

**A *PRIMER* ON
INCREASING PARTICIPATION OF GENERIC AND NON-GENERIC
CONTRACEPTIVE SUPPLIERS IN BECOMING ENGAGED IN
DEVELOPING COUNTRY MARKETS**

**Reproductive Health Supplies Coalition Meeting
The Hague
October 5-7, 2005**

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This paper will summarize the writer's personal views, thoughts, and impressions on how to further engage the private sector commercial hormonal manufacturers in collaborating with the RHSC in its reproductive commodity security initiative and strategic objectives in the developing world. The writer's intent is to not provide a rigorously analytical or polished document, but to provide a background, or primer, on issues that might need addressing by the RHSC members as they seriously begin to engage the commercial sector.

The first section of this paper will focus on issues relating to those enabling policy environments impacting the provision of RH commodities. These issues would relate to such policies as those impacting importation, distribution, marketing and advertising of RH commodities. Specifically, the enabling environment for RH commodities would relate to national government laws and policies that govern how these goods are used, or messages for their use in reaching the consumer. Furthermore, there are some action steps that could be taken by the donor, institutional, national government and NGO communities to address market medical, cultural and social barriers, quality assurance issues, high business transaction cost in developing country markets, ability to pay issues and market incentives for the commercial sector.

The second section of this paper will be on a more personal note. It will reflect on some of the things that I have learned in my career, that have helped make my job rewarding. These are not things that you will find in graduate schools of public health, in classes in health economics, nor in business school or medical school textbooks.

The following underlying beliefs underpin the thinking and recommendations in this paper:

- The RHSC should honor its pledge of the ICPD Program of Action to engage the private sector as stakeholders in RH commodity security deliberations.
- The private sector can contribute to social development *even if* governed by business objectives.
- Any development initiatives from the private sector will be sustainable and scalable *only if* it makes business sense.

The issues addressed in this paper will apply to both generic, research and development-based pharmaceutical companies, local and transnational companies, those corporate entities having complementary corporate social responsibility programs (CSR), and to companies in both OECD and non-OECD countries. Some of the key issues for private sector engagement in developing world country markets are the following.

Balancing profit and humanitarian investments: Even with the best of intentions, with respect to CSR or value added to corporate image, the owners or shareholders of a company expect some measure of profit or returns relating to intangibles or benefits such as improved public image. While company investment in donor-funded RH commodity

projects may not always meet corporate management objectives for income before taxes (IBT) and return on investment (ROI), these investments are nevertheless strategically beneficial to the corporate interest for the following reasons: exiting such collaborative activities would seriously injure a company's image at a time when the pharmaceutical industry is under increasing pressure to improve access to medicines in developing countries; supply of RH commodities to FP programs in the developing world would significantly suffer; companies have adopted policies of "helping the world's neediest achieve better healthcare."

Taxation, Tariffs and Duties: While generally accepted as a cost of doing business, they can be regressive and have chilling effect on management decisions to enter new markets. Typically, RH commodity supplies to the public sector market segment are in many cases exempt because the donor community has negotiated exemptions beforehand with recipient country national governments. As one moves up the pyramid from public sector to SM, to Tier Two, to Tier One, the potential for exemptions of RH commodities from these costs imposed by national government decrease and can significantly contribute to the business cost of entering new markets.

High Business Transaction Costs: Transaction costs are those costs incurred during the process of buying and selling, on top of the price of RH commodities changing hands. By reducing these costs, the price mechanism (the process by which markets set prices) will operate more efficiently. For example, the process of transitioning from a centrally planned market (such as the market for RH commodities in the public sector, or those heavily subsidized NGO SM models) to a market driven economy generally takes place in an institutional framework that is only partially developed, and is therefore by its very nature inconsistent and unstable. This leads to high transaction costs for companies looking to enter and commercialize these markets. Businesses choosing to partner with international donors, institutions and NGOs to enter these high-risk markets can select an entry mode that reduces their risks by sharing their transaction costs to launch and commercialize RH commodities. Given that markets for RH commodities are typically commercialized by the branded pharmaceutical manufactures, and not the generic manufacturers from non-OECD countries, this is an area whereby the RHSC can add value. Should decisions be made that other organizations, i.e., NGOs such as ICON or PSI, to commercialize undeveloped markets with RH commodities supplied by generic manufacturers, these high business transaction costs would not be assumed by the manufacturer. On the other hand, should these markets be primed by donor project funds and organizations such as AED, The Futures Group or other PSP-One contractors, the private sector commercial firms would assume a share of the business transaction costs.

Social vs Commercial Marketing (the issue of subsidy vs non-subsidy): In some country markets which will be priorities for the RHSC, there will be very little interest on the part of the private sector to commercialize its RH commodity product portfolio. The SMC of Bangladesh is a case in point. In these markets both generic and non-generic

manufacturers will supply their products via the international donor community. Product oversight and stewardship will vary by manufacturer, but the organization with primary market governance oversight and accountability will be the donor, national government authority or NGO charged with executing the program. Of particular concern to those manufacturers with established commercial markets will be to insure that mechanisms and procedures are in place to address product leakage and diversion. As markets mature and become more attractive to the private sector to commercialize, there will be an increased interest by the private sector in these markets. As companies invest to commercial their products, they become very sensitive to donor-funded SM practices, activities and initiatives that impact, marginalize or cannibalize their established commercial markets. Heavily subsidized products tend to distort the market, which can be a disincentive for a manufacturer to invest in market development activities. As markets mature, the preferable SM model would be the private sector, or Tier Two market development approach. Generally speaking, the NGO or subsidized SM model is viewed by the commercial sector as having high impact, high cost and low sustainability in the market. Conversely, the Tier Two or private sector SM model could be viewed as having lower impact, lower costs and higher sustainability in the market.

Appropriately Defining the Niche---Identifying and Maximizing Complementarities:

It is important for the RHSC and the private sector to identify and amplify those projects where the interrelationships are win-win and where the total package has greater value than the respective individual parts. The niche for the private sector might be FP programs promoting temporary spacing methods, championing injectables, demand creation programs activities such as detailing the product market for contraceptives, urban coverage and market creation activities for FP products, rural coverage and market development activities, advertising/media coverage, seals of approval, policy leverage and political clout, or workplace interventions.

Government Suspicion of Business and Business Suspicion of Government: Provide environment for more open and transparent communications and demonstrate that RHSC is fully committed to the private sector role and market expansion...both generic and branded.

Ability of Developing World Market to Pay: Conduct market segmentation and price elasticity studies and share this information with the private sector. In those markets that have not yet been commercialized, it may be necessary to develop programs to prime the market not yet served by the commercial sector by providing subsidized social marketing brands that will be phased out as the commercial market develops and expands.

Quality Assurance Associated with Product Stewardship, Transportation, Warehousing and Distribution Environments: This is a priority issue for all ethical pharmaceutical companies. There are many documented cases of counterfeit and non-therapeutic drugs finding their way into donor funded programs in the developing world. This serves no interest except for the unscrupulous trader providing the bogus product.

Examples of actions and assurances that can be provided by the RHSC and the international donor community are:

1. Post shipment testing is a common provision of many supply contracts, particularly with new suppliers. Such testing, however, may not always necessarily determine the true quality issues, unless the tests are done thoroughly done with every shipment.
2. In addition to physical tests, chemical testing by an independent and internationally reputable laboratory is an absolute must. Chemical testing must include not only assay of active ingredients, but also content uniformity, degradation and impurity profile, dissolution profile, and disintegration profile. Without these key tests the quality of the product cannot be verified.
3. Proper validation of equipment and all manufacturing processes is a major integral component of quality assurance. For example, ethical pharmaceutical companies having FDA certification validate every piece of machinery and every process to ensure that the output is, at all times, at the same desired level. Any change in machinery and or/or process should require new validation. Ethical pharmaceutical companies would not release any batch without evidence of such validation. This extends to validating even the process of cleaning the equipment.
4. Manufacturing sites should be audited periodically by independent and internationally reputable experts to ensure consistence with international GMP standards, including proper validation requirements. A one-time audit should not be enough to permanently qualify a new manufacturer.

Accountability: Given the power and impact of the constituent members of the RHSC, from billion dollar health reform programs and in-country RH initiatives, it is difficult for the private sector to engage in substantive dialogue with the key stakeholders who are responsible for designing, executing and managing these programs. As the RHSC moves forward to engage the private sector, there is a need for more accountability to be at the center of the agenda.

Overcoming Private Sector Image of Economic Imperialists: Historically there has been an “arm’s length” approach to dealing with the private sector. The for-profit private sector has traditionally been viewed with suspicion and distrust by members of the development community. It is gratifying to see this is changing. The RHSC, by adopting progressive policies for engaging the private sector, can help dispel the myths of the private sector by providing more and substantive opportunities for the for-profit sector to be a part of the solution to the health development agenda.

Cultural and Social Barriers (Women’s Groups, Religious Groups, Myths and Misconceptions about Product and Product Use):

- Medical Barriers (Cultures, Environments, Countries that do not have Capacity to Advocate or Counsel on Effective and Safe Use of Product)

- Support of programs and initiatives to remove myths and misconceptions about modern spacing methods will encourage the private sector to become more engaged in marginal markets.

A “THOUGHT PIECE” BASED ON MY BUSINESS EXPERIENCE

Be Flexible in Creating Alliances and/or Partnerships: The RHSC needs to keep in mind that the private sector is part of the solution and should not be ignored, nor have its role minimized, by governments, donors or NGOs. The government, donor, and NGO community cannot do it alone. The private sector is now providing more than 80% of the capital inflow to the developing world, as opposed to the international donor community’s 70% inflow of capital to the developing world just a few short years ago. There clearly are gaps and inefficiencies in meeting unmet need for RCH commodities in rural and village situations. Look outside the box for new approaches and means to address the strategic objectives of the RHSC. If this means partnering with consumer products companies such as Coca Cola or Unilever to achieve superior, efficient and profitable models for marketing and distribution systems that more effectively reach target consumers at the village level, so be it. The acid test of a good partnership is whether both the RHSC and the private sector feel better with the partnership than without it and both sides agree that contributions from both sides are critical to that success.

Know Your Potential Partners Objectives...and Don’t Begrudge Them: Profits, while important and must be realized to stay in business, aren’t everything. Wyeth and other big four pharmaceutical companies supply OCs to USAID and the international donor community at discretionary prices; Merck provides its *ivermectin* for river blindness: at the request of the WHO, Wyeth is now developing its *moxidectin* as an alternative to Merck’s ivermectin; Unilever established a micro-nutrient program to address developing world deficiencies in iodine, iron, zinc and vitamin A for addressing diet caused stunted growth, mental retardation, brain damage, damaged eyesight, anemia, still births and child mortality. Hindustan Lever trains village Indian women to become direct-to-consumer sales distributors and provides women with selling, commercial knowledge and book-keeping to teach them to become full-fledged micro entrepreneurs. While Hindustan Lever is intent on building its rural sales and market share, it is equally committed to improving the livelihoods and lives of people in India. With its newest initiative, *Shakti Vani*, Hindustan Lever is now training rural women to give talks to villagers about basic hygiene practices, disease prevention and pre- and post-natal care. The highly successful *Project Shakti* clearly represents an important opportunity for the RHSC. As the RHSC enters into collaborative discussions with the commercial sector, it will be difficult to agree on strategies and tactics if you don’t agree what the definition of success.

Don't Be Turned-off by "Informal" Partnership Agreements: In a "formal" vs "informal" partnership, choice of alliance is affected by the tradeoff between minimizing organizational complexity and maximizing control over the alliance by each partner. For the RHSC, I would suggest that from the perspective of the private sector, less is more. Don't create an overly bureaucratic entity that is cumbersome or inflexible. Provide for RHSC partnerships having vitality and the ability to be innovative, nimble and adaptable to changing market conditions in the developing world.

Meet With Potential Partners To Get Acquainted: Don't be afraid to get your hands dirty, early on. It is easy to be an economist working development issues for the World Bank, or a reproductive health policy geek working for an NGO, USAID, a well-funded foundation, or a management consultant offering "technical advice" to the RHSC. Get your hands dirty. Understand how the real work is done in driving a business enterprise: meeting a payroll, generating return on investment, meeting growth targets, discovering new chemical entities to create new medical therapies. The pharmaceutical industry spends about \$33.5 billion annually in developing new treatments, with each new drug brought to market requiring an investment of nearly a billion dollars. Legitimate research-driven pharmaceutical companies need to continue to invest billions of dollars every year on new therapies for the future. While supply of cheaper generic drugs from non-OECD countries is possible, and in many cases desirable, understand that US and European research-based pharmaceutical companies cannot compete on price with their generic competition in India or China. The economics just don't allow it. However, both OECD and non-OECD companies will find value in collaborating with the international donor, institutional and NGO communities on broadening access to their RH products in the developing world. While the research-based pharmaceutical companies cannot compete with the generic manufacturers on many supply contracts, they do have a role to play in many developing world markets. This is especially true in those social marketing projects and efforts by the RHSC to develop Tier Two markets. The RHSC needs to understand the core competencies and critical mass that larger pharmaceutical companies bring to the table: sales, marketing and promotional organizations, detailer organizations, knowledge of their markets. On the other hand, generic manufactures from the non-OECD countries typically do not have core market competencies and critical mass to add value to such Tier Two market development programs. However, they do have excellent price points and the ability to not only position their generic products in public sector and social marketing programs that are traditionally heavily subsidized, but also into new and creative Tier Two market creation schemes such as those proposed by TMA Working Group of the RHSC, ICON/eNet and those yet to be tested RH commodity new market development strategies that have been successfully launched in India by Unilever through their highly acclaimed Hindustan Lever *Shakti Project*. Don't be afraid of getting your hands dirty by trying new and innovative programs.

Be aware of Private Sector "Pros" and "Cons" of PPPs: The private sector "pros", for both generic and research-based companies include: improving outreach for the company and ability to reach a wider range of markets and customers; minimizing risks and high

transaction costs by sharing the risks with international organizations, donors, and NGOs; new opportunities; improved efficiencies in very inefficient markets; the international donor, institutional and NGO communities may be more motivated to succeed in the developing world than the private sector; PPPs provide some flexibility in national government regulatory schemes (removing barriers to advertising for RH products); and improved accountability for project success. On the other hand, the private sector “cons” include: suspicion of international organizations (which in many cases conversely true of the international donor and NGO community’s suspicion of the “for-profit” commercial sector), the World Bank is far too secretive and Byzantine, wasteful and supportive of corrupt regimes; developing world consumers do not have ability to pay; products sold in donor funded social marketing schemes are not profitable; legal barriers to market entry are too burdensome; national government fiscal policies in many developing world countries are not supportive of developing sustainable commercial markets; inadequate developing country systems in place to assure quality assurance; and very little accountability on the part of NGOs, international institutions and donors for addressing issues when things go wrong (product leakage and diversion, corruption, regime changes bringing in different policies, etc).

Identify and Agree on Pilot Project(s) and Agree Only to “Win-Win” Scenarios:

It is easy for smart people to be smart. Move away from the “silo” mentality of having all the answers and solutions to the problems. Be quick to listen and slow to speak. Recognize that the commercial sector brings market experience to the table, and the RHSC needs to determine the kinds of projects that will be supported by the private sector, both generic and R&D-based manufacturers. When the members of the RHSC demonstrate that they understand the reality of the private sector frontline managers and the frontline people who do the work in creating new markets, and that you empathize with them, then you will have a higher degree of buy-in from the private sector. It has been said before, but is worth repeating: *Over-communicate* with your private sector potential partners. Treat them as customers and resource partners. This will be appreciated ---and it will be seen as a sign of maturity of those members of the RHSC that will lead to bigger and more successful relationships.

Be Aware of Differences in Approaches and Philosophies of the Private Sector:

Accept this fact of life, and your job will be much easier and less stressful. Don’t try to make the private sector in the image of the international development community. Also, you need to be aware that *how, to whom and by whom* you present your proposal to the private sector will in a large degree determine the level of buy-in for the pilot project. In many cases, the *who* that you meet with is frequently as important as the *what* that you are proposing with respect to getting your concept accepted and agreed to by the private sector. Be aware that different manufacturers have different priority countries. For example, some companies may have inherent built-in advantages over their competition

in some markets: this may be a dedicated country management team, existing product registrations, or future market development strategies for specific countries that may be unique to them and not their competition.

Partnerships Based on Trust Will Provide Greater Long Term Benefits for RHSC:

Ask yourself each day, “is the way I operate and conduct myself earning the trust of those around me...including the private sector?” There are many things by which you will be measured, but the key to all successful relationships is trust. By exhibiting *behaviors* and communications methods that earn the trust of those around you, including the private sector, the RHSC will achieve the greatest good. Notice my emphasis on BEHAVIORS. It is well documented that many very intelligent people in international development leadership positions talk a good game. But at the end of the day, we will not be judged only by our talk. We will be judged by how we behave...by our actions. And it is our actions, not our rhetoric, that ultimately build the trust of our stakeholders...in any business or enterprise. Learn to *walk the talk*.