AN EVALUATION OF THE FACTORS INFLUENCING THE ESTABLISHMENT OF THE DOMESTIC PHARMACEUTICAL MANUFACTURING INDUSTRY IN ZAMBIA

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ABSTRACT

This study evaluates the factors that influence the establishment of a domestic pharmaceutical manufacturing industry in Zambia. The study was prompted by empirical evidence signifying a downward trend in the local pharmaceutical manufacturing capacity, which has led to a declining growth of the industry, despite the country's current positive economic growth of above 5% of Gross Domestic Product. Literature on the pull and push factors looked at the challenges that political, economic, social and technologic factors have on the industry. A critical assessment of the procedures involved in establishing medicine manufacturing, and an analysis of the appropriate marketing strategies employed by firms, provided a framework of the study. The study adopted a quantitative design approach using a questionnaire on a sample of 25 participants with relevant experience in the pharmaceutical sector in evaluating and assessing the various key factors related to the industry. The findings revealed that local manufacturing of essential medicines and developing domestic plants in Zambia meets with manifold challenges related to internal dimensions of manufacturing. The lack of incentives, adequately trained human resource, capital, market size, infrastructure and regulatory capacity on pharmaceutical standards and partnerships needed to foster innovation and technological transfer that have a direct impact on the growth of the industry. Data from the study has clearly indicated the need to enhance pharmaceutical production and promote its viability through the usage of appropriate marketing strategies. One of the key recommendations made from the study on how the industry can remain viable and improves its performance, is by the Government implementing the provisions of the National Drug Policy of 1999. The study clearly shows that the development of the industry is feasible, as policies and legal provisions are in place. The market should promote local pharmaceutical production that will enhance increased accessibility of medicines thereby improving the quality of health, contribute to employment creation, reduce poverty levels and improve the country's overall Gross Domestic Product.

Key Words: Factors; Establishment; Domestic; Pharmaceutical Industry; Imports; Economy; Diseases; Employment

Introduction

Zambia as a country, has been registering a positive economic growth of over 5% from the late 1990's, to date (Zambia Investment Guide, 2012:2). The Government of the Republic of Zambia has identified the manufacturing sector to be a leading sector in the revitalisation of the economy, as identified in the Strategy for Zambia's Social Economic Development and Poverty Reduction paper (International Monetary Fund, 2007:21). Despite this favourable economic status of the country, the Pharmaceutical manufacturing industry in Zambia has been lagging behind due to the inability to compete with the imported finished pharmaceutical products. The past two decades has seen a decline in the number of industries which has led to a reduction in the availability of locally produced medicines in the market. Data from the Pharmaceutical Regulatory Authority (2012) indicate that only 223 registered medicines are produced locally out of over 4000 medicines on the register as of 2011. The importation of medicines in Zambia is actually more favourable by most wholesalers, as they do not attract government taxes. This trend however, puts pressure on local manufacturers who are subjected to taxes, especially on packaging materials, electricity, water and other raw materials, with an exception of Active Pharmaceutical Ingredients (API). The resultant effect has brought about failure to compete with imported finished products which are cheaper than locally manufactured ones. The study evaluates the factors influencing the establishment of local pharmaceutical companies in Zambia.

LITERATURE REVIEW

Introduction

In this study, relevant literature pertained to: the outlook of the pharmaceutical industry in Africa and globally, challenges faced by the industry locally, a macro and micro environmental analysis of the pharmaceutical business, examination of the processes involved in setting up the industry and viability of the industry are discussed.

Africa and Global Pharmaceutical Business Outlook

Africa is confronted by a very high disease burden, with infectious diseases taking a heavy toll on people's health thereby impacting on the socio – economic status of these individuals (Mumbai, 2010: 4). Africa is also characterized by the lack of incentives and partnerships needed to foster innovation and scale-up research on neglected and emerging infectious diseases that affect its people. The lack of adequately trained human resources, infrastructure and regulatory capacity on health research and pharmaceutical innovation, greatly affects the drive for Africa in attaining technical and socio-economic development. African governments have, in recent years, taken significant steps to address their health challenges and access to medicines. In 2005, AU Conference on Health, Ministers in Gaborone adopted a clear policy position on the local production of generic medicines to make full use of flexibilities in the Trade and Related Aspects of Intellectual Property Rights (TRIPS), and the Doha Declaration on public health (Mumba, 2010: 3). The agreement on TRIPS is an international agreement administered by the World Trade Organisation (WTO), which sets down minimum standards for many forms of intellectual property regulation, as applied to nationals of other WTO Members.

UNIDO recognizes that the primary driver of economic growth, employment creation and reduction in poverty, is centred on the private sector, which is key in achieving the MDGs (UNIDO, 2009:9). The pharmaceutical manufacturing industries stand a good chance of enhancing poverty reduction and accelerating economic growth, once given the support.

Pharmaceutical industries in Zambia and most African countries have faced challenges in aligning to the current global trends in the market forces. The lack of an in-depth analysis into the rivalry amongst the industry players and the market environment, has led to a decline in the manufacturing output of the industry.

Overview and challenges faced by the Pharmaceutical industry

Zambia has five main manufacturers of pharmaceutical products. It is estimated that the local production represents between 10-15% of the demand for pharmaceuticals in Zambia (MeTA, 2010:12). According to the Cardino Shaping Future Report (2011:11), Zambia has no multinational pharmaceutical companies, and the five currently operating may be categorised as Uni-national pharmaceutical companies. These companies mostly do the secondary production which is the formulation of bulk pharmaceuticals into various pharmaceutical dosage forms, according to Management Science for Health (1997:47).

In 2001, developing countries were concerned that developed countries were insisting on implementing TRIPS, and thus pushed for the Doha Declaration which stated that TRIPS should be interpreted in light of the goal of promoting access to medicines. The obligations under TRIPS apply equally to all member states, including Zambia. The main controversy with TRIPS has mainly been that developed countries take advantage of being massive net-exporters of copyright, patents and trade mark related royalties. The TRIPS standard of requiring all countries to create strict intellectual property systems is therefore inimical to poorer countries.

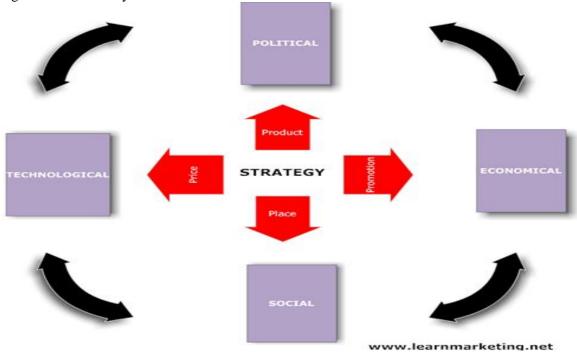
The current trend in Zambia is that there are no local manufacturers utilising TRIPS related flexibilities to locally produce on patent essential medicines. The existing manufacturing plants do not meet the required standards for acquiring compulsory manufacturing licences that would permit local firms to produce on-patent medicines (Beall and Kuhn, 2012:61). However, under the same law, established foreign pharmaceutical manufacturers are able to produce cheaper generics of on-patent medicines for export to impoverished developing countries thereby making it difficult for local manufacturers to compete.

The local manufacturing of essential medicines in Zambia meets with manifold challenges related to internal dimensions of manufacturing and also, the operating environment. The manufacturing companies do not meet WHO pre-qualification standards, limits their production and excludes them from participating in international public tenders. According to the Survey of Pharmaceutical Industries by Cardino Emerging Markets Report (2010), weaknesses in manufacturing plant levels, affects firms from reaching and maintaining quality standards in line with World Health Organisation Good Manufacturing Practices (GMP). The failure to attain these standards stem from the lack of capital and lack of highly specialized human resources skills required for the manufacture of medicines. Beyond the plant, the small size of domestic markets diminishes the prospects for achieving optimal production efficacy. Furthermore, the business environment in general has deficits and in particular, the pharmaceutical sector lacks effective support functions to promote local manufacturing. According to a study conducted by MeTA (2010), despite existing investment incentives for manufacturers of duty free importation on raw materials, the pharmaceutical sector have to pay import duties (5%-25%) and VAT (16%) on packaging materials. The study however, did not highlight the impact of VAT on profitability of the firms as no figures were substantiated.

Macro and Micro Environmental Factors affecting the Industry Macro Environmental Factors

In analysing the macro-environment, it is important to identify the factors that might in turn affect a number of vital variables that are likely to influence the organisation's supply and demand levels (inclusive of its costs) (Kotter and Schlesinger, 2005:112). It is important to categorize environmental influences such as political, economic, social and technological forces (PEST) in analyzing performance as highlighted by Figure 2.4.1. Kotler (2008:67) claims that PEST analysis is a useful strategic tool and as such, provides useful insights in evaluating the factors influencing the domestic pharmaceutical manufacturing industry in Zambia.

Figure 1. PEST Analysis



Source: www.learnmarketing.net

Political Factors

It is worth noting that the National Drug Policy (NDP) of 1999 was quite favorable in principle to promoting the growth of pharmaceutical manufacturing industries. The Ministry's Strategic Plan (2006-2010) is also categorical in specifying that the ministry would encourage the establishment of a strong local pharmaceutical industry to lower the costs of drugs (National Health Sector Strategic Plan, 2006:33). Section 5 of the NDP, has a provision that discriminatory tariffs promoting imported finished pharmaceuticals was to be abolished. Furthermore, the policy mentions that MoH shall use Government drug funds to procure locally manufactured pharmaceuticals (National Drug Policy, 1999:10). The Pharmaceutical Act No. 14 of 2004 is also in place that helps with registration and regulation of the pharmaceutical business.

The MoH in its procurement operations is guided by the Zambia Public Procurement Authority (ZPPA) laid down procedures for public procurement. Unfortunately, most pharmaceuticals are imported and less is procured locally by the Ministry, a situation which has contributed to the downsizing of the industry presented in Table 2.4.1.

Table 2.4.1: Total value of medicines procured by Ministry of Health

Year	Imports (value US\$ 000)	Locally produced (value in \$ 000)	Total value (value in US\$, 000)	Percentage of value spent
2008	24,000	890	24,890	3.6
2009	28,000	895	28,895	3.0
2010	16,000	100	16,000	0.6
Total	68,000	1,885	94,675	2

Source: MoH Procurement Unit (2004)

When compared with countries like Ghana, the market for pharmaceuticals is larger than that in Zambia, and with favourable trade policies, encourages more pharmaceutical companies penetrating the market (Ballous-Aares et al, 2008:45). As a result, the 35 local manufacturers in Ghana produce roughly 30% of total medicines, while in Zambia, the 5 local manufacturers account for a much smaller fraction of the supply (Dahlberg, 2008:24). The author however, did not illustrate how small this fraction is in comparison to the total medicines requirement in country.

From the political point of view, there has been willingness by the government in ensuring that appropriate policies are in place to stimulate local production despite the challenges in implementation.

Economic Factors

Zambia's economic performance in recent years has been positive, with real Gross Domestic Product (GDP) growth rising to 6.8% in 2011 from 5.3% in 2005, according to the Zambia Investment Guide (2012). The Government's macroeconomic objectives in 2011 were to continue with the diversification program, while increasing productive employment and maintaining a stable macroeconomic environment through attaining real GDP growth of above 6%; and reducing end-year inflation to 7%. With this level of economic growth, various sectors in the economy, especially the Pharmaceutical manufacturing, should take advantage of a conducive environment for business, as presented in Table 2.4.2.

Table 2.4.2 Selected Macroeconomic Performance Indicators, 2005-2010

	2005	2006	2007	2008	2009	2010	2011
Real GDP growth (end- Year %)	5.3	6.2	6.2	5.7	6.4	7.6	6.8
GDP per capita (end-year US \$)	650	908	949	1,170	1,050	1,200	1,463
Annual Inflation end- period (%)	15.9	8.2	8.9	16.6	9.9	7.9	7.2

Source: Zambia Investment Guide (2012: 4)

Reich (1987:22) mentioned that poor countries should develop a long pharmaceutical manufacturing industry to reduce medicines costs, cut foreign exchange expenditures, and provide employment opportunities for the locals, as part of the broader strategy of import substitution and economic development. Similarly, proponents of local pharmaceutical production, including activist organisations such as Medicines Sans Frontiers' (Doctors without Borders) are in support of Reich's publication (Bate, 2008:3).

However, according to Kaplan and Laing (2005:32), the raw materials and equipment used in pharmaceutical production may be imported, and therefore require foreign currency. This

supports the findings of Mhamba and Mbirigenda (2010), who indicated that pharmaceutical manufacturers in the respective countries studied, including Zambia, import most of the raw materials, equipment and spare parts from India and China thereby utilising foreign currency. Kaplan and Lang (2005: 41) observed that the local production may not necessary save foreign currency since most low-middle income countries in Africa import raw materials from international countries can be viewed to be correct, but this claim still requires more study.

Social Factors

Many other social or cultural factors influence market habits for consumption of healthcare products. This is true for the Zambian market which has an inclination towards foreign produced products. Zambian consumers prefer foreign brands to local and this was clearly highlighted by the Zambian Pharmaceuticals manufacturers' conference organized by MeTA in 2010. Social and cultural attitudes affect healthcare and pharmaceutical marketing outcomes. In China, the market penetration of modern medicines is lower than that of traditional Chinese medicinal products (Deccan, 2011:8). A good percentage of Zambians, especially in the rural areas believe in the usage of traditional medicines for treating many health ailments. Evidently, the public has confidence in Traditional Medicine Practitioners and the products they dispense. Traditional medicine has a long history of use in the country and it is an inseparable part of African culture (WHO, 2006: 22).

Technological Factors

An assessment of local production of medicines conducted by a WHO team of experts in some African countries indicated that out of forty six (46) countries, thirty four (34) have secondary level production and nine (9) countries have no production capacity. Mhamba and Mbirigenda (2010) revealed that the pharmaceutical manufacturing companies lacked advanced equipment or machinery, and skilled trained personnel. In the UNIDO report (2010), it is indicated that better machinery and equipment will increase production capacity for pharmaceutical companies. Zambian Pharmaceutical companies lack the advanced technology in modern day manufacturing thereby affecting productivity (MeTA, 2010:13).

Pharmaceutical production is capital, technology and knowledge intensive, which means that the appropriate technical expertise is absolutely critical, both in terms of sufficient numbers and appropriate skills, (Seita, 2005:7).

The pharmaceutical industry requires sophisticated and highly skilled workforce. It is capital and technology dependent and therefore, may not create entry-level employment (Kaplan and Lang, 2005:56). This supports the argument by Berger, Murugi, Buch, IJsselmuiden, Kennedy, Moran, Guzman, Devlin and Kubata (2008: 67) that local production is highly capital-intensive, requires skilled personnel and employs relatively few people.

Import and Export Considerations

Business enterprises, especially when setting up a pharmaceutical manufacturing industry, have to be aware of the import and export procedures, and other international trade considerations in the country. According to the Zambia investment guide (2012:8), all goods imported must pass through customs clearance and valuation. Zambia applies tariffs on the cost, insurance and freight basis. Custom tariffs are calculated on the basis of the dutiable value, based on the WTO Agreement on Customs Valuation.

The procedures above guide the prospective investor in understanding the processes involved in setting up a pharmaceutical manufacturing plant in Zambia.

Strategic Marketing and Business Environment of the Pharmaceutical Sector

Domestic production can only be a solution to fill the supply gap for medicines in countries where the environment will not prove to be a barrier to production. The economy and political system must be sufficiently stable to support this enterprise. It is important to note that domestic production of pharmaceuticals requires that producers offer prices that are competitive with the markets (World Bank Report, 2008:21). Many domestic manufacturers cite the high cost of bioequivalency tests, API import costs, inadequate market share, breaking into the supply chain that is already well- established, and lack of economies of scale as barriers to entry into the market (Perkins, 2009:33).

A business has to understand the dynamics of its industries and markets in order to compete effectively in the marketplace. Porter (1980:91) defined the forces which drive competition, contending that the competitive environment is created by the interaction of five different forces acting on a business. In addition to rivalry among existing firms and the threat of new entrants into the market, there are also the forces of supplier power, the power of the buyers, and the threat of substitute products or services. The intensity of competition is determined by the relative strengths of these forces. Pharmaceutical companies must seek to understand the nature of their competitive environment if they are to be successful in achieving their objectives and establishing appropriate marketing strategies. Haberberg and Rieple (2001:231) state that the nature of competition in an industry is strongly affected by not only porter's five force of competition but also the structure of the industry itself may play an important role. The structure of an industry determines organisations' competitive behaviour, which in turn determines their profitability. However, in the quest of encouraging domestic production, it is also important to note that Zambia does not have comparative advantage in the pharmaceuticals industry and as such, it would be very difficult to produce generics more cheaply than China or India, and this would render the industry non-viable (McGreevey, 2009:17).

However, it is also key to note that strategic alliances are being observed with big multinational companies and local African producers i.e. Chinese pharmaceutical company, Adams Pharmaceutical Co. Ltd agreed to a joint venture with Danpong Pharmaceuticals Ghana Ltd in the creation of Danadams; Indian Generic Pharmaceutical company, Cipla works directly with Ugandan pharmaceutical importer Quality Chemical Industries in the manufacture of ARVs combination therapy. Many of these large pharmaceutical industries are seeing opportunities in Africa and as such, Zambia can take advantage of this and position itself being a politically and economically stable country in the region. According to the Economics Review (2002:27), there is a fear that domestic production in Africa is an attempt at the infant industry model which always fails. Economics has revealed that the protection of a domestic industry using tariffs and trade barriers never benefits consumers, and decreases the net welfare of the country. Domestic producers should have to bid for the lowest prices like any other company so that they are forced to be efficient. The infant industry model was designed for the sole purpose of benefiting the domestic economy, disregarding the current level of supply. Kaplan and Lang (2010) explain that smaller local companies may not be in a position to compete with larger foreign companies who may enjoy economies of scale. Smaller companies may not often compete either in quality or in price with those products manufactured by larger companies. Most developing countries as already mentioned by Mhamba and Mbirigenda (2010), UNIDO - Kenya (2010), UNIDO -Uganda (2010) do export very limited products. This is supported by findings in the 2008 International Finance Corporation report as cited by Berger et al. (2008: 46) that Nigeria, Ghana

and Kenya together represent about 20% of Sub-Saharan Africa's pharmaceutical production. Among the three countries, only Kenya produces significant volumes for regional export.

Domestic production is what Zambia and most African countries need to embark on using the legal framework provided by Article 6(i) of the Doha Declaration on the TRIPS Agreement of 2003, coupled with financing from the World Bank. The World Bank in 2009, gave \$297.2 million solely for Sub-Saharan African private sector development, which is a good indication that countries like Zambia can benefit from these loans, as long as companies proposals are in line with Doha Agreement Clause which states that a producer in an economic community composed of more than 50% least developed countries, can produce without patents as long as more than 50% of the products are exported. The SADC region does qualify to this criteria, thereby pointing out that Zambia's manufacturing firms stands a good chance of meeting the requirements in accessing the loans. Zambia is well positioned to take up this challenge, especially because it borders with nine countries with a similar disease pattern of HIV/AIDS, Malaria and TB as the main public health notable conditions.

RESEARCH METHODOLOGY

Target Population

Cooper and Schindler (2003:179) define a population as the total collection of elements from which a researcher wishes to make inferences. The target population of one hundred (100), for the study, are personnel with industrial based knowledge in pharmaceutical manufacturing. This consisted of individuals situated at 13 pharmaceutical companies in Zambia.

Categories of Sampling

Bhattacharyya (2003:79) submits that there are two categories of sampling, namely probability sampling and non-probability sampling. Probability sampling implies that the chance or probability of each case being selected from the population is known and usually equal in all cases. Hence, it is possible to answer research questions and to achieve objectives that require that the characteristics of the population be estimated statistically from the sample. The criterion was that respondents need to be situated in a pharmaceutical manufacturing company.

Limitations of the Study

This study was limited to evaluating the factors influencing the establishment of a domestic pharmaceutical industry in Zambia. The research was also limited by looking at mostly personnel with an experience in the pharmaceutical industry in Zambia. The delimitations of for this study related to the use of a singular research design.

RESULTS, DISCUSSION AND INTERPRETATION OF FINDINGS

Section A: Challenges of the Pharmaceutical Industry

This section covered the challenges of the pharmaceutical industry in Zambia and looked at aspects of market size, human resource skills, government support, and Attainment of WHO standards. Respondents selected from the 5 point Likert-type scales for each of the questions and the findings are tabulated in graphical form.

Market Size

The question on market size wanted to establish whether pharmaceutical manufacturing can thrive in a country with a population of 13 million people. Findings from the study summarized in Figure 2, show that 52% of the respondents disagreed with the statement and 32 % strongly

disagreed representing 84% who indicated that Zambia's market is not small and as such can promote local medicines production. Only 16% of the respondents showed that the market is not adequate for medicine production.

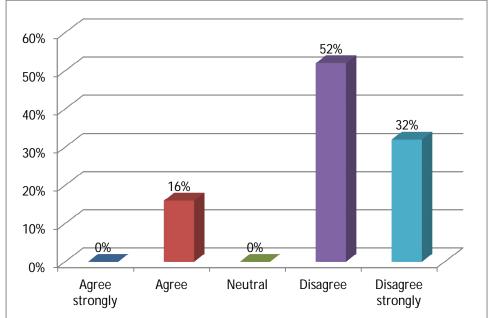


Figure 2: Inadequate market Size for Local Production

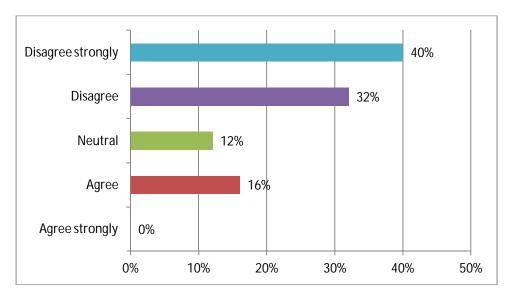
According to the literature review, Zambia has a small market and as such, it cannot encourage more pharmaceutical companies penetrating the market (Ballous-Aares et al., 2008:45). However, from the respondents view perspective, the market is large enough to sustain the industry. Zambia requires more favourable trade policies that will promote the development of the local pharmaceutical industry.

Local industries cannot attain WHO accreditation standards

The question aimed to ascertain whether the local pharmaceutical industries are in a position to meet WHO accreditation standards of encouraging Good Manufacturing Practices. The findings as summarized in Figure 3 indicated the following:-

The respondents that disagreed with the statement represented 32% and 40% strongly disagreed, signifying that 72% were against the statement that local industries cannot attain WHO accreditation standards. Only 12% of the views were neutral and 16% were in agreement that standards cannot be met locally.

Figure 3: Inability to attain WHO Accreditation Standards

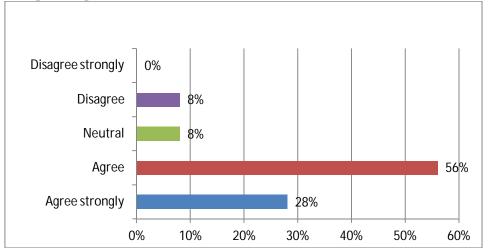


According to the Survey of Pharmaceutical Industries by Cardino Emerging Markets Report 2010, manufacturing companies in Zambia do not meet WHO prequalification standards due to weaknesses in manufacturing plant levels. However, this is not in line with the respondents' views who specify that local industries can attain WHO standards, once supported. These views are also in line with the efforts of the African union, SADC and other initiatives that encourage the local production of medicines.

Inadequate capital to modernize the industries

This question looked at the ability of the local firm in investing in modernizing the current pharmaceutical industries. The outcomes from Figure 4 showed that: The respondents that agreed and strongly agreed represented 56% and 28% respectively, which indicated that 84% of them are in support of the statement that there is inadequate capital to modernize the industries. This presents one of the challenges of the pharmaceutical industry's failure to improve operations in Zambia. Neutral respondents to the statement represented 8% and another 8% disagreed.

Figure 4: Inadequate Capital to modernize Industries



The respondents' views are in line with the UNIDO report of 2009, which states that the failure to attain good manufacturing standards, stem from the lack of capital and lack of highly specialized

human resources skills, required for the manufacture of medicines. Local firms are unable to generate adequate profits to re-invest in expanding their manufacturing capacity. Furthermore, the business environment for the pharmaceutical sector lacks effective support functions to promote local manufacturing.

Inadequate Human Resource skills for the industry

This question aimed at establishing the availability of key human resources required for the industry. Figure 5 findings were as follows:-

The respondents representing 48% disagreed and 20% disagreed strongly, which indicates that 68% were in disagreement with the statement that human resource skills are inadequate for the industry. An equal representation of respondents that showed 16% agreed to the statement and 16% were neutral.

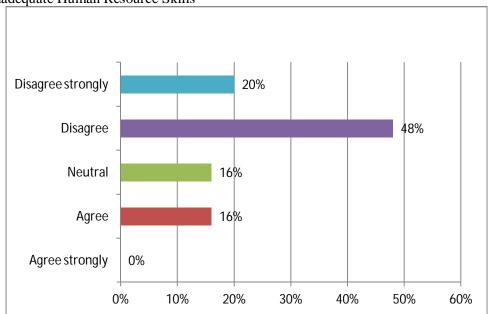


Figure 5: Inadequate Human Resource Skills

The respondent's views are however, not in line with literature which illustrate that the pharmaceutical industry requires sophisticated and highly skilled workforce. It is capital and technology dependent and therefore may not create entry-level employment (Kaplan and Lang, 2005:56). Another point from literature supports the argument by (Berger et al, 2008:27) that local production is highly capital-intensive, requires skilled personnel, and employs relatively few people. From the respondents' perspective, it is clear that there is a possibility of the majority not fully understanding the skills mix required in a pharmaceutical manufacturing industry, nonetheless, 16% that agreed came from the manufacturing sector and have an in-depth knowledge of the industry. There is need to perform detailed studies on the human resource skills mix for the industry to have a better understanding of the skills gap.

Limited Government support to the industry

This question aimed to assess Governments support to the industry. The findings from Figure 6 illustrate the following:-

The respondents representing 40% and 20% that agreed and strongly agreed respectively show

that 60% of those in agreement, supported the statement that there is limited government support to the industry. Only 12% of the respondents were neutral and 28% disagreed to the statement.

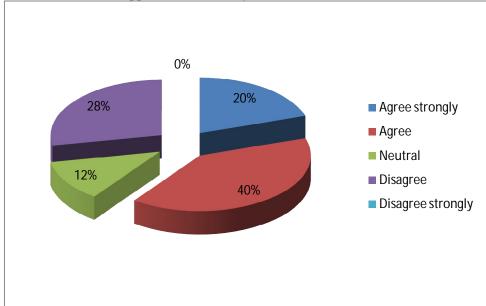


Figure 6: Limited Government Support to the Industry

Respondents' views are in line with literature which has indicated that locally produced pharmaceutical products are very low. Data from the Pharmaceutical Regulatory Authority indicate that only 223 registered medicines are produced locally, out of over 4000 medicines on the register as of 2011. The country spends almost 50 million US dollars on the importation of medicines, as per the Ministry of Health procurement statistics, and 2-3% of the total drug budget, is spent locally. This clearly shows that there is limited support by Government to the local industry thereby affecting its growth. However, it is important to note that pharmaceutical companies should improve their production efficiencies in order to be competitive in the bidding process.

Section B: Analysis of Pharmaceutical Industry

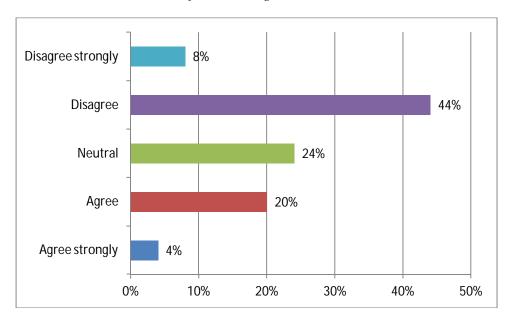
The following questions analysed the macro and micro environment of the local pharmaceutical industry through, closed-ended questions. Respondents used the 5 point Likert scale to respond to a number of structured questions, which looked at an in depth analysis of the industry.

4.3.1 Manufacturing capacity of medicines for local firms

The question on capacity of the manufacturing industry was looking at the ability to produce key essential medicines for the market especially medicines like ARVs, Anti-Malaria and Anti-TB. The findings of the study as in Figure 7 were presented as follows:-

The respondents that disagreed with the statement represented 44% and 8% strongly disagreed which indicated a 52% of the overall views that were not in support of the ability by most local pharmaceutical firms in manufacturing a wide range of medicines. Other results showed that 24% were neutral, 20% agree and 4 % strongly agreeing to the statement. These results also illustrate that there is some form of capacity in the manufacturing of most medicines.

Figure 7: Local Manufacture of Essential Medicines

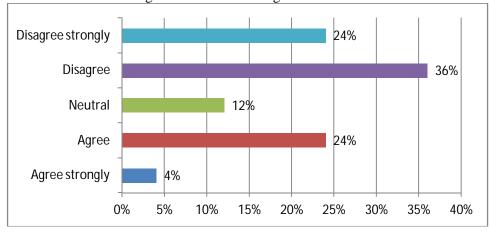


The views of the majority of respondents' are against the Meta Report of 2010 which stated that Local Zambian manufacturers have the capacity to produce over 30% of medicines required in public health institutions. This statement is also in line with the National Drug Policy of 1999 which also envisaged on the need to strengthen local manufacturing of key pharmaceutical drugs so as to improve on availability, affordability and accessibility of the lifesaving medicines. It is important that the Government and the private sector should be seen to be in the forefront supporting the enhancing of capacity in the pharmaceutical manufacturing firms, so as to ensure the availability of locally produced medicines. Nonetheless, 24% of the respondents are still in support that the capacity is there, but has not been exploited by the Government. Responses from this group of respondents will require an in-depth analysis of the statement and future research.

Political will in stimulating local medicine manufacturing

This question assessed the political will in stimulating local manufacturing and the views by respondents were as per Figure 8: 36% of the respondents disagreed with the statement and 24% strongly disagreed representing 60% of the views which did not support the statement that there is political will in stimulating medicine manufacturing. The other results showed that 12% were neutral, 24% agreed and 4% strongly agreed. Amongst those that agreed to the statement, it shows that political will is there but local manufacturers are not taking advantage of the policy guidelines.

Figure 8: Political will in Stimulating Local Manufacturing of Medicines



Majority of the respondents' views are in contrast with literature which is very clear that the Zambian Government has been part of a number of forums in enhancing the local manufacturing of medicines. The AU adopted the pharmaceutical manufacturing plan in 2007, and established a Technical Committee to undertake developments of these efforts. The Ministry's Strategic Plan (2006-2010) is also categorical in supporting the establishment of a strong local pharmaceutical and chemical industry to lower the costs of drugs (NHSSP, 2006:33). Furthermore, the policy mentions that, the Ministry of Health shall use Government drug funds to procure locally manufactured pharmaceuticals (NDP, 1999:10). From the political point of view, there has been willingness by the government in ensuring that appropriate policies are in place that will stimulate local production, despite the challenges in implementation of such policies and this is supported by 24% of the respondents in the research.

Local manufacturing of medicines is a profitable business venture

The findings from Figure 9 of the study show that, 56% of the respondents agreed to the statement and 28% strongly agreed, representing 84% of the views in support of local manufacturing being a profitable business venture. Other views showed that 12% were neutral and 4% disagreed, an indication that some respondents are of the argument that Zambia does not hold a comparative advantage in pharmaceutical manufacturing.

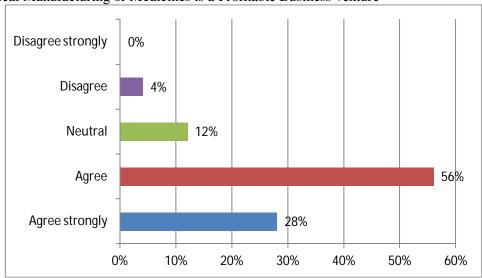


Figure 9: Local Manufacturing of Medicines is a Profitable Business venture

Most respondents' views are also in line with literature which highlight that the overall pharmaceutical market in sub-Saharan Africa is worth USD 3.8 billion annually, the pharmaceutical manufacturing sector in Africa contributes only 25-30 per cent of the continent's needs (Reinhardt, 2011: 2). With the high disease burden, development of local pharmaceutical manufacturing has the potential to positively impact the health outcomes and stimulate economic growth.

Imported finished pharmaceutical products affecting local manufacturing

This statement was looking at assessing the impact of imported finished products on the market. The findings from Figure 10 showed the following:-

72% of the respondents strongly agreed to the statement and 28% agreed, representing 100% of the views being in agreement with the statement that increased imported finished pharmaceutical products contributing to the downward trend in local manufacturing.

Disagree strongly 0% Disagree 0% Neutral 0% Agree 28% Agree strongly 72% 0% 10% 20% 30% 40% 50% 60% 70% 80%

Figure 10: Effects of Imported Finished Products on Local Manufacturing

All the respondents' responses are consistent with literature which states that domestic industries faces stiff competition from the finished imports of medicine from overseas. The results shows that imported finished products contribute to the challenges local pharmaceuticals manufacturers are facing on the market. If this trend continues, most local manufacturers businesses will fail to thrive as the market will be flooded with cheap imports.

Local manufacturing of medicines can help reduce unemployment and poverty levels.

This statement in the questionnaire aimed to assess the effects of local manufacturing on unemployment and poverty levels. The findings from Figure 11 of the study indicated the following:-

Approximately 76% of the respondents strongly agreed to the statement and 24% agreed, representing 100% of the views being in agreement with the statement that enhancing pharmaceutical manufacturing industry can contribute to an increase in GDP and help reduce unemployment and poverty levels.

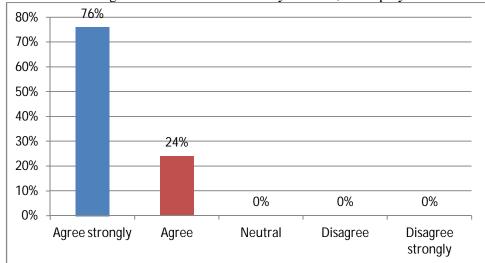


Figure 11: Effects of enhancing the Pharmaceutical Industry on GDP, Unemployment and Poverty Levels

The results of the findings are in agreement with literature, which state that local domestic industry has the potential of contributing to the increase in gross domestic product in the

economy, reduction in unemployment and poverty levels once supportive policies are strengthened.

Client inclination towards foreign manufactured products compared to local

This question aimed to examine customer preferences with regard to locally manufactured, compared to foreign produced medicine. The findings from Figure 12 indicated the following:-

About 40% of the respondents agreed to the statement and 12% strongly agreed, representing 52% of the views being in support of foreign produced products. Other responses showed16% was neutral, and 32% disagreed. Of those that disagreed, it is possible that consumer preferences are not a factor in accessing medicines whether from foreign or locally produced as long as there is an assurance of being an effective medicine.

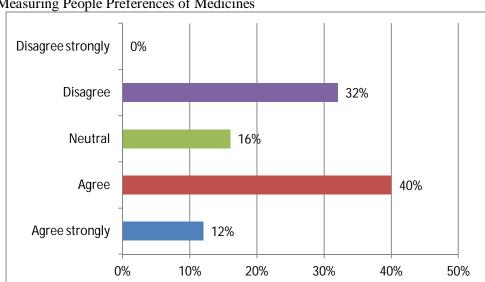


Figure 12: Measuring People Preferences of Medicines

The majority of the respondents' views support the Meta 2010 Pharmaceuticals manufacturer's conference report findings which did allude to the fact that Zambian consumers prefer foreign brands to local. This trend is very much linked to the social and cultural attitudes that affect healthcare and pharmaceutical marketing outcomes. Further research is required on consumer preferences to ascertain the influence.

Client inclination to traditional medicines affect local pharmaceutical production Findings from Figure 13 displayed the following:-

The graph indicated that 56% of the respondents disagreed with the statement and 28% strongly disagreed, representing 84% of the views which do not support that people are inclined to traditional medicines, thereby affecting local pharmaceutical production. However, 8% of the respondents were neutral and 8% agreed, which imply that this area requires further research to have an understanding why others are in agreement with the statement.

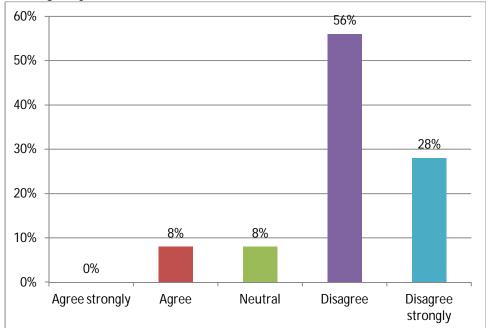


Figure 13: Assessing People's Inclination towards Traditional Medicines

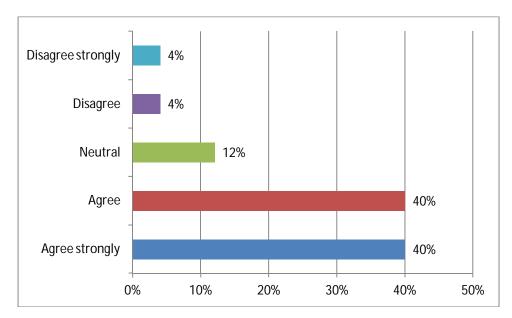
The majority of the respondents' views on the statement are not in line with literature which supports that a good percentage of Zambians especially in the rural areas believe in the consumption or usage of traditional medicines for treating many health ailments. Evidently, the public has confidence in Traditional Medicine Practitioners and the products they dispense but this has no correlation with affecting local manufacturing of pharmaceuticals. The World Health Organisation (WHO) also supports this notion on consumption as per the 2001 report on traditional medicines.

The cost of manufacturing medicines locally is very expensive

Findings from this statement as per Figure 14 elucidated the following:-

The figure shows that 40% of the respondents strongly agreed to the statement and 40% agreed, representing 80% of the views which support the statement that local manufacturing of medicines is expensive. Other respondents showed that 12% were neutral, 4% disagreed and another 4% strongly disagreed with the statement.

Figure 14: Cost of Locally Manufactured Medicines



A higher percentage of the findings from the study are consistent with literature review which states that local pharmaceutical production in many developing countries may not be a feasible or cost-effective option, and could bring to market more expensive products with limited ability to penetrate developing world markets. Given the low consumer and institutional purchasing power in most African countries, the market for finished product is almost entirely dependent on the ability to access international funds. Coupled with this information, Kaplan and Laing (2005), have indicated that the key raw materials and equipment used in pharmaceutical production is imported and costly which tend to push the costs of production.

High cost of equipment maintenance in order to maintain standards

The researcher wanted to have an understanding of the cost of doing business by also looking at maintenance costs of equipment. The findings from Figure 15 illustrated the following: - 40% of the respondents strongly agreed to the statement and 28% agreed, representing 68% of the views being in support of high equipment maintenance costs. The other responses showed that 16% of the participants were neutral and 16% disagreed to the above statement.

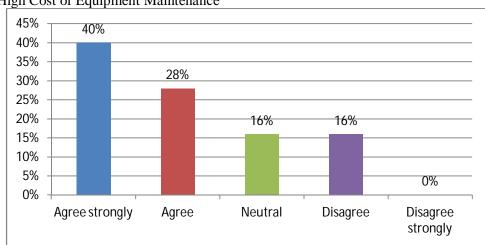


Figure 15: High Cost of Equipment Maintenance

The majority of the respondents' views are in tandem with literature and these findings are not unique, in most developing countries like Zambia where high operation and energy costs contribute greatly to the cost of doing business. This supports findings by UNIDO–Kenya (2010) UNIDO– Uganda (2010); MeTA (2010); Mhamba and Mbirigenda (2010) that pharmaceutical manufacturers in the respective countries studied, including Zambia, import most of the raw materials, equipment and spare parts used mainly from India and China, thereby increasing the cost of doing business. Zambian Pharmaceutical companies lack the advanced technology in modern day manufacturing thereby affecting productivity (Meta, 2010:13).

Banks willing to fund medicine manufacturing proposals

This statement assessed the capacity of the local manufacturers in accessing funds from the banks that will enhance local production of medicines. The findings from Figure 16 indicated the following:- 32% of the respondents disagreed with the statement, 20 % are neutral, 28% agreed and 20% strongly agreed. The results show that 48% of the views are in agreement with the statement that banks are in a position to give loans to firms or individuals with a sound business plan in medicine manufacturing. For those not in agreement, there is a need to get further details as to why banks are unable to fund a sound business proposal.

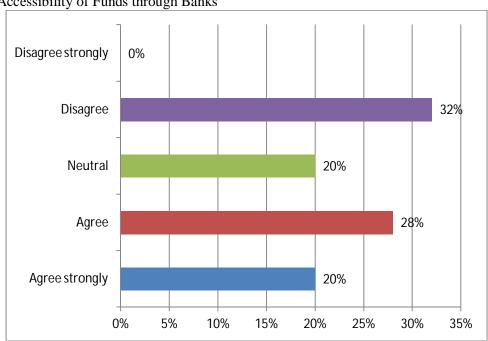


Figure 16: Accessibility of Funds through Banks

From the analysis of the bar chart, it is clear that the combined respondents for those that agreed and strongly agreed, that banks are willing to fund local production of medicines as long as they meet the set benchmarks, are in line with the literature review. The World Bank Report of 2009, reports that \$297.2 million was given out solely for Sub-Saharan African private sector development which is a good indication that countries like Zambia can benefit from these loans as long as companies proposals are in line with Doha Agreement Clause.

Section C: Setting up of a Pharmaceutical Manufacturing Plant

The following questions looked at processes involved in setting up of a pharmaceutical

manufacturing plant. It is asserted that establishing a pharmaceutical manufacturing plant is a major challenge but it is one way of ensuring that key medicines can be locally produced and made readily available in alleviating serious disease conditions like Malaria, TB, Sexually Transmitted Infectious diseases, HIV & AIDS. Having a strong manufacturing industry will enhance job creation and foster research and development of new products. A five-point Likert scale, with the options of agree strongly, agree, neutral, disagree and disagree strongly were used.

Clear guidelines are in place in setting up a pharmaceutical plant

This question looked at the availability of guidelines to assist with investors in following procedure for the pharmaceutical sector in Zambia. The findings are based on respondent's ratings on their perception of having clear guidelines in place looking at Figure 17:- The respondents representing 48% that agreed and 8% that strongly agreed totalling 56% of those in support of the statement that clear guidelines are in place in setting up a pharmaceutical plant. The rest of the respondents were distributed as follows, 28% were neutral, 12% disagreed and 4% strongly disagreeing to the statement.

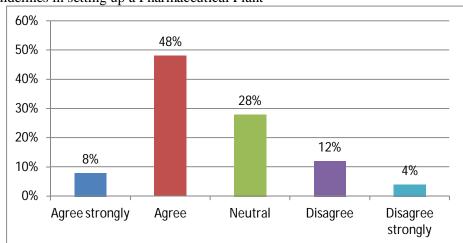


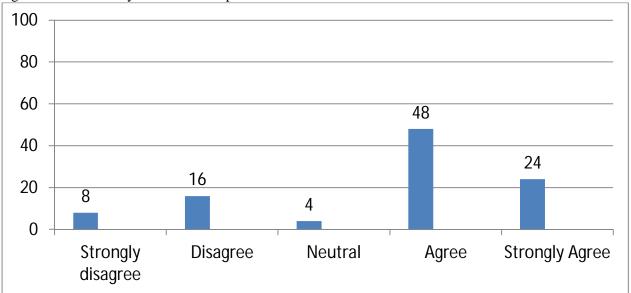
Figure 17: Guidelines in setting up a Pharmaceutical Plant

Majority of the respondents views are in agreement with the literature review, the Company's Act Cap 388 governs the registration of companies in Zambia. Registration is done at the Patents and Companies Registration Authority (PACRA). The Zambia Development Act No. 11 of 2006 provides for investment incentives and investment guidelines. Investors in the health sector especially pharmaceutical manufacturing, requires obtaining relevant licenses with the Pharmaceutical Regulatory Authority. In summary, it is very clear that guidelines are in place for setting up a pharmaceutical plant, despite 16% of respondents not agreeing.

Skilled manpower is available in managing and operating the plant

The question on skilled manpower was tailored towards understanding the ability of staff to operate the plant effectively. Findings from Figure 18 have shown that:- 48% of the respondents agreed to the statement and 24% strongly agreed, representing 72% of the views in support. 4% were neutral, 16% disagreed and 8% strongly disagreed. The results show that most respondents are in agreement that skilled manpower is available in managing and operating the plant.

Figure 18: Availability of Skilled Manpower

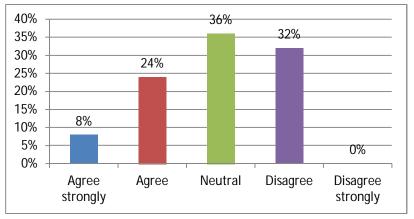


Despite the respondents' views indicating that there is availability of skilled manpower, literature reviewed show that pharmaceutical production is capital, technology and knowledge intensive, which means that the appropriate technical expertise is absolutely critical, both in terms of sufficient numbers and appropriate skills (Seita, 2005:3). Zambia in particular, has to invest in the production of more different skilled. The skills mix has not yet reached that level despite the training of pharmacist and pharmacy technologists in country. From the analysis of those that disagreed representing 24%, majority of them came from manufacturing firms implying that they understand the industries challenges in terms of the skilled workforce on the market.

Approval process to manufacture can take less than 3 months

The question aimed at analysing the period of time it takes before approval can be granted. Findings from Figure 19 have shown that:- 32% of the respondents disagreed with the statement, 36% are neutral, 24% agreed and 8% strongly agreed. The results show that 36% of the respondents are neutral, which imply that they are not sure. There is a tie between those for and against the statement which is an indication of not fully understanding the approval process by the respondents.

Figure 19: Approval Process



The findings are not consistent with the laid out process, but from the 32% of respondents that agreed, they understand the duration of the approval process which take less than 3 months upon submission of all the necessary documents. With the computerization process taking place at PACRA, this will be reduced to 48hrs.

Existing local manufacturers can partner with established foreign companies

The question looked at the capacity of local firms in partnering with foreign firms to enhance the local production of medicines.

The respondents were asked to rate and findings from Figure 20 have shown that; 40% of the respondents strongly agreed to the statement and 40% agreed, representing 80% of the views in support of formation of partnerships with established foreign firms. Additionally, 16% were neutral and 4% disagreed. The results show that most respondents are in agreement with the statement that existing local manufacturers can partner with established foreign pharmaceutical companies so as to enhance technological transfer.

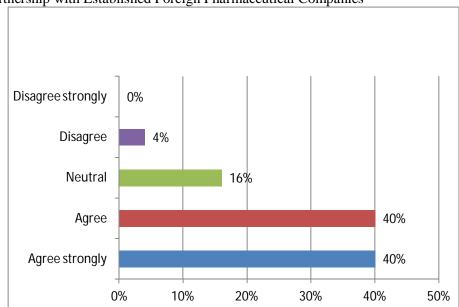


Figure 20: Partnership with Established Foreign Pharmaceutical Companies

Private partnership with foreign companies is one of the options a new domestic pharmaceutical company can engage in. Technological transfer between foreign and local industries is important as this increases the capacity of society to benefit economically from the innovation. The respondents views are in support of literature which, according to Abbot (2010: 61), domestic production will also enhance transfer of technology through joint ventures between a local and multinational pharmaceutical company. Bennet et al. (1997: 89) explained that local subsidiaries and joint ventures can result in transfer of technology and technical skills thereby improving domestic productivity.

Tax exemptions are in place for imported equipment and raw materials

The question on tax exemptions was drafted so as to look at what incentives are in place that will promote local production.

Findings from the respondents according to Figure 21 indicated the following:- 20% of the respondents disagreed with the statement, 12% strongly disagreed, 36% are neutral, 12% agreed and 20% strongly agreed. The results showed that 36% of the respondents are neutral which imply that they are not sure.

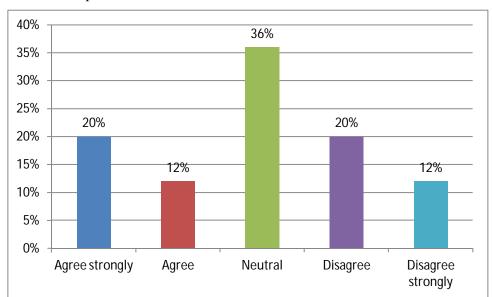


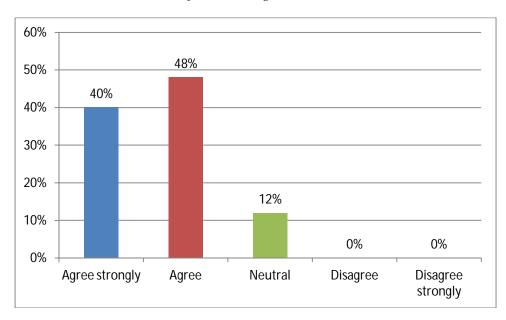
Figure 21: Tax Exemptions

However, according to a study conducted by MeTA in 2010, investment incentives for manufacturers are in place where there is no duty on importation of raw materials. The Zambia Development Agency (ZDA) Act of 2006 offers a wide range of incentives in the form of allowances, exemptions & concessions for companies. The Act provides for investment thresholds that investors have to meet to qualify for fiscal and non-fiscal incentives. Despite Zambia registering a positive economic growth of over 5% in the last six years, the pharmaceutical sector has failed to put in place market strategies that will tap into the current economic trend. Government has made pronounce of signing statutory instruments to promote local manufacturing of pharmaceuticals as of 2011 but no implementation has been made (Post Newspaper, 2011: 4). In summary, tax incentives are in place but the industry is lacking the application of marketing strategies that will critically analyse the environment.

Strive for GMP certification

Respondents were asked to rate their perception on the need for industries to strive for GMP certification. Results from Figure 22 have shown that:- 40% of the respondents strongly agreed to the statement and 48% agreed, representing 88% of the views that are in support of the statement. 12% were neutral and none disagreed. The results showed that most respondents are in agreement with the statement that manufacturers need to strive for GMP certification in order to assure quality in the production process.

Figure 22: Strive for GMP Certification



The responses are in line with WHO recommendations, of upholding Good Manufacturing practices which entails maintenance of quality standards. It is important to note that because of the nature of the business of saving lives, no compromise in the quality of the medicines should be tolerated.

Application of TRIPS flexibilities in manufacturing products on patent

This question looked at the ability or capacity of the pharmaceutical industry in utilizing the flexibilities in TRIPS as per the Doha Declaration. The findings from Figure 23 were as highlighted:- 60% of the respondents agreed to the statement and 24% strongly agreed, representing 84% of the views that TRIPS flexibilities can be applied locally to strengthen manufacturing. Additionally, 12% of the respondents were neutral and 4% disagreed with the statement. The results show that most respondents are in agreement with the statement that the industry can apply the TRIPS flexibilities as in the Doha Declaration to manufacture products on patent.

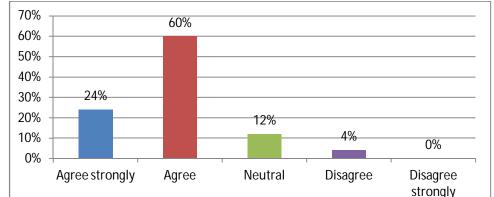


Figure 23: Utilization of TRIPS Flexibilities

Majority of the respondents are in agreement with literature on the need to utilize the flexibilities in the TRIPS as enshrined in the World Trade Organisation (WTO). TRIPS contains requirements that national laws must meet for copyright rights - including the rights of patents for

pharmaceutical products. The rationale behind this protection and enforcement of intellectual property rights is to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of the technology or innovation. With, this information, it is important that these flexibilities are capitalized upon so as to enhance local pharmaceutical production of on-patent medicines.

Section D: Business opportunities and strategic marketing

In the face of existing challenges in the local pharmaceutical manufacturing; opportunities are still there in enhancing the industry and making it more viable. A 5 point Likert-scale was used with the options of not important, somewhat important, important, very important and do not know, to probe the respondents on their response strategies. These questions were cardinal so as to indicate the level of importance of the following factors in promoting pharmaceutical industrial growth.

Open up markets in rural areas and neighbouring countries

This question was drafted with a view of understanding the marketing trends of the pharmaceutical industry. The finding as shown from Figure 24 indicated the following:- 68% of the respondents agreed to the statement that it is important, 16% very important, 8% somewhat important, 4% not important and 4% did not know. Overall findings showed that 92% of the respondents support the statement that opening up markets in rural areas and neighbouring countries will create business opportunities.

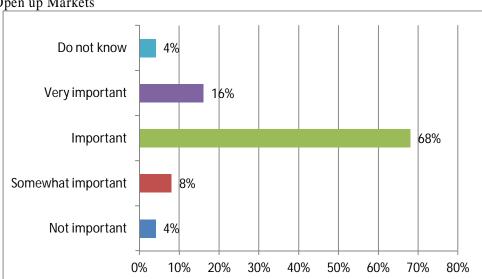


Figure 24: Open up Markets

Respondents' views clearly show that, there is need to open up markets especially in rural areas and in neighbouring countries. The fact that products have only been marketed to specific areas has limited the utmost performance of the industry and thereby affecting the potential for growth.

Lobby for introduction of tariffs on imported medicines that are available locally

The question was based upon understanding the tariff structure on imported medicines and lobbying the government to introduce them in order to enhance local manufacturing. The findings from Figure 25 has shown the following:- 60% of the respondents agreed to the statement that it is very important, 32% important, 4% somewhat important and 4% did not know. Overall findings indicated that 96 % of the respondents support the statement that lobbying for introduction of tariffs on imported medicines that are available locally will create business opportunities.

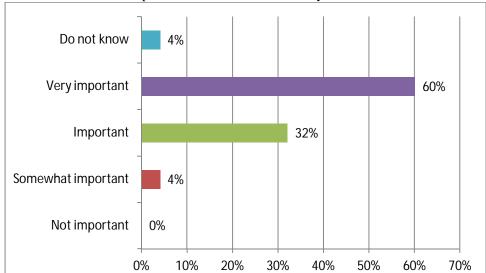


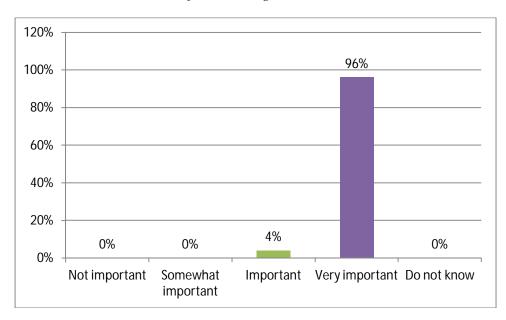
Figure 25: Tariff Introduction on Imported Medicines found locally

Majority of the respondents views are in line with literature, Section 5 of the NDP, which states that discriminatory tariffs in favour of imported finished pharmaceuticals will be abolished, and the policy furthermore mentions that MoH shall use Government drug funds to procure locally manufactured pharmaceuticals in preference to finished products as much as possible (National Drug Policy, 1999:10). However, according to the Economics Review (2002:13), protection of a domestic industry using tariffs and trade barriers never benefits the consumers and decreases the net welfare of the country. Domestic producers should have to bid for the lowest prices like any other company so that they are forced to be efficient and allow competition. With this key information, it should be noted that introduction of tariffs would allow for local manufacturers to be less innovative.

Manufacture products to meet international standards

The question was centred on assessing the ability to manufacture products to meet international standards to create business opportunities. The findings based on Figure 26 were as follows:- 96% of the respondents agreed to the statement that it was very important and 4% indicated that it was important. Overall findings indicated that, 100 % of the respondents support the statement that meeting international standards in the manufacturing of products will make them more competitive and thereby, enhance the business outlook.

Figure 26: Manufacture High Quality Products

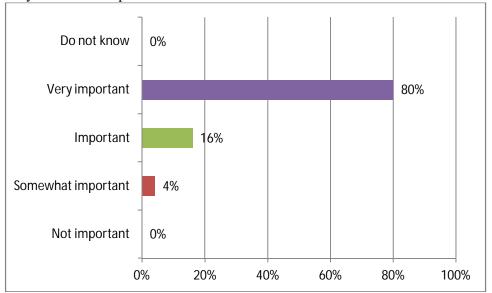


The respondents are in agreement with literature that most African countries do not have the capacity to produce pharmaceuticals as to the required standards, as highlighted in the report (WHO AFRO, 2005). This is a rationale for them to support the need to manufacture pharmaceutical products up to international standards.

Lobby for tax exemption on raw materials

The question was framed so that it highlights the need to lobby for tax exemptions on raw materials. Figure 27 findings showed that:- 80% of the respondents agreed that it was very important, 16% important and 4% somewhat important. In general findings indicated that, 100% of the respondents support the statement that lobbying for tax exemptions on imported raw materials will create a fair level playing field for the local manufacturers.

Figure 27: Lobby for Tax Exemptions on Raw Materials



The findings are in line with literature on the tax exemptions but it still remains unclear on how local pharmaceutical manufacturing industries will improve their productions efficiencies and become competitive.

Understand the disease burdens and manufacture medicines accordingly

The question on disease burden addressed the linkage between medicines being manufactured and the common diseases affecting the people. Findings from Figure 28 indicated the following:-

Approximately 64% of the respondents agreed that it was very important, 28% important and 8% somewhat important. Overall standings show that 100% of the respondents support the statement that understanding the disease burden will enable local producers' manufacture what is needed on the market.

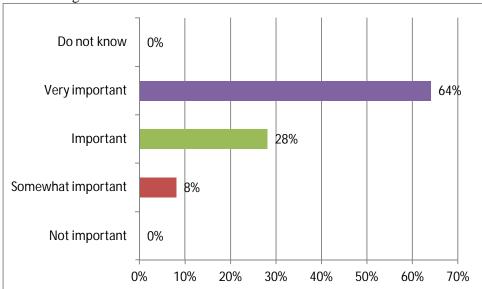


Figure 28: Understanding the Disease Burdens

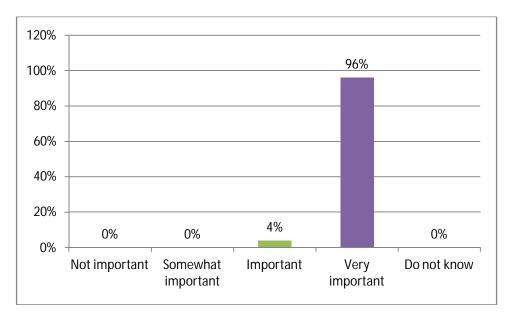
The respondents' views are in line with literature review, which has highlighted the need to understand the disease pattern. Concerning the three main diseases in Zambia, statistics indicate that the HIV&AIDS epidemic has a serious negative socio-economic impact on Zambia, with over 1.1 million living with the virus. With these statistics in mind, the local manufacturing industry should step in and play a key role in alleviating the diseases affecting the people.

Manufactured medicines should be safe, efficacious and competitively priced

The essence of this question was to understand the production efficiencies of the local manufacturing industries.

Findings from Figure 29 showed the following results:- 96% of the respondents agreed to the statement that it was very important and 4% important. Overall findings indicated that, 100% of the respondents support the statement that medicines should be competitively priced, safe and efficacious.

Figure 29: Manufacture Safe, Efficacious and Competitively Priced Medicines



The views from respondents on the need to manufacture products in the most efficient, safe and competitively priced is in agreement with literature, which states the importance of domestic production of pharmaceuticals requiring the producers to offer prices that are competitive with the markets (World Bank Report, 2008:21). It is imperative to assure the quality of the pharmaceutical products being manufactured in order to safeguard the health of the members of public.

Local production will improve or enhance self-sufficiency in medicine supply

The question focused on understanding the supply chain of locally produced medicines and also looking at formulation and research in new molecules.

The results from Figure 30 of the study indicated the following:- 48% of the respondents supported the statement that it was very important, 32% important, and 20% somewhat important. Overall findings indicated that, 100 % of the respondents support the statement that Local production will improve or enhance self-sufficiency in medicine supply and at the same time, stimulate proper formulation and research in traditional medicines

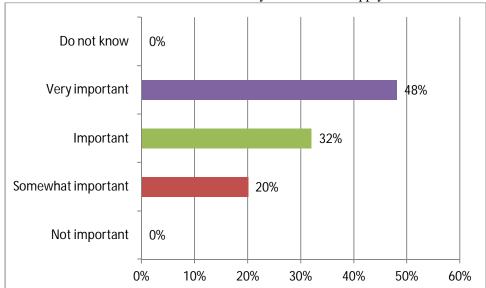


Figure 30: Local Production will enhance self-sufficiency in Medicine Supply

The views of the respondents are in agreement with literature which states that policy makers in developing countries should consider local production of pharmaceuticals as a way of promoting self-sufficiency, achieving independence from international pharmaceutical suppliers, developing domestic industrial capacity and creating jobs, this is according to Management Sciences for Health (2011). Many leaders in least and developing countries in Africa and Asia appear to believe that local medicines production will also help their nations achieve economic autonomy and sustainable development, this will also encourage research and development in traditional medicine and identify new molecules (Bate, 2008:37).

Create multiple and easily accessible medicine distribution channels

The question assessed the ease of access of medicine distribution channels. The findings from study based on Figure 31 showed that: - 56% of the respondents agreed with the statement that it was very important, 36% important, 4% somewhat important, and 4% not important. Overall findings indicated that, 96 % of the respondents support the statement that creating multiple and easily accessible medicine distribution channels will create business opportunities.

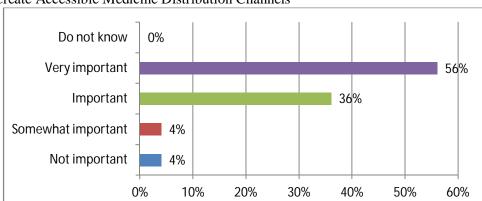


Figure 31: Create Accessible Medicine Distribution Channels

The views of the respondents are in agreement with literature on the need to create multiple and easily accessible distribution channels to enhance medicine availability. Referring to the literature review, it was mentioned that African countries can explore the need to have regional groupings

that would allow local producers to focus specifically on manufacturing medicines that will fill up the gap, lower transportation costs by importing the medicines from a regional producer, and also enhance sharing health concern through regional integration purposes. This avenue of analysis will stimulate accessibility of medicines so as to improve availability.

Invest in modernizing equipment to reduce on costs of production

One way of reducing costs in the manufacturing and production of domestically produced medicine is in the investment in equipment modernization. Respondents were asked to rate their perceptions of investing in modernization. The findings are summarized in Figure 32:- The percentage of respondents that were in agreement with the statement that it was very important was 68%, and 32% mentioned that it was important. From the findings, representing 100%, it is evident that investing in modernization of the industry is crucial in making it more viable.

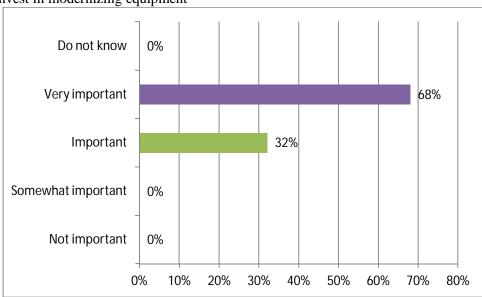


Figure 32: Invest in modernizing equipment

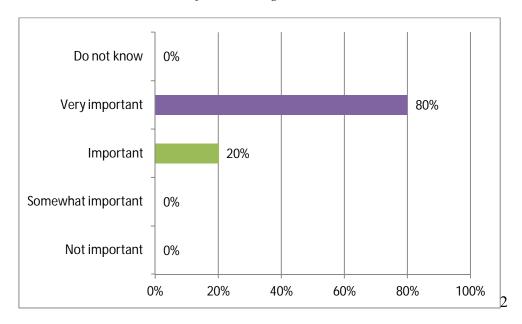
The respondents views are in line with literature, which supports that investing in modernizing equipment will improve the production capacity and as such, enhance the business profile of the industry.

Train and develop staff in Strategic Marketing of Commodities

The question on training and development of staff in strategic marketing was centred upon establishing what is key in creating business opportunities once staffs are adequately trained.

The findings from Figure 33 of the study showed that, 80% of the respondents are in support of the statement i.e. it is very important, and 20% important. Overall findings indicate that, 100% of the respondents support the statement that training and developing staff in strategic marketing of commodities will enhance business opportunities.

Figure 33: Train and develop staff in Strategic Marketing of Commodities

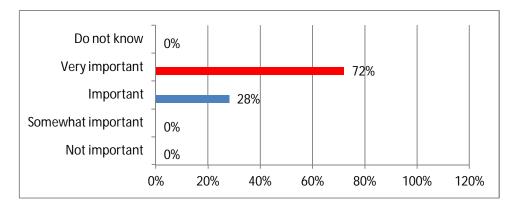


The views are in coherence with literature which states that a business has to understand the dynamics of its industries and markets in order to compete effectively in the marketplace. Porter (1980: 91) defined the forces which drive competition, contending that the competitive environment is created by the interaction of five different forces acting on a business. The findings reinforces the importance of training and development in pursuit of organisational success. Pharmaceutical companies must seek to understand the nature of their competitive environment, if they are to successfully achieve their objectives and establish appropriate marketing strategies.

Increase local pharmaceutical firms' participation in government tenders

The question looked at increasing local pharmaceutical participation in government tenders and the impact this would have on improving the business outlook through opportunity creation. The responses from participants as outlined in Figure 34 were as follows: - 72% of the respondents supported the statement that it was very important and 28%, important. Overall findings indicated that 100% of the respondents support the statement, that increasing participation of local pharmaceutical manufacturers in the government medicine tendering process will create business opportunities

Figure 34: Participation in the Government Medicine Tendering Process



The findings from the respondents are in line with literature which has shown that most local

pharmaceutical firms have failed to create a sustainable working environment, because of harsh economic circumstances which are particularly unfavourable to manufacturing. As a result of limitations in the market, local manufacturers are highly dependent on government contracts for their survival and this is why, increasing participation of locals will enhance business and employment opportunities. However, the government procures medicines through open tender processes, and the reason behind this is to gain economies of scale. This is supported by Reich in the literature review, who observed that international competitive bidding is cheaper than procuring from local producers.

CONCLUSIONS AND RECOMMENDATIONS

Introduction

The aim of this research was to evaluate the factors influencing the establishing of a domestic pharmaceutical manufacturing industry in Zambia. This chapter presents the conclusions and recommendations for the study. Areas for further research are suggested. The measure of success for any study is its ability to indicate the attainment of stated research aim and objectives and answering the research questions.

Findings from the Study

The key findings of the study are discussed under the subheadings of the objectives as outlined below:

- To establish the challenges being faced by the current local pharmaceutical manufacturers in Zambia.
- To analyse the macro (PEST) and micro (SWOT) environment of the pharmaceutical industry in Zambia.
- To examine the processes involved in setting up a pharmaceutical industry in Zambia.
- To implore appropriate strategic marketing and business environment assessments for the industry to remain viable and sustainable.

Findings from Literature Review

The literature study has been extensive, however, only a summarised version is presented under this heading:

Challenges faced by local pharmaceutical manufacturers in Zambia

- The pharmaceutical manufacturing industry in Zambia meets with manifold challenges related to internal dimensions of manufacturing and also originating from the wider operating environment.
- Beyond the plant, the small size of domestic markets diminishes the prospects for achieving optimal production efficacy. Furthermore, the business environment in general has deficits and in particular the pharmaceutical sector lacks effective support functions to promote local manufacturing.
- The manufacturing companies in Zambia do not meet WHO prequalification standards which limits their production and excludes them from participating in international public tenders.
- The weaknesses observed in adhering to quality manufacturing standards in most plant levels, affects firms from reaching and maintaining quality standards in line with World Health Organisation Good Manufacturing Practices (GMP).
- The failure to attain these standards, stem from the lack of capital and lack of highly specialized human resources skills, required for the manufacture of medicines.

Macro and micro environment of the pharmaceutical sector in Zambia.

- Pharmaceutical industries have faced challenges in aligning to the current global trends in the market forces, governed by microeconomic and macroeconomic factors. In analyzing the macroenvironment, political, economic, social and technological factors are important variables that influence the industries operations.
- The political influence through the National Drug Policy and other government pronouncements, the economic performance of the country, the social attitudes and technological aspects implored in the manufacturing capacity, have an impact on the overall function of the entire pharmaceutical industry.
- In assessing the micro-environmental factors, it is important to examine the strengths, weaknesses, opportunities and threats existing within the pharmaceutical industry.
- The industry's strength lie in the Doha declaration which supports local manufacturing of medicines and the Zambia Development Agency which has put in place incentives to stimulate operations.
- It is important to note that the weaknesses in the industries stem from the fact that mechanisms are inadequate in addressing the factors limiting growth.
- Opportunities for the industry to thrive exists, but requires tapping into initiatives that have been advanced by Government i.e. preferential procurement, the triangle of hope, research in traditional medicinal plants, attainment of WHO pre-qualification, high disease burden and a positive economic growth.
- The industry is currently threatened by a proliferation of cheap imported pharmaceutical products which do not attract any taxes, a lack of implementation of the NDP clauses, and a lack of market penetration in the SADC and COMESA regions.

Setting up of Pharmaceutical manufacturing in Zambia

- This is governed by the Company's Act Cap 388, which deals with the registration of companies in Zambia through the Patents and Companies Registration Authority (PACRA).
- The minimum share capital of a company should be US\$ 1,000 and the law requires that half the directors of the company be resident in Zambia, especially in the case of joint ventures or strategic alliances with foreign firms.
- All companies are required to submit annual returns with the Registrar of Companies within three months after the end of the financial year. The Company's Act allows foreign companies to register with the Registrar of Companies within 28 days of setting up or acquiring an established place of business.
- It is cardinal to note that pharmaceutical companies should abide by the procedures set forth by the Pharmaceutical Regulatory Authority. The Zambia Development Act No. 11 of 2006 also provides for investment incentives and investment guarantees so as to foster economic development by increasing investment and trade levels across the whole country.

Strategic marketing and business environment assessments for the industry

- It is very clear that a vibrant local pharmaceutical manufacturing industry is advantageous in reducing pressure on foreign exchange demands, enhances employment opportunities, improves health care delivery and in the long term increases the economic performance of the country.
- Pharmaceutical companies must seek to understand the nature of their competitive environment if they are to be successful in achieving their objectives and establishing appropriate marketing strategies.
- A business has to understand the dynamics of its industries and markets in order to compete effectively in the marketplace. In addition to rivalry among existing firms and the threat of new

entrants into the market, there are also the forces of supplier power, the power of the buyers, and the threat of substitute products or services.

• The intensity of competition is determined by the relative strengths of these forces and structure of an industry determines organisations' competitive behaviour, which in turn determines their profitability.

Findings from Primary Research

The summarized findings from the primary study have been arranged in accordance with the objectives:

Challenges faced by local pharmaceutical manufacturers in Zambia

- Zambia's market is not small and as such, can promote or sustain local medicines production as evidenced by 84% of the respondents. This observation counters what has been highlighted in literature.
- The study shows that 72% of the respondents support the idea that local industries potential to attain WHO accreditation standards, is possible even though this is not supported by literature.
- The findings on the availability of key human resources on the industry were however, supported by 68% of the respondents which was in contrast to the literature review as well.
- There was a positive response rate of 84% agreeing to the statement that there is inadequate capital to modernize the industries which is in line with literature.

Macro and micro environment of the pharmaceutical sector in Zambia.

- Majority of the respondents, representing 60%, were in agreement that there is limited government support to the industry which has affected the macro-environment factors thereby reducing performance. This observation is not in line with the literature review which articulates that there are incentives through the ZDA act and NDP to promote the industry.
- The increased importation of the finished pharmaceutical products which is a serious threat to the industry, is contributing to the downward trend in local manufacturing as supported by 100% of the respondents.
- It is also clear from the findings, representing 52% of the respondents, that consumers incline themselves to foreign produced and thereby put pressure on the production capacity of local firms.
- The cost of manufacturing medicines locally is very expensive, which makes it extremely difficult to compete with foreign products which have a comparative advantage; this is supported by 80% of the respondents.
- A great opportunity exists in the local manufacturing of medicines as this can help reduce unemployment, poverty levels and contribute to the economic growth of the country, 100% of the respondents were in support of the statement.

Setting up of Pharmaceutical manufacturing in Zambia

- The respondents' views representing 56% were in support that guidelines are available for setting up a pharmaceutical manufacturing plant, and this is line with literature under the company act cap 388 of the laws of Zambia, the ZDA act of 2006, and the Pharmaceutical Regulatory Act of 2004.
- The capacity of local firms in partnering with foreign firms so as to set up local production of medicines and technology transfer was supported by 80% of the respondents. Technological transfer between foreign and local industries is important, as this increases the capacity of society to benefit economically from the innovation.
- A very low response rate of 32% was observed towards the statement that tax incentives promoting local setting up pharmaceutical manufacturing are in place. The Zambia Development

Agency (ZDA) Act of 2006 offers a wide range of incentives in the form of allowances, exemptions & concessions for companies, but these are underutilized by prospective investors in the industry.

Strategic marketing and business environment assessments for the industry

- A maximum response rate of 100% of the respondents were in support of the statement that lobbying for tax exemptions on imported raw materials and tariff introductions on imported finished products, will create a fair level playing field for the local manufacturers, and thus enhance the viability of the industry. The findings are in line with literature on the tax exemptions, but it still remains unclear on how local pharmaceutical manufacturing industries will improve their productions efficiencies and become competitive.
- There was support from the respondents, representing 100%, towards the statement that medicines should be competitively priced, safe and efficacious, in order to improve domestic production of pharmaceuticals, and thus, offer prices that are competitive with the markets both locally and internationally.
- The statement that training and developing staff in strategic marketing of commodities will enhance business opportunities was supported by 100% of the respondents.

Conclusions

The study on the evaluation of the factors influencing the establishing of a domestic pharmaceutical manufacturing firm in Zambia concluded the following:-

- The findings revealed that local manufacturing of essential medicines and setting up of domestic plants in Zambia meets with manifold challenges related to internal dimensions of manufacturing.
- The lack of incentives, adequately trained human resource, capital, market size, infrastructure and regulatory capacity on pharmaceutical standards and partnerships needed to foster innovation and, technological transfer have a direct impact on the growth of the industry as outlined by the above responses. It is still very clear that access to funds, skilled personnel, ability to attain WHO standards, market size are issues that can be addressed and thereby, should not hamper setting up of domestic pharmaceutical industries.
- A number of macro and micro environmental factors play a key role in influencing how the pharmaceutical industry operates in Zambia, as outlined in the literature review. Political, social, economic and technologic factors have a greater influence on the macro environmental factors in the industry, as supported by the findings listed above.
- The SWOT analysis of the industry shows that the micro environmental factors in place do support the advancement of the industry despite the challenges as indicated by the responses from the research.
- Procedures for setting up the industry are in place and this is supported by the literature reviewed.
- Views from respondents support the need to enhance pharmaceutical production and promote its viability through appropriate marketing strategies, and study of the industries competitive advantage.

This study will add to the existing body of academic knowledge, particularly on the evaluation of the factors influencing the establishing a domestic pharmaceutical manufacturing firm in Zambia.

Recommendations

One of the objectives of this study was to recommend strategies to the Ministry of health and other line ministries, including potential investors in the business of pharmaceutical manufacturing. The following recommendations stem from the findings of the study to satisfy this objective:

- Local Pharmaceutical firms should be supported by Government in order to create employment opportunities and reduce on poverty levels.
- The National Drug Policy of 1999 should be fully implemented to address the current challenges being faced by the pharmaceutical industry.
- The current and future pharmaceutical plants should form strategic alliances with established foreign firms to enhance technologic transfer.
- The current curriculum for training pharmaceutical personnel should be expanded to carter for other specialized areas in medicine manufacturing and strategic management.
- Zambia requires more favourable trade policies that will promote the development of the local pharmaceutical industry, and penetrate the rural and regional markets.
- Pharmaceutical companies must seek to understand the nature of their competitive environment if they are to successfully achieve their objectives, and establish appropriate marketing strategies.

Areas for Further Research

This study had limitations and delimitations and the following areas are recommended for further research:

- A study on why incentives for local pharmaceutical manufacturers are not fully utilized by the industry.
- An assessment of the various skills mix in the pharmaceutical manufacturing industry.
- An evaluation of the compliance of WHO Good Manufacturing Practices in selected pharmaceutical manufacturing industries.
- A case study of the impact on consumers concerning the pricing mechanism for locally produced and imported pharmaceutical products.

Conclusions

The aim of this study was to evaluate the factors influencing the establishment of the domestic pharmaceutical industry, and make to recommendations concerning its viability. The study clearly shows that setting up the industry is very much feasible, as policies and legal provisions such as Doha declarations, National Drug Policy, ZDA Act 6 Chapter 11 of 2006, and other procedures and processes are in place. The market is readily available in enhancing local pharmaceutical production that will promote increased accessibility of medicines, sovereign control in the management of medicines linked to diseases affecting most citizens, increased regional integration, and improvement in the overall delivery of health. Domestic pharmaceutical production despite the economic, political, social and technologic challenges, issues of dynamic comparative advantage and important social costs attached to medicines, change the structure of this issue beyond a strictly classical economic interpretation.

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Kindly note that the entire bibliography is cited and a few references might not match the editing of the manuscript. In the event that anyone requires the entire study, he / she is requested to formally apply, stating reasons for wanting the dissertation and the organization requesting it to the following Email address: akarodia@regent.ac.za Regent Business School reserves all rights over the content of the dissertation.

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