Production and International Marketing of Generic Drugs and the Fight Against AIDS in Africa

Abstract

The fight against the AIDS pandemic is one of the New Millennium's major challenges, particularly in Africa which has a large number of HIV-carriers. The measure of success to be achieved in this fight will depend on innovations that will be done in the manufacture and marketing of drugs capable of treating the disease. However, manufacturing and selling such drugs are in themselves not enough; the drugs must be accessible to the people who need them most of whom are poor. The aim of this study is to explore possibilities of manufacturing and marketing generic AIDS drugs at affordable costs. Studying the production and marketing of AIDS drugs on the international market is important for two reasons. First, AIDS is spreading, with disastrous social and economic consequences for countries in search of growth and development opportunities. In Congo-Brazzaville, for instance, statistics show a sharp increase in the number of AIDS cases. In fact, from 1986 to 1999, the number of infected persons increased from 3,000 to 13,798, that is, an increase of 359.9 percent in 13 years. According to WHO (2002), only 5 percent of AIDS patients in developing countries have access to anti-retroviral drugs, that is, about 230,000 people. Half of those people live in Brazil. Africa stands out as the continent most affected by the pandemic. Indeed, Sub-Saharan Africa accounts for 70 percent of the world's 40 million infected persons and only 50,000 patients can afford treatment, that is, less than 2 percent of the cases (*Marchés Tropicaux et Méditerranéens* – MTM, 2002). The second reason is that AIDS has been little researched and analyzed by social scientists, in spite of the magnitude of the pandemic and its catastrophic consequences (UNAIDS, 2002). Indeed, adequate multi-dimensional research should be carried out with a view to understanding the socio-economic dimensions of AIDS and identifying not only medical, but also social, economic and cultural solutions, among others, that could contribute to the eradication of the pandemic. This study focuses on two issues: the characteristics of the manufacture and international marketing of AIDS drugs, on the one hand, and innovative possibilities of reducing prices to make the drugs more accessible to poor countries, on the other.

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1.Characteristics of the International Drugs Manufacturing and Marketing System

The international system is characterized by the concentra tion of production in a small group of corporations, and the weakness of the African pharmaceutical industry and market.

Global Supply of AIDS Drugs

The global supply of AIDS drugs is concentrated in the developed countries which have a quasi monopoly on production. In fact, almost ¾ of all AIDS drugs are produced in developed countries, particularly the US, France and the UK. India is one of the few developing countries competing with producers in the developed world. Its pharmaceutical industry supplies almost 24.39 percent of the anti-HIV products selected by World Bank experts. The table below illustrates the domination of corporations based in developed countries and highlights the strong dependence of developing countries, including African countries, in the manufacturing and marketing system put in place by a few major industrial groups in developed countries.

AIDS drugs supply on the international market is concentrated in developed countries where the major pharmaceutical production facilities are located. Hence, 75.61 percent of anti-HIV/AIDS drugs are produced by multi-national corporations based in industrialized countries. American pharmaceutical firms alone, located in the US, the UK and France, manufacture 31.7 percent of the drugs. This situation has an impact on drugs prices which are influenced by the industrialized countries' monopoly on production and market outlets. The industrialized countries therefore have a clear edge over the developing countries.

Another characteristic of the world pharmaceutical industry is its tendency, since the mid 1990s, to pool production and research activities. Alliances and mergers between the major groups are occurring at both national and international level (Oppenchaim, 2001). Such alliances and mergers are designed to strengthen the monopoly that increasingly fewer and fewer industrial consortiums have on patented drugs, and their financial acumen. This puts them in a position to release the enormous financial resources required for research and development.

Drugs Prices

Prices of AIDS drugs are generally high and therefore unaffordable to most patients in African countries, given their low levels of incomes. The estimated cost of treating an AIDS patient is 300,000 FCFA. In Senegal, the Government subsidized the purchase of generic AIDS drugs to the tune of 200 million FCFA. The cost dropped to 60,000 FCFA, thanks to state subsidies (UNAIDS, 2002). This is still quite high for poor households. Hence public health services should of necessity provide health care to AIDS patients in Africa and the cost of such care ought to be covered by the State budget. This would help guarantee a steady supply of essential drugs to health centres so as to alleviate the suffering of patients. However, African countries' capacity to procure essential drugs on a regular basis is limited by budgetary constraints. There are glaring disparities in the distribution of funds between the North and the South. It is obvious that 90 percent of the overall AIDS funding is used to treat only 10 percent of the world's AIDS patients living in the developed countries (MTM, 2002).

The African Essential Drugs Market

In the mid1980s, WHO conducted a survey on the general availability of essential drugs in 104 developing countries. The results of the survey are relevant as they shed light on the current difficulties encountered by African countries in procuring AIDS drugs. About 70 percent of the population of 17 countries (including Nigeria) with a total population of about 200 million inhabitants did not have regular access to essential drugs. The World Bank's estimates show that 60 percent of the population of Sub-Saharan Africa does not have regular access to the drugs they need. (World Bank, 1994).

In Angola, only 48 percent of health facilities are provided with the essential drugs required for treating patients. In Tanzania, difficulties faced by the Ministry of Health in financing drugs orders have resulted in significant shortages of drugs in hospitals, forcing the Government to resort to foreign aid to meet drugs supply needs in urban and rural areas.

The lack of a national pharmaceutical industry in most African countries leaves the latter with no choice but to import large quantities of pharmaceutical products at very high cost. In 1998, Congo-Brazzaville imported drugs worth 17.5 billion FCFA (UNDP, 2002). Even generic drugs are sold at prices which the majority of the people cannot afford. A recent survey revealed that the high drugs prices compelled approximately 33 percent of poor households to buy their drugs not from pharmacies, but from street vendors selling products of very doubtful quality (J.C. Boungou Bazika and R. Samba, 2002). About 3,000 generic drugs specimens are sold on the Congolese market. Public and private health facilities spend an estimated 30 percent of their operating budget on pharmaceutical products (UNDP, 2002).

Profit-making private health facilities encounter less difficulties in procuring drugs. They have the necessary resources for purchasing at high cost, drugs needed by their limited clientele which comprises well-to-do households living in urban areas. Multi-national pharmaceutical corporations prefer to work with private operators who have a higher purchasing power. In Niger, for instance, drugs sales increased to 46 percent in Niamey, and to 35 percent in the chief regional towns, whereas 80 percent of the people live in rural areas (World Bank, 1994).

The African Pharmaceutical Industry

The African pharmaceutical industry is still teething, compared to that of Western countries. Similarly, the marketing of drugs is still very limited in comparison to that of some developing countries in Asia and South Africa.

The above data illustrates the limited production and marketing capacity of the African pharmaceutical industry. The production capacity of the 3 African countries account for only 27 percent of the total production, representing half of the production of Malaysia's pharmaceutical enterprises. The gap is even wider in terms of sales. The percentage of pharmacies with a license is derisory; only 13 percent of the pharmacies in the three African countries have licenses, compared to 43.9 percent of pharmacies in Malaysia alone. The weak position of the African drugs industry is due to lack of the capital and human resources required for setting up a pharmaceutical industry. This also accounts for the insufficient number of licenses granted to drugs marketing agents (suppliers and pharmacies). The problem is compounded by the fact that African pharmacies tend to be concentrated in urban areas, deserting the rural areas that are more densely populated, but with a low purchasing power. It is self-evident that the number and quality of experts involved in the manufacture and marketing of pharmaceutical products is of paramount importance. For instance, Glaxo, the multi-national pharmaceutical corporation, employs 16,000 researchers and 40,000 salesmen. These figures underscore the decisive role played by human capital (Oppenchaim, 2001).

However, the existence of drugs manufacturing enterprises in African countries (Tunisia, Uganda, Zimbabwe, Kenya, Ethiopia and DRC, among others) is a first step towards the establishment of a genuine pharmaceutical industry akin to that of India and Brazil, which could in future constitute a base for large-scale production of generic drugs.

Brazil is a showcase in this regard. As a matter of fact, 8 out of the 12 AIDS drugs used in the country are produced locally. Brazil's high production capacity makes drugs available to patients at low cost. This has cut by half the number of AIDS-related deaths. Since 1996, the AIDS mortality rate has dropped by 73 percent, while the number of reported cases has fallen by 2/3 enabling Brazil to save US$470 million on its health budget (Lethu, 2001; WHO, 2002).

The Role of the World Trade Organization (WTO)

The WTO plays an important role in the manufacture and international marketing of pharmaceutical products by regulating the issue of patents and licenses. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) protects patents and one of its articles (Article 30) provides for "*limited exceptions to the exclusive rights conferred by a patent*". However, the article further provides that the said exceptions apply on condition that "*they do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner*" (Tethu, 2001).

This clearly means that the manufacture of generic drugs, including AIDS drugs, is protected by patents and therefore comes under the exclusive jurisdiction of the corporation that has ownership of the patent. Since the overwhelming majority of pharmaceutical corporations are based in developed countries, they have a real monopoly buttressed by WTO provisions regarding intellectual property rights. Whenever a developing country manufactures an imitation drug without the authorization of the patent holder, it is in breach of WTO regulations and can be prosecuted. That was the case with South Africa which recently had a dispute with some pharmaceutical corporations because it was manufacturing imitation AIDS drugs without those corporations' authorization. Brazil had the same problem at WTO.

Possibilities of Reducing Prices and Increasing Global Access to Generic Drugs

Manufacturing generic drugs in developing countries and selling them to African countries poses certain problems which should be studied in an in-depth manner with a view to identifying ways and means of providing quality treatment at lower cost.

The use of generic drugs continues to pose a problem at the international level. The problem has two dimensions: safety and accessibility.

Safety and Accessibility

Regarding safety, there is still no international harmonization system capable of guaranteeing both the quality of drugs and their effectiveness in treating HIV symptoms. Hence the doubts cast on the effectiveness of *Nevirapine*, one of the drugs used to prevent HIV transmission from mother to child. It is important to note that HIV transmission from mother to child is one of the most common modes of infection. It is estimated that 600,000 children worldwide are infected every year during pregnancy (WHO, 2002). In 1997, the University of Makerere (Uganda) and Johns Hopkins University (USA) jointly conducted a study to test the effectiveness of *Nevirapine* in preventing AIDS in new-born babies. The results of the study were positive and WHO approved them. That study was important because *Nevirapine* is one of the low-cost retroviral drugs that are accessible to low-income African households.

The Role of the Internet

The internet can be a very useful tool for scaling down drugs prices. In fact, drugs bought on the internet seem to cost at least 20 percent less than their normal market value. African drugs importers could avail themselves of this opportunity. In Germany, where such e-business has already been experimented, an internet pharmacy with 1.8 million clients has been set up. That system has enabled health insurance companies to save $US363 million (WHO, 2002). African countries, with their growing internet services, could draw inspiration from the system. Public and private drugs procurement agencies could reduce their prices by ordering directly on the internet.

The Role of United Nations Agencies

United Nations, particularly WHO, can play a decisive role in the fight against AIDS, similar to the role it has played and continues to play in eradicating certain diseases in Africa, such as measles, poliomyelitis, tuberculosis and leprosy, among others.

This project, initiated by the World Bank, is of paramount importance. In fact, the World Bank, in partnership with such UN agencies as WHO, UNICEF and UNAIDS, and the Pharmaceutical Inspection Cooperation Scheme, has set up a project aimed at financing the supply of retroviral and other drugs that treat AIDS opportunistic infections. That project will enable UN agencies to assist countries experiencing difficulties because of the high drugs prices. An invitation to tender for selected products has been published and some multi-national corporations have already responded (see list in annex). Considerable progress seems to have been made in that initiative which was launched in October 2000. It draws inspiration from the HIV vaccine trials supported by UN agencies and is expected to make essential drugs more accessible to a large number of developing countries, notably African countries.

Debt Relief and the Fight against AIDS

Funds from the joint World Bank/IMF HIPC (Heavily Indebted Poor Countries) Initiative could also be used in fighting AIDS. In this regard, one of the requirements for eligible countries to benefit from HIPC relief could be that they adopt an AIDS control policy whereby the funds that should have been used to service the external debt are reallocated to the fight against the pandemic. Such funds would then be used for purchasing large quantities of drugs and setting up adequate structures for effective treatment of all infected persons.

The Role of Private and Public Corporations

The big private and public corporations should also develop a health care system for their staff, that would prevent HIV infection and treat reported AIDS cases. This is necessary since the cost of treatment would be by far lower than that of replacing infected staff, particularly where the infected workers are executive officers who, by virtue of their training and experience, cannot easily be replaced. Even when they can be replaced, this would be too expensive for the corporation, in view of the considerable financial resources and time required for training a senior executive officer or a highly qualified worker.

Breaking the Monopoly on Drugs Supply

International regulations could be adopted to oppose drugs manufacturers' cartels so as to guarantee fair competition in the pharmaceutical sector. Anti-trust laws should be enacted to prevent mergers and alliances designed to control the drugs market and to impose monopoly prices. Admittedly, fair competition in the sector will trigger a drop in prices of pharmaceutical products, including AIDS drugs of course. This would be beneficial to African AIDS patients since a large number of destitute patients would thus have access to treatment.

Relocation of Drugs Supply

Experience has shown that essential drugs manufactured in developing countries are less expensive than those manufactured in developed countries. This is true of drugs manufactured in India and Brazil. Relocating drugs manufacturing facilities therefore would seem to be beneficial to patients if the said facilities were relocated from industrialized countries to developing countries. It is thus important to know the measures that could encourage and facilitate such relocation.

Such measures could include tax and customs exemptions on imports of equipment. The host country could also assist by providing appropriate land for the drugs production unit and also contribute in facilitating the establishment of production subsidiaries. Clauses could also be inserted in regulations obliging pharmaceutical firms to relocate production units. Brazilian legislation contains such clauses. In fact, Article 68 of the said law, obliges firms exporting their products to Brazil to build a local production unit within three years of the granting of an export license.

Development of a South-South Trade in Drugs

Importing retroviral drugs from developing countries seems to be one of the strategies envisaged by African states for reducing the cost of treatment and making drugs accessible to patients. Côte d'Ivoire has decided to purchase its drugs from countries like India and Brazil. Burkina Faso has adopted the same strategy. South Africa has opted to establish a local retroviral drugs manufacturing industry. Such an industry would help meet not only the drugs needs of South African hospitals, but also those of a good number of African countries through drugs exports.

Revision of Certain Protective Provisions relating to Intellectual Property Rights

The protectionism supported by developed countries is an obstacle to the manufacture and marketing of generic drugs in developing countries. Such protectionism prevents price reductions since Western pharmaceutical corporations, by manufacturing the drugs in developing countries, could reduce production costs and thus sell the drugs at lower prices. The question here is how to attain that objective. It is possible to increase the number of unpatented generic drugs or at least to set a timeframe beyond which the generic drugs could be produced and marketed freely on the international market. Such a decision presupposes multilateral negotiations between the drugs manufacturers, the governments of the developing countries and United Nations agencies.

Promotion of Medical Research

The promotion of medical research is crucial to the fight against AIDS. Research aimed at finding drugs that could contribute in treating the disease must be prioritized by public authorities. Such research could lead to the discovery of alternative products that are both inexpensive and better adapted to symptoms of the disease in each country or group of countries with the same epidemiological traits.

The exorbitant prices of drugs are a result of the monopoly that a few multi-national corporations have on research. It is important to understand that the funding of medical research by African countries is one way of curbing such monopoly. The benefits accruing from such research are by far greater than the social and economic cost of AIDS.

Conclusion

We have seen how the industry and international market for pharmaceutical products, notably those meant for treating AIDS, is organized. The pharmaceutical industry and market are mainly characterized by the monopoly that a small number of corporations have on them. Such a monopoly keeps drugs prices high and unaffordable for the overwhelming majority of patients. Several solutions can be envisaged, such as relocation of drugs manufacturing facilities, review of certain protectionist provisions relating to intellectual property rights, development of South-South trade in drugs, among others. What matters is, above all, to understand that African countries must develop their own pharmaceutical industry which is still in a rudimentary phase. The debate remains open and further research is needed to explore new avenues to adopting a genuine international drugs policy that would make AIDS drugs accessible to the poor.

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