

## Review Article

# Small and Medium Enterprises and Biopharmaceutical Innovations in Africa: Challenges and Prospects

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## Abstract

*Biopharmaceuticals can be described as medicines or medicinal products manufactured through biotechnological processes with links to biological sources especially those of live organisms or their active components. The biopharmaceutical industry is presently experiencing tremendous revenue growth rates projected at more than \$167 billion worldwide in 2015. There are more than 500 biopharmaceutical products that have been approved with about 400 presently marketable in the United States and European markets. The full potential of biopharmaceutical, biotechnology, genomic, genetic and biogeneric compounds is best realized in small entrepreneurial firms which have the capacity for creativity, risk, flexibility and iteration that no large biopharmaceutical entity can match. Although there are challenges facing African Small and Medium Enterprises (SMEs) in biopharmaceutical industry, the prospects on the other hand can be lucrative taking into cognizance Africa's ever increasing population and the need for affordable health care. To facilitate the contribution of SMEs in Africa, this article presents a perspective on the prospects of African SMEs in biopharmaceutical innovations such as new products, processes and services. The roles of SMEs in the global biopharmaceutical industry are reviewed. Additionally, selected critical factors to accelerate the contribution of African SMEs in global biopharmaceutical innovation are described. Finally, the prospective areas for biopharmaceutical innovation in Africa include research and development, marketing, workforce development and contract manufacturing.*

**Keywords:** *Small and Medium Sized Enterprises, SMEs, Biopharmaceuticals, Research and Development, Contract manufacturing.*

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## INTRODUCTION

Biopharmaceuticals can be described as medicine or medicinal products with links to biological sources especially those of live organisms or their active components that has been manufactured through biotechnological processes [1]. The biopharmaceutical industry's foundation can be traced back to research by Stanley Cohen and Herbert Boyer on recombinant deoxyribonucleic acid (DNA), which has now grown into a multi-billion dollars industry that currently spends \$21 billion on research and development (R&D) annually and has successfully commercialized over 400 products [2].

Presently the biopharmaceutical industry is experiencing tremendous growth as the industry witnessed between 15%-17% revenue growth rates in 2004, amounting to \$45 billion, which is twice the growth rate of the global pharmaceutical market [3]. Therefore, it is projected that revenues will hit a mark of \$90 billion in 2011. Global revenues are projected to increase by more than \$167 billion by 2015 [4]. Further, the biopharmaceutical market in the United States (U.S.) accounted for about 60% of the global pharmaceutical market in 2004, followed by Europe with about 20% and lastly Asia and the Middle East with Africa significantly absent [4]. BioPlan Associates in 2005 (reported by [5]) conducted a research on capacity constraints in the biopharmaceutical sector and found that amongst the respondents, 34% were currently faced with serious capacity constraints and more than 42% will experience constraints in about five years. Nevertheless, the growth rate of global biopharmaceuticals manufacturing is expected to exceed demand; with around 1.37 million litres in 2004 to 3.13 million litres increase in 2011 [5].

Various estimates exist in connection with pharmaceuticals R&D investments, and time required to market a product. The cost of

pharmaceutical product development in the U.S. increased from \$54 million in 1979 to \$800 million in 2001 [6]. Factors that contribute to the cost include the place where development and clinical trials are carried out as well as issues associated with meeting regulatory approval. The time from beginning of R&D to marketable product is estimated as 7 to 18 years [7].

Small and Medium Enterprises (SMEs) are independent firms with the number of employees varying from one region to another. The growth of biopharmaceutical innovations (for example, introduction of new products, processes and services) in the United States and Europe has been attributed to SMEs. Though raw materials (such as medicinal plants) for biopharmaceutical R&D abound in Africa, the contribution of Africa countries to biopharmaceutical innovation has not been significant. The possible reasons for this situation include inadequate funding for various aspects of the biopharmaceutical development.

There are current national and continent wide initiatives to catalyze biopharmaceutical research and development in Africa. For example, in Nigeria, the National Biotechnology Development Agency (NABDA) through World Bank assistance is catalyzing the infusion of biotechnologies for biopharmaceutical product development into the country's pharmacy training curriculum [8]. Further, the African Network for Drug and Diagnostics (ANDI) established in 2008 has the goal to promote and sustain African-led product R&D innovation through the discovery, development and delivery of affordable new tools, including those based on traditional medicines [9]. The African Network for Drug and Diagnostics recognizes the importance of African entrepreneurship especially to sustainably address the burden of neglected tropical diseases of poverty [10].

To facilitate the contribution of SMEs in Africa, this article presents a perspective on

the prospects of African SMEs in biopharmaceutical innovation. The roles of SMEs in the global biopharmaceutical industry and then provides a model for the contribution of African SMEs in global biopharmaceutical innovation.

### **Small and Medium Enterprises (SMEs) in biopharmaceuticals**

The European Union (EU) defines SME as the number of employees of around 250 whereas in the United States (U.S.) it is set at less than 500. Some other countries consider SMEs as those firms with not more than 200 employees while others have no fixed limit [11]. However, in line with the EUs definition, enterprises with less than 250 employees should have turnover of less than €50 million and yearly balance sheet of less than €43 million [11].

The full potential of biopharmaceutical, biotechnology, genomic, genetic and biogeneric compounds is best realized in small entrepreneurial firms, which have capacity for creativity, flexibility, risk and iteration that no large biopharmaceutical entity can match [12, 13]. SMEs have proven to convert federal funding into patents, licenses and products introductions more than larger companies [14].

There are indications that SMEs have not played significant role towards innovation in the pharmaceutical industry in the past [15]. It has been argued that SMEs have contributed towards innovation process where the conventional "academia-industry" research model has transformed to form a triangular model. However, this has been contradicted by some other research [16, 17]. Alliances between small biotechnology and big pharmaceutical firms in the U.S. show that the later are more drawn to alliances solely for commercial exploitation rather than for exploration purposes. This obviously leaves the small biotech firms to wind up in the cause of time [18]. A detailed review of the

trend in U.S. biotech/pharma sector concluded that cumulatively SMEs have created impressive revenue growth with profitability still at a low level in comparison to the pharmaceutical industry in general [19].

Over the years, research have shown that biopharmaceuticals industry is a lucrative business area and also growing at a fast pace [19]. The global biopharmaceutical market experienced growth of between 15-17% increase in 2004, which is even twice more than the global pharmaceutical market [3]. It accounted for \$45 billion in revenues in that same year which is estimated to be about 8.1% of the total global pharmaceutical market. Projections show that revenues might reach \$92 billion in 2011 at an average annual growth rate of 10.3% between the 2004 and 2011. Further, research have shown a move from the traditional trial-and-error drug discovery approaches to a more science based deductive approaches, through the search for new target, but with great emphasis on forming ties between biotechnological and biopharmaceuticals companies [20, 21].

There is no doubt that biopharmaceuticals continues to be an important and developing aspect of the pharmaceutical market with its increasing profit margin. There are more than 500 biopharmaceutical products that have been approved with about 400 presently marketable both in the U.S. and European markets. Of this number, 159 are recombinant protein and monoclonal antibody products. As of September 2010, the FDA had granted 14 full approvals to new biopharmaceutical products (Table 1). It was estimated that up to 20 approvals will be granted before the end of 2010 which will be the largest number approved by FDA since 1998 [22].

The current trend is that most of the biopharmaceutical firms invest close to 15% of their sales revenue on R&D and in some cases the total annual cost sum up to

**Table 1:** Biopharmaceutical products approved by FDA in 2010

Product	Company	Indication(s)
Xeomin (Botulinum Toxin A)	Merz Pharmaceuticals	Cervical dystonia or blepharospasm
Glassia (alpha-1 antitrypsin)	Kamada Ltd.	Alpha1-antitrypsin deficiency
Prolia (RANKL Mab, rDNA)	Amgen	Osteoporosis
Lumizyme (glucosidase alpha)	Genzyme	Pompe disease
Provenge (cellular vaccine)	Dendreon Corp.	Prostate cancer
Pancreaze (pancreatic enzymes)	Johnson & Johnson	Pancreatic insufficiency
TachoSil (Fibrin Sealant Patch)	Nycomed Austria GmbH	Control bleeding
Vivaglobin (Immune Globulin Subcutaneous)	CSL Behring	Primary immunodeficiency
Glucocerebrosidase, rDNA (velaglucerase)	Shire Pharmaceutical	Gaucher disease
Prenar 13 (13-antigen pneumococcal vaccine)	Pfizer/Wyeth	Pneumonia prevention
Menveo (Meningococcal vaccine)	Novartis	Meningococcal disease prevention
Collagenase (enzyme)	Auxilium Pharmaceuticals	Dupuytren's disease
Victoza (Glucagon-like peptide-1, Actemra (Interleukin-6 receptor Mab, rDNA)	Novo Amgen	Type 2 diabetes Rheumatoid arthritis (RA)

Source: Langer, [22] p4

billions of dollars. The globalization of markets, regionalization of technical and scientific knowledge and complexity of drug discovery process are reasons advanced for this investment decision. For the past 20 years, there has been a shift from the basic research operations from the trial-and-error drug discovery process to science focused deductive approach. This has led to a close connection between biotechnology and biopharmaceutical firms to carry out biopharmaceuticals research [20, 21, 23].

The big traditional pharmaceutical firms are taking advantage of biotechnology through the forming of alliance with biotechnology firms at different stages of the drug development life cycle. Also, there is an increasing number of big pharmaceutical companies that are forming strategic alliances with innovation-rich biotechnology firms, or outright purchase of the firms. Among the Top 10 biopharmaceutical companies in 2004 were Amgen, Genentech, Sero, Biogen Idec, Genzyme (Table 2) [3].

In 2006, Big Pharmaceuticals companies spent roughly \$17 billion for more than 250 biotech deals, up from 150 in 2003 [24].

## PROSPECTS FOR AFRICAN SMES IN BIOPHARMACEUTICALS

The development of SMEs in Africa is seen as boosting up the realization of wider economic and socio-economic activities thereby alleviating of poverty through the provision of employment, generating of extra source of capital for large-scale production. However, a report by the International Finance Corporation (IFC) indicates that there are between 30 to 37 million SMEs in Africa that are not adequately financed; this has consequently created a value gap in credit financing of around \$140 and \$170 billion. SMEs plays a key role in Africa economies with a contribution of about 75% in terms of employment within the continent [25].

**Table 2:** Top Biopharmaceutical companies profit in 2004

<b>Companies</b>	<b>Total Profit (Billion) \$</b>	<b>Top Products</b>	<b>Growth rate %</b>
Amgen	9.97	Epogen, Aranesp, Enbrel, Neulasta and Neupogen	27
Genentech	3.74	Avastin, Herceptin, Nutropin/Protropin and Activase/TNKase	43
Serono	2.17	Rebif	17
Biogen Idec	2.11	Avonex	23

Source of Data: Parmar [3].

Factors such as privatization, specialization, corporate restructuring and downsizing are encouraging the growth of SMEs within Africa [26-28]. However, there are many major challenges being faced by entrepreneurs in Africa. These include financial resources, tools and the required skilled labor [29-31]. The trend however is changing as African countries are now embracing possible ways to tackle the issue of finance through the introduction of credit facilities to SMEs either as startups or for expansion purposes. Government of many developing countries in Africa are formulating policies and measures to support SMEs given that they now recognize its contribution towards the growth of economy [32].

A workshop organized in 2000 by the Economic Commission for Africa (ECA) found that SMEs within Africa function under unstable, unregulated, unintegrated and uncompetitive environments which has adverse effect on the education and training policies, and R&D facilities and deficient capacities [33]. There is the notion that unless adequate environment for productive functionality is in place, integration into the global scene would almost be impossible. Though the workshop was help over 10 years ago recommendations to African governments may be still be relevant. These recommendations include: (1) introduce policies and regulator structure with the intention of developing the industries' competitiveness locally and internationally; (2) get involved in programs that promotes suitable environment for business; (3)

formulate mechanism to bring together close association between private and public sector; and (4) introduce strategies and programs for national economic development through access to income-earning opportunities, training and development of human resources, formulation of enterprise development programmes and financing schemes targeted at women entrepreneurs, access to improved quality of working conditions, as well as access to domestic and international markets and promotion of good relations between employers and workers thereby increasing the productivity of enterprises and organisations through a shared vision [33].

The success of African SMEs in biopharmaceuticals would depend on some critical factors such as innovation, R & D, marketing, contract manufacturing and work force development. Prospects for African SMEs in the biopharmaceutical industry in terms of innovation lie in the strength of alliance, a current trend in the biopharmaceuticals industry. With efforts from developing countries to promote innovation, there are prospects that African SMEs benefiting from such ventures that will lead to economic growth. African SMEs will benefit from the international biopharmaceutical industry through the sharing of knowledge in the development and marketing of new products or processes. Through alliance, African SMEs will be able to access newly emerging technologies for biomanufacturing. Further, inter-African SMEs partnerships can accelerate innovation and competitiveness of

African SMEs in the global biopharmaceutical industry.

Marketing is a crucial component in the biopharmaceutical industry. The effective introduction of biopharmaceutical products into the African market or African biopharmaceutical products to the international market can be hindered by limited capital. Alliances for marketing of biopharmaceutical products from African SMEs can help boost sales and provide an efficient avenue for biopharmaceutical product sale in the Africa.

Biomanufacturing is both capital and labor-intensive and requires specialized and experienced workforce. Often, many firms in Africa may face the problems of adequate funding and poor quality of the workforce. African SMEs in biopharmaceuticals can gain advantage through the contracting of the manufacturing of its herbal medicines to international biomanufacturing companies. The possibility that African SMEs can utilize the expertise of contract manufacturing companies will enable African SMEs to focus on core areas. This strategy has the potential of lowering production costs and improving manufacturing efficiency.

With the advent of new manufacturing technologies, there is increase need to develop the workforce in advanced technologies. Developing countries will benefit from international biopharmaceutical companies in the area of training the needed workforce to cope with the technological change in the industry.

## CONCLUSION

The biopharmaceutical industry is experiencing tremendous growth in terms of revenue and new biopharmaceutical products with small and medium enterprises contributing to its growth. The contribution of Africa SMEs has not been significant due to financial constraints and deficient quality workforce. However, new governmental

initiatives for SME financing as well as research and development in academic institutions provide inputs for catalyzing significant contributions of African SMEs in the global biopharmaceutical industry. Finally, the prospective areas for biopharmaceutical innovation in Africa include research and development, marketing, workforce development and contract manufacturing.

## DISCLOSURE

The authors report no conflicts of interest in this work.

## DISCLAIMER

The views and conclusions contained in this document are those of the authors and should not be interpreted as necessarily representing the official policies, either expressed or implied, of the funding agencies.

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