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West Africa Reproductive Health Commodity Security

Study Phase 1
Task Report: 4

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Local Manufacturing

Paul Dowling

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Contents

Introduction

One option for improving contraceptive security in the West African region is to have more local manufacturing of contraceptives and other reproductive health commodities.

This paper—

- defines local manufacture
- outlines the rationale for local manufacture
- reviews current regional initiatives in this area
- defines the current regional capacity for manufacture
- lists the obstacles to local manufacture
- describes possible realistic options for manufacture.

To determine the feasibility of local manufacturing and to define areas for further research, the authors also outline the key policy issues that must be addressed.

Define Terms

When policymakers talk about local manufacturing of drugs or contraceptives, they may mean different things, so it is important to define what is meant by *local manufacture*.

Pharmaceutical manufacturing includes “all operations, including purchase of material, processing, production, packaging, quality control, release and storage of drugs” (Kaplan 2003). We can have a different definition for the manufacture of active pharmaceutical ingredients (APIs) or primary manufacturing, and the manufacture of finished dosage forms or secondary manufacturing. The primary manufacturing of APIs can be through chemical synthesis or by biological processes (for example using microorganisms or plants). We can further define secondary manufacturing of finished dosage forms according to the extent of the processing that takes place. This can range from simple packaging of dosage forms into the final consumer presentation; to the processing, blending, and manufacture of the actual dosage form; whether it is solid (tablets, capsules, and powders) or liquid. Many countries package bulk drugs into consumer presentation packs. Other countries have complete secondary manufacturing; they take APIs and process them into final dosage forms. When stakeholders talk about local manufacturing, they may be referring to any combination of these.

Local manufacturing can also be classified by ownership. For instance, manufacturing can be by a locally owned company or by the local subsidiary of a multinational enterprise (MNE). Even local subsidiaries of MNEs can be wholly owned by the parent organization, or partially owned by local managers or shareholders. The state may wholly or partially own a local entity.

For our purpose, local manufacturing means any processing that takes place in the region, whether it is by a national organization or an MNE.

Health Policy versus Industrial Policy

In the past, various rationales have been put forward to justify the local manufacturing of pharmaceuticals. Most of the justifications can be classed in terms of health policy or industrial policy. The two are very different, and the justifications for local manufacture have consequences for policy decisions.

Industrial Policy

Reasons to justify local manufacture from an industrial policy perspective have focused on the benefits that will accrue to the local economy from having national manufacture of pharmaceuticals, including savings on foreign exchange through import substitution, employment creation, and the creation of exports. Several economists have questioned those benefits (Foster 1986). Briefly, their arguments questioning the validity of these assumed benefits are—

- *Foreign exchange savings*: Because most of the inputs—raw materials, plants, and packaging—have to be imported, this saving is questionable; profits on secondary manufacturing, at least for generics, are marginal (EFPIA 2004). Profit margins may be higher for API production but, because this requires significant capital investment, and West Africa has no current capacity for manufacturing APIs, the region is at a competitive disadvantage compared to countries with both primary and secondary manufacture, such as China and India.

- *Job creation*: Local manufacturing does create some jobs. For pharmaceuticals, the main areas of job creation are those where West Africa is most lacking: university and high school graduates with skills and experience in disciplines such as pharmacy, industrial chemistry, analytical science, pharmacology, quality assurance, and regulatory affairs. A study of the South African pharmaceutical industry (LABAT Africa (2001) Pharmaceutical Manufacturing Sector Study CMCS Consulting Group) found that major shortages in these skill areas constrain the development of that industry.

- *Export creation*: This is possible but only if exports can compete with products from other countries.

Health Policy

Health policy justifications for local manufacture are based on increasing access to essential medicines. In the case of contraceptives, contraceptive security would be improved if West African countries had improved access to affordable commodities with the required quality. If local manufacture could improve access, then that would be justification from a health policy perspective. Countries, such as Brazil and India, have succeeded in creating local pharmaceutical industries capable of producing cheap quality drugs. Brazil has increased access to antiretroviral (ARV) drugs for its population through local manufacture although, for various reasons, India has not increased access despite being a significant manufacturer of ARVs.

Another argument says that it is in a country's vital national interests to have locally made medicines to ensure continuity of supplies and national security. Two arguments can be made against this. First, no country is self-sufficient in manufacturing drugs. Even countries like the United States and India, net exporters of drugs, are to some extent dependent on imported medicines. Second, drug markets are now

global and the World Trade Organization (WTO) and other global trade agreements have made medicines readily available on world markets. Countries like Cuba have found it necessary for its national interest to develop a national pharmaceutical industry, but this does not apply to West Africa.

Current and Recent Regional Initiatives

Economic Community of West African States Pharmaceutical Manufacturers Association

In late 2002, the Economic Community of West African States (ECOWAS) Pharmaceutical Manufacturers Association was formed to "increase access to drugs, boost formal export market and increase the capacity utilization of pharmaceutical companies in the West African sub-region" (World Bank 2003). It is unclear how active this group has been.

Manufacture of ARVs

There have been several proposals and discussions around local manufacture of ARVs in West Africa, either on a national basis (Nigeria and Ghana), or involving regional cooperation. Much of this effort has centered on south-south partnerships with manufacturers in countries like Brazil and India. While the rationale for local manufacture was strong when ARV prices were prohibitive, recent decreases in prices of generic front-line regimens, combined with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement that allows imports of generic ARVs, have weakened the economic justification for this effort.

PHARMESA

In 1996, the member countries of the 23 nation Common Market of East and South African nations (COMESA) created a syndicate of five local drug manufacturers that met the World Health Organization's (WHO) good manufacturing practice (GMP) standards and would seek to supply more of the local market for pharmaceuticals. The rationale was that because these organizations had excess capacity, low labor costs, and reduced transportation costs compared to imports, they could supply more of the regions' needs (at the time COMESA countries were buying only 10 percent of their pharmaceuticals from each other). Nothing came of the initiative.

Manufacturing in West Africa

Obstacles to Local Manufacture in West Africa

Some of the difficulties of local manufacturing have already been mentioned in the preceding sections. Briefly, they include—

Absence of a Pool of Educated and Trained Professional Personnel

Pharmaceutical manufacturing requires skilled, trained staff, at the high school level for factory positions, and at the university level for technical and managerial positions. West Africa has s limited pool of people with these skills. India has successfully developed a pharmaceutical industry due, in no small part, to the presence of a pool of trained and relatively low-paid chemists, pharmacists, and engineers.

Absence of Economies of Scale

Pharmaceutical manufacturing is a low profit margin operation with significant economies of scale. Larger manufacturers can spread their fixed manufacturing costs across larger production volumes and be more competitive on price than smaller operators. Scale economies result from several factors, including large initial investments in plant and equipment, and an often overlooked fixed cost—the huge investment needed in quality systems and testing to attain current Good Manufacturing Practice (cGMP)[1] status. Local manufacturing in West Africa would have to compete on price with identical products being manufactured in Europe, the United States, and the new pharmaceutical players like India, China, and Brazil. Most existing manufacturing plants in West Africa are small, with only a few hundred employees. Local manufacturers in Ghana report an inability to compete on price with Chinese and Indian manufacturers on very low-margin drugs like aspirin. Their only competitive advantages are reduced transportation costs and personal relationships with customers, including an ability to respond quickly to customer needs because they are close to the customer.

Necessity to Import Most Inputs

Because West Africa has a small existing industrial base, most inputs for pharmaceutical manufacture must be imported. For instance, pharmaceutical manufacturers in Ghana import APIs, excipients, and packaging materials (AGI 2003). A study of the South African pharmaceutical industry revealed that local manufacturers locally sourced 39 percent of APIs, 49 percent of excipients, and 97 percent of packaging materials. By contrast, Indian manufacturers were locally sourcing 93 percent of APIs and all their excipients and packaging materials (Kaplan 2003). In many cases, pharmaceutical manufacturers in countries like India, China, and Brazil are integrated, making both APIs and finished dosage forms. At the very least, they are located close to API producers. Large-scale manufacturers can also obtain raw materials at better prices than smaller manufacturers. Because most equipment for production or testing is highly specialized, it has to be imported. The availability of spare parts and maintenance are also issues.

[1] cGMPs or current GMPs refer to the principles, guidelines, and standards used in the development, manufacture, and control of medicinal products. Different regulatory bodies (e.g., Federal Drug Authority, European Union) will have cGMPs that differ slightly from each other.

Technology

Pharmaceutical manufacture requires certain basic technologies for production, e.g., powder technology and clean room technology, as well as expertise in related technical areas such as documentation, analytical testing, product development, and drug registration. Plants tend to locate in clusters where these skills and services are readily available and close to consumer markets, e.g., Mumbai and Hydrabad in India, New York-New Jersey, and Shanghai, China. Studies have shown shortages (or at least a lack of information on availability) of most of these technical skill areas in Africa (Olliaro and Navaratnam 2002).

Infrastructure

Pharmaceutical manufacture requires basic infrastructure like reliable electrical current, a clean reliable water supply, and reliable transport links—all areas where West African industry has had past problems.

Advantages and Opportunities

Market Size

With the exception of Nigeria, with a population of more than 129 million, none of the countries of West Africa has a sufficiently large domestic market to offer significant advantages to a local manufacturer in terms of domestic market size. However, the West Africa region, with a population of more than 265 million (World Bank 2003), offers that potential. Population growth rates vary between 1.8 percent in Ghana to 3.1 percent in Niger. In Nigeria, population growth rates are around 2.2 percent. Total gross domestic product (GDP) in 2001 was almost U.S.$91 billion (in current dollars), with Nigeria accounting for U.S.$41 billion of the total. That said, there are serious limiting factors in assessing the size of the West African market. Total per capita health expenditures range from a high of $57 (current USD in 2001) in tiny Cape Verde, to a low of only $6 in Niger. In Nigeria, the figure is only $15 (WHO 2004). There are few reliable estimates of per capita average expenditure on drugs in sub-Saharan Africa. Obviously the figure is only a fraction of the total expenditure; the percentage for drugs related to reproductive health are still smaller.

Local Knowledge

The main competitive advantage for local manufacturers is their knowledge of local markets, personal relationships with decision makers, fast turnaround due to their proximity to customers (including the end user), and reduced transportation costs. The relatively small size of West African markets may work to their advantage because the market does not attract a lot of attention from large multinational manufacturers or manufacturers from developing countries.

Current Manufacturing Capacity in West Africa

It is difficult to obtain solid information on the current capacity for manufacturing in West Africa. Of necessity, the following is a brief discussion and needs to be validated during field visits. Most countries do not appear to have significant manufacturing capacity, with the exception of Nigeria and Ghana. Cameroon, Côte d'Ivoire, and Senegal are also likely to have some manufacturing—possibly subsidiaries of French firms—but it is difficult to obtain information.

Nigeria has some manufacturing, with a mix of locally owned companies (Emzor) and subsidiaries of MNEs. The recent trend has been for MNEs to divest ownership, either partially (e.g., GlaxoSmithKline retains 46 percent ownership of Smith Kline Beecham Nigeria plc) or fully, to local ownership (e.g., management buy out of Pfizer Nigeria to create Neimath International Pharmaceuticals Ltd.). An Indian pharmaceutical manufacturer—Ranbaxy—plans to open a plant in Nigeria to manufacture pediatric ARV syrups. The Nigerian pharmaceutical market is fragmented; no one company, except Glaxo Smith Kline, have more than 10 percent market share (NIPC). Major players include GlaxoSmithKline, NGC (formerly Hoechst; they claim to be number two in the Nigerian market), Emzor, Neimath, and Parke Davis.

Ghana has a number of pharmaceutical plants, both locally owned, and one—Phyto-Riker Ltd.—is owned by an American venture capital fund. Industry respondents estimate that 20 percent of the pharmaceuticals used in Ghana are manufactured in-country. It is difficult to verify this figure but it does indicate the extent of local manufacture in Ghana.

For both countries, manufacturing is, for the most part, restricted to secondary manufacture of finished dosage forms, with the production of tablets, capsules, and liquids (mainly syrups). Some sterile injectable antibiotics and intravenous (IV) solutions are manufactured. The main manufactured products appear to be limited to drugs on the essential drugs list—antibiotics, antimalarials, anthelmintics, over-the-counter (OTC) painkillers, cough syrups, and vitamin formulations.

Many plants, in both Nigeria and Ghana, claim GMP certification; for the most part it seems to be local GMP standards. NGC in Nigeria manufacture, under subcontracts from Hoechst Marion Roussel and Pfizer, claim to manufacture to U.S. Federal Drug Administration (FDA) standards, although this could not be verified. Phyto-Riker of Ghana claim to be the only manufacturer in ECOWAS to have International Standardization Organization (ISO) certification (a general international quality standard not specific to the pharmaceutical industry).

What Is Realistic?

We make the following assumptions for manufacturing capacity in West Africa:

- Because there are significant financial and technical barriers to starting pharmaceutical manufacturing, it is not realistic to consider new *greenfield* companies or plants; any local manufacturing should come from existing plants and organizations. This could involve existing capacity or expansion.
- Given the lack of primary manufacturing of API or intermediates, local manufacturing for the short- or medium-term should only consider the manufacture of finished dose forms.
- Likewise, because there is no existing capacity in-country for manufacturing condoms, intrauterine devices (IUDs), or implants, local manufacture should consider only pills, capsules, and liquids. The main products to be considered (see list in the annex) should be hormonal pills and injections, and antibiotic and antibacterial tablets and capsules.
- Active public sector participation in manufacturing is not desirable. Private manufacturers will drive local manufacturing, with the government having a role in the regulation and creation of an environment that will help the private sector.

Key Questions

Size of Market

For a discussion of market size, see Task Report 3, Encouraging Greater Private Sector Participation; section 6, Overall Market Size and Attractiveness.

Quality Issues

All commodities manufactured locally must adhere to cGMP. The exact standard will vary depending on the donor/purchaser but, at a minimum, the World Health Organization (WHO) cGMP standards and/or local country standards will be appropriate.

Price Issues

Locally manufactured products must compete on price with current products. Currently, prices for oral hormonal products vary from U.S.$0.31 per cycle for branded product from a MNE to approximately U.S.$0.17 for a generic equivalent from India. Shipping costs to a coastal country with a major port, for example, Nigeria and Côte d'Ivoire, vary from around 20 percent of consignment value for condoms to 10 percent for most other commodities. Additional shipping inland can add significantly to this cost, as much as 10 to 20 percent. Because local production will, in all likelihood, be from one of those countries, the total price shipped to one of these countries is the approximate price that local products must match.

Donor Issues

The main donors for drug purchase in West Africa are USAID, DFID, and KfW. USAID is a major supplier of contraceptive commodities, with almost all commodities procured in the U.S. by USAID. This is unlikely to change in the near future. DFID and KfW encourage procurement of the most economically priced commodities, if they meet European Union manufacturing standards. The main issues surrounding donor procurements are—

1. For donors that allow open sourcing, products must be competitively priced.
2. Products must meet predetermined GMP standards.
3. Products must be procured transparently, i.e., through an open bidding processes.

Donor procurement of drugs tends to follow complex, bureaucratic procedures. Local manufacturers report that the main difficulty in tendering for these orders is the lack of information about the procedures.

Pooling Orders

The willingness of the various countries in West Africa to pool their drug procurements has been discussed in detail in another section. The issues involved are twofold:

1. What, if any, are the economic benefits of pooling?

2. What technical, political, and financial obstacles must be overcome?

It is not clear if pooling orders would benefit local manufacturers. A pooled order would be less likely to be based on personal relationships, client knowledge, or quick turnaround, which are all likely sources of competitive advantage for local manufacturers. It is also not apparent that countries would accept a pooled procurement from a manufacturer based in another West African country, especially if those countries had their own capacity. Indeed, they would probably be more likely to accept procurement from a country not in the region.

Future Research Needs

The most immediate research need is to assess the capacity of local manufacturers to produce the required commodities. In cases where they are already manufacturing drugs—for example, antibiotics and antibacterials like ampicillin capsules and cotrimoxazole tablets—they are more likely to assess their capacity to scale up. In cases where they are not currently manufacturing—for example, hormonal contraceptives—they are more likely to assess their ability to produce these in the short term. Capacity refers to plant, equipment, and financial and human resources, not just production, and also for the quality control and quality assurance of those products. Part of the research would be to assess these manufacturers: What are they making? How are they making it? What standards are they using? What/who are their customers?

Conclusion and Recommendations

Local production of maternal health pharmaceutical commodities in West Africa can only occur if the local products are up to the required international quality standards, and the products are being competitively priced. These products must compete with products from either multinational pharmaceutical suppliers from the developed world or generic products from the pharmaceutical manufacturers of Asia and Latin America.

Locally produced products cannot be given any preferential treatment in procurement decisions; international trade agreements and donor procurement guidelines will not allow this. Even if they did, it is a wasteful allocation of resources to procure more expensive locally produced product just for industrial policy reasons. Local manufacturing should occur only in the context of health policy, with the specific policy being to make these products more accessible for the people of West Africa, which means products of the requisite quality, at the best possible price.

Given the major economies of scale in manufacturing and the major barriers to entry for new manufacturers—financial, technical, and personnel—local manufacturing should focus on existing companies with the production, and technical and human capacity to manufacture solid and liquid dose forms. This means that, initially at least, any local manufacturing would be hormonal products, both orals and injectables.

Governments and donors should give technical assistance to local manufacturers in preparing bids for contracts. The complexity of the bidding process is often cited as one of the main difficulties in winning these contracts. While local companies must offer the equivalent quality at competitive prices, the complexity of the contract process should not be a disadvantage to winning these contracts.

Experiences with public sector manufacturing of pharmaceutical products have almost all have had problems, and in the current political and economic environment, it is unlikely to gain donor support. It is also doubtful that West African governments will agree on a location for one joint manufacturing plant. These factors preclude the creation of a regional manufacturing entity. The role of government should be to create an environment (legal, economic, and social) that would foster manufacturing, rather than being actively involved in actual production.

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