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IMPROVING HORMONAL CONTRACEPTIVE SUPPLY THE POTENTIAL CONTRIBUTION OF MANUFACTURERS OF GENERIC AND BIOSIMILAR DRUGS - Executive Summary

January 2006

This publication was produced for review by the United States Agency for International Development. It was prepared by Françoise Armand, Private Sector Partnerships-One project.



PSP-One

PRIVATE SECTOR PARTNERSHIPS FOR BETTER HEALTH

EXECUTIVE SUMMARY

Demand for hormonal contraceptives has been increasing consistently in developing countries. In the absence of affordable commercial products, commodity supply in those countries is often donor or government-supported. This paper explores the factors that affect the availability, affordability and/or sustainability of hormonal contraceptive supply, and suggests strategies to increase the participation of Southern-based manufacturers in international procurement programs as well as commercial markets.

WORLDWIDE AVAILABILITY OF HORMONAL CONTRACEPTIVES

Large multinational pharmaceutical manufacturers, commonly referred to as research and development (R&D) companies, are responsible for most new hormonal-contraceptive formulations, also known as innovator brands. As patents expire, other manufacturers around the world have the opportunity to develop and sell the same formulation as their own brand.

The most popular combined oral-contraceptive formulations are now off-patent and manufactured locally in several middle-income countries, as well as a few developing ones. The most widely available formulation is levonorgestrel 0.15 milligram/ethinyl estradiol 30 microgram, which is produced and marketed worldwide with more than 40 brand names, as well as in a generic form. Dedicated emergency-contraceptive brands also have become widely available in many countries, though mostly through the commercial sector. The most-commonly used injectable contraceptive formulation is Depot Medroxyprogesterone Acetate, known as *Depo-Provera*, which is manufactured by Pfizer, as well as a number of manufacturers in Thailand, Indonesia, and South Africa. Monthly injectables are increasingly popular in Latin America where several locally-produced formulations are sold commercially.

MANUFACTURERS OF BRANDED CONTRACEPTIVES

R&D companies (such as Schering, Wyeth, Organon, and Pfizer) have established a considerable worldwide presence and tend to dominate both the commercial and public sectors in developing countries. R&D brands sold commercially carry high margins to finance marketing activities and the development of new formulations. Selling products through donor or government channels is also an important strategic area for these companies because it allows for substantial economies of scale. Although R&D manufacturers share many characteristics, they often have different corporate strategies, particularly when it comes to investing in the development of new contraceptive products.

Manufacturers of generic contraceptive products developed from off-patent formulations have made considerable inroads in the North American and European markets. Because of the large investment required for bioequivalence testing, generic manufacturers tend to be based in developed countries. Generic manufacturers in India, China, and South Africa, however, also are competing increasingly in these markets. So-called biosimilar products, which are not bioequivalent but based on the same formulation as existing R&D brands, primarily are found in middle-income and developing countries.

DISTRIBUTION AND MARKETING

Contraceptive manufacturers tend to respond to business opportunities within the channels they have chosen to sell their products. R&D manufacturers that can invest in costly marketing activities, such as provider detailing, public relations, and continuing education, tend to dominate commercial channels. Both R&D companies and manufacturers of generic and biosimilar products can compete for government tenders in developing countries,

but development and donor organizations generally favor Western-based companies that can satisfy stringent prequalification requirements. Contract manufacturers that sell exclusively to government or social-marketing programs compete on the basis of price and usually have limited distribution and marketing capability.

Social-marketing organizations marketing their own brands use the same supply mechanisms as governments and donors (usually a competitive bidding process) or receive donated commodities. Prompted by dwindling commodities donations or changing donor policies, these organizations increasingly are purchasing products from Southern-based manufacturers. Social-marketing programs based on public/private partnerships use commercially available brands, but have traditionally involved R&D manufacturers with a history of supplying donor-funded programs.

EXPANDING THE SUPPLY POOL

Key Challenges

The most-significant barrier to expanding the pool of suppliers to the developing world appears to be the extent to which their products meet international quality standards. Although some countries have achieved acceptable levels of production quality, others have been found to lack adequate regulatory and manufacturing control. Assessing the quality and safety of products made in countries with less-than-stringent regulatory environments is a challenge for procurement and donor organizations. Despite established manufacturing standards, there is no centralized, uniform system to assess and monitor manufacturing facilities. Prequalification programs, such as those the World Health Organization developed for condoms and antiretroviral drugs, are still years away. As a result, international procurement tenders tend to favor companies that have obtained FDA approval or undergone an equally stringent certification process.

In the commercial sector, the presence of domestic contraceptive brands is subject to market potential and business strategies by local entrepreneurs. Manufacturers in Thailand, Brazil, and Chile market contraceptives commercially because there is high demand for affordable products and no large-scale subsidized program in those countries. Indian manufacturers on the other hand see limited opportunities on their market, which is dominated by R&D and subsidized brands. Exporting branded products is also difficult for small contract manufacturers, because of high registration costs and the lack of local representation. An increasing number of Indian suppliers, however, are developing the capacity to market products commercially both in and outside India.

Access to Procurement Programs

Contract manufacturers of off-patent hormonal-contraceptive products can compete in the international procurement business, provided they adopt quality-assurance systems that meet international standards. The fragility of the local regulatory environment in developing countries does not necessarily imply that products manufactured in those countries are unable to meet international quality standards. Procurement and quality-assurance experts report that reliable manufacturers can be found in India, Indonesia, Thailand, and South Africa. Increasing their participation in large procurement programs requires relaxing current prequalification requirements while developing cost-effective quality-assessment and monitoring systems. Recent collaboration between procurement organizations is expected to help promote information and cost sharing, as well as open up competition from new low-cost manufacturers.

Commercial Markets

R&D firms tend to see developing markets as divided between commercially sold private brands, targeting high and upper-middle income customers, and public-sector or social-marketing brands, targeting lower-income users. Multinational companies benefit from this type of segmentation because institutional contracts help develop economies of scale and maintain brand loyalty, while private markets contribute to profits.

A middle-market approach, consisting of affordable commercial brands targeted at average users in low-income countries potentially can increase the sustainability of the product supply, but its viability in highly subsidized markets remains to be tested. Attracting new commercial suppliers willing to market lower-priced products requires freeing up a market segment that is occupied by free and subsidized contraceptive brands. Planned phase-outs of donated commodities in some countries may provide an opening for these suppliers.

Manufacturers of generic and biosimilar products are promising partners for interventions designed to increase the sustainability of product supply because they are able to generate profits while targeting low and middle income consumers. Thus, public/private partnerships may involve these suppliers, as long as they are willing to develop and support their own brands. Contract manufacturers that only supply government programs, however, are least likely to enter commercial markets and most likely to pursue new opportunities in the tender business. A few appear to be receptive to other approaches, but may need to partner with organizations with strong marketing capacity. Their capacity and willingness to support extensive marketing and demand-creation activities, however, are unlikely to match those of R&D companies.

Bioequivalence-testing programs, which can improve the affordability and safety of the drug supply in developing countries, remain too costly and politically sensitive. As a result, R&D companies, suppliers of untested biosimilar brands, and contract manufacturers serving the public sector will continue to dominate emerging pharmaceutical markets. A growing number of entrepreneurs, however, understand that bioequivalence testing is the cost of doing business in an increasingly regulated pharmaceutical environment. The combination of generic substitution programs, market-building policies, and competitive forces can ultimately bring users in the developing world a choice of sustainable, high-quality products at prices they can afford.