inventory management. Increased collaboration and collaborative forecasting efforts across the value chain are crucial. Organisations within the value chain that are close to the demand point such as wholesalers, distributors, retailers and hospitals will be more accurate than those that are further (Merkuryeva et al., 2018). It is therefore critical to reduce gaps to the demand point to improve forecasting accuracy and to decrease inventory hold.

Additionally, the internal capacity for data and information within an organisation is crucial in managing complex demand in an equally complex supply chain. Data and information regarding demand should be as accurate as possible. Improvement and optimisation needs to be informed by real-time, quality data (The Inventory Challenge for the Pharmaceutical Industry, 2023). Inventory optimisation and surveillance of data and operations should be an ongoing exercise in order to identify opportunities for improvement and increased efficiency. Investment is therefore essential to cultivate a culture that recognises and actively drives inventory optimisation and improved forecasting.

Operational excellence is all encompassing. The management of inventory is not only about decreasing the holding time and reducing cost. But how organisations ensure that waste is properly managed is an activity directly reflective of operational excellence. Waste management demands a clear view of all the operations of the business to understand waste generating activities and intervene appropriately. In pharmaceutical manufacturing, physical waste can be potentially hazardous and its safe management and disposal is equally reflective of a commitment to operational excellence (WhoOwnsWhom, 2020).

The growing identification of pharmaceutical chemicals and traces of different medicines in the local water system is suggestive of manufacturers that are contravening environmental regulations (WhoOwnsWhom, 2020). Pharmaceutical manufacturing is a high waste generating activity and good waste management entails continuous improvement and innovation aimed at making the process more efficient. The real legislative implications as well as brand risk concerns should drive manufacturers to ensure that good manufacturing practices (GMP) are in place. Inversely the brand advantages and, in some instances, the possibility to generate revenue from greener approaches to waste management and disposal should incentivise operational excellence (Oldham, 2021).

Sustainability (ESG)

Sustainability is now a more prominent factor for industry with growing concerns for significant environmental, social and governance practices. Sustainability is not a quick fix but a long-term investment. Decisions made today have real implications on the future environments which demand extensive evaluation and consideration. Life-saving medication should not poison or harm the living due to compromised manufacturing or production processes (Miller, 2022). The COVID-19 pandemic has increased public awareness regarding sustainable healthcare for patients, placing greater responsibility on compliance from manufacturers (Bhattacharya & Bhattacharya, 2023). In the backdrop of the current depressed economic climate and the advocacy for improved healthcare accessibility, pharmaceutical companies are feeling the pressure to make medicines more affordable.

Environment, social and governance (ESG) frameworks are becoming more integral to operations and assessing how effectively organisations manage risk. Sustainability is a reflection of an organisation's holistic commitment and extends beyond environmental issues. The social pillar commands corporate accountability and evaluation of the effect of business operations on local communities. Governance encompasses the commitment to regulation, meaningful action and transparency (Datwyler, 2022).

Pharmaceutical manufacturers must continuously evaluate the disposal of medical waste including factors relating to API disposal, energy consumption, carbon emissions as well as the use of plastics and water. Understanding the impact of production and operations is crucial to sustainability. Establishing KPIs and targets that continuously incentivise staff is key to cultivating a workforce focussed on sustainability.

In the South African context, GMP and adherence to GMP aligns with sustainability initiatives. Visualisation of GMP adherence is essential in enabling organisations to have a consistent view on their sustainability performance (Datwyler, 2022). Manufacturers can position themselves as sustainable through additional focus areas, including staff safety, sustainable procurement, equitable hiring practices and improving access to medication for disadvantaged populations. Transparent operations that ensure adherence to regulation are crucial for societal trust. The pharmaceutical industry is overshadowed by a legacy of fraudulence, price fixing, corruption in dealings and unlawful advertising, to name a few (Datwyler, 2022). Advancements in technology enable digital tools to track performance and ultimately increase commitment to sustainable manufacturing.

In addition to the manufacturing risks, patients have a responsibility to sustainability. As consumers, patients should handle medication in a manner that is not detrimental to the environment. Numerous concerns have been raised regarding the manner in which patients dispose of medication (Ndongeni-Ntlebi, 2021). The improper disposal of packaging can result in reputational consequences for the company identified. Consumer education must be a proactive exercise to combat improper disposal and reduce environmental risks (Anderson, 2022). This presents more opportunities for interaction between organisations and consumers which can be leveraged for loyalty benefits. Sustainability goals are not limited to manufacturing, and collaboration across the value chain is integral in ensuring that sustainability is realised throughout the entire sector.

This drive defines internal commercial opportunities for local manufacturers. Opportunities across the African continent are also attractive for South African pharmaceutical companies. The maturity of the South African manufacturing market, contrasted to the Sub-Saharan region, represents export opportunities which some local firms already explore. Partnership opportunities manifest as the maturity of the local market results in international drug makers considering local manufacturers as reliable 'launching platforms' that they can invest in for also entering surrounding sub-Saharan markets. The government is finding creative ways to upskill local manufacturers through collaboration with established international manufacturers. An example is the Biovac Institute, which is a partnership between the government and local investment holding firm Immunotek, primarily aimed at increasing ARV treatment output. In addition, the Biovac Institute has partnered with other large international manufactures to also address other disease areas through collaborative upskilling and technology transfers.

Serialisation (end-to-end traceability of a product)

To combat the counterfeiting concern in pharmaceutical manufacturing there needs to be reliable traceability from production to patient consumption (Lemay, 2022). Regulators must be able to trace finished goods and their journey across the value chain all the way from manufacturing. The movement of medication across the supply chain should be visible and traceable (Rwanda FDA, 2022). Serialisation defines the generation unique identifiers for pharmaceutical products and printing the code on the label or packaging prior to distribution (Lemay, 2022). This allows for the identification of substandard or counterfeit products, greater batch control and oversight, improved return logistics, improved pharmacovigilance and ultimately increased product visibility for manufacturers (Rwanda FDA, 2022).

Increased importation means the serialisation and traceability demands, as well as commitments to data, are equally increased from local manufacturers. Regular and consistent collection of product data and assessment of its adherence to serialisation guidelines is crucial in driving operational excellence. Improved visualisation and data over a product allows for more efficient root cause analysis. It is equally important in an organisation's commitment to continuous improvement (Lemay, 2021). Organisations should focus on improved governance structures that oversee operations and ensure product visibility is readily available. Increased collaboration across the supply chain, and improved collaboration with regulators, are equally important in enhancing serialisation.

An established internal capacity to validate quality as well as stringent quality control processes remain crucial in the manufacture of medication. More specifically for local manufacturers that don't have a view of the API or excipient manufacture process. The advantageous provisions of technology should equally be considered. Investment in technology that supports serialisation is equally important in ensuring manufacturers have greater control over the products they produce. Investment in Manufacturing Execution Systems (MES) and Manufacturing Information System (MIS) speaks to the commitment needed to drive the monitoring, tracking and control requirements in pharmaceutical manufacturing.

Across different territories, the knowledge that patients are consuming the right product, as well as the intended product, remains crucial. While some manufacturers have their own guidelines, adherence to the Global Standard 1 guidelines (GS1), which are global supply chain standards, is largely accepted in the standardisation of serialisation. The growing complexity in pharmaceutical manufacturing means that the amount of data is equally growing. In trying to operate on a global stage, across different countries, it is pivotal that standards speak a common language. Through these standards businesses are able to accurately identify, capture and share information about products, locations or assets (How GS1 Standards Work, 2023). Within the South African context the use of the Global Trade Item Identification Number (GTINTM) for the unique identification of medicines, using the GS1 standards, is required. This places organisations in an advantageous position through the provision of compliance in multiple territories.

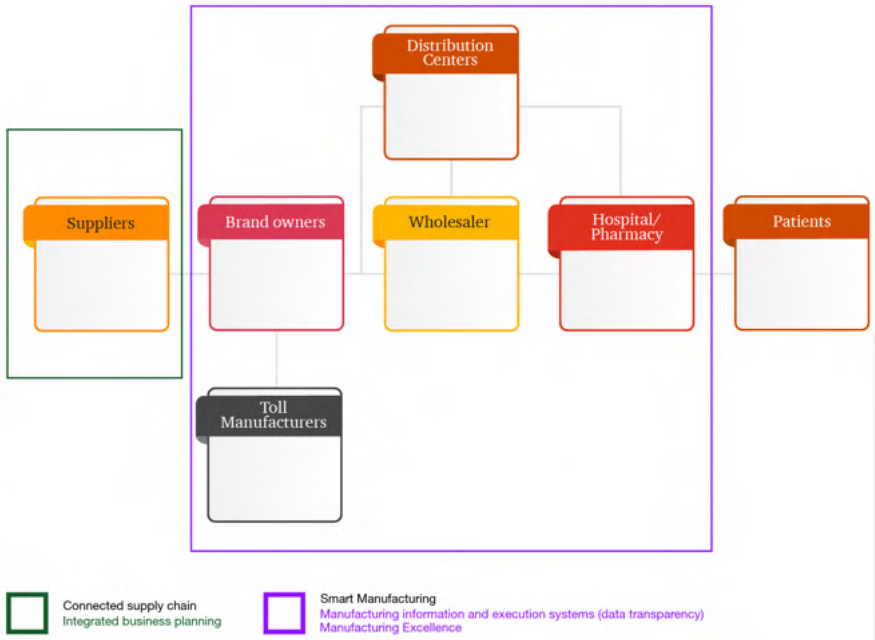
The pertinence of standardisation is especially great for local manufacturers producing high risk, high consumption medications. Medication for HIV and antibiotics experience a high degree of counterfeiting - placing a high traceability demand for local manufacturers and, in turn, the need to ensure. Traceability starts in the manufacturing plant. Manufacturers should have the knowledge and the confidence that the API and excipients used in production have in no way been adulterated. This knowledge is only possible in an environment focussed on manufacturing excellence with a commitment to providing high quality and safe medication to consumers.

Opportunities for the region

A value chain approach to addressing key issues across the supply chain

Based on our review of these key challenges in the industry we believe that a value chain approach is key to regaining control and capitalising on some of the gaps in the supply chain. Understandably not all of these areas of pain for pharmaceutical companies are directly in their control. However, applying an operational excellence lens across the value chain can provide pharma manufacturers with some options to optimise on these gaps and create a level of differentiation in the market.

These opportunities present themselves in three distinct categories that should be prioritised to ensure that the industry can remain competitive in a market that is highly regulated and congested.



Priority 1: Connecting and maintaining a robust supply chain

We see an increasing need to create visibility across the supply chain. Dealing with a market that sees both stable and unstable demand profiles means that the ability for pharmaceutical companies to respond to changes in the supply chain becomes imperative. This, coupled with the need to manage both large networks of manufacturing facilities and global suppliers, means that issues of serialisation, cold chain management and inventory management are harder to control.

This presents the opportunity for local manufacturers to smooth production and manage inventory through the use of advanced supply chain technology. Harnessing the ability to predict demand, and then balance plant production, allows the business to further optimise core operations and reduce the cost of production.

We have seen the adoption of integrated business planning technologies across the heavy industries to support the need for a more integrated supply chain. This need is exacerbated in the pharmaceutical industry and could provide the edge when competing both on a local or global scale. Collaboration in the supply chain is seen as an optimal method of controlling and growing.

Key benefits of these types of initiatives are:

- Higher velocity of data to improve the decision-making capabilities of the business
- Better understanding of the trends for new products introduced into the market
- Improved responsiveness of manufacturing facilities to changes in customer demands
- Optimised stock holdings and reduced working capital
- Visibility over product movements and tracking capabilities
- Built in compliance and regulatory conditions into the supply chain systems

Investing in supply chain technology provides an opportunity for pharmaceutical businesses to compete in the market through better control over their core operations.

Priority 2: Creating a higher degree of control over shop floor operations

The shop floor becomes the perfect place to start addressing some of the main pain points for pharmaceutical manufacturers. Creating excellence on the shop floor has been discussed in the PwC Manufacturing Excellence 4.0 Report. The topics discussed in that report are also relevant when discussing the pharmaceutical industry. What needs to be highlighted is the need for the industry to improve the level of efficiency through the shop floor and also provide a higher granularity of data visibility. These topics directly speak to the ability to address the need for serialisation and create transparency over the cold chain. Generally, manufacturers are addressing these issues through the use of data platforms or traditional MES / MIS solutions.

Aside from addressing the optimisation of core manufacturing functions, the data that is being provided by these systems unlocks the opportunity to connect functions that would otherwise not speak to each other - opening the door to insights and opportunities that the business may not be aware of. One of the most cited use cases is the fact that these systems can now be used to address ESG issues - because information related to waste, quality, consumption and production is now at the fingertips of the engineers who manage these processes.

The need for this visibility and elimination of factory blindness through digitalisation drives the following agenda for pharmaceutical manufacturers:

The effort required to institute change and optimise processes has been reduced significantly since the introduction of digital tools to monitor and sustain manufacturing excellence solutions. To reignite the competitiveness of South African pharmaceutical businesses, a high-tech digital shop floor must be considered to bolster the overall performance of the local industry.

1. Improve the availability and trustworthiness of information to make decisions and perform problem solving.
2. Decrease waste created through the process of implementing manufacturing excellence.
3. Alignment of wider business goals with the manufacturing process (in the pharmaceutical industry specifically speaking to ESG goals, opportunities for product development and supply chain competitiveness).
4. Support the integration between core manufacturing processes and support functions.
5. Support the R&D processes by elevating manufacturing data to support new business ventures and innovate on the shop floor.

Priority 3: Developing strong base ESG principles and controls

ESG is no longer viewed as a box ticking exercise but rather a way to create tangible business value to organisations. Understandably in the pharmaceutical industry the requirements from a compliance perspective seem to drive the discussion (with waste disposal, patent renewals and API disposals driving the discussion). However the new perspective is that companies that have embraced ESG into their operations have seen positive trends to their business including better risk management and value preservation.

This is the perspective that needs to be embraced across the pharma manufacturing industry. A holistic approach to the ESG topic can drive business value without escalating cost or eroding the underlying value of the production. The idea is to search for opportunities to create circularity in the manufacturing environment and look for ways the business can recycle, reuse and repair. Measures like these require product engineering, rethinking the manufacturing processes and redesigning value chains. Although an expensive investment, there is opportunity to increase competitiveness, stimulate innovation and boost growth.

The PwC Sustainable Business transformation playbook suggests a standard approach to driving this agenda whereby businesses need to start by understanding their current maturity in the ESG space, then develop a robust strategy to achieve their sustainability goals and chart a course through road mapping initiatives to achieve the targets, implement and then operationalise.

The importance of preparing one's ESG strategy and imbedding it into the core of operations is growing. Furthermore, the window of opportunity to capitalise on the competitive edge this would provide is closing.

Conclusions

Pharmaceutical manufacturers are facing unprecedented challenges within their supply chains from both a core operational perspective and increasing regulatory requirements. The pressure to perform optimally is important not only for the local market to remain competitive but also to meet the varying demands of patients. One of the ways pharmaceutical companies can achieve this is through addressing key challenges in data visibility, control and prediction of demand and balancing compliance. Reimagining the possibilities when it comes to manufacturing excellence, connecting the supply chain and taking advantage of opportunities in ESG can be decisive when operating in a turbulent market. Remaining competitive is dependent on taking the opportunity to digitise and transform the supply chain and shop floor environment.

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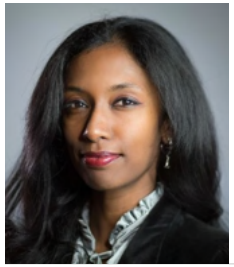

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Landing Page key bullet points:

1. Pharmaceutical manufacturers are facing unprecedented challenges within their supply chains from both a core operational perspective and regulatory requirements.
2. The pressure to perform optimally is important not only for the local market to remain competitive but also to meet the varying demands of patients.
3. Key challenges remain in data visibility, control and prediction of demand and balancing compliance.
4. Remaining competitive is dependent on taking the opportunity to digitise and transform the supply chain and shop floor environment.