Business Development in the Developing World

a primer for market entry

Introduction

This primer was developed to assist medical product organizations considering market expansion into developing countries. There are many unique aspects to consider when bringing a new product or technology to market in these countries, whether as a commercial business, as a subsidized offering, or as a donation.

The information and guidance draws primarily on experience from diagnostics, essential medicines and medical devices launched into Sub-Saharan Africa, and primarily based on HIV/AIDS, TB and Malaria programs.

This primer will provide an overview for businesses and organizations new to the general issues involved in entering a market for medical products in developing countries.

It is key to keep in mind, that while there are many similarities between countries and between products, there are also many differences. It is crucial to understand the specifics in each country and for each product. Thorough research and analysis is essential for strategic planning, financing and tactical success.

And although much can be elucidated through traditional secondary resources, there is no substitute for on-the-ground market research and in-country face-to-face interaction with informants, potential partners, key opinion leaders and other players and stakeholders.

Global Health

Global Health is an umbrella term often used to describe health and medical initiatives in developing countries – in particular those funded and/or managed by Governments, donors and development organizations.

The "Global Health Space" operates significantly differently than the United States and other industrialized countries.

In addition to standard market research, a new entrant must, at a minimum, gain a thorough understanding of the following:

- The Complex Network of Market Participants (the 'Stakeholders")
- The Decision Making Processes
- The Technical & Regulatory Standards
- Funding Entities & Processes
- Treatment/Testing Algorithms
- Expected Timelines

Many companies have learned this the hard way. Lack of understanding regarding market dynamics and the basic rules of engagement is, at best, time consuming and costly. In the most severe cases, it can be catastrophic.

Market Participants

There are numerous participants that play a significant role in market entry and expansion. These are often referred to as "Stakeholders" and include:

Medical Decision Makers/Influencers
- Ministries of Health (MOH)
- Local Opinion Leaders

Regulatory & Registration Bodies
- National Drug Regulatory Authorities (local)
- Stringent Regulatory Authorities (international)
- World Health Organization (WHO)

Funding Entities
- Local Governments
- Multi-Lateral Funders
  (e.g. World Bank, Global Fund, etc.)
- Bi-Lateral Donors
  (e.g. PEPFAR, USAID, CIDA, DANIDA, etc.)
- Charitable Organizations
  (e.g. Foundations, Churches, etc.)

Implementing and Technical Assistance Organizations
- UN Agencies (e.g. WHO, UNDP, etc.)
- International/National Non-Governmental Organizations (NGOs)
- Consulting Groups and Specialized Consultants

Local Businesses
- Importers & Distributors
- Manufacturers
- Market Research Companies and Consultants

Regulatory issues

Market entry into the Global Health market entails several regulatory steps, including Registration, Pre-qualification, and Stringent Regulatory Authority (SRA) clearance.

Registration

As a starting point, all medical products must be registered with the authorities of each country into which they will be imported. Generally speaking, unless a waiver is obtained, importing non-registered products is illegal.

Registration is the market authorization, or approval, for product sale and distribution issued by a country's National Drug Regulatory Authority (NDRA). In some countries this process may be referred to as "Licensing". Successful registration permits a manufacturer or distributor to locally market a specific product for a defined period of time. Registration must be renewed periodically, commonly every 3-5 years.

Registration entails verification of recognized technical competency standards. This process includes:
- Product Dossier Analysis
- Clinical & Analytical Criteria Assessment
- Verification of Equivalence (for generic medicines)

Effective navigation of the Registration process requires much more than secondary research of specific requirements. Very frequently, the most current procedures and guidelines are not published on the internet, or otherwise readily accessible.

It is therefore essential to engage the assistance of a local individual or business with the appropriate experience, contacts and know-how – someone who understands the process, how the rules apply to the product in question, and how to navigate through the inevitable bureaucracy and barriers.

Typically, this means partnering with a local distributor with a track record of successful registrations. *Important Note: the distributor will usually also submit and hold the title to the registration.*

Pre-Qualification

Many developing countries lack the regulatory capacity to effectively screen and evaluate new products (dossier review, testing, etc.). It is therefore a common procurement agency practice to require that products meet a recognized international Quality Assurance standard.

This is often accomplished through a requirement for WHO Pre-qualification, or Stringent Regulatory Authority (SRA) clearance – see the SRA section below.

Pre-qualification refers to the process of manufacturing standards assessment, verification of quality, and supplier capacity. *This is accomplished prior to procurement.* It applies to specific products and unique manufacturing sites. Pre-qualification is also only valid for a specific period of time.

In the Global Health space "pre-qualification" usually refers to the WHO pre-qualification scheme. Managed by the World Health Organization, WHO PQ is designed to ensure the procurement of high quality products into countries that lack sufficient regulatory capacity. The program analyzes and tests candidate products and inspects manufacturing facilities. Manufacturers will often find that products must attain WHO PQ. Even where this is not strictly the case, preference is often given to WHO PQ products.

Additional Pre-qualification criteria may also be defined to establish bid eligibility for a specific tender. The particular eligibility requirements will be described in the tender document.

Stringent Regulatory Authority (SRA)

SRA refers to those regulatory agencies of countries able to scrutinize products to a high standard.

SRA members include:

- USA (FDA)
- EU (CE-mark)
- Japan
- Switzerland and Canada (Observer members)
- Australia, Iceland, Liechtenstein and Norway (Associate members)

Typically, if a product is not WHO PQ, a qualifying Stringent Regulatory Authority (SRA) approval is required.

SRA approval is, in practice, also a pre-requisite for obtaining WHO PQ.

Exceptions & Waivers

Occasionally it may be possible to obtain an exception to the normal process of Pre-qualification and registration. Humanitarian disasters, clinical trials, and research work may form the basis for a waiver into a specific country. Also, agencies including the United Nations, charitable NGOs, mission hospitals, and other groups may be able to secure waivers for specific products, or donations, under certain circumstances. Generally speaking however, the process is onerous and the exception must be obtained for every consignment.

Reliance on waivers it is not a mainstream approach to market penetration and is not a viable strategy for sustained commercialization.

Funding

In many sub-Saharan African countries, the annual Ministry of Health (MOH) budget frequently falls below $50* per year, per capita. Therefore, international donors often provide a substantial proportion of the funds needed for public sector healthcare provision. The actual contribution varies from country to country, disease to disease, and product to product.

One consequence of this is international donor involvement in fund utilization: from procurement to programmatic implementation, clinical guidelines to testing algorithms, etc. As such, disbursement of funds is typically tied to detailed implementation plans, achieved performance indicators, and itemized, multi-year budgets.

Although it may appear from a high-level perspective that there is an abundance of funding available for a particular program or disease, almost all funds are allocated in great detail in the early stages of program development. There is rarely short-term flexibility in shifting funds and/or programmatic approaches once they are underway. For these reasons, market potential may be significantly lower, and penetration may be much slower, than initially anticipated. Estimating market potential involves many more factors than simply identifying the total funds attributed to a specific country or disease.

This is particularly important for products that require a shift in practice or approach. In other words, the very products that are likely to have the biggest impact. This requires that the marketing strategy and plan must include early and multi-faceted engagement in the program planning and decision-making processes. Preparation and patience are essential. *The initial sales cycle is long – 1½ to 2 years is typical.*

Procurement

For internationally funded projects, the procurement agent must usually adhere to the procurement rules and policies of the donor. While there are some differences between donors (PEPFAR for example may require the procurement of US made products, or only products that are FDA cleared), the goal is a transparent competitive process aimed at procuring high-quality products at the lowest cost. As such, a tender is almost always open to several international bidders.

However, specific requirements, such as WHO PQ or pre-selection, may limit a manufacturer's ability to bid on a particular tender.

Distributors

Unless a new entrant is willing to set up its own in-country office, it must partner with a local distributor. It is critical to identify and work with a good local distributor. Minimal requirements include a comprehensive understanding of the product market, established stakeholder relationships, product registration experience, and sufficient sales and logistics capacity. *The importance of distributor selection cannot be overstated. It is a "make-or-break" step in the early marketing effort.*

In every country there are respected, credible and successful distributors. The first challenge is finding them. Most are not listed in directories or trade publications, or have web sites. They are not easily identified from standard internet searches. One must get in-country to find them and evaluate their capabilities in person.

The importance, role and capacity of distributors is one of the most misunderstood areas of Global Health marketing – and is in many cases a source of great frustration.

Much of the frustration stems from not having clear and realistic expectations of what the distributor can, and cannot, do. Beyond identification, assessment and selection of a distributor, a formal contract that clearly defines roles, responsibilities, targets, and escape clauses is arguably the single most important business development activity. **This is an on-the-ground, on-site, in-person exercise – there is no substitute.**

It is strongly recommended to engage the services of an individual or company with developing country experience in distributor identification, selection and management. Making the wrong distribution network decisions can have severe consequences.

* See for example: Trends and Opportunities in Public-private Partnerships to Improve Health Service Delivery in Africa; Tonia Marek, Catherine O'Farrell, Chiaki Yamamoto, Ilyse Zable, The World Bank, 2005

Standard Treatment Guidelines and Testing Algorithms

For some diseases, most developing countries have Standard Treatment Guidelines (STGs) guiding how healthcare providers must treat.

Similarly, for some diseases, including HIV/AIDS, each country follows a government sanctioned "testing algorithm", i.e. a nationally approved process for testing and screening patients.

This standardization serves to ensure consistency and quality, but is also a barrier for new products attempting to enter the market. In principle, when procuring products, the buyer should not specify particular brands. However, due to the very significant effort required in changing an STG or a testing algorithm (consultations, re-training providers across a country, etc., and the risks involved due to incorrect testing), the motivation to retain a known brand or product is strong.

Because STGs and testing algorithms are developed at the highest MOH levels, often involving extensive expert consultations, WHO guidelines, and regulatory mandates, reasons for change must be compelling.

For marketing purposes, these standards provide both a significant barrier to entry and, on the other hand, a preferential position for an established product. Again, the need for early, strategic and patient participation is needed.

Conclusion

Marketing medical products into developing countries offers both an opportunity for doing good business, and for having a positive impact on health. *This is assuming one knows how to go about getting the job done.*

The very first step is to accept that marketing and business development in the Global Health space have dimensions, dynamics, and participants that are different or non-existent in western countries.

It is very unlikely that a newcomer to this space will know where to start, what questions to ask, or where to look. And each country is different - the marketing effort must be individualized, country-by-country.

Partners with first-hand experience, and contacts, in this space are indispensable for a successful venture.

Therefore, three decisions must be made early on:

1. Retain a professional to do the (secondary) market research – to identify and research each primary target country.
2. Retain the services of a commercial *and* public health expert for primary, in-country market research and distributor identification.
3. Select and contract with a local distributor.

Steps 2 & 3 must take place in-country. In this space there is no substitute for on-the-ground, on-site, in-person research and interaction with stakeholders.

And plan for patience -the initial sales process is long – 1½ to 2 years is typical.

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In all, Mr. Beer possesses 20 years of international experience in commercial and not-for-profit marketing, business, program development, and supply chain management in the private and public sectors. He has a successful track record in building business and programs from scratch, from conceptualization to strategy development to daily management and implementation. His strengths lie in an unusual combination of experience and skills:

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