Pharmaceutical Manufacturing in Africa

A research agenda towards competitiveness and social inclusion

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Acronyms and Abbreviations

ADRs	Adverse Drug Reactions
AMRC	African Medicines Regulatory Conference
AMRH	African Medicines Regulatory Harmonization
ANDI	African Network for Drugs and Diagnostics Innovation
API	Active Pharmaceutical Ingredients
APS	African Pharmaceutical Summit
AU	African Union
AUC	African Union Commission
BoP	Base of Pyramid
BRI	Biopharmaceutics Research Institute
CoEs	Centres of Excellence
CRO	Contract Research Organization
CSOs	Civil Society Organizations
EML	Essential Medicines List
FAPMA	Federation of African Pharmaceutical Manufacturers Associations
FEAPMA	Federation of East African Pharmaceutical Manufacturers Associations
FKPM	Federation of Kenya Pharmaceutical Manufacturers
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
IDRC	International Development Research Centre
IP	Intellectual Property
IPOs	Initial Public Offering
MAHs	Marketing Authorization Holders
MEL	Monitoring, Evaluation and Learning
NCDs	Non Communicable Diseases
NQCL	National Quality Control Laboratories
NEPAD	New Partnership for Africa's Development
NGOs	Non-governmental Organizations
NMRAs	National Medicines Regulatory Authorities
OECD	Organization for Economic Co-operation and Development
PMPA	Pharmaceutical Manufacturing Plan for Action
PPB	Pharmacy and Poisons Board
PV	Pharmaco-vigilance
RAS	Rapid – Alert - System
RECs	Regional Economic Communities
R&D	Research and Development
SPS	Strengthening Pharmaceutical System
SSA	Sub Saharan Africa
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	United Nations Programme on HIV and AIDS
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization

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Executive Summary

It has been 10 years since the African Heads of State and Governments adopted the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2005. Since then, the continent has intensified its efforts to strengthen its pharmaceutical manufacturing capacity as a driver of socioeconomic and industrial development. There has been significant progress in certain areas.

For example, the AU has continued to provide leadership in facilitating the implementation of a package of solutions to the challenges confronting the pharmaceutical industry as well as the medical product regulatory systems proposed in the PMPA Business plan; there have been significant efforts to create an enabling regulatory and legislative environment for medical products regulations, including the African Medicines Regulatory Harmonisation (AMRH) programme (2009), African Medicines Agency (2014) and a AU Model Law on Medical Products Regulations (2015); Platforms such as the African Medicines Regulators Conference (AMRC) and AMRH governance structures to encourage dialogue among regulators have been established.

While the successes in some areas are laudable, it is also noteworthy that there have been implementation challenges in a number of areas as well. Pockets of progress are in some cases dwarfed by the weight of challenges in others. Both successes and failures provide opportunities for learning, adaptation and re-orientation. Besides, over the last decade, new issues have arisen. Identifying the knowledge/research gaps and knowing what we don't know is therefore a good starting point.

It is noteworthy that while local manufacturing is gaining momentum in Africa with new actors entering the manufacturing scene, others are exiting either being squeezed out due to competition; unfavourable business environment; or simply unable to penetrate the market. These challenges have led some observers to question the viability of local pharmaceutical manufacturing in Africa[1] and whether such local production could lead to cheaper medicines for the end users. While such critical reviews provide important insights, the debate on local manufacturing should be transitioned from the pro- and anti-local manufacturing posturing on 'whether Africa can or even should engage in local pharmaceutical manufacturing' to discussing 'how Africa can manufacture pharmaceutical products more competitively to address access to medicines and social inclusion'. It is in this spirit that this proposed research agenda opts to frame the discussions around **competitiveness and social inclusion** and highlight hitherto unanswered questions that should be addressed to improve the business environment, support policy decisions on investment and trade as well as create the requisite infrastructure for scientific research and innovation.

The research issues presented here have been derived through a series of key informant interviews with a wide range of stakeholders in the policy domains, private sector, civil society, industry associations, development partners and research organizations. They have been supplemented with extensive literature reviews on the current status of pharmaceutical manufacturing in Africa and a mapping of the activities; focus and priorities of most research and development partners operating in the continent. The resultant research agenda and priorities have been subjected to stakeholder reviews and feedback and presented at regional forums for validation and refinement. While not intended to be exhaustive, the research issues presented reflect what has been prioritized by the stakeholders.

In summary, the agenda proposes that to become 'globally competitive', research on local pharma manufacturing should address: **(i) Research, Innovation and Skills Development** – how to build, incentivize and retain talent and scientific research excellence in the continent, including harnessing the opportunities provided by scientific cooperation and the role of the African diaspora. **(ii) Financing, Upgrading and Capacity Utilization** – the need for long-term investment in technology upgrading, R&D laboratories and associated infrastructure, affordable financing mechanisms including a better understanding of

[1] Kaplan & Laing, 2005

'the politics of lending' and strategies for promoting widespread innovation and commercialization(iii) intellectual property rights, and technology transfer – including flexibilities in international agreements such as TRIPS, R&D collaborations and academia – private sector linkages.

Similarly, to build a 'socially inclusive' local pharma, new research is required into the following issues: **(i) Affordability –** including how to use public health procurement as a tool for enhancing local production and the variety of pricing models and their impact on the ability to serve the poor and marginalized; **(ii) Access –** including the distribution patterns and supply chains and whether local manufacturers can better serve the rural and marginalized communities and **(iii) Quality –** including whether standards and regulations lead to technological upgrading or constitute entry barriers for local manufacturers, role of technology and policy in curbing counterfeits, and learning and intelligence sharing on pharmaco-vigilance and post market surveillance.

This research agenda is conceived as an "open menu" from which different actors would pick their research issues based on their mandates, interests, objectives, resources and contexts. It is a public document and an open resource intended to benefit all actors working on African pharmaceutical manufacturing and access to medicines. The African Union Commission (AUC) and NEPAD have the official mandate to coordinate the implementation of the PMPA and associated activities and will be the institutional home(s) for the implementation of the research agenda."

The Context

There is a growing international interest in Africa and recent studies[2] have shown that as growth opportunities continue to move away from the traditional pharmaceutical markets, most multinationals are turning to Africa in efforts to expand their footprints. The appeal of Africa lies not only in its size but also in the dynamics that drive sustainable growth at a time when the major established pharmaceutical markets face a more uncertain future. Such growth drivers include but are not limited to:

At the political level, local pharmaceutical manufacturing has received support from the continent's highest policymaking body – the African Union – which launched the Pharmaceutical Manufacturing Plan of Action (PMPA) in 2005. Reviews of the 10th anniversary of the PMPA during its 6th Technical Committee Meeting in November 2015 has concluded that there has been notable progress made in creating an enabling regulatory and legislative environment for medical products regulations with notable examples including the African Medicines Regulatory Harmonisation (AMRH) programme (2009), African Medicines Agency (2014) and a AU Model Law on Medical Products Regulations (2015); and Platforms such as the African Medicines Regulators Conference (AMRC) and AMRH governance structures to encourage dialogue among regulators.

This political support has been cascaded down to the regional economic communities (RECs) which have also developed their regional pharmaceutical manufacturing plans and are working with Ministries of Industry and Health to create harmony between continental, regional and national strategies and approaches. Continental bodies such as the African Union Commission (AUC) and the New Partnership for Africa's Development (NEPAD) are championing continental-level initiatives.

Secondly, Africa is witnessing unprecedented economic growth with six out of the thirteen world's fastest growing economies being in Africa[3]. This has been accompanied by a fast growing middle class and a youthful population (seen as a dividend – labour supply, skills and markets). The rising middle class creates opportunities in at least two fronts: first, the increase in prosperity comes with a corresponding increase in lifestyle diseases. Secondly, the disposable income brings in to play a discerning consumer that looks for quality regardless of price. These characteristics offer opportunities for local pharma to meet demand for medications to control lifestyle diseases as well as for niche pharma products. Further, regional integration is expanding markets and trade opportunities as countries move towards common markets/common tariff areas.

Third, institutions of higher learning and research (comprising of universities, research institutes, and think-tanks) have trained their eyes on Africa's health innovation, drugs and diagnostics. The African Network for Drug and Diagnostics Innovation (ANDI) is rallying African research institutions to focus on health innovation through its Centres of Excellence (CoEs) and encouraging results and collaborations are beginning to emerge. Academics have also begun paying attention to local pharmaceutical manufacturing in Africa and bringing in the much-needed analytical rigour into the debates. The most recent example is the new book on *"Making Medicines in Africa: The Political Economy of Industrializing for Local Health*[4]*"* which brings together a wealth of case studies by renown academics from Africa and Europe to interrogate various aspects of local pharma manufacturing.

Fourth, civil society and the private sector are beginning to mount pressure on African governments to provide concrete support to local pharmaceutical manufacturing. For example, The Pan African Civil Society Platform on Access to Medicines is a coalition of over 30 CSOs working on access to medicines in Africa and their sole mandate is *"to promote the successful implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA), TRIPS and all other relevant policy commitments in order to increase access to quality and affordable medicines for all*

[2]Skhumbuzo, 2014
[3]Holodny, 2015

[4]Mackintosh, Banda, Tibandebage & Wamae, 2015

underprivileged citizens of Africa especially in the sub-Saharan region of the continent."

Similarly, the pharmaceutical manufacturers are organizing themselves into continental federations (such as FAPMA); regional federations (such as FEAPMA) and national federations (such as FKPM) with mandates ranging from industry-specific agenda such as adherence to quality standards and regulations to policy advocacy and representation of members' interests at key forums.

Despite the resurgence of international interest in Africa, there are still challenges to be overcome for the continent to realize its full development potential. For example, Africa's disease burden continues to be the highest (24% of the world's); NCDs are on the rise and predicted to be worse over the next 30 years; diseases outbreaks such as the recent Ebola in West Africa exposes the continent's underbelly and the level of unpreparedness in the face of disasters. The political support demonstrated at the continental and regional levels (through AU and RECs) rarely translate into policies, programmes and projects at the national level. As such, the private sector continues to suffer the weight of incoherent, and sometimes, punitive policies that undermine the development of endogenous capacity.

The investments in health R&D, innovation and financing remains far below recommended levels; skills and technical capacities are sub-optimal; markets remain segmented and disjointed even though regional integration and harmonization efforts are taking root, implementation of the harmonized regulations and protocols still face opposition in some countries. The linkages between academia (and other institutions of higher learning and research) and industry has remained weak and ineffective, hampering the free flow of knowledge within national economies. The private sector are organizing themselves but their capacity to engage in policy debates/advocacy remains weak, partly because of their inability to generate, package and use evidence to back their policy demands.

While international agreements such as TRIPS provides opportunities for technology transfer and has in-built flexibilities that could be exploited for national interest, only a few of African countries have taken advantage of the opportunities under TRIPS. Intellectual Property is viewed largely as a hindrance, rather than a facilitator in the manufacture of medicines, even though WHO reports that up to 95% of drugs in its essential medicines list (EML) are off-patents[5].

This mix of challenges and opportunities demands renewed momentum and targeted action backed by solid evidence if Africa's economic take-off is to remain on a sustainable trajectory. It is in this context that the research agenda has been crafted. It takes note of the progress made so far, the new and emerging challenges, the knowledge gaps and suggests areas that call for new inquiry in order to generate the empirical evidence that will inform policy, investments and trade decisions.

[5]Kinsley, 2009

The Process: How Did We Get Here?

Developing this research agenda has been consultative and priority issues highlighted have been identified through multiple interviews with key players in the industry including private sector actors (both firms and their industry associations), key policy organs (at the continental, regional and national levels), regulatory agencies, civil society representatives, academics, research networks, university departments and public research institutes as well as policy think-tanks.

These interviews have been complemented with detailed literature reviews on what has been published on African pharmaceutical manufacturing, incorporating works that have been conducted by academics, NGOs and UN organizations such as UNIDO, WHO, UNICEF, UNAIDS etc. Initial drafts have been shared with key stakeholders at key continental, regional and national workshops, conferences and seminars and feedback incorporated into the final document. While noting that such consultations and reviews can neither include everybody nor review every available document, it is considered that the spread of actors interviewed and documents reviewed presents a fair representation of issues affecting the industry. Some of the specific methods and approaches included:

(i) Scoping interviews with selected key informants: Key informant interviews were conducted with 45 selected actors at the regional level including the officers in charge of the continental Pharmaceutical Manufacturing Plan of Africa (PMPA) at the African Union headquarters in Addis Ababa, the officers in charge of the regional plans (RECs); private sector representatives, particularly the regional or national pharmaceutical industry associations; selected civil society organizations working on improving access to medicines in Africa and regional research networks with programmes on health and pharmaceuticals.

(ii) A detailed review of past and on-going research to identify knowledge gaps: This review covered all the 37 sub-Saharan Africa countries where there is some local pharmaceutical manufacturing. The reviews focused on the status of the industry and its evolution in the various countries; the policy and regulatory frameworks; infrastructure and innovation facilities; R&D collaborations and networks; market information and access and the impacts of procurement policies and imported medicines. The reviews were limited to published data and supplemented with annual reports, newsletters, financial data and technical reports by leading research and development agencies. Such reviews built on the key issues raised by stakeholders during the scoping interviews but raised additional issues which were incorporated in the draft agenda.

(iii) Mapping of funding agencies and research organizations supporting programmes on health

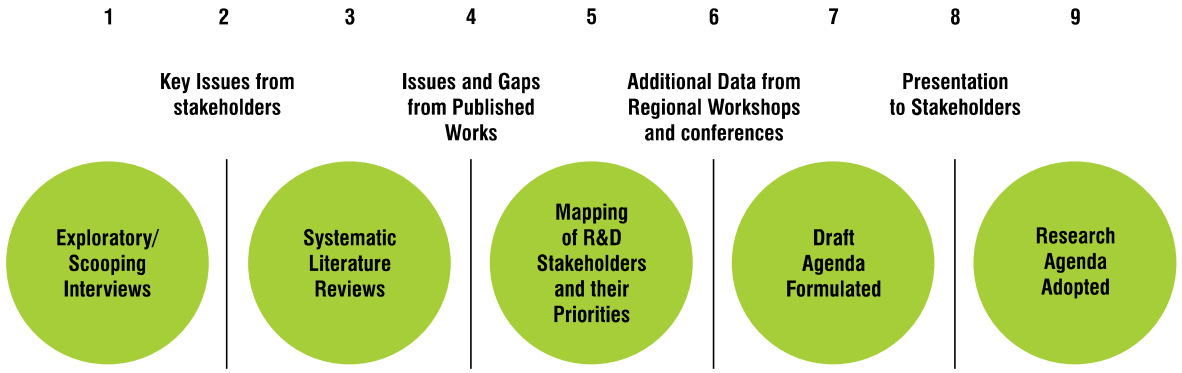

Figure 1: The process of developing the research agenda

innovation, access to medicines and pharmaceutical production: This involved an extensive literature search of both printed and electronic documents including websites and annual reports to highlight the priorities (by diseases, geographical localities, and target groups). Information emanating from the scoping interviews and literature reviews in (i) and (ii) helped in identifying the main research organizations/funding agencies working on pharmaceutical manufacturing and access to health in SSA. Additional information on these organizations were obtained from the regional conferences and workshops as well as from referrals from other organizations. The programmes and projects of some 40 organizations including UN bodies, development NGOs, funding agencies; research networks, civil society groups were mapped by their disease focus, geographical scope and localities and target groups. This mapping also helped in identifying the priority issues amongst what had been proposed by the various stakeholders.

(iv) Dialogues and feedback: Up to 8 regional conferences and workshops on health, pharmaceutical production and access to medicines organized by the key players including the African Union, NEPAD, UNCTAD, ANDI, PharmAfrica amongst others provided opportunities for sensitizing stakeholders, conducting additional interviews, sharing the evolving draft agenda and obtaining feedback. The initial draft was presented to stakeholders at the African Pharmaceutical Summit (APS) held in Nairobi, Kenya in February, 2016. The draft was shared with representatives of pharmaceuticals manufacturers (through their national/regional associations), research organizations and funding agencies for comments and feedback which have been incorporated into the document.

Building a Competitive and Inclusive Local Pharma in Africa: A Conceptual Framework

This research agenda is underpinned by two key concepts: Competitiveness and Social Inclusion. While the former seeks "benefits to industry" and to ensure that local pharma survives the onslaught of imports from large international pharma, the latter seeks "benefits to society" and focuses on ensuring that local production translates to increased access to affordable, high quality medicines to those who need it the most.

In this context, **competitiveness** is defined simply as "the set of institutions, policies and factors that determine the level of productivity of a sector, country or economy"[6]. As such, competitiveness is viewed both a national and firm-level context. Building a competitive local pharma requires enhancing the capabilities of the sector actors to lower their production costs, have better monitoring and coordination mechanisms; more efficient distribution systems and a culture of continuous innovation. As other authors have observed, such capabilities consist of 'a range of capacities that allow an economic system to understand best practice technology on a world scale and use this understanding to promote more rapid economic growth than would otherwise have been possible'[7] and incorporates the resources needed to generate and manage technical change[8] . As such, enhancing capabilities of the actors confers industry-wide competitive advantage[9] .

In this agenda, these capabilities are grouped into three main dimensions: **(i) Research, innovation and skills development** – comprising the 'the difficult–to–imitate know-how, talents and experiences', which are embodied in employees/individuals; **(ii) Financing, upgrading and capacity utilization** – seen as more than artifacts but as an embodiment of knowledge in themselves; **(iii) intellectual property rights, and technology transfer.**

The other key concept – **inclusion** – refers to whether the locally produced medicines reach the patients at affordable costs and whether local regulatory systems can assure high quality and efficacious medicines. Inclusion comprises three main dimensions including: **(I) Affordability** – including procurement and pricing; **(ii) Access – distribution and supply chains** and **(iii) Quality** – standards, counterfeits and pharmaco-vigilance. Critics of local pharma production in Africa have advanced the arguments that the majority of Africans are poor and may not constitute a viable market opportunity. This argument may not hold for long for a number of reasons including: that available data show an ever increasing middle class in Africa; Africa is witnessing an impressive upward trend in economic growth and regional economic blocs are providing not just the numbers of potential customers but regional harmonization is easing the cost of cross-country trade. Conceptually, the focus on inclusion is premised on the idea of the 'Base of the Pyramid (BoP) as a market opportunity' as espoused by C. K. Prahalad in his book *"The Fortune at the Bottom of the Pyramid"*.

Drawing inspiration from this seminal book, it considers the millions of 'poor' Africans as a viable market opportunity rather than beneficiaries waiting to benefit from free government support or philanthropic donations. At the same while it views this big population emerging from regional trading blocs as an opportunity for revenue growth and increasing access. At the same time it recognizes that benefitting from this will require local pharmaceutical companies to be innovative in their business models, change their attitudes, values and norms as well as make structural and managerial changes in their distribution systems to capture and develop this market. They will need to be more aggressive in seeking and exploiting technology transfer options, joint ventures and explore available funding options such as IPOs amongst others. Similarly, government support through implementation of coherent policies, incentives and reward systems would be paramount.

Within this framework, **innovation, institutions and policies** are cross-cutting themes and apply both to factors on the 'competitiveness' as well as the 'inclusion' arm of the framework.

[6]Schwab & Sala-i-Martín, 2013
[7]Lall, 1992
[8]Bell & Pavitt, 1993
[9]Leonard-Barton, 1992

Some analysts[10,11] have emphasized that enhancing capabilities affords actors 'the ability to sense and then to seize new opportunities, and to reconfigure and protect knowledge assets, competencies and complementary assets and technologies to achieve sustainable competitive advantage.' This ability to 'sense and seize new opportunities,' highlights the important role of **innovation** to generate economic and/or social benefits. **Institutions** spell out both the 'rules of the game' as well as 'the roles of the different actors' while **Policies –** help to rally actors towards desired developmental outcomes besides guiding resource mobilization and allocation.

Policies and institutions, supported by various incentive and reward systems, shape the direction of innovation and change.

In effect, the agenda views "the benefits to industry" (better profits) and "the benefits to society" (increased access to quality medicines) not as mutually exclusive exploits but rather as mutually reinforcing principles that can be pursued by both public and private sector actors without compromising their values and mandates. Ultimately, the interplay between the factors underpinning competitiveness and social inclusion; a conducive environment characterized by coherent policies, functional legal and administrative framework and linkages between different actors could lead to a sustainable, competitive African pharma industry. This conceptual framework is presented in Figure 2 below:

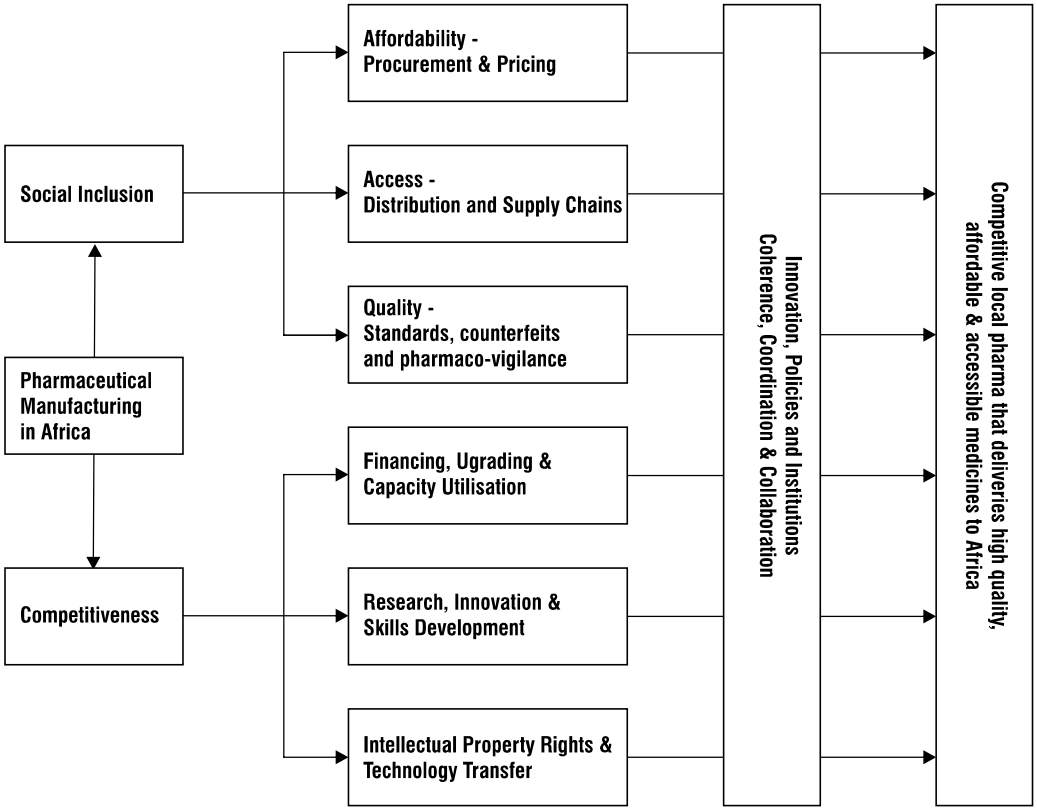

Figure 2: Conceptual framework: towards building a competitive local pharma industry

[10]Teece, Pisano and Shuen (1997)

[11]Teece (1998)

Towards a 'Socially Inclusive' Local Pharma

Sub-Saharan Africa (SSA) hosts about 11 percent of the world's population, but it carries 24 percent of the global disease burden in human and financial costs, and represents less than 1% of global health expenditures. Access to health services and quality medicines remains a big challenge resulting in millions of deaths each year, caused not only by the major pandemic diseases (malaria, TB and HIV/AIDS) but also by other communicable or non-communicable diseases (NCDs). African pharmaceutical manufacturers have only been able to make a limited contribution to the needs of the continent leading to over-reliance on imports and donor-supported programs. Only about 30% of the continent's needs in medicines are covered by local production with 37 countries in SSA that are engaged in pharmaceutical manufacturing.

In order to meet the objectives of social inclusion, local pharma will need to address issues of **affordability** (including the role of public procurement and pricing models); **access** (including distribution mechanisms and supply chain management) and **quality** (including standards, counterfeits, pharmaco-vigilance and post-market surveillance issues).

Affordability: Procurement and Pricing

Medicines account for 20 – 60% of health spending in low and middle-income countries, compared with 18% in countries of the Organization for Economic Co-operation and Development (OECD). Up to 90% of populations in developing countries buy medicines through out-of-pocket payments[12]. While a number of factors will affect the affordability of medicines, two inter-related issues have been identified and highlighted by stakeholders interviewed as part of this agenda setting: **(i) procurement policies** and **(ii) pricing models.**

Procurement of pharmaceutical products by public agencies is usually based on the quoted price, with a tendency to select the cheapest suppliers. The quoted price alone rarely equates to the real cost of procurement since it does not cover the hidden costs associated with inventory management, rush shipments, product redesigns, product failures or unscheduled downtime. Guidelines on Country Pharmaceutical Pricing Policies set by the World Health Organization (WHO), seek to assist national policy-makers and other stakeholders in identifying and implementing policies, to manage pharmaceutical prices with improved access to essential medicine[13].

KEY RESEARCH ISSUES

One of the key challenges facing local pharmaceutical manufacturers is under-investments and under-resourced public health systems. Chataway, Banda, Cochrane and Manville (2015) have noted that public procurement is viewed as a potent mechanism to direct the demand for goods and services and therefore a tool for achieving both industrial policy and innovation policy goals. The fundamental questions remain:

How can African governments use public health procurement as a tool for enhancing local pharmaceutical production? In cases where countries have experimented with this tool (e.g. in South Africa and Ethiopia), what has been the effect on production and consumption patterns? What lessons could be learnt from within and beyond Africa? What are the actual effect/experiences on firm financial cash flows of the various drug procurement methods i.e. advance payments; cash on delivery or credit terms?

There are broadly two types of public procurement (Chataway, Banda, Cochrane, & Manville, 2015): regular public procurement[6] and public technology procurement[14]. While both create markets for goods and services, they may have different developmental/learning outcomes. What has been the experiences of countries that have experimented with these approaches?

What is the effect of public procurement policies on the growth and capabilities of local manufacturing of pharmaceuticals? How

[12]Kindermans & Matthys, 2001

[13]WHO, 2015

[14]Regular procurement is purchase of goods and services ordinarily produced within the country

[15]Technology procurement is purchase of goods and services that could be new to the world or new to the country (but not new to the world)

do these policies affect the ability of local manufacturers to serve the poor? Is preferential sourcing a viable route to supporting local production? Does domestic financing lead to access to affordable medicines for the poor and marginalized?

The role of development partners in supporting local pharmaceutical manufacturing has come under sharp focus. Donor markets, the Africa Malaria Medicines Access Project promoted by Clinton Foundation is alleged to have led to loss of local capacity to produce anti-malarials because they subsidized malaria medicines (Coartem brand) supplies to the point it was no longer viable for local companies to produce and sell generic versions. Similarly, the insistence of Global Fund on buying only from WHO PQ facilities in India has had an effect of locking African companies from donor markets. Studies are required to establish the full effect of these donor policies and generate evidence that would support African governments not only in negotiating with their development partners but also in crafting their own domestic industrial and health policies.

Access – Distribution and Supply Chain Management

Skills and capacities that can support effective distribution of medicines and ensure that patients get the drugs they need, at the right place and time, are largely deficient. The key challenges range from lack of infrastructure such as roads; to the fact that only very few distributors reach out to low-income communities and the very low numbers of skilled experts in the medicines logistics and supply chain management. Besides, there is limited data and studies addressing the scope of local manufacturing to improve access to medicines, especially for the rural (and disadvantaged populations). A recent study in Tanzania[17] addresses this gap by presenting empirical evidence of 'urban bias' in the distribution of imported essential medicines in Tanzania i.e. *"while medicines manufactured in Tanzania are equally likely to be found in rural and urban outlets, imported medicines – especially those manufactured outside the region – are less likely to be available in rural areas."* This finding has immense policy implications for health and industrial policy and lends credence to the clamour for local manufacturing, and more importantly, the need to source from local producers. As the authors conclude: It "provides prima facie evidence that locally produced medicines are more accessible than imports for rural consumers…"

KEY RESEARCH ISSUES

Given that in most parts of Africa the rural areas constitute a disproportionately large number of poor and disadvantaged households, the findings by Mujinja et al, (2014)– that locally produced medicines have higher chances of reaching the rural areas as compared to imports – warrants further investigation into the distribution strategies, partnerships and other factors that have made this possible.

One other area that has largely been ignored is the issue of patient acceptance i.e. whether medicine is packaged and presented in a manner that is acceptable and sensitive to the cultural norms of the patient? Issues of culture, gender, religion and their influence on patients' receptivity to drugs have been pointed out as a key consideration for enhancing access and call for deeper inquiry.

Quality - Standards, Counterfeits & Pharmaco-vigilance

Closely related to affordability and access is the quality of medicines. The risk of poor quality products is minimized through a complex interplay of regulatory oversight that encompasses Good Manufacturing Practice (GMP); Good Laboratory Practice (GLP), Good Distribution Practice (GDP) as well as conducting pharmaco-vigilance activities to monitor products on the market, including a functioning and efficient adverse event reporting mechanism.

In discussions with stakeholders and literature reviews, three main issues underpinning social inclusion have been prioritized including: **(i)** standards and regulations **(ii)** counterfeits and sub-standard medicines and **(iii)** pharmaco-vigilance and post-market surveys.

Standards & Regulations

The quality standards to which companies in SSA produce vary both across different countries, regions as well as within individual countries. Similarly, there is significant variation in the Good Manufacturing Practices (GMP) standards with which pharmaceutical manufacturing firms are required to comply. The African Medicines Regulatory and Harmonization (AMRH) programme was formed in 2009 and aims to promote harmonization of medicines regulation in Africa. The AMRH initiative works with Regional Economic Communities (RECs) to increase access to good quality, safe and effective medicines through harmonizing medicines regulations and expediting registration of essential medicines. It is expected that harmonization will enable national medicines regulatory authorities (NMRAs) to use their limited resources more effectively.

One of the key findings from a recent pilot study in Kenya, India and South Africa show that while standards for the pharmaceutical industry are sometimes seen as independent drivers of technological capability upgrading, the reality is far more complex. Standards change over time and are shaped by a complex mix of firms' innovations, lobbying, procurement politics and market protection. The study concludes that 'standards may both help to ensure safe and efficacious medicines, and also act as an undesirable market entry barrier'[18].

[17]Mujinja et al., 2014

[18]Mugwagwa et al, 2015

KEY RESEARCH QUESTIONS INCLUDE:

What is the role of standards on innovation and technological upgrading? In which contexts and under what conditions have standards been applied as drivers of technological capability building and upgrading? What is/has been the impact of various standards on access to medicines in developing countries? Are there cases where standards have been used as a technical barrier to trade and how have these been resolved? Harmonization of standards and regulations is on-going and has been concluded in some cases. What are the implementation challenges that arise from these harmonized standards? How are regions responding to such challenges?

Counterfeits and Sub-standard Medicines

Sub-standard[19] medicines and counterfeits[20] are a major global health concern resulting in unnecessary morbidity and mortality and undermining progress in the fight against infectious diseases due to increasing drug resistance.

The WHO estimates that 30% of all medicines in Sub-Saharan Africa (SSA) as opposed to 1% in the developed world may be counterfeit. In 2005, a survey by the Pharmacy and Poisons Board (PPB) Kenya and the National Quality Control Laboratories (NCQL) showed that 30 per cent of medicines sold in Kenya were counterfeit (Kibwage, 2008). Data from the Pharmaceutical Security Institute (PSI) indicate that poor-quality medicines were found in 124 countries in 2011, with the problem more severe in low- and mid-income countries than in developed countries. Due to the discrepancies in national definitions for counterfeit pharmaceuticals, misclassification of substandard drugs and a reliance on the results of studies with varied methodological quality, the exact scale of the problem and prevalence of counterfeit pharmaceuticals in SSA is yet to be established.

The sub-Saharan Africa (SSA) region offers minimal or no national reporting on seizures of counterfeit drugs. One third of the WHO member states have either no means or very limited means of controlling counterfeit medicines. The globalization of the pharmaceutical market, high prices for genuine drugs, lack of pharmaceutical regulation and inadequate jurisdiction against counterfeiters contribute to the high prevalence of counterfeit drugs in SSA. Further, due to the clandestine nature of pharmaceutical counterfeiting it is difficult to get a valid figure for the global scale of the trade. There is also a scarcity of official documents that analyze the prevalence of counterfeits drugs around the world, since only 5-15% of the 191 WHO member-states report cases of pharmaceutical counterfeiting. Finally, the accumulation of small-scale prevalence studies in SSA are compiled using different methodologies, so substandard drugs could be misclassified as counterfeit drugs.

The WHO has achieved some successes in harmonizing and coordinating the fight to eradicate counterfeit pharmaceuticals and taken steps to improve the reporting of counterfeit pharmaceuticals around the world through the online Rapid-Alert System (RAS), allowing NMRAs to quickly report batches of counterfeit pharmaceuticals. In 1999, the WHO released 'Guidelines for the Development of Measures to Combat Counterfeit Drugs', which proposed national strategies to tackle the practice. However, the problem of transnational jurisdiction continues to be a barrier to curbing counterfeiting in pharmaceuticals.

KEY RESEARCH ISSUES

New studies are needed to determine the scale of the problem and prevalence levels; the role of technology in detection and deterrence and international cooperation/coordination mechanisms amongst other issues.

Pharmaco-vigilance and Post Market Surveillance (PMS)

An overview on the findings of WHO assessments performed at national medicines regulatory authorities (NMRAs) in 26 African countries over a period of eight (8) years showed that structures for medicines regulation existed in the countries assessed, and the main regulatory functions were addressed, although in practice the measures were often inadequate and did not form a coherent regulatory system (WHO, 2010).

The study also highlighted the lack of mechanisms and procedures that would enable NMRAs to benefit from the scientific assessments and inspections carried out by other well-resourced and established regulators. In almost all countries assessed, health budgets were low and lack of sustainable funding restricted the regulatory operations. On the whole, the countries did not have the capacity to control the quality, safety and efficacy of the medicines circulating on their markets or passing through their territories.

Similarly, according to a report *"Safety of Medicines in sub-Saharan Africa: Assessment of Pharmaco-vigilance systems and their performance"* by the Strengthening Pharmaceutical Systems (SPS) program (2012), 33 countries are official or associate members of the WHO

[19]Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient

[20] "A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

Programme for International Drug Monitoring[22]. Of the 46 SSA countries, 41% have a national policy related to PV and medicine safety while 30% provide a legal mandate to monitor medicine-related adverse events.

Only 28% of countries have legal provisions that require marketing authorization holders (MAHs) to report all serious ADRs to the NMRA and 17 % require MAHs to conduct post-marketing surveillance activities. 74% had a PV unit with a clear mandate and formal organizational structure, 39% had national PV guidelines, 39% have a safety advisory committee and 45% had a drug information service.

However, these countries were limited in enforcing medicine safety monitoring and only 28% had a strategy to coordinate PV activities at the national level. Although 74% had spontaneous reporting systems, less than 50% monitor product quality, medication errors and treatment failures through existing systems[23].

KEY RESEARCH ISSUES

These issues call for further inquiry including:

- **A detailed analysis of the extent to which regulatory functions are being performed/implemented in the different countries to identify gaps, training needs and share lessons of good practices.**
- **Review of the legal and regulatory frameworks to identify overlaps, inconsistencies and areas that need consolidation/coordination**
- **Mechanisms for information and data sharing that enable NMRAs to benefit from scientific assessments conducted by other well-resourced and established regulatory counterparts**
- **Role of technology and innovation in product/supplier selection; pre- and post-shipment inspection and analytical/ pharmaceutical testing.**

[22] Nwokike & Choi, 2012

[23] SPS, 2012

Towards a Globally Competitive Local Pharma

Despite the demand and the market for pharmaceutical products in SSA, most countries struggle to compete for a number of reasons including the high costs of active pharmaceutical ingredients (APIs) which has left most companies unable to compete on price with Asian generic manufacturers, inability of local manufacturers to implement good manufacturing practices (GMP) and ensure quality production and the deficiency in human capital. While the list is by no means exhaustive, it highlights key elements relating to competitiveness of the local pharmaceutical manufacturing industry. The range of issues undermining the competitiveness of Africa's local pharma have been grouped into three broad categories: **(i) Research**, Innovation and Skills Development **(ii) Financing**, upgrading and capacity utilization and **(iii) Intellectual** property and technology transfer.

Research, Innovation and Skills Development

The pharmaceutical manufacturing system requires specialized skills and despite the availability of training institutions in SSA, there is shortage of technical staff such as pharmaceutical engineers, validation experts and product development scientists and the technology, installations, precursors, intermediates and synthesis pathways experts required in production of pharmaceutical substances are deficient in most SSA countries.

A 2008 health product survey identified the most significant human resource capacity gaps for pharmaceutical innovation as being in preclinical/safety pharmacology and raw material processing to GMP standards[24]. The report also highlighted gaps in capacity to conduct clinical trials quality assurance systems and drug regulation. This shortage of researchers on the continent is exacerbated by the loss of skills to the developed world. For example, it is estimated that more than a third of practicing highly skilled African scientists are now living in the developed world[25]. However, the situation is changing, with the emerging need to promote research and development at the continent level and with the formation of key institutions like the African Network for Drugs and Diagnostics Innovation (ANDI). It is also noteworthy, that a significant number of pharmaceutical companies in Kenya, Nigeria and South Africa are setting up R&D units for development of new products. Schools of pharmacy such as the University of Nairobi (Kenya) and Kilimanjaro School of Pharmacy / St. Luke Foundation (Tanzania), have designed programs in industrial pharmacy intended to meet the needs of the pharmaceutical manufacturing industry. St. Luke, for example, has comprehensive Program to teach the fundamentals of quality drug production.

KEY RESEARCH ISSUES

The contribution of Africa's rich biodiversity to drug development has not been fully studied. Capacity building is still needed for handling of traditional medicines and phytomedicines and cultivation of medicinal plants. This includes capacity development of national regulatory authorities, including expertise in taxonomy, quality control of medicinal plants and microbiology. Whereas it has been suggested that herbal medicines are a potential source of new APIs, R&D should aim at characterisation, purification, standardisation and chemical engineering to make them not only relevant in industrial application but also for new treatments.

There are centres of research excellence (created mainly through ANDI) and centres of regulatory excellence (spearheaded by NEPAD). More work needs to be done to understand the workings of these centres; pick their lessons in R&D partnerships, lessons on collaborations and how that model can be improved, replicated in other situations so that such partnerships are the norm rather than the exception in Africa.

There's also the need to determine the role of the knowledge institutions and research networks such as universities and specialized laboratories (both in developing countries, as well as in the developed countries) in supporting local pharma. This demands in-depth academic inquiry beyond the often-friendly external reviews.

Finally, there is limited work on the role of the African diaspora in the pharmaceutical manufacturing sector. Studies on how India and other Asian countries have harnessed the skills and expertise

[24]Berger et al., 2011

[25]Lowell & Findlay, 2001)

from their diaspora, including the incentive and reward structures put in place to attract and retain talent would be useful lessons for Africa.

Financing, Upgrading and Capacity Utilization

Inadequate supporting industries pose significant challenges for the African pharmaceutical sector. For example, lack of laboratories that can perform bio-equivalence studies is a big challenge, and this is compounded by the fact that bioequivalence studies in foreign laboratories are very costly and out of reach of the local pharmaceutical companies. Currently, there is only one accredited CRO in Africa i.e. Biopharmaceutics Research Institute (BRI), Rhodes University, South Africa. The proof of bioequivalence is an essential element for the WHO prequalification of multi-source (generic) medicines and also a requirement for market authorization for some pharmaceutical products.

Achieving international standards for African products call for specific capacities, facilities and for personnel skilled in pre-qualification standards. The high capital investment needed to meet the minimum standards and the prohibitive costs of borrowing capital are a major hindrance. There's need to facilitate access to affordable long term investment capital of sufficient magnitude to enable upgrading of facilities to international standards.

KEY RESEARCH ISSUES

There are minimal theoretical and empirical studies on financing of local pharmaceutical manufacturing in Africa (Banda, 2013). This constitutes a major knowledge/research gap since lack of knowledge on who finances this sector; the extent of such funding; the terms and conditions for lending; the interest rates, duration and margins limits the choices/options for local firms wishing to access these services.

Secondly as Banda (2013) has argued, there has been very little consideration of the "politics of lending", in other words, the institutional considerations that determine decision-making on whether to fund, at how much, under what terms and conditions. This lack of understanding of the politics behind the lending process undermines the chances of African firms in accessing some of these loans. While the numbers may be minimal, some firms have successfully obtained financing from local banks and other financial institutions. What has been their experience and what could other firms learn from it? How about those who have accessed external financing from international institutions and lenders, what have been their experiences? What are the policy options for African governments wishing to support local pharmaceutical production? How does dependence on external financing for essential medicines affect the chances of local manufacturers?

The available production capacity in SSA is underutilized by most manufacturers. The UNIDO country profiles for the pharmaceutical sector carried out between 2008 and 2012 for Nigeria, Uganda and Kenya reported capacity utilization of 40% in Nigeria , between 30% and 55 % in Uganda and in Kenya, one shift production capacity varied between 53% and 67%. This implies that there is a large volume of underutilized manufacturing capacity which could be applied to produce new products upon demand. In spite of this expansion potential, African local pharmaceutical production accounts for only 30% of the local demand. This under-utilization of installed capacity is attributed mainly to the failure of local companies to meet international GMP standards and achieve WHO pre-qualification standards in order to benefit from international tenders and compete against their Asian counterparts.

While there is pressure on local firms to upgrade and attain WHO-GMP standards, and WHO pre-qualifications, this is expensive and often leads to local firms becoming less competitive and out placed as suppliers by imports. This means that their products become unaffordable to the poor and that governments are unlikely to award them tenders under the current procurement rules and structures. There have been concerns that while the pressure to upgrade and attain GMP is welcome, the responsible agencies are raising the regulatory standards without thinking about the level of investment required. Studies are required to establish the mix of policies, incentives and support structures required for local pharma to upgrade and still maintain their competitiveness.

Intellectual Property Rights & Technology Transfer

A number of companies in SSA are venturing into collaboration and partnership for technology transfer utilizing TRIPS flexibilities to acquire the skills required for drug development. The TRIPS Agreement links trade liberalization with the protection of intellectual property (IP) and provides for technology transfer, technological innovation and capability building. Article 7 states, "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations[26].

Similarly, Article 66.2 encourages developed countries to provide industry incentives for pharmaceutical technology transfer and capacity building in developing countries (WTO, 1994). Such technology transfer can occur through various mechanisms and the TRIPS agreement is generally

[26]WTO, 1994

silent on which methods/mechanisms will technology transfer occur. Neither does it define clearly what technology transfer actually means. This leaves technology transfer amenable to interpretation by the parties involved. While the developing countries expect a comprehensive programme involving capability development, including the skills that would enable local institutions and companies to produce their own medicines, developed country firms are contented with providing general development assistance in the form of infrastructure (e.g. hospitals and schools) and enhancing regulatory capacity.

KEY RESEARCH ISSUES

It is not clear, to what extent the provisions of article 7 and article 66.2 have been fully utilized in the African context. In cases where there have been technology transfer agreements involving north-south collaborations, it would be worth studying the effect of these agreements on domestic capacity to manufacture medicines locally. Equally interesting would be a comparison (where possible) between north-south collaborations and south – south collaborations (involving India, China, Brazil etc).

In 2001, Aspen Pharmacare (from South Africa) became the first in the world to receive a voluntary license for ARVs, followed by Cosmos Ltd. in Kenya in 2004. Similarly, other African countries including Zimbabwe, Mozambique, and Zambia issued compulsory licenses for ARVs. Tanzania, Ethiopia and Uganda, have utilized TRIPS transition period to manufacture generic ARVs. The use of TRIPS Flexibilities has largely been under-utilized due to lack of other enabling factors for promoting local production including – the right skills mix, suitable financing options, deliberate efforts to promote access for local manufacturers etc.

These examples of technology transfer arrangements (voluntary licencing, compulsory licensing and use of transition periods) require in-depth empirical analysis to elucidate the circumstances (in the domestic contexts) that led to their negotiation, to draw out the experiences and lessons from the countries/parties involved. These could provide useful exemplars for other African countries and firms.

Similarly, there have been complaints of predatory tendencies by big pharma when engaging in voluntary licensing. For example they may grant the license to a local company but go ahead and cut the price of the innovator molecule to the level where the licensee is unable to produce profitably. Similarly, most ARVs are under multiple product and process patents, so even though a company may get a voluntary licence, a crucial process may not be accessible due to existing patent protection. A key question is whether the VLs in Africa have contributed to improving access to medicines? In-depth case studies involving companies that have experimented with such voluntary licensing/technology transfer such as Cosmos, Universal, QCIL – may highlight the links (or lack thereof) between these voluntary licences/technology transfer agreements with profitability and access.

Practical Considerations: Approaches, Concepts & Implementation

The emerging research issues call for an understanding of the relevant technical and social aspects that influence competitiveness of the African pharmaceutical manufacturing and access to high quality, affordable medicines for its population. It is expected that generating empirical evidence through interdisciplinary inquiry will lead to better understanding of the challenges and opportunities that exist in the African pharmaceutical sector. Moreover, focused, in-depth analysis and interrogation of the research questions will inform policymaking as well as trade and investment decisions.

Indicative Programmes & Activities

The proposed research agenda could be implemented through a number of programmes, projects and activities aimed at generating empirical evidence, sharing information, lessons and experiences, exchanging staff/expertise, training in specific areas of research, and providing technical assistance where necessary. It is expected that collaboration and partnerships involving **(i)** both natural and social sciences as well as engineering and technology disciplines **(ii)** public, private, civil society organizations **(iii)** academia and industry **(iv)** north - south and south – south collaborations and other relevant actor configurations as may emerge over time would form the cornerstone for implementing the research agenda.

While the actual design and scope of specific programmes and projects will be decided by implementing organizations and partners, indicative approaches may include comparative country case studies; national/in-country assessments; firm level studies or even shorter (single/multiple) case studies addressing specific issues in the industry. Other activities may involve establishment of learning forums and platforms. These could be virtual, but supplemented with physical meetings in conferences and symposia addressing specific industry questions. Dissemination and outreach activities targeting different stakeholder categories should form an integral part of the programmes. Monitoring, learning and evaluation (MEL) to tease out and document key lessons, adjust to changing contexts and address emerging issues should play a central role in implementation and innovative ways of ensuring uptake and utilization of the evidence/knowledge generated should be considered.

Comparative Country Studies

To achieve a detailed understanding of the issues that apply to more than one country, it is recommended that comparative country studies be conducted to generate empirical, comparable data. Such studies will need to be guided by a coherent conceptual framework to ensure that the theoretical basis, data collection methods and tools as well as analysis and presentation of results allow for meaningful comparison.

National/in-country studies

Some issues are specific to national contexts and would be better approached through in-country/national level studies. Most public policy related issues such as public procurement, taxation, industry incentives; domestic infrastructure; policy coherence etc would fall in this category. Whereas lessons from such studies could be applicable in other countries, the immediate target beneficiaries would be national governments or in countries with devolved systems, country/federal governments.

Firm level studies

Specific firm level issues such as technological capabilities; GMP standards and procedures; utilization of installed capacities; pricing; supply chain management; curbing of counterfeits etc could be addressed through firm level surveys and/or case studies. The focus of such surveys could be individual firms, national, regional or even continental depending on the scope of the studies and their objectives. The units of analysis could be departments, or even specific projects or functions.

Single/multiple case studies

These would be useful in cases where specific programmes have been implemented and the studies are geared towards drawing lessons and experiences on the outcomes, impacts or challenges. Examples could include programmes designed to increase access to medicines in rural areas; or the effect of subsidies on pricing and access; pooled procurement; utilization of common facilities etc.

Institutional arrangements for implementation

This research agenda is conceived as an "open menu" from which different actors would pick their research issues/questions based on their mandates, interests, objectives, resources and contexts. It is thus a public document and no single institution or group of institutions can claim exclusivity to any of the research issues/topics. It must be viewed as an open resource to benefit all actors working on African pharmaceutical manufacturing and access to medicines. In order to meet its objectives though, some form of coordination is necessary. The African Union Commission and NEPAD have the official mandate to coordinate the implementation of the PMPA and associated activities. As such, AUC and NEPAD will be the institutional home(s) for coordinating the implementation of this research agenda. They will organize for and provide updates on the status as well as create opportunities for knowledge sharing, including platforms for stakeholder dialogues where possible. Synergy amongst organizations working on pharmaceutical manufacturing and access to medicines is highly desirable and efforts will be made to ensure that organizations working on similar issues/priorities are encouraged to join forces for wider impact.

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