



## **Center for Global Development**

Securing the Supply of Essential Medicines to Sub-Saharan Africa

October 2020

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## 1.0 Introduction

### 1.1 The Problem

The COVID-19 pandemic has resulted in shortages of the supply of 68 (Sixty-Eight) essential medicines to Sub-Saharan Africa (SSA); this has shone a light again on the reliance SSA has on the supply of medicines from Asia (and more specifically India) and the insecurity of that supply.

This paper investigates the manufacturing system (from raw materials supply to in-country distribution) that forms part of the SSA essential medicines supply chain and changes that would build longer term capability and resilience within the very specific context of the region.

Policy proposals are made which could reduce the inertia of growing indigenous capacity and capability and reducing barriers whilst creating an investable and competitive market supplying affordable pharmaceuticals.

### 1.2 The Method

The target level of SSA indigenous manufacturing vs imported medicines is not easy to deduce, however we can take as a first step the required capacity to theoretically manufacture and supply 100% of the listed 68 Essential Medicines reported as being in supply shortage (WHO). Although not proposed as a specific solution, this offered a reasonable approximation of the scale of manufacturing which would have a significant effect on overall supply robustness.

Morbidity data (GBD, 2020) was linked to the list of Essential Medicines allowing the calculation of a hypothesised demand for each region and country based upon population. Each medicine was associated with its primary therapeutic indication (EMC, 2020) for both chronic and acute conditions and linked to the prevalence of the associated morbidity. Using course and dosage data (IBID) the kg of Active Pharmaceutical Ingredient (API) and the number and form of dosage were ascertained. After adjusting for the number of treatments available for each condition a capacity was calculated to cover the median demand using Chip modelling (see inset)\*.

#### Chip Method

##### What is a chip?

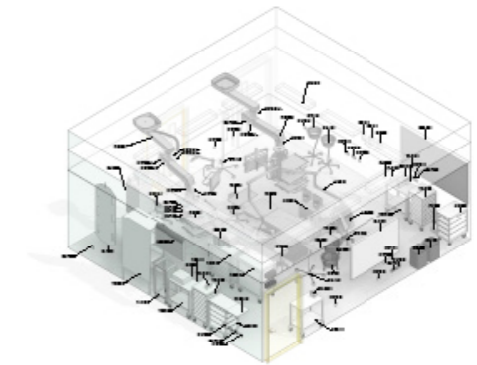
Chips are a set of interacting or independent components making up a 'chunk' of the supply chain. They enable a common language allowing everyone to focus on the project/business requirement. This could be associated with an element of a supply chain such as the facility, an element of a site such as a building, or an element of a process such as an operating theatre or a packaging line.

##### Benefits of modelling using chips

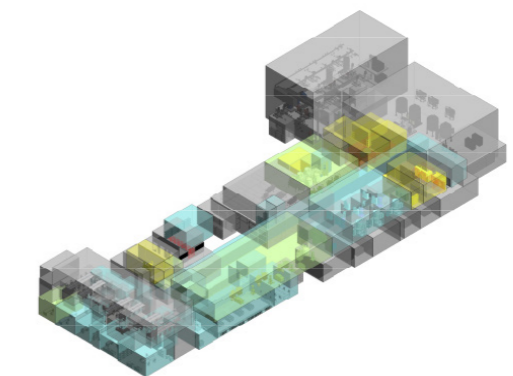
When the requirements of the client have been assessed, a chip library can enable the design team in a variety of ways.

- Straightforward comprehension of project brief
- Help kick-start a project by providing minimum spatial requirements for each process and consequently provide the land requirements
- Easy future facility expansion and phasing
- Quick costing method for all options
- Assessment of utilities requirements
- Standardisation and design optimisation

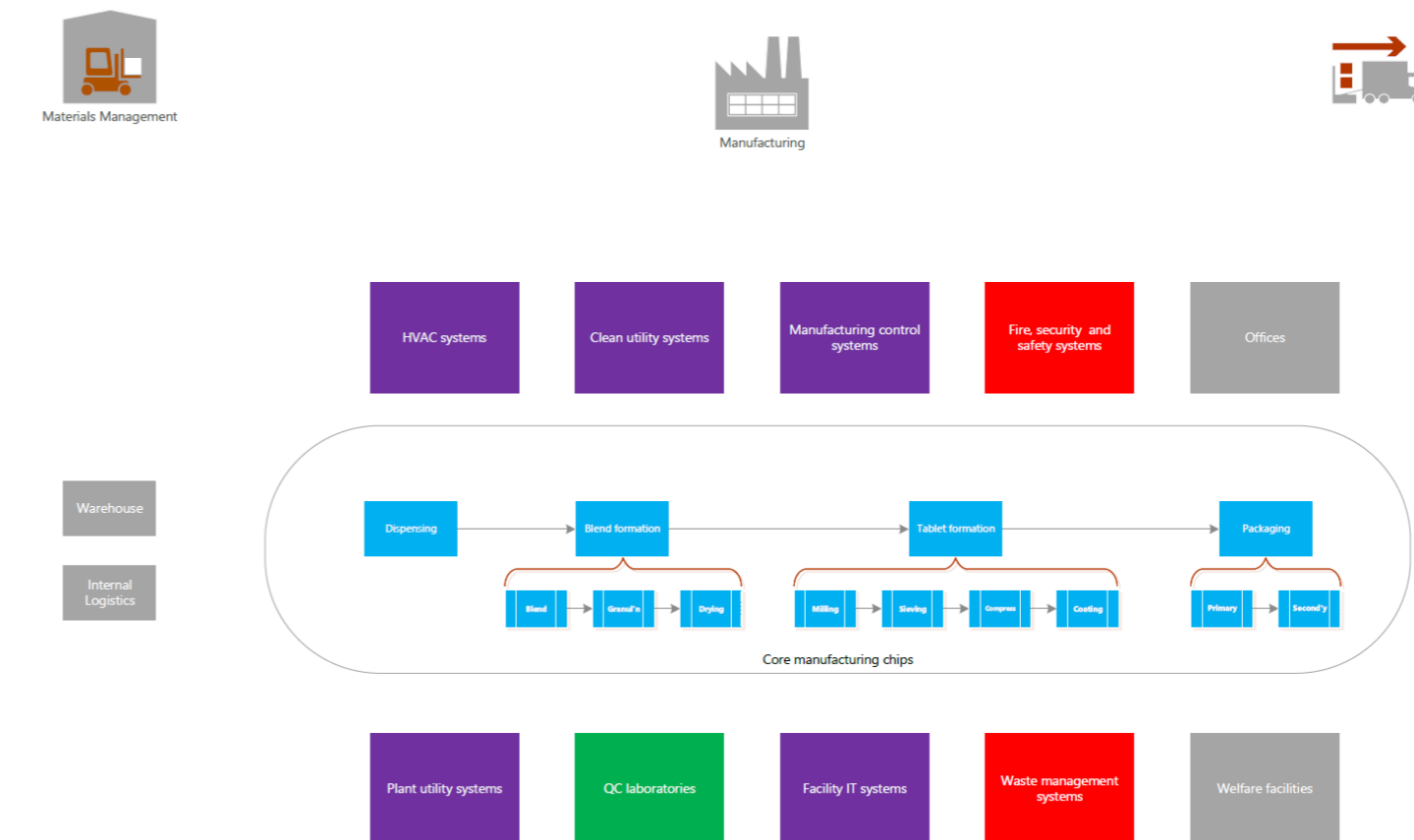
For this analysis, focussing on one chip type as defining production (a capacity-defining chip) helps to make a quick assessment of scale of manufacturing. For OSD, for instance, this chip requires all of the other upstream and downstream chips plus supporting systems in that facility to make it work. A CHIP diagram for a generic OSD facility is shown below; the colours show the capabilities required to run that CHIP. The capacity-defining chip for OSD are defined as the tablet press, for parenteral it is the filling machine and for API it is the product dryer.



Chip outlining space and equipment



Chips assembled as a complete facility



### 1.0 Introduction

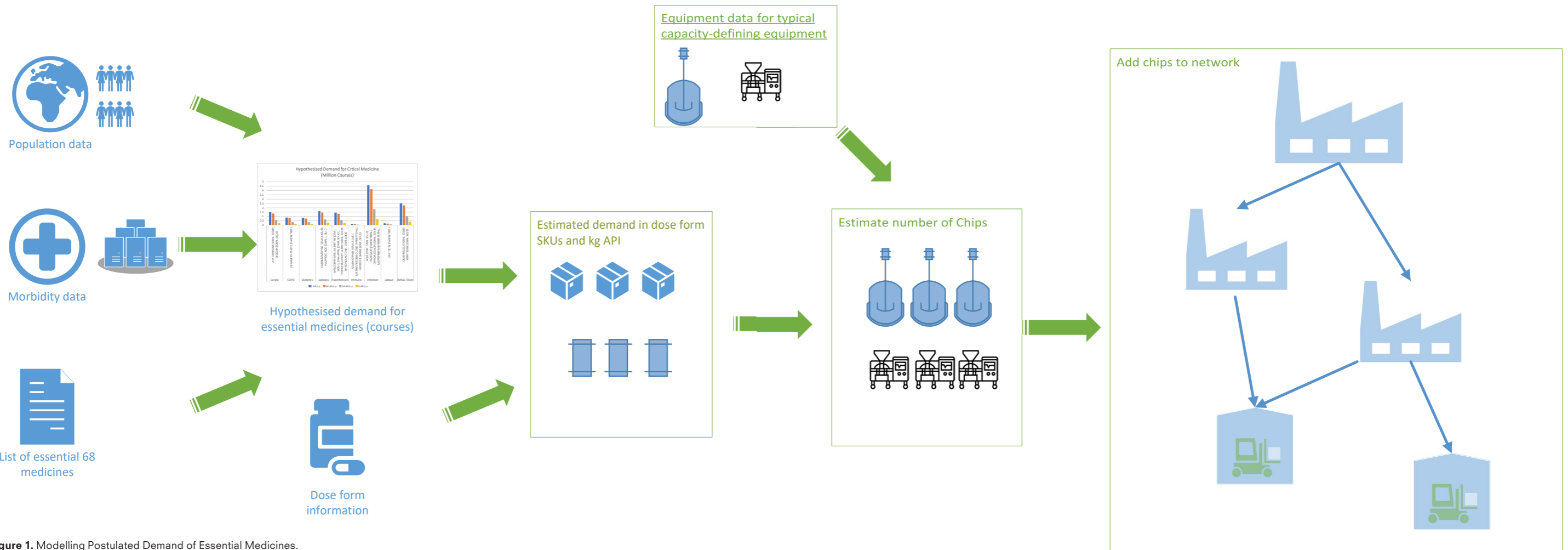


Figure 1. Modelling Postulated Demand of Essential Medicines.

## 1.0 Introduction

### 1.2 The Method (cont)

The high-level conclusion was that Oral Solid Dose (OSD) manufacturing requirements for essential medicines are modest with an assessed need of 3-12 OSD production units (Chips) accounting for the needs of production separation of certain products, equating to 1-4 economic facilities as specified by McKinsey (2020).

The required capacity of Parenteral (PA) manufacturing is smaller than OSD, equating to a requirement of 3-10 PA units (Chips) in 1-5 facilities based upon experience-based norms in the EU. For PA manufacturing, based upon traditional models, this was deemed unsustainable and uneconomic. Therefore a modified approach to establishing and growing the manufacturing systems for these products was needed (see "Solutions").

For Active Pharmaceutical Ingredient (API) synthesis we estimated a requirement of 9-36 units/CHIPS in 2-7 facilities if traditional batch technology is used. Some APIs may be needed in quantities that are different orders of magnitude to others (tens of thousands vs hundreds of kilos) and therefore the number of Chips/unit could be reduced with a range of batch sizes arising from a more detailed analysis. There is very little current capability of API production in Africa outside South Africa and thus the approach is one of establishment rather than growth. More detailed solutions are proposed later in this report.

Liquid oral dose forms account for approximately 1/30th the volume of OSD and given that the levels of facility and capability are similar the proposals for OSD can be assumed to include these medicines. Topical medicines account for approximately 1/100th the volume of OSD. Processing and filling capability could be added to sites where the APIs are handled as part of capability development. We have not considered inhaled medicines as the volumes are very low: these often require complex components and processes and thus could be seen as products to be introduced in the much longer term.

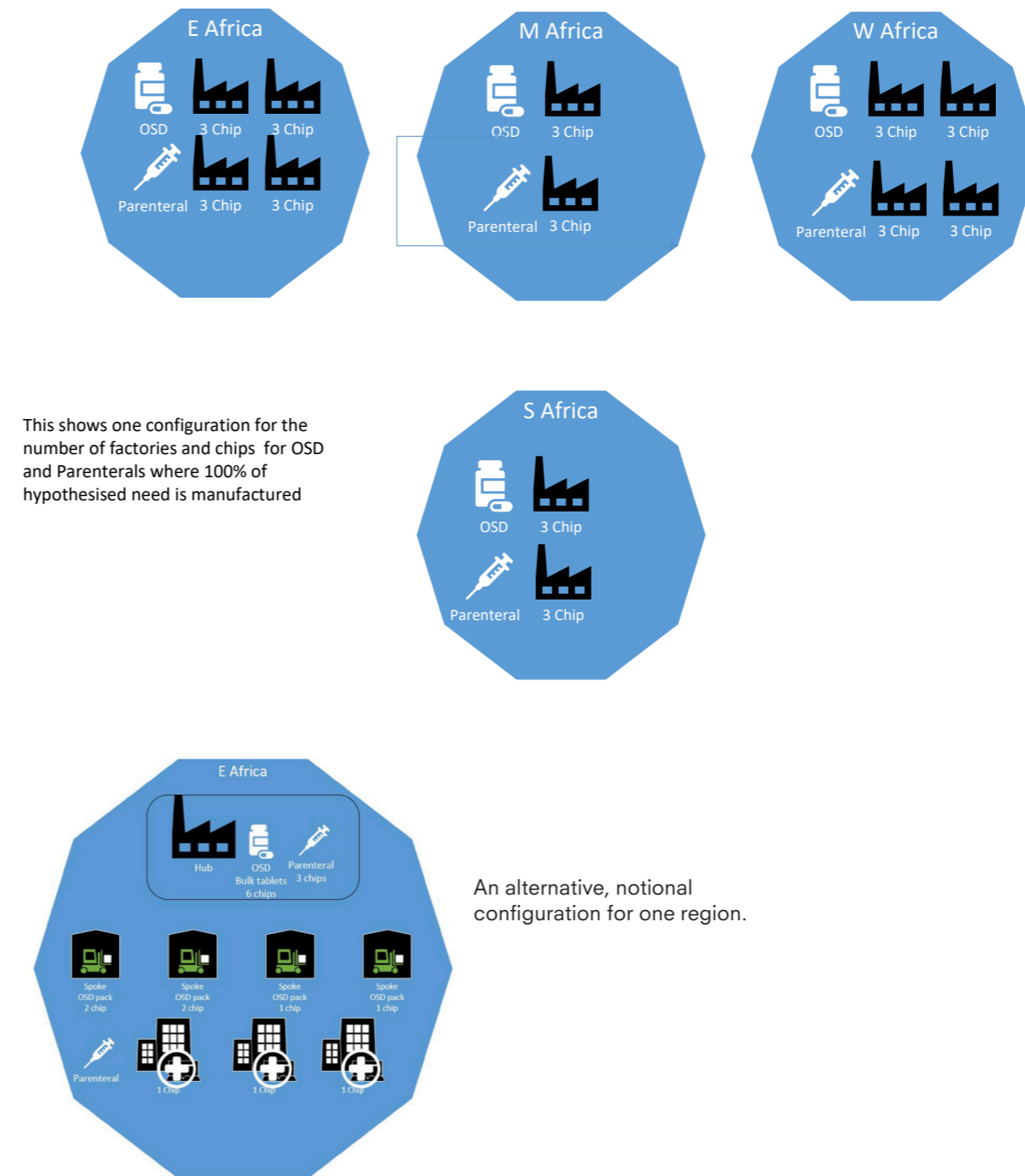


Figure 2. Required (Simplified) Capacity Units (chips) and Factories by Region

## 2.0 Manufacturing System

To successfully manufacture and supply efficacious and safe medicines requires a high level of capability both within the factory facility and in the supporting ecosystem.

### 2.1 Suppliers

- Active / Fine Chemical – API manufacturing is almost absent in Africa outside of South Africa;
- Inactive materials;
- Consumable materials, PPE etc;
- Engineering equipment and services – most specialised pharmaceutical equipment is manufactured in Asia, Europe & North America. Supply of equipment with appropriate support will be economically focused on the current focuses of manufacturing e.g. Ethiopia, Kenya, Nigeria & Ghana;
- Construction – the ability to deliver suitable and sustainable facilities at an economic investment cost;
- Waste handling – the disposal of clinical waste is a key safety and environmental issue;
- Specialist services (GMP).

### 2.2 Logistics

- Safe and secure material transportation;
- Cold chain – most parenteral medicine requires controlled temperature transportation between -80°C and <5°C. In vial form this is bulky and delicate.

### 2.3 Manufacturing Capability

- Hygienic facility management – understanding of how to maintain the facility fabric and supporting services operating within conditions which prevents contamination of the products and dangerous exposure of staff;
- Equipment / process operation – set-up, operation, cleaning, change-over of equipment and ancillaries to produce products in an accident-free manner and within specified tolerances;
- Operational management – Strategy, HR, Finances, Quality, Safety;
- QA / QC – Laboratories – Deploying staff, methods, equipment and facilities to independently ensure the facilities, processes and products meet the required specifications;
- Financial Management;
- Warehouse & storage.

### 2.4 External Capability

- Agreed and recognised standards (quality & safety);
- Regulatory authorities;
- Specialist services (GMP).

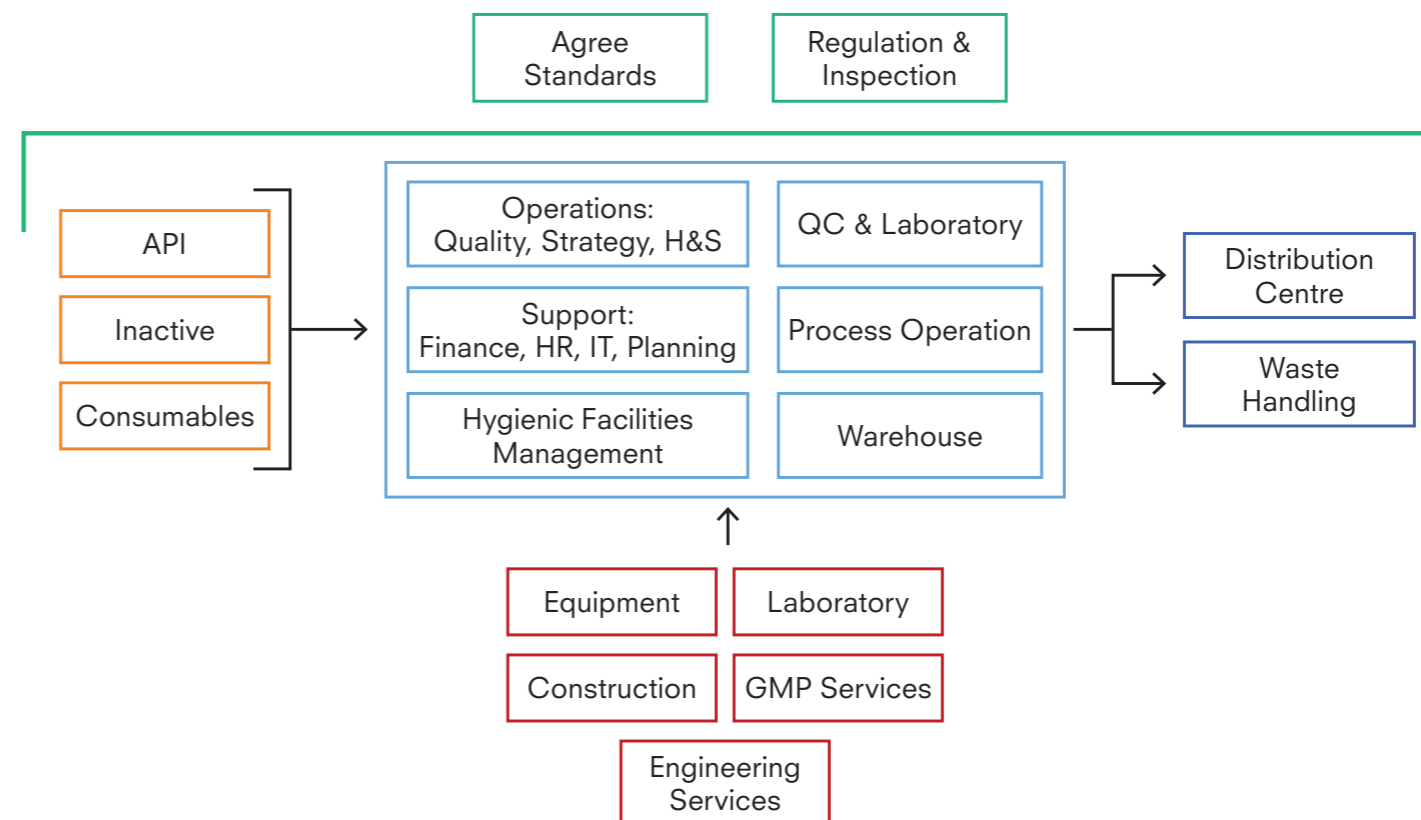


Figure 3. Key requirements for a Pharmaceutical Manufacturing System

### 3.0 Blockers

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There are many factors restricting the growth of manufacturing systems in SSA and these have been previously documented: economics (McKinsey, 2020), quality (WHO) and regulatory (Ndomondo-Sigonda, 2011).

Our analysis of the situation identified the blockers as:

#### 3.1 Capabilities

The human capabilities of knowledge, know-how and experience are interlinked. The need for high levels of specific capability at the factory, the logistics supply level and the supporting ecosystem levels is a major factor. In SSA 9% of the population enter tertiary education (Economist, 2019) of which 25% of enrolments are in STEM subjects; this is growing however compares poorly to Asia (25%) and Latin America (51%). Combined with a potential ‘brain drain’ (STEMpedia, 2019), growing the required capability is a challenge of time. There needs to be pull from a vibrant and growing industry to accelerate the current trajectory, whereas the actual growth rate is less than 10% over the last 10 years (I4D, 2020). Solutions are required which bridge the capability gap in the short term, catalysing change for the longer term.

#### 3.2 Technology (Equipment)

The basic equipment and processes for the manufacturing of simple OSD medicines are relatively easy to augment in areas where there is already established capability and would then be relatively easily expanded into new countries. However, this accounts for only a small percentage of the required medicines. Solutions are needed which can facilitate the distributed manufacturing of these products while also opening up the potential of manufacturing more technically complex medicines e.g. high containment and sterile products.

#### 3.3 Economics

The time and costs associated with the establishment of a new facility, staffing and training of staff are a fundamental blocker to making indigenous manufacturing economic. This is exacerbated by the potential of high fluctuation of demand for medicine driven both by the treatment of acute and epidemic disease (infections) and the procurement processes of countries which leaves tenderers with either high or no demand. Solutions need to be found that lower the barrier to investment while being highly adaptable.

#### 3.4 Infrastructure

Goods are moved all over Africa so at a simple level distribution of intermediates or final medicines should be achievable. The overall speed of transportation in SSA, however, is reported as the slowest in Africa of any other continent. External investment is being made to improve both transport routes and cross-border trade processes to improve the flow of goods without augmenting costs through legal taxes and illegal payments. Due to a multitude of factors transported goods can be subject to damage, spoilage and theft: this poses a particular risk for medicines requiring cold chain. The supply chain needs to be designed to simplify transportation and ideally needs to align with a recognisable pattern of investment and improvement.

#### 3.5 Quality of Facilities

The difficulty in building, commissioning and running facilities which meet basic WHO standards has been reported. One reason (assessed elsewhere in this report) is the lack of capability in the architecture, design, construction and engineering supply chain, operator companies and authorities. Pharmaceutical regulations often need a great deal of knowledge and experience to translate them into reality. Solutions are required which assist in delivering fit-for-purpose assets with a background of lower, while growing, capability.

## 4.0 Context

Having assessed some of the identified key blockers to the development of an indigenous manufacturing system, the SSA context for such growth was analysed.

### 4.1 Population and provision

Health care provision in SSA is funded through a diverse mix of models: in Nigeria it is estimated that 75% is paid for directly by the patient whereas in Namibia, Mozambique, Rwanda and Botswana 'out of pocket' contribution is less than 10%.

Any policy direction needs to be able to account for business ecosystems at both ends of this economic scale.

Population is a major factor in driving the demand for essential medicines: although the relative 'health' of populations due to factors like poverty, war and access to food and clean water are critical, we do not directly address them.

There is a density of population around the middle band of SSA with less in the extremities. This picture aligns with the current pharmaceutically developed countries of Ghana, Nigeria, Kenya and Ethiopia, while also demonstrating the need to build this capability towards countries with significant demand but without current capability.

### 4.2 Physical Infrastructure

Analysis of regional road networks gives a picture of some key developed routes flowing from the current nodes of manufacturing and forming a ring around those countries with high populations and limited capability.

Although road quality and condition are important factors, border crossing delays is one of the main issues with freight movement and is a key focus of infrastructure development.

With most of the supplies required for pharmaceutical manufacture (whether API, inactive ingredients, consumables, equipment or specialist construction material) being imported, sea ports are also an important node in manufacturing capability: aligned to the road structure they provide points from which an overall infrastructure can be developed.

A logistical assessment of countries (Figure 7.) gives another overview of the potential of developing a natural pattern of growing capability away from the current focuses on investment.

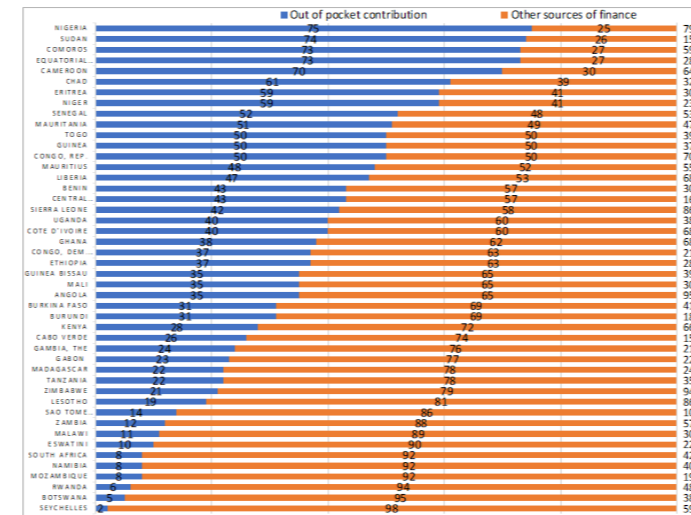


Figure 4. Healthcare Provision Funding (xxxx)

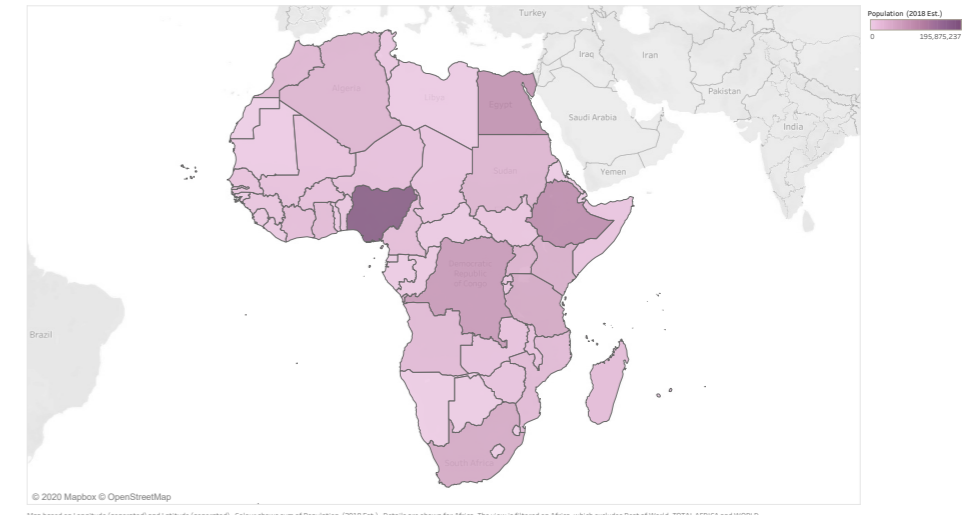


Figure 5. Population Density 2018 (UN, 2020)



Figure 6. Analysis of missing major roadways. (Infrastructurefrica, 2020)

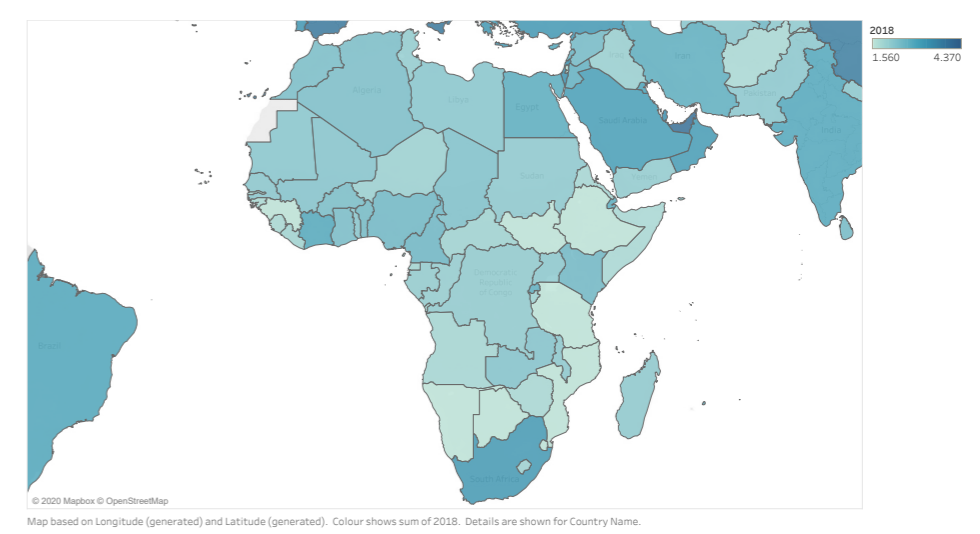


Figure 7. Logistics Performance Index (WorldBank, 2020)



## 4.0 Context

### 4.3 Regulatory Framework

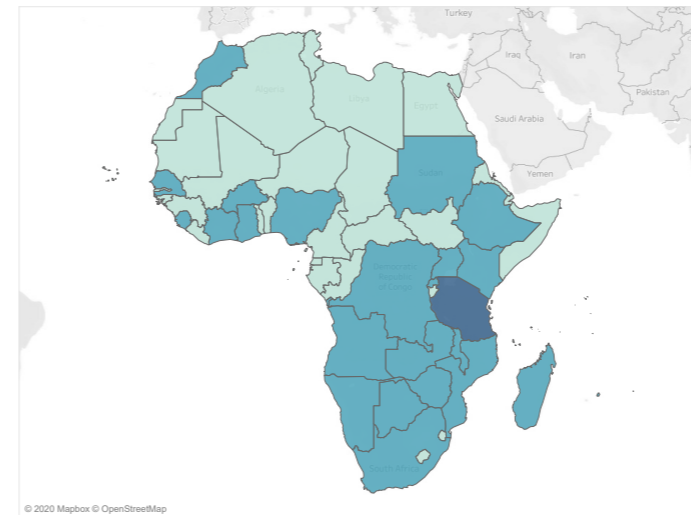
Although hardware is needed for the manufacturing system, people capability within the supporting ecosystem will be a rate limiting step.

A regulatory framework is vital to ensuring the supply of safe and efficacious medicines: an assessment of current regulatory capability (Figure 8) shows that many countries have the apparatus to set standards and carry out inspections.

Further, there are clear signs of international cooperation on regulatory standards, and this can only be a positive direction of travel (Figure 9).

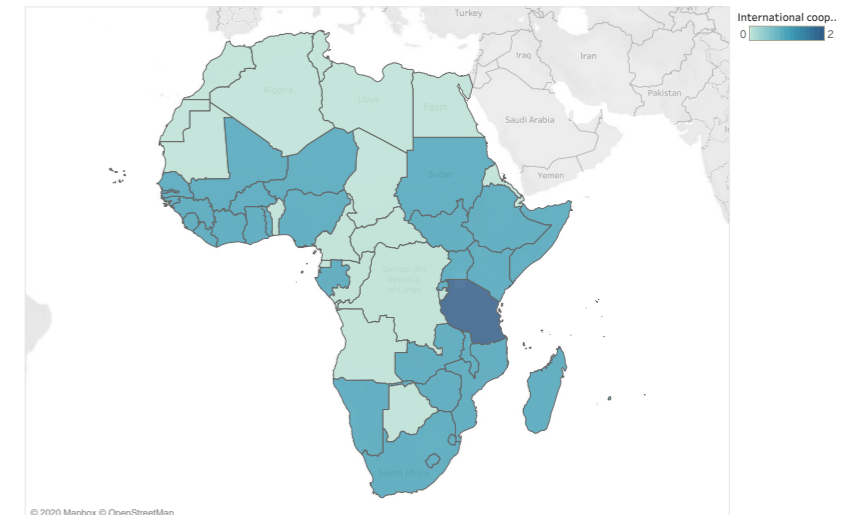
The regulatory picture needs to be viewed alongside a corruption index: without the laws and culture which allows regulation to work ethically and imbuing confidence in donors, investors and patients, growth will be stymied.

If the underlying legal and cultural conditions are present, longer term capability will be driven by education. There have been programmes invested in to build people capability: we concluded that their failure to make significant progress is due to the lack of pull from the industry and linkages to provide real work experience. This is a circular dilemma: policy and investment need to continue to support education but in synchrony with a growing industry (Figure 11).



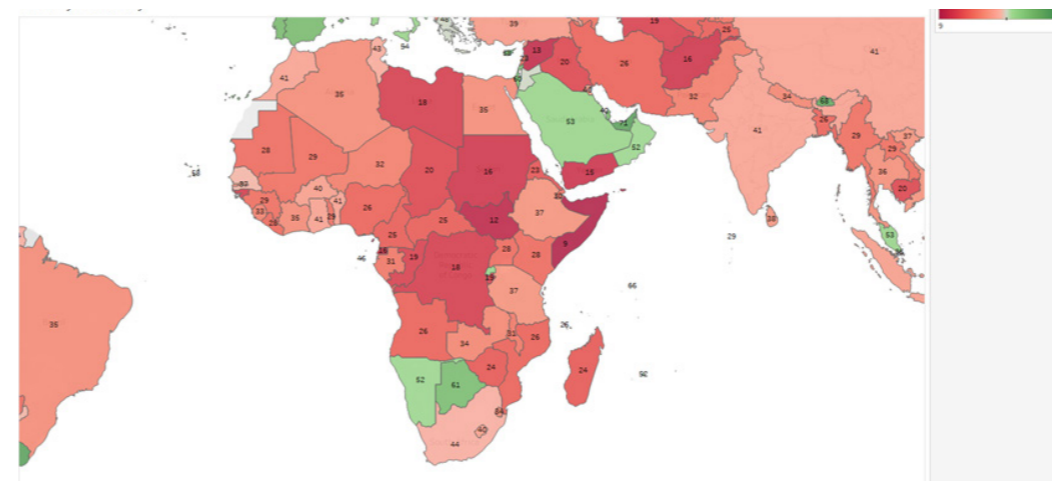
Map based on Longitude (generated) and Latitude (generated). Colour shows sum of Inspection of manufacturing establishments. Details are shown for Country.

**Figure 8.** Regulatory inspections of Manufacturing (data from Ndomondo-Sigonda & Ambali, 2011)



Map based on Longitude (generated) and Latitude (generated). Colour shows sum of International cooperation & harmonization. Details are shown for Country.

**Figure 9.** Regulatory International Cooperation and Harmonisation (data from Ndomondo-Sigonda & Ambali, 2011)



**Figure 10.** Corruption Index (xxxxx)



**Figure 11.** Key Universities in Africa (Economist, 2019)

## 5.0 Specific Solutions

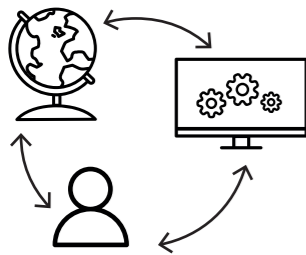
### 5.1 Security of supply through a network

Previous commentaries on the development of pharmaceutical capability in SSA focus on points of investment: looking at countries and economic zones with the perspective of traditional paradigms of manufacturing. We propose an approach which is based upon developing a wider network of smaller adaptable units.

A network would be much more resilient to both global, regional and local issues as stock, manufacturing know-how and plant is distributed while connected. A network with levels of redundancy would be the most resilient to regional and global issues and demands.

The growth of the manufacturing system should be seen in three dimensions running synchronously together:

- Geographic expansion;
- Human capability (growth);
- Technological advancement.



### 5.2 Corridors

Existing manufacturing presence is grouped around major ports of entry. In order to create a network, capability should be expanded through the opening of corridors of development.

These corridors should follow the natural contours of growing maturity in logistics, transport infrastructure and regulatory systems while also remaining focused on supplying the population.

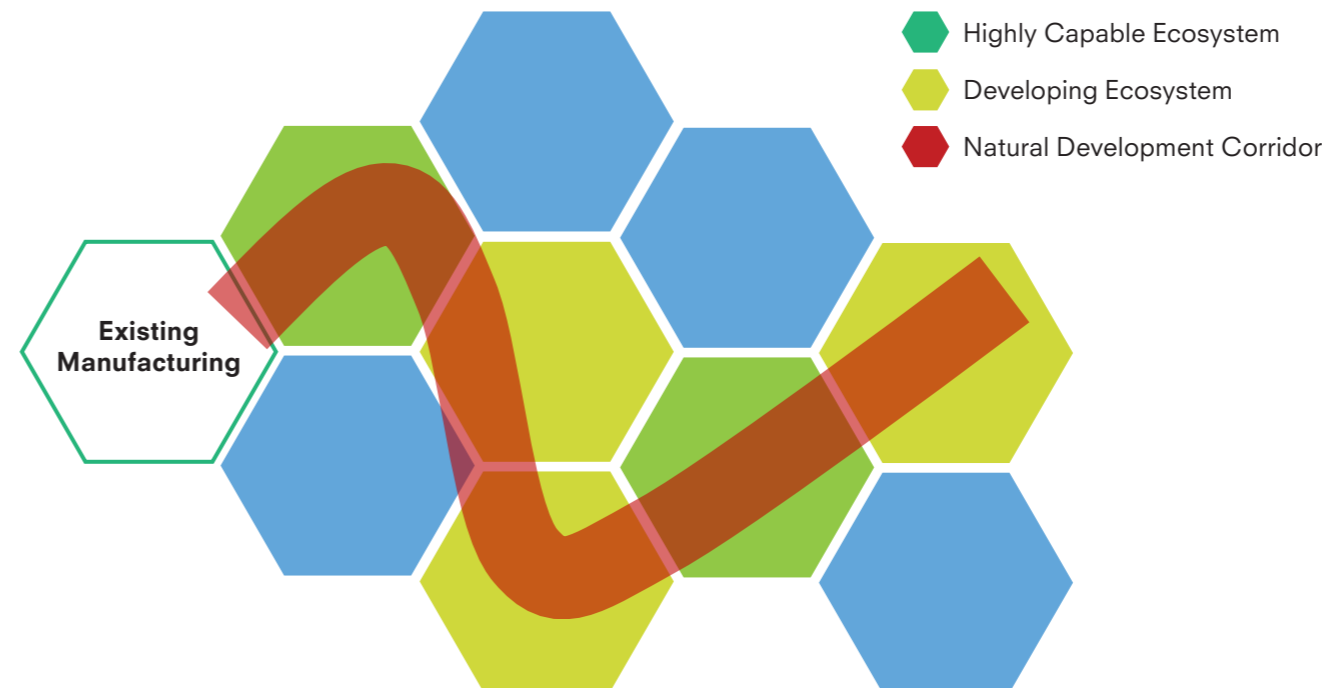
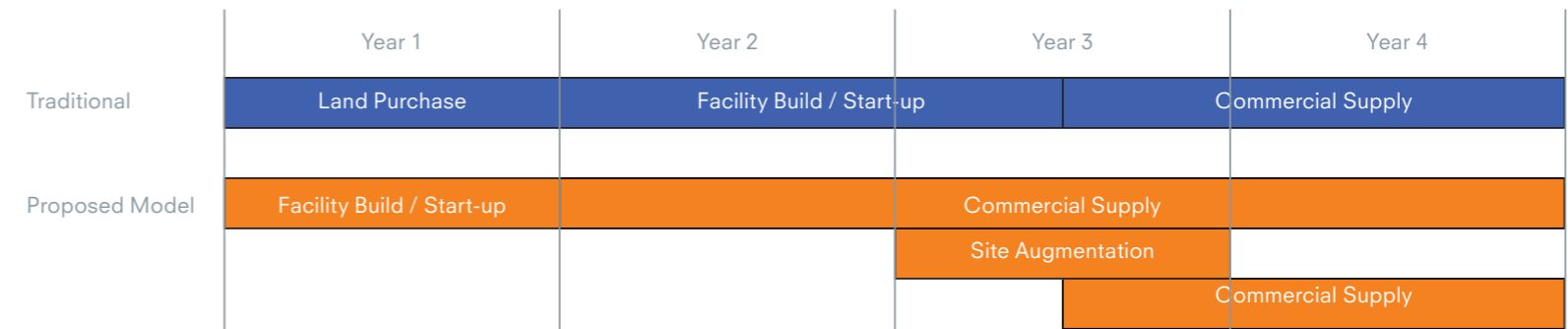
Corridors would strengthen, and be strengthened by, closer cooperation between countries and provide a stimulus to allied service industries: for example, laboratory and waste services would place themselves along corridors.

The corridors would be physically established through the building of base facilities (nodes).

Each base facility node would offer an attractive opportunity for investment. Reliably serviced, GMP warehouse spaces would:

- Ease the flow of drug products and materials between nodes and markets; providing storage for resilience and response;
- Facilitate the accelerated delivery of manufacturing capacity, reducing manufacturing construction schedules from 2 years to 6 months (see Facility Build Kitting);
- Significantly reduce the start-up costs of a new or expanded business (40%), attracting both external investment and entrepreneurial entry into the market within a recognised development corridor.

The nodes would act therefore like mini-science parks, natural places where companies and entrepreneurs can establish or grow their business.



## 5.0 Specific Solutions

### 5.3 Hub and spoke manufacturing model

Almost all pharmaceutical facilities are structured to be self-contained. The hierarchy of both business and technical management represents a significant fixed cost burden. This poses a substantial economic impediment particularly in areas with scarce expertise. This is the basis of most economic assessments of viability (McKinsey, 2020).

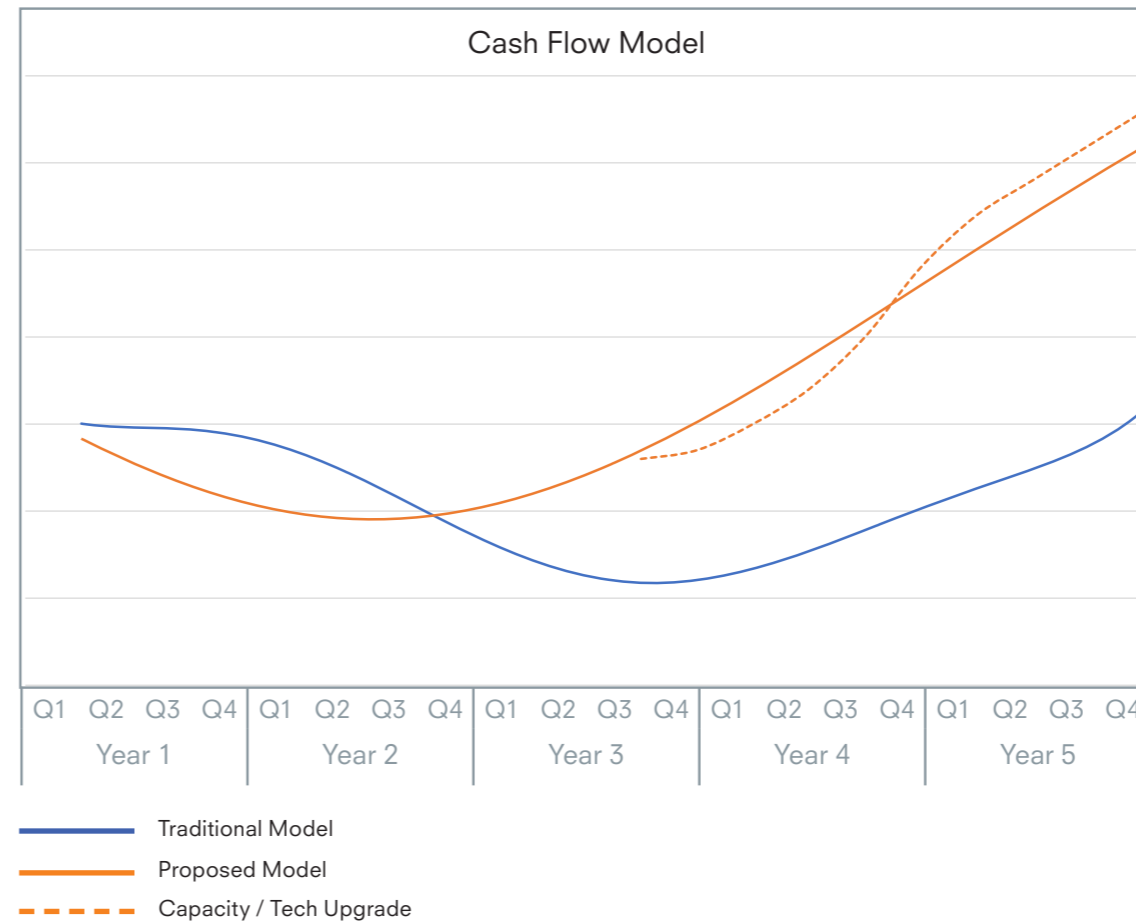
We propose that much of the expertise and key roles are shared across manufacturing nodes including Hub nodes (established with a depth of capability) and Spoke start-up nodes (lower staff and capability). In its most diminutive state, a manufacturing site needs only one “qualified person” in residence along with competent supervised operational staff. While the final quality decisions can be made on-site, production plans, procedures, support, strategic oversight and other key operational decisions could be carried out remotely. In fact, during the COVID-19 crisis this has been witnessed across many facilities. Such a model, combined with investments in base spoke facilities, would reduce economic pay-back periods by 50%, encouraging both initial and repeat investments.

Spoke nodes would be encouraged to build capability and resources over time and in line with product demand, thus allowing them to remain financially viable.

As the human capability in the facility rises with guided experience, the facility would grow both in capacity and technical capability, moving from more simple products and operations to multiple stages of manufacture with more demanding processes.

For example; a facility may start with packing operations, building capability in the running of Good Manufacturing Practices (GMP) with minimal risk, then moving to blending and tablet compression and packing etc.

In support of the developing spoke facilities, the established hub facilities would carry out more complex operations as well as sharing expertise and supplying pre-processed materials to the spoke sites as discussed in the next section “Production Kitting”.



## 5.0 Specific Solutions

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### 5.4 Production Kitting

Taking the example of a high containment tableting process, a Hub site would receive all the materials, dispense and pre-blend the product. This dilution would significantly lower the exposure risks for further processing. A container would be loaded at a Hub with the pre-blend and all required materials to produce a campaign of production at a spoke site. This would be securely transported and tracked. At the satellite facility it would be processed and the end product stored in the warehouse for quality hold and distribution. Special waste and product samples would be returned back to the Hub.

Such a model provides a secure platform to build a network of increasing capability and technology.



### 5.5 Facility Build Kitting

From an installed base of GMP warehouse facilities, constructing a secondary pharmaceutical facility involves the relatively simple process of assembling a number of interconnected hygienic and serviced boxes. Traditionally constructed this is often a messy, labour intensive process which delivers unpredictable results in quality and longevity. The alternative is to use pre-fabricated components and products which are assembled quickly, safely and cost effectively to deliver the shape and size of facility needed.

A study demonstrated that even with components sourced from Europe such a system could be built in Nigeria (Factory in a Box, Farmer Review) competitively when benchmarked against local construction costs. If components and products were sourced from local or other regional suppliers (Asia), they would be highly price competitive. Developing a scheme of pre-approved systems of construction could both significantly increase quality while providing a stimulus for businesses to meet the demand.



### 5.6 Regional Specialities

With specific countries rightly looking to focus investment and advancement domestically there can be unhelpful competition. One approach to help to ease this would be to agree that certain regions or countries would focus on building expertise and capability in a specific medicinal area. Of course, this could be aligned to specific medical or health needs. These focused centres of expertise should involve academia and focused development funding and thus attract commercial interest.

## 5.0 Specific Solutions

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### 5.7 Parenteral (Sterile Manufacturing)

Parenteral (injectable) drugs are the second largest group by number of drugs and number of SKUs in our analysis. Given the significantly higher capabilities required to manufacture sterile products the proposal is that expansion would lag 5-10 years behind OSD. The hub and spoke model with kitting remains viable but the physical geographic expansion would be by a different route. Parenterals are often administered directly by hospitals where there already exists a degree of sterile practice. Given the relatively low volumes and the closeness to patients, small filling suites could be set up in hospitals, acting as spokes from hub facilities that blend and supply bulk products.

There is clear potential for 'skipping a technology step' with sterile filling technology. These state-of-the-art filling systems use robotics, removing most human intervention. The systems are flexible regarding container types and so are suitable for sites where larger numbers of smaller runs are used (i.e. a hospital). These systems are neither low cost nor operationally simple, but they are mechanically simpler than conventional systems and crucially rely less on the skilled operators. Robotic systems are well suited for remote monitoring and control. Quality assurance can be aided by the capability of continuous monitoring and recording of data, all of which could be performed remotely.

As such technology becomes industrialised (5-10 years) it would provide an appropriate platform for introducing PA manufacturing systems.

We believe Lyophilisation should be avoided due to its complexity and high capital costs.

### 5.8 API Manufacturing and Supply

Outside of South Africa, SSA has almost no API manufacturing capability today and to establish capability would require significant levels of investment, expertise and support services to establish the manufacture of APIs safely and effectively. The starting point of the proposal is therefore to establish site Hubs (OSD & Parenteral) with good connections to ports where API can be received. API should be sourced from diverse regions and, given the general stability of safety stock of API, is the first step in securing EM supply.

Although API costs can be a large part of a final drug product's cost of goods there is still substantial benefit in local drug product manufacture using imported API.

Our preliminary analysis estimated that up to 7 batch-reactor based API plants would be required for local manufacture with investment of £500-1,000 Million. In addition, API manufacturing has a different set of capability requirements related to the use of hazardous chemicals and establishing this without a local chemicals industry would require these skills to be developed in addition to the GMP-related skills needed for OSD. Traditional API plants benefit from the economics of concentration but there are examples of relatively small manufacturing facilities in the contract manufacturing sector.

We consider that there is a technological jump in API manufacture that could help SSA bring parts of the chemical supply chain in-region. Continuous processing has been proven to be effective in certain stages of chemical processing. Small scale units have been run in laboratory fume cupboards, and can, with continuous running over months, produce significant amounts of API or precursors. Given the relatively small inventory of solvents and the very low volumes of reaction they pose significantly lower hazards. Continuous processing can be harnessed with small scale batch processing into hybrid facilities with wide application. Continuous and intensified batch processing are technologically advanced, but the bulk of the investment is needed in the process development stages. Once the design is complete the cost to build them and the skill level needed to operate them is lower. Their high level of monitoring and automation again makes them amenable to remote monitoring and control.

A focus for investment could be universities (where chemistry skills are available) to understand and develop this technology in ways which would best fit the specific requirements and context of the region.

## 6.0 Policy Recommendation

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Solutions have been proposed which provide key building blocks to build an adaptable network of manufacturing capability and as such overcome many of the current blockers to the expansion of pharmaceutical manufacturing in SSA, thus securing the supply of essential medicines to the continent.

The approaches rely on some fundamental and structural building blocks within both countries and regions.

### 6.1 A stable and predictable market

An IQVIA report (Rosen) estimated the total market for pharmaceuticals in Africa could be \$40-50 billion. Although this is a good starting point the realities of the market, local demand and the procurement processes make it very unattractive to both large and small investors. We have made proposals that reduce the financial and technical risks of establishing additional capacity and offer 50% reduction in pay-back periods. Having solutions, on paper, will only work in practice if commercial demand can be secured.

The processes of sourcing essential and other medicines, for government and supranational supply, needs to be integrated into this overall approach. The solutions give the possibility of lower guaranteed volumes over shorter times being economically supportable; however there still needs to be demand assurance of 3-5 years for any business case to work.

Essential medicines for the response to chronic illness offer a specific opportunity for commercial production as there is consistent demand for these products.

Given the significant issues experienced with meeting adequate efficacy and safety of medicines in this market, procurement and sourcing needs to be selected on the basis of the ability to supply to the right quality in advance of considerations of cost of goods.

### 6.2 Regulatory harmonisation

We have proposed some specific solutions about how the sharing of expertise within and from outside SSA could be a way to accelerate the processes on creating and enforcing clear regulatory structures and processes in the region. Such solutions will only work with a continuing and concerted effort to create a harmonised regulatory framework. An agreed set of common and fit-for-purpose standards with shared recognition of regulatory audits, inspections and approvals has to remain a key priority. Encouraging geographic and technical development without this will either completely stifle growth or allow the supply of unsafe and ineffective medicine to the population.

### 6.3 Build infrastructure which encourages entrepreneurs & established businesses to invest

Our analysis of the problem of Essential Medicines supply and the failure or inertia of previous programmes leads us to two key conclusions. Firstly, that networks are inherently more resilient than single points of supply; secondly, that adaptability is crucial for businesses and capability to grow in complex and volatile markets.

Adaptability requires quicker delivery, lower costs of entry and the ability to change and grow. The solutions proposed require investment in base facilities. These, we propose, significantly reduce the establishment cost for manufacturing systems (40%), with the hub support reducing the fixed cost of operations (35%).

The investment cost of each base facility would be £2-8m depending on size and location. If they are sited on pre-owned land, they could be delivered in 6-12 months. This gives an opportunity for the first spoke-nodes to be in production in 2-4 years, with further waves leading to a substantive improvement in essential medicine supply in 5-10 years.

### 6.4 Knowledge sharing and growth

There is a clear technology and engineering dimension to this approach. We recommend that there would be a specific group working party for developing a road map aligned to that of geographic and operational expansion. This could be allied to existing organisations like International Society of Pharmaceutical Engineering (ISPE). Through wide linkages this would act as a conduit to share developments and knowledge. This would be key to developing the appropriate standards of process, engineering and construction to support the overall agenda.

### 6.5 Education and Research

We have proposed that developing technologies like intensified API manufacturing is part of a future phase in bringing parts of the whole pharmaceutical supply chain to SSA. Finding and funding opportunities to bring lab-based technology into the region needs to be part of a 5-10 year plan as these technologies mature.

The immediate need is to continue to invest in and develop graduates who will be the scientists and leaders of this growing industry. The idea is not new, however, and like many initiatives we see that a key point of failure is the initial scale of ambition and thus investment. We would propose a focus on very adaptable and practical approaches. Courses can be configured by bringing together existing high-quality distance learning content and combining this with work experience in the Hub and Spoke nodes.

## 7.0 Conclusion

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The overall approach differs from many attempts to grow a successful pharmaceutical manufacturing system in SSA in that it aims to build a network of capability which will be fundamentally more adaptable and thus resilient. The second difference is that it looks to use forward thinking solutions to create an entrepreneurial ecosystem, giving exciting and viable investment opportunities for business, governments and external funding organisations. It looks to remove the obstacles to growth of upfront funding, improve the speed of financial return, leverage the current capability and grow from the current success stories.

The proposals avoid the pull into historic models of pharmaceutical manufacturing. The global industry is full of unused older technology which stifles technological progression. SSA has the opportunity to build an industry based on small-adaptable plants, ripe for rapid technology upgrades as new manufacturing platforms for API, Steriles and OSD mature. Quality can be improved through the parallel growth of understanding and capability, and even more definitively by adopting approaches to construction and engineering which the global industry has so far been slow to adopt.

The proposed model would work well in tandem with growing links SSA has with other countries. In short it exploits the biggest opportunities SSA has: - a young and vibrant population, a clear need and thus market for medicine; and a lack of legacy practice and aging assets.

Big pharma talks a great deal about the need for speed and agility: SSA has the ability to build an industry with these values front and centre.

## 8.0 References

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