TheScinnoventCentre
SCIENCE, INNOVATION AND ENTERPRISE

INCENTIVISING AFRICAN PHARMACEUTICAL MANUFACTURING:

Policies for sustaining the take-off

Technical briefing note no. 1

November 2016

INCENTIVISING AFRICAN PHARMACEUTICAL MANUFACTURING:

Policies for sustaining the take-off

Corresponding author: Maurice Bolo

Email: Bolo@scinnovent.org

Editing, design and layout— Islet Investments, Nairobi.

Cover photo—e-Magine Art

Citation: Bolo, M. and Vugigi, S. (2016). Incentivising African Pharmaceutical Manufacturing: Policies for sustaining the take-off. The Scinnovent Centre Technical briefing note no. 1. Nairobi, Kenya: The Scinnovent Centre.

About the Scinnovent Centre

The Scinnovent Centre is a policy and development think tank registered in Kenya as a not-for-profit company.

Our primary concern is that despite advancements in science, technology and innovation (STI), poverty levels in Africa are increasing; environmental degradation is worsening; the ecosystem has become more fragile; sustainability has been compromised and livelihoods threatened. So the big questions remain: why have the developments in science, technology and innovation not made any significant difference in African development? Why have STI policies not translated into practical change on the ground? How come pockets of success piloted across countries have not scaled?

Our work focuses on understanding the barriers to the adoption and use of science, technology and innovation for decision-making and wealth creation. We focus on three main barriers namely: (I) Policies and legal frameworks that shape incentive structures for the generation, sharing and application of science, technology ad innovation (ii) Institutional and governance frameworks including the rules, norms, habits, structures, practices and mindsets that condition behavior towards science, innovation and entrepreneurship and (iii) individual and institutional capabilities including technical, organizational and managerial skills required to turn science and technology into business and social enterprises

Our goal is to link the ends (societal development needs) with the means (science and technology-enabled innovations) and act as the bridge that closes the gap between advances in STI research on the one hand, and the uptake and application of research outputs for social and commercial needs on the other. To achieve this goal, we conduct research to generate evidence that supports policy and decision-making; offer targeted training programmes that enhance the skills for innovation; and facilitate dialogue and interactive learning amongst different actors with a view to helping our key stakeholders (rural communities, the private sector and decision-makers) translate the knowledge, technologies and skills into practical action that changes lives.

For more information, contact us:

The Scinnovent Centre

P.O. Box 52486- 00100, Nairobi, Kenya

Tel/Fax: + 254-20-2173433

Tel: +254-20-2470946

Email: info@scinnovent.org

Web: www.scinnovent.org

Twitter: @Scinnovent

Facebook: www.facebook.com/scinnovent

Blog: www.scinnovent.wordpress.com

Slideshare: www.slideshare.net/Scinnovent

LinkedIn: www.linkedin.com/company/the-scinnovent-centre

YouTube: https://www.youtube.com/user/TheScinnoventCentre

TheScinnoventCentre
SCIENCE, INNOVATION AND ENTERPRISE

Gate 123 | Mountain View Estate | Off Waiyaki Way, behind Total Petrol Station
P. O. Box 52486 - 00100 GPO, Nairobi, Kenya
Tel/Fax: +254 – 20 217 34 33 | Email: info@scinnovent.org
Website: www.scinnovent.org

Table of Contents

Acknowledgements

This work was carried out with the aid of a grant from the International Development Research Centre (IDRC), Ottawa, Canada

Introduction

Support for local production in developing and least developed countries is largely construed as a means to improve access to essential medicines. Access to treatment is heavily dependent on the availability of affordable[1] medicines. Medicines account for 20–60% of health spending in low and middle-income countries, compared with 18% in countries of the Organisation for Economic Co-operation and Development (OECD). Up to 90% of populations in developing countries buy medicines through out-of-pocket payments (Watu & Kungu, 2014).

Other perceived benefits of local production include: saving (i) promoting intra-African trade and stimulating exports, for example, it is estimated that Local pharmaceutical production contributes approximately 30% of the SSA pharmaceutical market; hence opportunity for market expansion exists. Further market consolidation and integration within the regional economic communities (RECs). Within the EAC and COMESA, for example, the harmonization protocols for pharmaceutical regulation are developing rapidly. The Common Market for Eastern and Southern Africa (COMESA) has a population of 400 million with 19 member states. The Tripartite (COMESA-EAC-SADC) is expected to unleash immense new opportunities for increased trade and investments that will be offered by an enlarged market of a total of 625 million (ii) fostering new skills, local innovation in new treatment regimes and technologies. The pharmaceutical production system requires specialized skills in many disciplines, including pharmacy, chemistry, biological sciences, engineering, life sciences and information and communication technologies. These constitute direct job opportunities for skilled workers and (iii) creating jobs/employment. In 2011, Germany, India and Egypt employed a workforce of 126,000 and 1.1 million, 22,000 people respectively, in the pharmaceutical manufacturing whereas the Kenya and South Africa workforce is approximately 4,000 and 9,500 respectively (Khurana & Jaipuriar, 2014). Further, the existence of the local industry indirectly contributes to the economy through complementary activities such as the supply of raw materials and packaging materials amongst others.

Lessons and experiences from across the world

There are 37 countries in SSA engaged in pharmaceutical manufacturing supplying about 30% of the local market (see annex 1 for additional details). Of these, South Africa, Kenya, Nigeria, Ghana have substantial pharmaceutical manufacturing plants. There exists huge demand for pharmaceutical products with the existence of trading blocs, such as the East African Community (EAC), Economic Community of West African States (ECOWAS), the Southern African Development Community (SADC) and the Common Market for Eastern & Southern Africa/East African Community (COMESA), offering an increasingly attractive market opportunity. The move towards harmonized medicine regulatory processes and removal of trade tariffs will strengthen the ease of doing business. However, a variety of hindrances are experienced by the pharmaceutical industry including importation of almost all pharmaceutical inputs, shortage of skilled labour, lack of advanced/modern technologies and relevant training institutions, weak legal and regulatory systems, poor infrastructure, unreliable energy supply amongst other challenges. These have made local production uncompetitive in many of the countries.

Given the multifaceted nature of efforts required to promote local pharmaceutical production, a comprehensive approach may be needed to address simultaneously the many issues that require attention – for example, access to technology, strengthening absorptive capacity, access to capital and infrastructure and a business-friendly regulatory system that enhances quality production while supporting local manufacturers. While some of these challenges will require technical and operational responses, the role of public policy in supporting the continued growth of the African pharmaceutical manufacturing sector cannot be over-emphasized.

Lessons and experiences from successful producers around the world provide helpful insights into how African countries may further incentivise the sustained growth of local pharmaceutical manufacturing. This brief reviews examples from the developed world, particularly the United States and Germany, as well as developing world experiences from India, Bangladesh and Brazil and distils five key policy lessons.

Experiences from Developed Countries

The pharmaceutical manufacturing industry was founded in the late 19th and early 20th centuries. Switzerland, Germany and Italy had particularly strong industries, with the UK, US, Belgium and the Netherlands following suit. The industry progressed remarkably from the 1950s, due to the development of systematic scientific approaches, understanding of human biology (including DNA) and sophisticated manufacturing techniques. North America is the major pharmaceutical market accounting for around 48% of global pharmaceutical sales, followed by Europe (30%) and Japan (9%) (Shah, 2012). Germany is the world's fourth largest and Europe's largest economy. A common feature of these countries is the existence of human capacity, regulatory framework, technology and infrastructure to develop and produce competitive quality products that meet market demand. A detailed overview of the factors that led to the success of the pharmaceutical industry in the USA and the Federal Republic of Germany are herein discussed.

[1]Affordability is the relationship between the prices of the medicines and the user's ability to pay for them. Affordable prices are designated by WHO as a determinant of access to medicines.

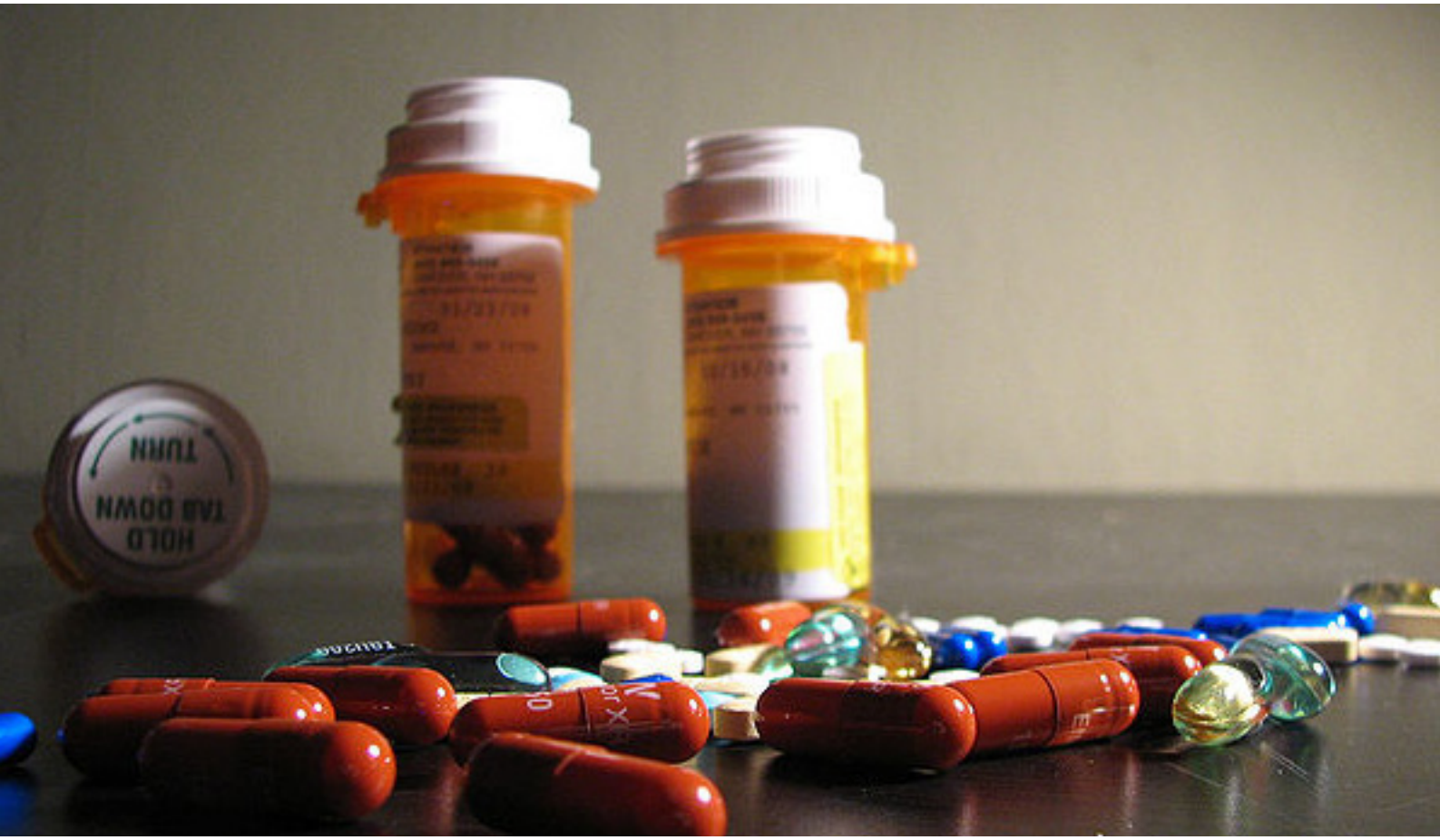
Case Study 1: United States of America

Between 1940 and 1950 the American pharmaceutical industry transformed itself from a collection of several hundred, small, barely profitable firms to a small group of 15 large, highly profitable firms, and together they accounted for 80% of the entire industry's sales and 90% of its profits (Shah, 2012). The successful firms had a significant advantage having been selected by the federal government to participate in the penicillin production program. Due to the high demand for penicillin during World War II, the Office of Science Research and Development (OSRD) was given the authority to involve private corporations in the research and development processes for mass production, sharing with these selected firms all the previously classified information about penicillin production. The OSRD signed a total of 17 American firms to government contracts over the course of a few years. These firms were selected irrespective of whether or not they had the capability to manufacture penicillin. The firms ranged from some of the largest and most successful pharmaceutical companies of the day (e.g. E.R. Squibb & Sons) to several of the smallest (e.g. Merck, Eli Lilly and Pfizer), to several companies that had no prior experience in the pharmaceutical business at all (e.g. Schenley Industries, Cutter Laboratories). The choice to use these firms was based on the need for a specific set of manufacturing equipment. There is a high degree of correlation between the 17 firms selected to participate in the program and the largest firms as at 1955. Direct governmental intervention, measured by the signing of penicillin contracts with the government, proved critical in determining which firms succeeded. Of the ten largest pharmaceutical firms in 1979, nine had participated in the OSRD penicillin program. By 2005, twelve of the seventeen still existed and they comprised all ten of the largest American pharmaceutical firms (Shah, 2012).

Case Study 2: Germany

In sales terms, Germany is the world's fourth largest pharmaceutical market. In 2013, 817 companies were registered as pharmaceutical companies in Germany. In the same year, revenues amounted to € 33.6 million (Thurbon et al., 2006). The country's pharmaceutical industry employed 110,036 staff in 2013 and exported products valued at € 57.1 billion in sales terms. The success of the pharmaceutical manufacturing industry in Germany may be attributed to factors that are in part similar to those that contributed to the success of the USA pharmaceutical industry.

The pharmaceutical industry in Germany benefits from internationally renowned scientists and world-class research institutions. German universities enjoy an excellent research and teaching reputation; All of the internationally established German research associations are highly active in the field of life sciences. The innovation work done in companies located in Germany is reflected in impressive patent figures. For example, in 2007, Germany was the European number one with 581 resident patent filings per million inhabitants, ahead of countries like Finland, Denmark and the UK. Germany is placed first in clinical trials conducted in Europe and second worldwide, with data quality at par with the US (Thurbon et al., 2006). More than 100 institutes are involved in clinical trials.



Collaboration between universities and pharmaceutical companies ranks high, for example, Bayer-Schering cooperates with the University of Cologne in the fields of preclinical research and clinical trials.

Federal Government Support ranks high. The German federal government invests approximately € 4billion in its "High-Tech Strategy" each year. By 2011, it is estimated that it provided €1.2 billion for R&D projects within the healthcare and biotechnology industries (Thurbon et al., 2006).

Experiences from Developing Countries

Argentina, Bangladesh, Brazil, China, India, Egypt, Jordan and South Africa have been significant producers and suppliers of cheaper medicines that presently serve the needs of their local markets and much of the developing world. Factors that account for the success of pharmaceutical industries in these countries are illustrated by the case studies of India, Bangladesh and Brazil.

Case Study 3: India

The Indian pharmaceutical industry is the world's third largest by volume, after USA and Germany (Germany Pharmaceutical Industry Association, 2013). This industry leads the manufacturing sector of India with over 20,000 registered drug manufacturers (Agrawal, Dua, Garg, Sara, & Taneja, 2006). The industry has been growing at approximately 10% per year. Currently, it is fourteenth in terms of value. India exports to 65 countries, with USA being its biggest market. The pharmaceutical industry's export was worth US$ 3.75 billion dollars in 2006 (Global Pharma, 2013).

At the time of independence in 1947, the pharmaceutical market in India was dominated by foreign companies. There was little or no control over the quality of drugs, prices tended to be high and ungoverned, and profiteering was rampant. It is against this backdrop that the Drug (Display of Prices) Order was passed in 1962 followed by the Drug (Prices Control) Order in 1963 (India Press Release, 2009). In 1970, the scope of price control was limited to 33 essential medicines. The government also set up production units in the public sector to manufacture new drugs needed for treatment of infectious diseases. The Intellectual Property Rights (IPR) system was radically changed through the Indian Patents Act of 1970 with the intention of creating a major incentive for domestic pharmaceuticals producers to innovate and develop new processes and products. Compounded with a favorable and enabling environment from the government, this Act made the Indian market undesirable to multinational companies. Local companies therefore carved a niche in both the local and world markets.

The government of India has undertaken several policy initiatives for the growth of the local pharmaceutical industry. The Indian Patents Act of 1970 created a major incentive for domestic pharmaceuticals producers to innovate and develop new processes and products. The first comprehensive pharmaceutical policy in India was formulated in 1978 (Department of Pharmaceuticals India, 2016). This policy has seen a number of changes through new policy guidelines issued in 1986, 1994 and recently in 2000 and 2006. The main objectives of the policy include: (i) to strengthen the indigenous capability for cost effective quality production and export of pharmaceutical products by reducing trade barriers in the pharmaceutical sector, (ii) to ensure quality control system for pharmaceutical production and distribution and to make quality an essential attribute of the domestic industry (iii) encouraging pharmaceutical Research & Development that is compatible with the country's needs. The country has public Research& development laboratories (iv) to encourage new investment in the pharmaceutical industry and the introduction of new technologies and new drugs.

Case Study 4: Bangladesh

The State of Bangladesh with a population of about 150 million is the only country among the 50 least developed countries (LDCs) that has a well-developed pharmaceutical industry and is nearly self-sufficient through local production (Bangladesh Bureau of Statistics, 2009). All the essential drugs are manufactured locally. Locally produced drugs account for over 80% of the market share and meet over 90% of the local demand (Bangladesh Bureau of Statistics, 2009). The competitive advantage for essential drugs manufacturing in Bangladesh as a LDC results from the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health which states that LDCs are exempted from the obligation to implement patent protection for product patents until 2016 and possibly beyond (Ulrike, 2007). The legal opportunities are concentrated around manufacturing of patent-protected drugs for the domestic market and for export to other LDCs without sufficient own production (Ulrike, 2007). Bangladesh, through the assistance of Indian and other foreign producers, has established itself as a major manufacturer and exporter of pharmaceutical formulations.

Bangladesh formulated its National Drug Policy and established the Drugs Control Ordinance in 1982, to ensure availability, affordability and safety of essential drugs (Bangladesh, 1982). The Drugs Control Ordinance regulates the manufacture, import, distribution and sale of drugs in Bangladesh. The Drugs Control Ordinance bans certain types of drugs with limited therapeutic usefulness from the market, limits the marketing rights of foreign companies and establishes a price control for both finished drugs and their raw materials. Foreign brands are not allowed to be manufactured under license in Bangladesh if similar products are being manufactured in the country. Multinational companies that do not have a production facility in Bangladesh are not allowed to market their products even if manufactured in the country by contract manufacturing.

The Ordinance identified 150 drugs as essential, with controlled price. For these, level prices are fixed for the finished drugs as well as for their corresponding raw

materials. No manufacturer can set maximum retail prices for their goods beyond that limit. Changes in these level prices are decided by the Drug Control Committee. For drugs that do not fall into the "Controlled Category", the manufacturer can set his own price, which must, however, be approved by the Drug Control Committee (Bangladesh, 1982). This resulted in withdrawal of many foreign companies from the market (in which they had had a share of around 70% in 1970) and strong growth in local production. The major impact of this Ordinance was the rapid development of local manufacturing capability (Amin, M. and Sonobe, T. 2013). As a result, the industry is dominated by local manufacturers. There are 224-licensed factories in the country, six of which are owned by multinational companies. Being a drug exporting LDC, Bangladesh has a unique position in the region, for not having to adhere to the TRIPS agreement till 2026. This has created huge export opportunities for Bangladesh (Alam, 2009). Bangladesh is exporting pharmaceutical products to 87 countries.

Case Study 5: Brazil

Brazil is the eleventh largest pharmaceutical market in the world in sales, and the sixth in volume. More than 300 companies, including subsidiaries of most major multinational laboratories and local pharmaceuticals, compose this industry (Shafiuzzaman, 2004). The overall capacity utilization stands at 74% (2009). The demand for pharmaceutical products grows approximately by 10% per year. This is due to better income distribution and improved access to health services and medicines. Multinational companies use Brazil as a production platform, exporting to Latin America, North America and Europe. The rise of domestic firms was mainly driven by three factors: the Brazilian government's industrial policy, new regulations and the introduction of generics. Domestic firms dominate this market segment and are expanding and modernizing production capacities. Research and innovation are concentrated at public institutions. There are more than 100 small biotechnology companies, most of them located in clusters linked to public universities and research centers. Brazil also produces 260 million doses of (human and veterinary) vaccines per year. The strong growth of generic drugs in Brazil is due to the combination of quality products with prices around 50% lower than brand products. Brazil has built a generic market based on internationally accepted scientific criteria (pharmaceutical equivalence, bioequivalence tests and cGMP certification) to establish efficacy and safety for generics and allow full interchangeability. The National Health Surveillance Agency, (Agência Nacional de VigilânciaSanitária, ANVISA) defines the reference product brand to which generics have to be therapeutically equivalent and also certifies local and international contract research organizations (CROs) through annual inspections. Pharmaceutical equivalence and bioequivalence tests are conducted by certified CROs only. The cGMP certification is mandatory for manufacturers of generic medicines. Local pharmaceutical manufacturing plants are inspected annually by ANVISA, which verifies whether drugs are being produced within the required quality standards and issues the cGMP certificates.

Policy Implications for Local Manufacturing in Sub-Saharan Africa

It is evident from the case studies that success in pharmaceutical industry both in the developed countries and the developing countries is pegged on demand for the products, governments have policies and business incentives to encourage production, regulation is enforced, sufficient human capacity availability, adequate infrastructure, and the individual manufacturers have heavily invested in GMPs, research and product development.

There are 37 countries in SSA engaged in pharmaceutical manufacturing supplying about 30% of the local market. South Africa, Kenya, Nigeria, Ghana have substantial pharmaceutical manufacturing plants. There exists huge demand for pharmaceutical products with the existence of trading blocs, such as the East African Community (EAC), Economic Community of West African States (ECOWAS), the Southern African Development Community (SADC) and the Common Market for Eastern & Southern Africa/East African Community (COMESA), offering an increasingly attractive market opportunity. The move towards harmonized medicine regulatory processes and removal of trade tariffs will strengthen the ease of doing business. However, a variety of hindrances are experienced by the pharmaceutical industry including importation of almost all pharmaceutical inputs, shortage of skilled labour, lack of advanced/modern technologies and relevant training institutions, weak legal and regulatory systems, poor infrastructure, unreliable energy supply amongst other challenges. These have made local production uncompetitive in many of the countries.

Given the multifaceted nature of efforts required to promote local pharmaceutical production, a comprehensive approach may be needed to address simultaneously the many issues that require attention – for example, access to technology, strengthening absorptive capacity, access to capital and infrastructure and a business-friendly regulatory system that enhances quality production while supporting local manufacturers. While some of these challenges will require technical and operational responses, the role of public policy in supporting the continued growth of the African pharmaceutical manufacturing sector cannot be over-emphasized. From the case studies presented above, there are lots of lessons that Africa can learn from both the mature and developed countries such as the USA and Germany as well as from developing countries such as India, Bangladesh and Brazil. In the sections below, we distil some of these policy lessons

Enhance the Role of Government as a Key Facilitator, Investor and Regulator

As all the cases demonstrate, whether in the developed or developing world, successful emergence of pharmaceutical manufacturing has benefitted from immense government support. The specific roles may differ, but in all cases the government has been a facilitator, a key investor and regulator. In the case of the USA for example, government enlisted the participation of private firms in the penicillin programme and the Office of Science Research and Development (OSRD) was given the authority to involve private corporations in the research and development processes for mass production, sharing with these selected firms all the previously classified information about penicillin production. Some of the firms that participated in this programme are the world leaders in Pharmaceutical production even today. In Germany, the federal government invests approximately € 4billion in its "High-Tech Strategy" each year. By 2011, it is estimated that it provided €1.2 billion for R&D projects within the healthcare and biotechnology industries. Similarly in Bangladesh, the role of government as a regulator is key: For example, the Drugs Control Ordinance (1982) regulates the manufacture, import, distribution and sale of drugs in Bangladesh. Under this Ordinance, no medicine of any kind can be manufactured for sale or be imported, distributed or sold unless it is registered with the licensing authority. The Drugs Control Ordinance bans certain types of drugs with limited therapeutic usefulness from the market, limits the marketing rights of foreign companies and establishes a price control for both finished drugs and their raw materials. As these examples show, all the successful cases have received direct support from their national governments. The spotlight turns on African governments and their level of practical support to the local manufacturing beyond the rhetoric.

Use of National Emergencies and Disasters as Opportunities to Build Response Capacities

The USA took the opportunity afforded by the high demand for penicillin during the World war II to enhance its capacity to manufacture not just penicillin but pharmaceuticals more generally. They saw the opportunity and seized it in a case of turning emergencies into opportunities. In 2014 and much of 2015, the Ebola crisis ravaged most of the West African countries leading to loss of lives and destroying the already weak health systems in these countries. Did Africa just bungle an opportunity afforded by the Ebola crisis? How have African governments utilized national disasters and emergencies to galvanize national institutions and support them to address such national challenges? African responses always seem to look outside for immediate help and quickly forget to build endogenous capacity to respond to similar emergencies and disasters tomorrow or in neighbouring countries.

Form Strategic Partnerships for Research and Innovation

Critical to attaining and sustaining competitiveness is the ability to develop linkages with a wide set of knowledge inputs and/or build the requisite capabilities in-house. Choices about the development trajectories (whether to simply import or manufacture locally) is likely to lead to significantly different learning outcomes. Knowledge creation (research) and application (innovation) are rooted in institutional contexts (Mytelka, 2000). Building the knowledge base and strengthening the linkages between knowledge producers and users is critical in shaping the direction of development.

The success of the German pharmaceutical industry is closely linked to its excellent R&D landscape in the Universities and Research Institutes and the close collaborations with private sector firms. This allows for knowledge exchange, skilled manpower, infrastructure sharing. In Brazil, for example, research and innovation are concentrated at public institutions with more than 100 small biotechnology companies, most of them located in clusters linked to public universities and research centres, Brazil produces 260 million doses of (human and veterinary) vaccines per year. In SSA, it is 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 in 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.

Consolidate to fewer, more Viable Companies

Currently there are over 500 local pharmaceutical manufacturing firms in 37 countries in Africa. Their capacities vary greatly and they produce mostly the same range of products, supplying the same markets. Africa may learn from the experiences of the USA where between 1940 and 1950 the American pharmaceutical industry transformed itself from a collection of several hundred, small, barely profitable firms to a small group of 15 large, highly profitable firms, and together they accounted for 80% of the entire industry's sales and 90% of its profits. It may make sense for some of these companies to merge and form stronger companies with requisite capacity to compete in the international markets.

Actively Utilize International Agreements such as TRIPS to facilitate access to Technology and Infrastructure

The competitive advantage for essential drugs manufacturing in Bangladesh as a LDC results from the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It is the only country among the 50 least developed countries (LDCs) that has a well-developed pharmaceutical industry and is nearly self-sufficient through local production. All the essential drugs are manufactured locally. Locally produced drugs account for over 80% of the market share and meet over 90% of the local demand (Bangladesh Bureau of Statistics, 2009).

Africa is yet to reap the full benefits of the TRIPS agreement but there are few notable examples. In a notable case of south – south technology transfer, Uganda represents a country where a firm from a developing country (Cipla, India) has opted to transfer technology to manufacture finished pharmaceutical products in an LDC. The Government of Uganda reached out to Cipla Ltd, one of the world's leading pharmaceutical manufacturers, urging them to partner with a local firm, Quality Chemicals Ltd (QCL), to enable the country to locally manufacture antiretroviral drugs to combat HIV/AIDS and anti-malarial drugs. The TRIPS agreement allows Least Developed Countries like Uganda to set up pharmaceutical facilities and manufacture medicines that are still under patent. QCL took advantage of the flexibilities and founded QCIL which has been approved by the World Health Organization (WHO) as an additional contract manufacturing site for Cipla Ltd's antiretroviral and antimalarial drugs.

Similarly, the case of Aspen Pharmacare in South Africa demonstrates that with appropriate government incentives, voluntary licenses and technology transfers from multinationals, generic pharmaceutical manufacturers located in developing countries can become low-cost producers of the life-extending drugs that HIV-infected individuals require. Aspen took good advantage of the voluntary license offered by GSK, to successfully develop into and sustain a viable local ARV manufacturing company. By signing voluntary license agreements with Boehringer Ingelheim and GlaxoSmithKline (GSK), Aspen was permitted both the production and the sale of nevirapine, AZT and lamivudine (commonly known as 3TC) within South Africa and for export to 47 countries in Africa for a royalty of no more than five percent of net sales.

Aspen Pharmacare is currently producing significant amounts of first and second line ARVs, as well as multi-drug resistant (MDR) tuberculosis drugs under voluntary licenses with Eli Lilly, GlaxoSmithKline, Gilead Sciences, Boehringer Ingelheim, Bristol-Myers Squibb, F. Hoffmann-La Roche Ltd., and Merck Sharpe & Dohme. These agreements demonstrate that voluntary licenses could, in the right environment, be profitably exploited to improve access to medicines. African governments need to step up efforts to exploit flexibilities under the TRIPS to bolster local production.

Employ Tax and Fiscal Incentives to Finance Research, Innovation and Technology Development

In India, the government has adopted several measures to promote local production including tax breaks such as eligibility for weighted tax reduction at 150% for the research and development expenditure obtained. Under the existing provisions of section 35 of the income tax act, a company is allowed weighted deduction of 150% of the expenditure incurred on scientific research on an approved in-house research and development facility. To further promote this investment in research, it is proposed to increase this weighted deduction from 150 % to 200%. Two new schemes namely, the New Millennium Indian Technology Leadership Initiative (NMITLI) and the Drugs and Pharmaceuticals Research Program have been launched by the government with the objective to synergize the strengths of publicly funded research and development institutions and Indian pharmaceutical industry and to create an enabling infrastructure, mechanisms and linkages so as to facilitate new drug development. India has one of the highest import duty regimes, with ranges of between 25 and 35% for API, and up to a maximum of 56% for finished formulations (India Press Release, 2009).

Similarly in the USA, tax credits have been used to support the pharmaceutical sector and three kinds of tax credit are available to pharmaceutical companies including:(i) a research and experimentation credit allows companies to lower their taxes in return for increasing the amount they spend on in-house research, (ii) a basic research credit encourages companies to fund scientific investigations at universities and (iii) an orphan drug credit rewards the development of drugs for rare diseases as part of the Orphan Drug Act. The Government supports all patents by granting inventors 20 years from the date of filing to prevent anyone else from manufacturing, distributing or selling their invention (Hedwig, 2012).

Meanwhile, African governments shy away from using tax credits as a means of supporting R&D due to weak legislations that expose governments to abuse. Further, the investment in R&D by African governments is low and insignificant. Convincing studies on Return on Investment for R&D are hard to come by.

References

Agrawal, A., Dua, K., Garg, V., Sara, U. & Taneja, A. (2006). Challenges and opportunities for the Indian Pharma Industry. Health Administrator 20 (1&2): 109-113.

Alam, F. (2009). Bangladesh's Growing Pharmaceutical Sector. Retrieved from http://www.thefinancialexpress-bd.com/2009/08/17/76297.html on 18th December 2014.

Amin, M. and Sonobe, T. (2013). The success of the industrial development policy in the pharmaceutical industry in Bangladesh (No. 13-07). National Graduate Institute for Policy Studies.

Bangladesh Bureau of Statistics. (2009). Parishankhyan Bhaban, E-27/A, Agargaon Sher-e-Bangla Nagar, Dhaka-1207, Bangladesh. Statistical Pocket Book - 2009, pg. 12.

Department of Pharmaceuticals India. (2016). India pharmaceutical policy (2002). Retrieved from: http://pharmaceuticals.gov.in/policy. Accessed on 18th May, 2015.

Germany Pharmaceutical Industry Association. (2013). Pharma - Data 2013. 43rd revised edition, Berlin. Retrieved from: http://www.bpi.de/fileadmin/media/bpi/Downloads/Internet/Publikationen/Pharma-Daten/Pharmadaten_2013_EN.pdf. Accessed on 18th May, 2015.

Global Pharma. (2013). Unlocking the potential of the Indian pharmaceutical market, MC Kinsey& Company.

Hedwig, N. (2012). Impact of public procurement on economic growth and development A Case Study of the Pharmaceutical Industry in Kenya. The Procurement and Supplies Professionals and Technicians Board Annual Conference, Arusha, Tanzania.

India Press Release. (2009). New Millennium Indian Technology Leadership Initiative (NMITLI). Retrieved from http://dst.gov.in/whats_new/press-release09/new-millennium-scheme.htm on October, 30, 2013.

Khurana, G. & Jaipuriar, N. (2014). The Indian Pharmaceutical market Indian Pharmaceutical Market - India Law Offices. Retrieved from www.indialawoffices.com/pdf/pharmaceuticalmarket.pdf on December 15th 2014.

Mytelka, L. K (2000). Local Systems of Innovation in a Globalized World Economy, in Industry and Innovation, Vol. 7, No. 1, June, pp. 33-54.

Shafiuzzaman, S.M. (2004). Bangladesh Pharmaceutical Sector: A vision of Success.

Shah, V. (2012). Evolution of Pharmaceutical Industry: A Global Indian & Gujarat Perspective. Journal of Pharmacetical Science and Bioscientific Research (JPSBR). 2271-3681.

Thurbon et al. (2006): The business of buying America: public procurement as a business strategy in the USA. Review of international political economy 13(701-724).

Ulrike, P. C. (2007). Study on the Viability of High Quality Drugs Manufacturing in Bangladesh, Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH.

Watu, B. W. & Kungu, J. K. (2014). Pharmaceutical manufacturing in Kenya: Key Trends and developments; Africa centre for technology studies, Working Brief No. 3, September 2014.

Annex 1: Status of pharmaceutical manufacturing in Africa

Country	Regulatory authority	Number of companies	# of PQ labs	# of PQ firms	Share of local market	Source of raw material	Export/ regional trade	Status, policies and government incentives
Algeria	Directorate of Pharmacy and Medicines	30	1	1	50%	Import	No	• In 2008, importation of products that are manufactured locally prohibited (409 products). • Foreign companies must establish local sites with R&D within 2 years of product registration • Foreign companies must have local partnerships95
Egypt	Egyptian Drug Authority (EDA)	68	1	2	83%	Import/ Local	30% of regional market	• Government encourages voluntary licensing
Ethiopia	Ministry of Health	13	0	3	15%	Import	yes	• Products include medical supplies; finished product formulation using imported raw materials and one company produces empty gelatin capsules. • Price preference for locally produced products in government tenders, • 100% exemption from payments of customs duties on capital goods, such as plant machinery, & equipment • Those exporting will be exempted from income tax for a defined period based on percentage export Free' land for pharmaceutical expansion
Ghana	Food and Drugs Board	38	0	0	30%	Import/ local	Yes/ to west Africa	• 20% price preference for locally produced products in tenders, • Locally manufactured products are zero rated under the value added tax law • No duties on imports of raw material/packaging material, pharmaceutical equipment, spares and change parts. Importation prohibited for 44 pharmaceutical products.
Kenya	Pharmacy &Poisons Board	30	2	1	30%	Import	25-40%; mainly to EAC/ Comesa	• Dates back to 1940s; engaged in secondary manufacture and produce mainly non-sterile products; tablets, capsules, liquid preparations, creams and ointments. • The local industry exhibits varied cGMP standards with one company, Universal Corporation having achieved WHO prequalification status in 2011, three obtained PIC/s accreditation in 2007 and others are upgrading their facilities in line with the prescribed Kenya cGMP Roadmap – 2014 • 15 % price preference for locally produced products in tenders, • The manufacturers face internal competition and increasing volumes of low priced imports. Kenyan producers are also disadvantaged especially regarding donor-funded procurement mainly due to the non-WHO prequalification status, high production costs and importation of more than 90% of the pharmaceutical inputs
Malawi	Pharmacy, Medicines and Poisons Board	4	0		10-15%	Import	No	• Produce over the counter (OTC) medicines and some IV fluids. • Locally manufactured pharmaceutical products tend to be 100% more expensive due to high cost of imported materials and labour • Although local manufacturers produce less than 5% of the country's needs, they produce about 140 products, including essential medicines. • 10% price preference for locally produced products in government tenders,

Country	Regulatory authority	Number of companies	# of PQ labs	# of PQ firms	Share of local market	Source of raw material	Export/ regional trade	Status, policies and government incentives
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	150+	4	4	25%	Import	No	• Nigeria has about 12 manufacturers of ARVs and 18 manufacturers of ACTs. • The sector has a potential market value of around US$ 600 million and employs about 500,000 persons in the manufacturing and distribution chain. • About 60% of pharmaceutical production in the Economic Community of West African States (ECOWAS) is domiciled in Nigeria. • All active pharmaceutical ingredients (APIs) used in Nigeria are imported, mainly from India and China • Product range include: Analgesics/anti-rheumatic, anti-bacterials, multivitamins, haematinics, anti-malarial medicines anti-hypertensives, cough and cold preparations, anti-retroviral medicines, external/topical preparations and Anti-TB medicines. • Currently, 4 local drug manufacturers, have obtained World Health Organization (WHO) prequalification status which would enable them to take part in international tenders. • In April 2005 the import of 18 essential medicines was banned in order to encourage local production • Up to 120 % of expenses on (R&D) are tax deductible
South Africa	Medicines Control council	32	2	2	40%	Import/ local	Yes	• The largest in Africa and was worth US$ 3.7 billion, in 2011, forecasted to reach US$ 4 billion in 2012. The manufacturing base comprised 26 companies (32 Plants) with a direct workforce over of 9,500 in 2009. • The top 3 manufacturers in South Africa are Aspen Pharmacare Holdings Ltd, Adcock Ingram Healthcare (Pty) Ltd and Cipla Medpro • Aspen's maturity in the domestic market resulted from a strong partnership with GSK which included product licensing arrangements as well as skills and equity transfer. • According to World Bank (2005), locally owned South African manufacturers sourced 39% of active ingredients, 97% of packing materials and 49% of excipients locally (Gauteng Company Agency, 2014). • South Africa has zero customs duty and exports products to Zimbabwe, United States, Zambia, Hong Kong, Kenya, Mozambique, Mauritius, Netherlands, Australia and Tanzania. • Government encourages voluntary licensing and technology transfer • South Africa designates certain products and portions of some tenders for procurement only from locally manufactured products (now moving to 75% local content law)
Tanzania	Tanzania Food &drugs Authority	8	1	0	30%	Import	Yes	• 15 % price preference for locally produced products in tenders
Tunisia	Directorate of Pharmacy and Medicines	20	0	0		Import	Yes/ Middle east	• Once a generic product is produced in sufficient quantities (and quality) to meet the local demand, importation of the finished product is prohibited.

Country	Regulatory authority	Number of companies	# of PQ labs	# of PQ firms	Share of local market	Source of raw material	Export/ regional trade	Status, policies and government incentives
Uganda	Uganda National Drugs Authority	13	1	1	5%	Import	Yes	• Produce mainly injectables, tablets, syrups and liquid mixtures and surgical gauze • There is no customs duty on pharmaceutical products in Uganda, hence local production faces strong competition from similar imported finished products • As of end January 2010, out of the 13 local pharmaceutical manufacturers, only Quality Chemical Industries Limited (QCIL) was WHO GMP certified and no locally produced ACTs and ARVs were WHO prequalified. • Government encourages voluntary licensing and technology transfer
Zambia	Zambia Medicines Regulatory Authority	7	0			Import	No	• Locally manufactured products consist of over-the-counter medicines such as tablets, analgesics, syrups and also some antibiotics and sterile products • Almost all of the raw materials are imported (from India, China and South Africa) except for sugar • The main export destination is Malawi with some exports to southern DRC. • The 15% preference over imported products in government tenders
Zimbabwe	Medicines Control Authority of Zimbabwe	14	1			Import	Yes	• None of the manufacturers are owned by, or subsidiaries of, multinational companies. • Zimbabwe imposes duties on raw pharmaceutical materials but none on imported finished products • Zimbabwe exports to countries in the region, namely Zambia and Malawi. These exports were worth a total of US$1.8million in 2009 • 25% local preference on public and government tenders • Removal of duties and VAT on pharmaceutical raw and packaging materials • Reduction in utility tariffs • Import bans on products which are manufactured locally

Source: Compiled by authors from various sources

For more information, contact us:
The Scinnovent Centre
P.O. Box 52486 - 00100, Nairobi, Kenya
Tel/Fax: + 254-20-2173433
Tel: +254-20-2470946
Email: info@scinnovent.org
Web: www.scinnovent.org
Twitter: @Scinnovent
Facebook: www.facebook.com/scinnovent
Blog: www.scinnovent.wordpress.com
Slideshare: www.slideshare.net/Scinnovent
LinkedIn: www.linkedin.com/company/the-scinnovent-centre
YouTube: https://www.youtube.com/user/TheScinnoventCentre