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ASSESSMENT OF INDIA'S LOCALLY MANUFACTURED CONTRACEPTIVE PRODUCT SUPPLY

March 2006

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

PSP-*One*
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Technical Report

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Recommended Citation: Beer, Kim, Françoise Armand. March 2006. *Assessment of India's Locally Manufactured Contraceptive Product Supply.* Bethesda, MD: Private Sector Partnerships-*One* project, Abt Associates Inc.

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Contract/Project No.: GPO-I-00-04-00007-00

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Global Health/Population and Reproductive Health/Service Delivery Improvement
Center for Population, Health, and Nutrition
Bureau for Global Programs, Field Support, and Research
United States Agency for International Development

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ASSESSMENT OF INDIA'S LOCALLY MANUFACTURED CONTRACEPTIVE PRODUCT SUPPLY

ABSTRACT

This report, prepared under the aegis of the Private Sector Partnerships-One (PSP-*One*) project, examines Indian manufacturers of generic versions of hormonal contraceptives (oral contraceptive pills, emergency contraception, and injectable contraceptives) and intrauterine devices. The principal question this report addresses is whether Indian manufacturers of contraceptive products are in a position to serve as a main source of contraceptives for the domestic and regional markets in a commercially viable manner. Brands multinational corporations produce and market dominate the high-end market in India, while free and subsidized products the government and social-marketing organizations underwrite occupy the low-end. This assessment finds that Indian manufacturers have the capacity to supply middle- and low-end markets with affordable, quality contraceptives. These manufacturers, however, face two significant problems: a lack of marketing and distribution capability, and the difficulty and risk involved in approaching new markets, domestically and internationally.

The report draws on existing technical information and market research, but is based primarily on interviews conducted with manufacturers and people involved in promoting and distributing contraceptives in India.

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ACRONYMS

ANE	Asia and Near East
API	Active pharmaceutical ingredients
CPR	Contraceptive prevalence rate
CSMP	Contraceptive social marketing program
DFID	Department for International Development
DMPA	Depot medroxyprogesterone acetate
DOFW	Department of Family Welfare
EC	Emergency contraception
ECP	Emergency contraception pills
FDA	U.S. Food and Drug Administration
GMP	Good manufacturing practice
HLL	Hindustan Latex Ltd.
IC	Injectable contraceptive
IDPL	Indian Drug and Pharmaceutical Ltd.
IUD	Intrauterine device
MNC	Multinational corporations
NFHS	National Family Health Survey
OCP	Oral contraceptive pill
PATH	Program in Appropriate Technologies in Health
PSI	Population Services International
PSP-*One*	Private Sector Partnerships-*One* project
R&D	Research and development
SMO	Social-marketing organization
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

ACKNOWLEDGMENTS

The project staff thanks Sashwathi Banerjee and Anand Sinha of PSP-*One*/India for their insights and guidance and R. Sridharan of PATH/India for much assistance before, during, and after the mission to India. PSP-*One* also is grateful to the individuals who gave their time and shared their insights during interviews and follow-up inquiries. Carol Sobel and Zach Everson edited and revised the final draft.

KEY CONCEPTS AND DEFINITIONS

BRANDED GENERICS

Copies of pharmaceutical formulations marketed under a different brand name are often referred to as branded generics. Commercial-sector marketing requires all products to carry a brand name. Generics manufacturers are free to market their products with brand names. When they do so, they often market the same product under different brands in different markets, segments, and countries.

In the family-planning sector, several manufacturers often package and market the same product under different names for different organizations to distribute. For example, the same few manufacturers in India produce all of India's social-marketing organization (SMO) brands. Each SMO then develops its own marketing mix related to price, packaging, promotion, distribution, and so forth and then distributes the product.

The for-profit retail sector for contraceptives in India—and most developing countries—rarely uses branded generics. For example, several Indian companies were unfamiliar with the concept of a store brand.

CONTRACT MANUFACTURING

Many generic manufacturers are contract manufacturers; they manufacture products for another company that is expected to market and distribute those products. During the past decade, the Indian pharmaceutical industry has emerged as a world leader in pharmaceutical contract manufacturing, but it lacks expertise in research and development (R&D) or marketing and distribution.

GENERIC PRODUCTS

In the pharmaceutical field, generics are bioequivalent copies of preceptor (original patented) products. They do not have brand names. One producer's product is identical to another's. The availability of generics permits several sources to distribute a given product. Until recently Indian patent laws did not recognize international patent protection, enabling Indian companies to "reverse engineer" patented products. For most contraceptives, international patents have now expired.

RESEARCH & DEVELOPMENT (R&D) COMPANIES

R&D companies refers to pharmaceutical firms whose strategy is to develop new drugs, obtain patents for their discoveries, and market the resulting products with patent protection. During the period of patent protection, the company may set prices at a high level, partly to recover the cost of R&D. Most R&D companies are Western-based. This report often refers to them as multinational companies.

EXECUTIVE SUMMARY

India's pharmaceutical industry has made significant advances during the past decade. It now supplies almost all finished pharmaceutical formulations for the domestic market and has leveraged that experience to become a major player in the international generic markets.

Indian manufacturers of generic hormonal contraceptives (oral contraceptive pills (OCPs), emergency contraception (EC), and injectable contraceptives (ICs)) and intrauterine devices (IUDs) have a prominent role in supplying products to family-planning programs in many developing countries. The buyers for these programs are governmental or multilateral institutions, such as the United Nations Population Fund (UNFPA); multilateral and bilateral donors; ministries of health; and social-marketing organizations. Given their performance in these international tenders, Indian manufacturers may be able to serve as a main source of affordable, quality contraceptives in domestic and regional markets.

MANUFACTURING

Contraceptive manufacturing is subject to significant economies of scale. While the capital investments are high, the variable costs are low. Contract manufacturing, which does not involve developing and marketing a brand, is a high-volume, low-cost business where increased volumes are key to driving down costs and realizing a profit.

The production of OCPs and ECs is specialized. The potency of hormones and the minute quantities in which they are used require production facilities separate from other pharmaceutical products, a controlled environment, and stringent manufacturing standards. Four entities produce generic OCPs—two private companies, and two government of India public undertakings.

In contrast, the production of IUDs is more of an assembly process. Almost all parts are imported and assembled in India. Other than the need for clean rooms, the assembly of IUDs does not require the same level of investment as hormonal products. Five companies produce generic IUDs: Famy Care, Hindustan Latex Ltd., Contech Devices, SMB Corp., and Pregna.

Pfizer imports the only injectable marketed in India, *Depo-Provera*. ICs are not produced in India, although the capacity to do so does exist. There are signs that Indian manufacturers have an interest in this product category, however, and are preparing to produce and/or market depot medroxyprogesterone acetate domestically and overseas.

India's Drugs and Cosmetics Act governs the quality of contraceptives, in line with international good manufacturing practices. All manufacturers have supplied domestic institutional buyers, such as the Department of Family Welfare (DOFW), UNFPA, and/or social-marketing organizations (SMOs), and they have adhered to stringent quality control measures. There have been no serious quality issues in recent years.

THE INDIAN MARKET

While India has the second-largest population of any country, the market for hormonal contraceptives is small, because of a low contraceptive-prevalence rate (CPR) (42.8 percent) and a high reliance on sterilization. Female and male sterilization comprises more than 80 percent of contraceptive use. In addition, there has been little growth in the CPR; the majority of what growth there has been involves sterilization, resulting in a flat market for hormonals.

The Indian hormonal-contraceptive market is bifurcated into high-priced products, dominated by multinational corporations' (MNCs) brands, and a low-end market, dominated by products that are free or the government or SMOs subsidize. The DOFW coordinates the government and contraceptive social-marketing programs, compiling demand, contracting with manufacturers, and supporting social-marketing efforts with product and promotional subsidies.

While there are no direct price controls for contraceptives, regulatory schemes for contraceptives in India influence market dynamics. Social marketing brands and commercial brands tend to be subject to different rules. For example, SM brands, which are deemed in public interest products, can be marketed directly to consumers. In contrast, commercial brands are typically marketed to providers and carry much higher profit margins. MNCs dominate the prescription market through extensive provider-directed activities, making it unattractive to new entrants without the capacity or resources to develop a similar approach.

MARKETING ISSUES

One of the barriers to market entry for generic-contraceptive manufacturers is their narrow product lines. These manufacturers cannot spread their marketing costs throughout a large portfolio of products; therefore, they cannot sustain the cost of a sales force and other expenses of commercial distribution. Contech Devices is the only Indian company marketing its own brands of OCPs and IUDs commercially, albeit on a small scale.

Discussions with manufacturers about developing commercially viable mid-priced products were not encouraging. The wide availability of subsidized and free products is a deterrent to introducing such products. The customer base for these products would have to come from social-marketing users and would require large and sustained marketing investments to overcome the price advantage of subsidized products. IUDs face a similar challenge. Government facilities provide IUDs for free, while Organon's *Multiload* dominates the upper end of the market. Injectables have a troubled history in India. Pfizer's *Depo-Provera* dominates the limited market for this product, but it is embroiled in legal battles.

INDIAN MANUFACTURERS IN THE ASIA AND NEAR EAST REGION

Indian generic-contraceptive manufacturers already contribute to the supply of quality, low-cost contraceptives on the international market, mostly through international tenders for government programs.

Domestic experience shapes these companies' perceptions of market conditions in other developing countries. Namely, they are thought to be similar to India: MNCs dominate one end of the market and

free or subsidized products control the other end. Therefore, new commercial suppliers consider these countries unattractive.

While all companies expressed interest in international markets, it was almost exclusively in supplying institutional buyers or distributors that would brand the products and market and distribute them in-country. There has not been much effort to identify and develop markets or to find distribution and marketing partners. When export opportunities materialize, inquiries from foreign agents and importers trigger them. Three manufacturers, however, are making inroads into new markets through commercial distribution channels. Their strategy consists of registering a product in high-potential developing countries to take advantage of both public-sector tenders and market opportunities in the private sector.

CONCLUSIONS AND RECOMMENDATIONS

Indian generics manufacturers can provide quality, low-cost products in large quantities to other developing countries. Contraceptive manufacturers, however, see themselves as makers of products for others to market and distribute. These companies are not suited to the challenges of commercial-market development, nor do they have the interest or resources to enter such markets. Indian contract manufacturers are likely to keep doing what they are currently engaged in: bidding on domestic and international procurement tenders. These companies are preparing to supply SMOs, public programs, and other institutional buyers, likely at prices that are attractive compared with those of MNCs.

Indian companies whose strengths are in marketing and distribution are likely to be the ones supplying commercial markets. These companies are larger than contract manufacturers, with broader product lines, established marketing structures, and an international presence. These companies may start their own production, as Cipla did, or subcontract production to contact manufacturers. These companies also may seek entry into developed markets.

Commercial opportunities for Indian manufacturers are limited domestically. The most-likely segment for them is the middle market, which is unattractive as a result of sluggish demand and the availability of subsidized brands. Rectifying distortions and expanding demand would be necessary to create incentives for Indian manufacturers to invest in the commercial markets. Internationally, where more opportunities may exist to market mid-priced products, there is a need to support links between Indian manufacturers and potential marketing and distributing partners.

1. INTRODUCTION AND BACKGROUND

The United States Agency for International Development (USAID) has a strong interest in expanding the sustainable availability of affordable contraceptives. This assessment is a response to USAID's Asia and Near East (ANE) bureau's request to assess the possibility of Indian manufacturers of hormonal contraceptives and intrauterine devices (IUDs) meeting the need for sustained product supply in India and the region.

Patents no longer protect most contraceptive products distributed in the developing world. As a result, locally manufactured equivalents of well-known brands are available in several developing countries, notably India, China, Indonesia, Thailand, and Pakistan. International donors and social-marketing organizations (SMOs), however, procure commodities from large Western-based pharmaceutical companies, even though Southern-based manufacturers may be able to offer quality, low-cost alternatives.

Generic versions of the original patented products can address most family-planning needs. Given that original and generic products are bioequivalent, contain the same ingredients in the same dosages as the original product, and work in the same manner, they should be considered carbon copies of the original products.

During the past decade, India's pharmaceutical industry has made enormous strides in transforming itself into a player in the international market for generic pharmaceutical products. This dramatic advance is the result of several factors, including a high-skilled, low-cost labor force and a regulatory framework that allows Indian companies to copy pharmaceutical products that patents still protect in other countries.

Policies directed at import substitution (the encouragement of local manufacturers to replace imported products) have provided additional momentum for domestic contraceptive production. India's size has permitted manufacturers to gain significant experience by supplying the government's family-planning programs. As a result product quality has improved, with all contraceptive manufacturers incorporating World Health Organization good manufacturing practices (GMPs) and often earning International Standards Organization and European Union certification for their processes. Leveraging their production experience of the past several years, Indian manufacturers are beginning to bid successfully on international tenders that will afford them a major presence in global markets.

1.1 WHY THIS ASSESSMENT?

The distribution of free and subsidized contraceptives has an important role in achieving acceptance of contraception and increasing many countries' contraceptive prevalence rate (CPR). Funding for such programs, however, is subject to increasing fiscal pressure. The more successful these programs are, the greater the resources needed to sustain them. Increasing the commercial share of the market may help relieve the demand for public subsidies, provided that market opportunities can be demonstrated to commercial suppliers.

In many developing countries, including India, the market for contraceptives is split into two strata:

- The upper stratum consists of middle- and upper-class individuals who are educated, generally reside in urban areas, seek and receive counseling on contraception from obstetricians/gynecologists, and purchase contraceptives on prescription. Multinational corporations (MNCs) marketing their products to healthcare professionals through their extensive, trained sales forces serve this segment. Consistent with this approach and the profile of their target audience, MNCs price their products at the high end of the market.

- The lower stratum consists of everyone else. SMOs sell their products at subsidized prices or public-health facilities distribute them at no charge. Often people in the lower stratum have few other options for obtaining contraceptive products and reproductive services. SMOs and public-health facilities focus on affordability and accessibility. The support these organizations receive allows them to maintain prices that are lower than what is required for commercial viability, creating a barrier for commercial companies to enter the market.

The transfer of demand to a commercial sector that serves a middle market (that is, one that is commercially viable and offers affordable products) can ensure the sustainability of supply while freeing up resources that can be targeted to those who can not afford to pay for contraceptives through the commercial market. This approach causes an increase in the use of contraceptives, particularly among those with limited means and understanding of contraceptives.

As Indian manufacturers are experienced in manufacturing products for the Indian government, local and international SMOs, and other institutional buyers, they may be in a position to develop commercial markets and market their products to ministries of health, social-marketing programs, and others—in India and abroad.

1.2 SCOPE OF THE ASSESSMENT

This assessment focuses on the manufacturing and supply of four contraceptive products:

- oral contraceptive pills (OCPs)

- injectable contraceptives (ICs)

- emergency contraception (EC)

- IUDs

The first three items generally are termed hormonal contraceptives. The assessment did not include barrier methods (such as male and female condoms and diaphragms), spermicides, or other methods. Indian manufacturers of the aforementioned contraceptives were assessed for their current and potential role in sustaining and increasing the availability of affordable, quality products in India and other countries in the region.

This assessment encompasses available products and efforts to maintain contraceptive supply through existing public, social-marketing, and commercial channels. This exercise included:

- an inventory of brands commonly sold in India
- an overview of India's policies and regulations affecting contraceptive manufacturing and marketing
- an analysis of commercial and social-marketing data
- a review of the strategies Indian manufacturers have adopted
- a discussion of technical, cultural, and other barriers affecting Indian manufacturers
- an analysis of the factors that determine commercial expansion
- recommendations for actions to address barriers and challenges
- proposed next steps in developing partnerships with Indian manufacturers for national and regional expansion

Key Issues

This assessment addressed several hypotheses and questions, such as:

- Will an increase in the supply of generic contraceptives improve access to quality, affordable contraceptive products for Indian and regional users?
- Do generic-contraceptive manufacturers in India have the capacity to produce the necessary quantities of low-cost, quality products for India and other markets in the ANE region?
- Do Indian manufacturers have the interest, resources, skills, business acumen, and organizational capacity to market their products in India and other countries in the ANE region?
- Are developing-country commercial markets attractive to Indian generic manufacturers?

2. MANUFACTURING OF PHARMACEUTICAL CONTRACEPTIVES

2.1 PREREQUISITES

It is accepted[1] that four conditions must be satisfied to justify the manufacture of pharmaceutical products for domestic use:

- a functioning national drug-regulatory authority
- a competent national quality-control laboratory
- a sophisticated pharmaceutical-industry base
- adequate market demand

India satisfies all four conditions and, therefore, has a sound foundation for expanding its pharmaceutical industry into global markets.

2.2 MANUFACTURING COST AND ECONOMIES OF SCALE

Generics manufacturers do not enjoy the cost advantages that accrue to the manufacturer of the preceptor product (referred to in this report as the research and development (R&D) company). By the time a product goes off patent, the R&D company has amortized its fixed capital investments, such as the upfront investment in plants, equipment, and quality-assurance processes. Such costs pose a barrier to entry for new producers. Moreover, the company has established and refined all aspects of the manufacturing processes. Finally, most R&D companies have broad and deep product lines and, consequently, are better able to optimize their use of resources (for example, labor and equipment).

In contrast, direct variable costs, primarily raw materials, packaging, and labor are inexpensive. According to a Department for International Development study (Department for International Development 2005), variable costs constitute about 15 percent of the total costs of producing pharmaceuticals. Thus, contraceptive manufacturing is subject to significant economies of scale, whereby additional quantities can be produced at low cost. Contraceptive production is a high-volume, low-cost business in which increased volume is critical to increased profitability. Table 1 summarizes the minimum economic-production levels for hormonal contraceptives.

[1] This section draws on Program for Appropriate Technology in Health (PATH) 1994

TABLE 1. MINIMUM PRODUCTION LEVELS FOR PROFITABLE CONTRACEPTIVE MANUFACTURING

Method	Minimum production for profitability	Approximate manufacturing cost (US$)
OCPs (cycles)	15 million	<0.10
EC (pack of two tablets)	Not available	<0.30 (sale price by Hindustan Latex Ltd.)
IUDs (units)	1 million	<0.25
Injectables (doses)	5 to 10 million	<0.83 (Pfizer's price to not-for-profit organizations)

Sources: Stanback 1997

2.3 PRODUCT-SPECIFIC ISSUES

ORAL CONTRACEPTIVE AND EMERGENCY CONTRACEPTIVE PILLS

Given the potency of hormones, any drug-manufacturing process involving them must be conducted in strict manufacturing conditions that have dedicated facilities that are separate from facilities producing other drugs. The manufacturing process occurs in clean rooms with sophisticated systems for controlling the flow of air, water, waste, raw materials, and so forth. Workers wear protective clothing and are tested for their hormone levels. Quality-control procedures ensure adherence to exacting standards for content uniformity and, thus, product safety and effectiveness.

India has the technical capacity to meet these requirements. The domestic market also provides sufficient demand to meet minimum economic-production quantities for OCPs. From a manufacturing perspective, producing emergency contraceptive pills (ECPs) is an add-on, as it involves one of the same active pharmaceutical ingredients (API), levonorgestrel, that is used in OCPs. India does not produce APIs for OCPs, but imports them from China.

INJECTABLE CONTRACEPTIVES

The manufacture of ICs is subject to requirements similar to those for OCPs and EC. *Depo-Provera,* the only injectable contraceptive marketed in India (by Pfizer), is manufactured in Belgium for packaging in vials and in the United States for packaging in pre-filled syringes. It is estimated that it would cost $2 to $3 million to establish a facility for manufacturing injectables in India (Stanback 1997). While not a focus of this assessment, India probably possesses the technical capacity to manufacture ICs, although demand and marketing issues may dictate otherwise.

INTRAUTERINE DEVICES

The production of IUDs is more of an assembly process than a manufacturing one. India imports nearly all of the individual parts from Europe, the United States, Japan, and Malaysia; assembles the devices; and then undertakes final gamma sterilization in-country. India has established itself as the world leader in the production of IUDs. Every company interviewed for this assessment noted that it had additional capacity for IUD production. While some companies attempt to develop value-added features, IUDs have become a commodity, that is, the product and quality are uniform throughout the industry—a point manufacturers acknowledge.

3. THE INDIAN CONTRACEPTIVE MARKET

3.1 BASIC DEMOGRAPHIC DATA

With a population of more than 1 billion, India is the second most-populous country in the world after China. In contrast to China, however, India's population is growing and it is expected to exceed that of China by 2025. India has about 248 million women of reproductive age. On average the GDP per capita is $603. The economy has posted solid growth of 7 to 9 percent annually for more than a decade—a trend that is expected to continue for the foreseeable future. India's middle class is growing in size and economic prowess and is estimated at 250 to 300 million. Half of the population, however, lives in poverty and discrepancies in wealth represent to a large extent the differences between rural and urban areas. Table 2 summarizes some demographic, health, and development indicators.

TABLE 2: DEMOGRAPHIC, HEALTH, AND DEVELOPMENT INDICATORS

Indicator	Status	Indicator	Status
Total population	1.028 billion (2004)	Number of women of reproductive age	248 milion
Percent of population that is urban	25.7 (1991)	Total fertility rate	2.9 (2001)
Percent of population that is rural	74.3 (1991)	HIV prevalence	0.9 (5.1 million)
Population growth rate	1.9 (2004)	Infant mortality (per 1,000 live births)	66 (2001)
Per capita income ($)	603 (2004)	Maternal mortality (deaths per 100,000 live births)	2/1000 (2007 projection)

3.2 REPRODUCTIVE HEALTH AND FAMILY TRENDS IN INDIA

India has long had a program to promote "responsible and planned parenthood through voluntary and free choice of family planning best suited to individual acceptors."[2] Sterilization has gained widespread acceptance as a permanent contraceptive. Before 1996 (Holmes 2005) India's national sterilization program relied on aggressive techniques, such as quota systems and rewards, to encourage sterilization. While this conduct is no longer the case, Indian society has become comfortable with limiting family size through permanent means.

Table 3 summarizes important family planning and reproductive health indicators. In 1998–1999 (the latest numbers available), 42.8 percent of women used some form of modern contraception, up from 37 percent in 1991. Of these people, 34.2 percent used female sterilization while the rest relied on OCPs (2.1 percent), IUDs (1.6 percent), condoms (3.1 percent), and male sterilization (1.9 percent). The

[2] DHS/NFHS-2 2001

National Family Health Survey (NFHS) did not report on injectable contraception, probably because it is not included in official programs. The 42.8 percent of modern contraceptive users compares with 83 percent for China and 62 percent for Asia as a whole.

Knowledge of contraception among women of reproductive age is high, with 99 percent of them aware of at least one modern method. Nearly all women (98 percent) are knowledgeable about female sterilization, whereas their knowledge of OCPs, IUDs, and condoms ranges between 70 and 80 percent. The intention among married women to use contraception in the future doubled to 60 percent in 1998, compared with 1993. Of those women, 65 percent intend to use female sterilization, up from 59 percent in 1993. The next most-preferred method are OCPs, chosen by 16 percent (down from 19 percent).

Despite India's large population, the market for hormonal contraceptives is small and stagnant, a situation manufacturers and marketers recognize. Without growth in demand for hormonal contraceptives, existing firms and new market entrants must capture market share from other companies to grow their business. Combined with difficult market dynamics, India's limited demand for hormonal contraceptives makes for a market with little potential and explains why more companies do not market OCPs.

TABLE 3: FAMILY PLANNING AND REPRODUCTIVE HEALTH INDICATORS

Contraceptive prevalance	1992–93 NFHS–1	1998–99 NFHS–2
All methods	41%	48.2%
By method		
Traditional methods	4%	5.0%
Modern methods	37%	42.8%
OCPs	OCPs, IUD, male condom: total 6%	2.1%
IUDs	—	1.6%
Male condoms	—	3.1%
Injectables	N/A	N/A
Implants	N/A	N/A
Vaginal method	N/A	N/A
Emergency contraception	N/A	N/A
Female sterilization	Male and female 31%	34.2%
Male sterilization	—	1.9%

N/A indicates statistics not available.
- indicates the data is included in the aggregated number in a previous cell.

3.3 POLICIES, LAWS, AND REGULATORY BODIES

Several policies, laws, and regulatory bodies govern India's pharmaceutical industry; the most significant of which are listed in Annex A. Contraceptives are not subject to price controls, theoretically leaving manufacturers free to set prices. The schedule under which contraceptives are classified, however, has important implications on their pricing, marketing, and distribution (see the following description of Schedules H and K).

On March 23, 2005, India adopted international patent-protection standards. Until that time India did not recognize international patents and agreements. Nonetheless, the patent law's affect on contraceptives will be minimal, at least in the short to medium term, as only formulations patented after 1995 will be protected. All currently marketed contraceptives are already off patent. As a result, generic-contraceptive manufacturers can continue their operations with no change in practice, including exporting their products. With the exception of *Depo-Provera*, all hormonal contraceptives and IUDs manufactured in India are for domestic consumption. The Janani program of DKT International, an SMO, reportedly obtained a license and registration to import an IC from Indonesia.

SCHEDULES H AND K

Hormonal contraceptives in India are marketed in accordance with two regulatory schemes:

- Schedule H. Products Schedule H covers may be marketed only through a physician's prescription (for ECs, IUDs, ICs, and some OCPs) and may not be advertised to the public. All MNCs market their products in accordance with Schedule H.

- Schedule K. Products Schedule K covers are deemed to be in the public interest—currently, only condoms and some OCPs. For OCPs, Schedule K specifies the exact formulations. All other formulations, regardless of whether dosages are higher or lower than the specified formulations, are regulated by Schedule H. Schedule K products may be advertised to the public and sold over the counter. All social-marketing OCP brands are regulated by Schedule K and tend to have the same formulation.

The government and its implementing partners, such as SMOs, subsidize most contraceptives Schedule K regulates. This mechanism is intended to ensure access to affordable, quality contraceptives. Because social-marketing prices are not commercially viable, commercial marketers tend to concentrate on the higher-margin product segment, where Schedule H brands dominate and are marketed through providers rather than the mass media. Thus, while the Drug Price Control Order does not subject contraceptives to direct price controls, the existence of government subsidies for certain products has a significant affect on OCP marketing and pricing in India.

QUALITY STANDARDS

The Drug Policy of 1986 (revised in 2002)[3] set forth the objectives of the government's pharmaceutical policy, including "strengthening the quality control system for drug production and distribution to make quality an essential attribute to the domestic industry." The policy calls for the Ministry of Health and Family Welfare to progressively benchmark regulatory standards against international manufacturing

3 Available http://chemicals.nic.in/pharma4.htm

standards, harmonize clinical testing with international practices, streamline drug-approval processes, and set up a world-class Central Drug Standard Control Organization. In addition to the Drug Policy, the Drugs and Cosmetics Act of 1940 (and later amendments) establishes specific regulations associated with manufacturing standards, including a strong emphasis on internationally recognized GMPs.

The government of India intends to achieve and adhere to international quality standards. Whether enforcement matches intentions, however, is beyond this assessment's scope. The few companies manufacturing hormonal contraceptives and IUDs have been subject to intense scrutiny by the Department of Family Welfare (DOFW) and international institutional buyers, such as the United Nations Population Fund (UNFPA). The manufacturers have responded by obtaining several internationally recognized quality certifications.

3.4 THE CONTRACEPTIVE MARKET

The total market for commercial OCP brands is estimated at 10 to 15 million cycles per year. According to the DOFW, the public sector supplied 57.4 million cycles of OCPs for free distribution in fiscal year 2002–2003 and SMOs sold 47.8 million cycles during that period. According to the DOFW, 7.52 million IUDs were inserted in fiscal year 2002–2003. (Commercial IUD or injectable sales figures for India were not available at the time of this assessment.) Table 4 lists hormonal contraceptive and IUD brands and the organizations that supply them.

TABLE 4: HORMONAL CONTRACEPTIVES AND IUDS SOLD IN INDIA

Marketer	Brand	Price (Rupees)
OCP		
Commercial		
Organon	Novelon	82/cycle
Organon	Femilon	94/cycle
Organon	Cerazette	Unavailable
Wyeth	Ovral-L	55/cycle
Wyeth	Ovral-G	72/cycle
Wyeth	Loette	72/cycle
German Remedies	Duoluton-L	70/cycle
German Remedies	Triquilar	49/cycle
German Remedies	Diane	220/cycle
Contech	Marilyn	35/cycle
Famy Care	Various	N/A
Cipla	Ginette 35	195/cycle
Government and SMO*, **		
Central government supply, Indian Drug and Pharmaceutical Ltd. (IDPL)	Mala-N	Free
DOFW	Mala-D	2/cycle
Dey's Medical Store, Kolkata	Mala-D	2/cycle
DKT	Choice	7/cycle
Eskag Pharma	Suvida	7/cycle
Hindustan Latex Ltd. (HLL)	Arpan	5/cycle
IDPL, HLL, Famy Care, Phaarmasia	Mala-D	2/cycle
Janani	Apsara	10/3 cycles
Parivar, Patna	Hamjoli	10/3 cycles
Parivar Seva Sanstha	Ecroz	12/3 cycles
PHS, Hyderabad	Khushi	5/cycle
PKK	Sugam	N/A
Population Services International (PSI)	Pearl	10/3 cycles
World Pharma	Julie	5/cycle
EC		
Win-Medicare	NorLevo	45/2 pills
Cipla	Pill 72	34/2 pills
Central government supply	E Pills	Free
German Remedies	ECEE2	
Population Services International (PSI)	Preventol	20/2 pills
IUD		
Cont Palmer, ech	Nugard	123/each
Pfizer	IUD	
Pregna	Pregna	Tender
SMB Corporation	SMB	Tender
Famy Care	Exacta	Tender
Organon	Multiload	250/each
Injectables		
Pfizer	Depo-Provera	172/each
German Remedies	Net-en	
Non-steroidal OCP		
Hindustan latex	Saheli (Novex)	12/8 pills

Sources: Commercial sales—IMS 2004, ORG Retail Surveys, DOFW.

* IDPL, HLL, Famy Care, and Phaarmasia produce OCPs for SMO and government programs.

** The formulation of all SMO brands is levonorgestrel 0.15 and ethinyloestradiol 0.03.

*** HLL, Famy Care, Pregna, SMB Corporation, and Contech Devices produce IUDs for SMO and government programs.

Given that India's population is 1.03 billion people, its gender ratio is 950 women to 1,000 men, and 50.7 percent of all women are of reproductive age, the total number of women of reproductive age is calculated at 248 million. Using the CPR per method, rough estimates of the number of contraceptives users per method were calculated (see table 5). A 1 percent CPR for a method equals roughly 2.5 million users.

TABLE 5: ESTIMATED NUMBER OF CONTRACEPTIVE USERS PER METHOD

Method	Current CPR (percent)	Number of users (millions)	Number of procedures, cycles, or units needed	CPR if all unmet need is to be met*
Female sterilization	34.2	84.8	84.8 million	45.6
Male sterilization	1.9	4.7	4.7 million	2.6
OCP	2.1	5.2	62.4 million	2.7
IUD	1.6	4.0	2 million***	2.2
Condom	3.1	7.7	770 million**	4.2
Traditional methods	5.0	12.4		6.7
Total	48	119		64%

Author's calculation, assuming unchanged distribution as estimated in NFHS-2, ** based on 100 events per year, *** assuming that an IUD is kept for two years, on the average.

While the public sector provides three-quarters of all modern methods, the number is highly skewed because sterilization makes up 70 percent of such methods, with 85 or more percent of sterilizations performed in the public sector. Sixty-eight percent of condoms and 62 percent of pills are sourced in private pharmacies and shops. Interestingly, close to half of IUD insertions are performed in the private sector. Table 6 summarizes the breakdown of contraceptive sources.

TABLE 6: SOURCES OF CONTRACEPTIVE METHODS BY PERCENT

	Pill	IUD	Condom	Female Ster.	Male Ster.	Total Modern Methods
Public	20.6	54.1	13.9	85.3	88.6	76.0
NGO	0.4	1.5	0.2	1.1	0.7	1.0
Private	40.6	43.1	39.3	13.1	8.9	17.3
(pharmacy/chemist)	(27.9)	(0.0)	(30.6)	(0.0)	(0.0)	(3.5)
Other, shop	35.1	1.0	37.7	0.1	1.3	4.6

Source: NFHS-2

Despite India's large population, the market for methods that must be obtained regularly (resupply methods) and IUDs is small. While consumers obtain most such methods from the private sector, the brands largely are subsidized.

3.5 MARKETING OF CONTRACEPTIVES

By the time a product goes off patent, it has established a position in the market. Manufacturing a bioequivalent product and selling it to professional audiences, including ministries of health and SMOs, allows generics companies to capitalize on a product's established position. In turn, the buyer may brand the product for resale, as SMOs do. In other cases, such as in the public sector, the product may be supplied in bulk with its generic name.

From a public-health perspective, it is desirable to offer the end user a choice of methods. While many of the issues involved in expanding the availability and affordability of generic contraceptives cut across the four contraceptive-product groups, logistical and marketing considerations differ among them. In some cases a company may manufacture a range of products that does not constitute a basket of complementary products to the target audience. In other cases the different products may not reach the target audience through the same channel. Therefore it is essential to analyze contraceptive methods in terms of distribution and marketing rather than in terms of manufacturing. Table 7 illustrates some characteristics of contraceptives.

TABLE 7: CHARACTERISTICS OF CONTRACEPTIVES

	Provider-based	Prescription	Over the counter	Remarks
One-time purchases (long- term methods)	IUDs Sterilization Diaphragms Norplant	ECs		Are not considered resupply methods
Regular purchases (medium-term methods)	ICs	OCPs (Schedule H)	OCPs (Schedule K)	Requires regular resupply
Frequent purchases (single-use methods)			Condoms (male and female) Spermicides	Requires frequent resupply. Condoms and spermicides are dual-protection methods.

Schedule H OCPs and EC are prescription-based methods, whereas IUDs and injectables are provider-administered ones. Schedule K OCPs are consumer products. The marketing strategy and mix differ for consumer versus professional products. For provider-based and prescription methods, the provider typically has considerable influence about patient-care decisions. The marketing effort for these products, therefore, is directed at the health care provider. To be commercially feasible, a strategy aimed at healthcare providers requires trained sales force whose members represent a basket of products of interest to the customer. Large companies with diversified product lines are positioned to offer an array of products. It is unlikely that a basket of only hormonal contraceptives would generate sufficient business to sustain a sales force and cover related distribution and marketing costs.

In the case of IUDs, the product is not only provider-based, but also requires a facility for the insertion procedure. Therefore, producers market IUDs to a subset of providers working within or with direct access to a facility. The basket of products for these providers may differ from what is targeted to obstetrician/gynecologists who maintain only consultation practices.

As for prescription contraceptives, India prohibits the promotion of prescription brands and methods to the public. Instead, some companies attempt to raise awareness of the availability of family-planning

methods with specific characteristics to drive clients to the doctor. These companies' awareness-raising activities advise patients to "ask your doctor if XYZ type of contraceptive protection is right for you." Manufacturers of Schedule H OCPs cannot promote their brands to the public, even though the products may be identical or similar to those promoted in accordance with Schedule K.

Logistically, IUDs and injectables pose fewer marketing challenges because they are distributed to a limited number of distribution points and have a long shelf life of five years. And a wholesaler frequently delivers them to the facilities. In contrast OCPs and EC must be available at a large number of retail outlets that are convenient to patients, thus requiring an extensive system of distributors, wholesalers, and retail pharmacies. OCPs and EC also have shorter shelf lives of two years.

While it may be tempting to conclude that generics marketers are at a disadvantage compared with their larger R&D counterparts, it is important to note that in the contraceptive market, generics companies do not compete in the same market segment as R&D companies and they likely would face stiff competition from resourceful organizations if they tried to do so. Instead, market share for commercially viable, branded generics must be taken from SMOs and public-sector segments.

ORAL CONTRACEPTIVES

Of the hormonal products examined here, OCPs are the best known and have gained international acceptance. Their efficacy is proven and products have evolved through several generations to minimize side effects and address special needs, such as estrogen intolerance.

There is a long-standing bias among users and providers against hormonal contraceptives. Concerns usually relate to the short- and long-term effects of hormones, such as weight gain, nausea, irregular bleeding, and return to fertility. While some of these concerns are not fact-based, they are nevertheless important in the public's perception and acceptance of OCPs. A recent focus group conducted by HLL found that pill consumption might be associated with illness in people's minds. Increasing the acceptability of this method in India remains a challenge for marketers.

EMERGENCY CONTRACEPTION

EC is a new product in India. Because it is used in unforeseen, time-sensitive situations, this product requires a unique marketing approach. One challenge is to generate sufficient awareness to get potential users to recall EC's existence and what to do to in the rare cases when they need the product. Healthcare provider also must be aware of and educated about the product. And ECs must be readily available in pharmacies.

The production volume of EC is low, leading to higher production costs per unit. As for regular OCPs, however, marketing and distribution costs and what the market will bear drive pricing, rather than production costs. Hindustan Latex Ltd. (HLL) sells ECs to Population Services International (PSI) at Rs. 10 to 12 for two tablets, while *NorLevo*, commercially marketed by Win-Medicare, retails for Rs. 45.

While India permits EC, the method is not free of controversy. Since 2003 the government family-planning program has included EC, but does not promote its use. In many other countries, EC is controversial as well.

INTRAUTERINE DEVICES

At first glance, IUDs would seem to be an ideal method for a woman who desires medium- to long-term contraception. The device is inexpensive, cost-effective, has few side effects, and often involves a one-time procedure and expense. IUDs have an unfavorable reputation, however, owing to misperceptions and quality-of-care concerns. The misperceptions include a belief that IUDs cause infertility. A major qualify-of-care issue is that trained providers and IUD services are not adequately available at the primary and sub-center levels, sometimes causing complications not to be addressed in a timely manner.

IUDs are not only provider-based, but also require a facility for the insertion procedure. The cost of the IUD itself is low relative to the extended period of protection. In India, public-sector clinics, hospitals, and other healthcare facilities provide and insert most IUDs. The public sector purchases the devices through tenders from generics suppliers, meaning that suppliers compete primarily on the basis of price.

In addition, some private providers sell and insert IUDs. Organon, the only R&D supplier of IUDs in India, targets the private-provider market with its proprietary brand, *Multiload*. Contech Devices, an Indian manufacturer, is the only Indian company selling IUDs in the private sector. Contech estimates that the government supplies approximately 7.5 million units in the public sector and that the private-sector market is approximately 2 million units.

INJECTABLES

While all hormonal products face some perception and image challenges in India's market, injectables face a special set of difficulties, as they have had a long and troubled history in India. They still are associated with Western attempts to control India's population. Injectables often are viewed as an inferior method foisted on developing countries but scarcely used in developed ones.

While it has long been known that depot medroxyprogesterone acetate (DMPA), known as Depo-Provera, causes bone loss, it recently was discovered that the osteoporotic effects of the injection grow worse the longer *Depo-Provera* is administered and they may last long after the injections are stopped. For this reason, on November 17, 2004, the United States Food and Drug Administration (FDA) and Pfizer agreed to put a black-box warning on *Depo-Provera*'s label. This warning is adding fuel to pervasive doubts about injectables' safety in India. ICs have become a banner issue for the feminist movement and a topic of impassioned political debate at the highest levels of government. The government of India has gone as far as issuing an assurance that ICs will not be included in state-mandated family-planning programs. ICs also have been included in a court case that challenges the safety and efficacy of a number of pharmaceutical products sold in India.

ICs are associated with irregular bleeding and amenorrhea, which are not culturally accepted in India and are a serious barrier to its use. Hence, Pfizer's marketing strategy focuses on women who are educated enough to accept ICs' limitations and on those who already experience irregular bleeding, such as lactating women. The barriers ICs face in India, however, might not be issues in other markets. In India injectables may represent a case in which the export business is more promising than the domestic one.

Is there a viable market for injectables?

The Concept Foundation is in preliminary talks with Famy Care, a major Indian manufacturer, about introducing *Cyclofem,* a monthly injectable, to the Indian market. Famy Care, however, focuses on public tenders and ICs are not included in the DOFW program. The government is insisting that the clinical study for *Cyclofem* continue for another three years. In addition, the Concept Foundation requires

contractual minimum quantities, which are difficult to commit to in the current environment. DKT's Janani program is importing ICs from Indonesia for programs its clinics run. HLL, the largest provider of OCs and condoms to the Indian government, recently signed an agreement with Helms Pharmaceutical to distribute *Petogen*, a generic DMPA brand produced in South Africa.

The demand figures for injectables are not publicly available. A prevalence rate of 1 percent, however, would be needed to achieve the demand of 10 million units (four uses per year) that is needed for an economical level of production. Such demand appears unlikely given the low CPR for hormonal contraceptives and the controversy engulfing injectables. Opportunities may exist for Indian manufacturers that are developing a presence outside the country, particularly companies that bid on large government tenders in countries with high-injectable use.

4. SUPPLY CHANNELS AND MAJOR PLAYERS

During the 1980s and 1990s, the Indian government promoted policies of import substitution (that is, replacing imported products with Indian-made ones). Combined with no patent protection, the policies were a significant factor in the rapid expansion of India's pharmaceutical industry, particularly the manufacture of generics. Imports currently represent only 10 to 12 percent of India's pharmaceutical market, the large share of which takes the form of bulk drugs, especially from China. Manufactures in India produce almost all formulations domestically for the Indian market, including about 70 percent of its bulk drugs. (Bulk drugs are individual chemical ingredients that are combined with other ingredients to make specific formulations, which are then packaged for retail sale and consumption.)

Aside from the import-substitution and patent policies, the growth of India's pharmaceutical manufacturing base is attributable to the government's support and implementation of national programs in the 1970s that provided free and subsidized products—including contraceptive products—to all. Since the late 1980s, the existence of social-marketing programs has boosted the demand for contraceptives. This increase gave rise to a number of manufacturing companies in the contraceptive field. Two types of contraceptive manufacturers emerged: subsidiaries of MNCs and indigenous companies. Often the latter companies reverse engineered existing products and started producing them locally for the Indian public sector.

In India, as in many developing nations, family-planning products are available to the public through three channels: commercial, social-marketing, and public-sector. To a large degree, an organization's marketing and distribution strategy reflects the channels through which it works and the segment of the population it targets. In the commercial channel, which focuses on the higher socio-economic segments of the population, marketing usually is directed at service providers and products are distributed through a network of private wholesalers and retailers. Social-marketing efforts, which target lower socioeconomic and hard-to-reach groups, also work through private distributors and retailers, but marketing usually is directed at the final consumer, as well as retailers. The public sector, which focuses on the lowest socioeconomic groups, markets through training public health care providers and distributes products through its own distribution system.

There are two kinds of commercial companies operating in India: affiliates of MNCs and indigenous Indian companies.

4.1 MULTINATIONAL CORPORATIONS

The MNCs active in contraceptives in India are Pfizer, German Remedies, Organon, and Wyeth. These multinational R&D companies operate their own manufacturing facilities in India or contract Indian companies to manufacture their products. Among this group the only imported product is Pfizer's *Depo-Provera*.

Pfizer. Pfizer markets *Depo-Provera* and is the only marketer of an injectable contraceptive in India. Although Upjohn introduced *Depo-Provera*, following a series of mergers, Pfizer took it over. Pfizer

provides *Depo-Provera* to SMOs in vials at about half of market price (Rs. 70) versus Rs. 150 for the pre-filled syringes supplied to the open market.

German Remedies. German Remedies markets OCP brands *Duoloton-L* and *Triquilar*, with the latter being the only triphasic OCP in the market. The company previously marketed *Net-En*, a two-month injectable. It also discontinued marketing *ECEE-2*, its EC brand.

Organon. Organon markets *Novelon* and *Femilon* OCPs and the IUD *Multiload*. Internationally Organon markets *Megestron*, a two-month injectable. It is not known whether Organon is considering registering *Megestron* in India.

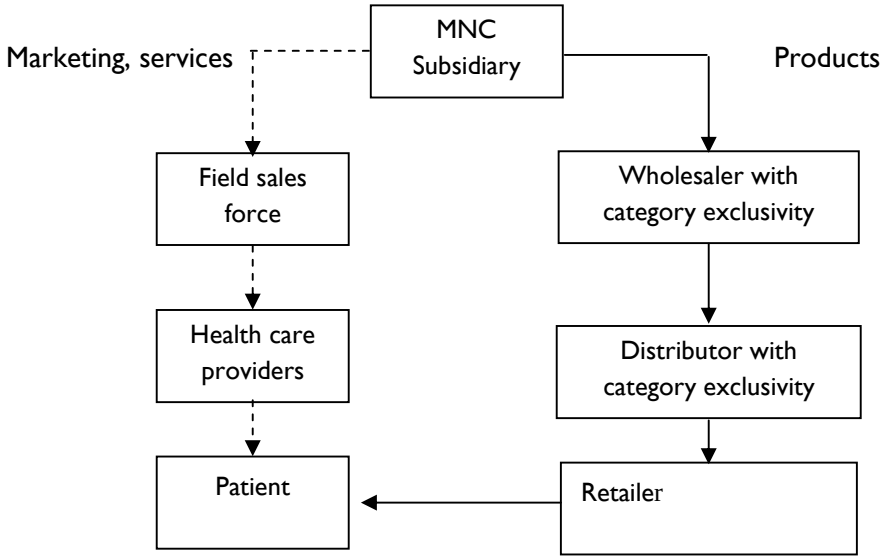
Wyeth. Wyeth markets several brands of OCPs: *Ovral-L*, *Ovral-G*, and the low-dose *Loette*.

All MNCs market their products per Schedule H and follow similar strategies that focus on branding and segmentation. R&D brands are promoted through ethical marketing to respected healthcare providers serving upper-level socioeconomic clients. As the brand becomes established, other healthcare providers choose to prescribe them.

Figure 1 illustrates the chains by which the MNCs' marketing efforts and products reach the public:

- marketing targets the healthcare provider, who interacts with the patients
- products are supplied through a network of wholesalers, distributors and, finally, retailers supplying the patients

FIGURE 1: SUPPLY CHAIN FOR MNCS' SERVICES AND PRODUCTS



R&D brands are perceived as the top brands in the market. For this reason, they compete against each other rather than against low-end or low-price products. Given that multinational corporations target the well-off segment of the market and the healthcare providers' large influence on the patients' decision-making, price elasticity is low. It is unlikely that an obstetrician/gynecologist would prescribe a

low-price or generic contraceptive. Such practice would be inconsistent with the position of the provider and the client. Price is not an important competitive parameter for this segment.

Chemically, the products MNCs market may not differ much from low-price brands. It is consumers' and healthcare providers' confidence in a company and its products that, in their minds, justifies the higher price. While R&D brands do not compete with SMO brands, MNCs do believe that they benefit from category promotion as more people are likely to move up in the consumer hierarchy. The strategy can be summarized as follows:

- Target audience. The target audience consists of obstetrician/gynecologists for whose patients the price of the contraceptive is not an issue. Often the consultation costs more than the product.
- Promotion and distribution. A trained sales force calls on doctors and pharmacists. Products are sold only through selected distributors, wholesalers, and licensed pharmacies.
- Product. Products are internationally recognized brands whose formulations usually differ from Schedule K formulations so the product can be positioned as specialized and superior.
- Price. To be consistent with the physician and patient profiles, a high price reflects the specialized nature of the product and its higher marketing expenses.

In the view of all companies, the market for OCPs is small and flat, lacking current and potential demand that would justify the expenditure of resources on market development. In addition, the low end of the market is flooded with brands and, thus, offers no business opportunities.

4.2 INDIAN MANUFACTURERS

For Indian generic-contraceptive manufacturers, the Indian market is tied to the government's Contraceptive Social Marketing Program (CSMP) and the free distribution of contraceptives through public health facilities. In India the DOFW is for all practical purposes the buyer.

A small group of generics manufactures produce the contraceptives India's SMOs and public programs distribute. All of these companies share a similar business outlook: they see themselves as contractors, manufacturing products for others to market and distribute. As one executive stated, "This does not require any marketing—just submission of a bid." Price and, therefore, manufacturing cost are the predominant parameters. Thus, they do not market their own brands in commercial channels.

Once a year the DOFW collects the requirements from the public-sector facilities and the SMOs and floats a tender on which manufacturers bid. The following companies typically compete for contraceptive tenders:

Indian Drug and Pharmaceutical Ltd. (IDPL). IDPL is a public-sector undertaking that is strictly a contract manufacturer of OCPs and supplier to SMOs and the public sector. It has the capacity to produce ECs and the non-hormonal OCP *Centchroman*. Competitors indicated that IDPL is curtailing its activities and possibly going out of business. It engages in no marketing of brands on its own and apparently has not considered doing so.

HLL. This manufacturer, based in Trivandrum, is the biggest supplier of contraceptive products to public-sector and social-marketing programs in India, with a production capacity of 180 million cycles a

year. The company has three main divisions: a manufacturing unit, an SMO, and a commercial operation. Condoms and OCPs HLL manufactures typically are sold through social-marketing programs. HLL, however, has a presence in the commercial market with progestin-only pills, non-steroidal pills, ECPs, and other medical products, such as blood collection bags and auto-destructive needles. The company markets these products through sub-distributors and maintains its own sales force and 48-person detailing team. HLL is about to venture into the injectable market through a recent agreement with Helms Manufacturers to distribute *Petogen*, a DMPA product manufactured in South Africa. This product will be marketed commercially because injectables are not part of the Indian government's social-marketing program.

Phaarmasia. Phaarmasia is a contract manufacturer that produces generic products, including contraceptives for SMOs and public programs. This company is part of a larger pharmaceutical concern (the Manesh Group) which gives it access to a strong commercial distribution company, Svizera Healthcare. Although Phaarmasia's business model has been almost exclusively to supply the government of India, its association with Svizera has resulted in the introduction of *Ovipause*, a mid-price commercial OCP, in competition with Wyeth's lowest-priced brand, *Oral L*. An ECP brand, *Ovistop*, also is scheduled for commercial introduction.

Pregna International. This firm focuses almost exclusively on IUD production and largely relies on DOFW business, but since the mid-1990s it also has been supplying UNFPA and other international institutional buyers with IUDs. Pregna produces 4 to 5 million units per year and hopes to expand to 6 to 8 million units. It makes an effort to develop value-added features such as the safe load, which is a mechanism that helps fold the "T" of the IUD into the insertion tube. The company estimates its capacity at 8 million units per year.

SMB Corporation. This company's core business is a line of sutures. In the early 1990s, however, it expanded into IUD production and is now one of four Indian companies supplying the government. For its IUD business, SMB relies on government orders. The company estimates its capacity at 20 million units per year.

Famy Care. Famy Care is one of the main suppliers of OCPs and IUDs to the SMO and government markets. It does not engage in any domestic commercial marketing of its products. Famy Care has made a name for itself by aggressively and successfully bidding on international institutional tenders from UNFPA, the World Bank, ministries of health, SMOs, and others. The vast share of Famy Care's business is institutional through tenders. This company, however, is looking for partners in the social-marketing and commercial sectors, particularly in countries that do not receive donor support or issue government tenders, such as Venezuela, Thailand, and Algeria.

Contech Devices. This company is an IUD manufacturer that traditionally has supplied government programs, but also sells its IUD brand in the commercial sector. It now markets a low-dose OC (*Marilyn*) that is procured from a contract manufacturer. This brand is about a year old and is undergoing pilot testing in selected states in the south.

Win-Medicare. Win-Medicare is part of a conglomerate with interests in a variety of fields and industries. In pharmaceuticals Win-Medicare carries a range of brand-name products. In contraceptives it holds the license to market the EC brand *NorLevo* for the French company HRA Pharma and it is the only company in India commercially marketing an EC product. The EC marketing effort started in October 2004 and Win-Medicare recently hired a product manager to focus on that product. Win-Medicare follows the classic ethical-marketing model.

All of the indigenous Indian companies manufacturing contraceptives have narrow product lines; in fact, some manufacturers are single-product companies. As a result, they are unable to spread overhead so that a broad or deep product range can support market-development costs. Such limitations make it difficult to maintain a field sales force calling on doctors, which is the only way to promote specific brands of provider-dependent products. Companies noted that they have unused manufacturing capacity in the form of underused existing capacity or additional capacity that easily can be brought online.

In addition to these contraceptive companies, **Cipla**, the largest generic manufacturer in India, just completed production lines for several hormonal-contraceptive formulations. The company appears interested in entering the United States and European markets, as well as bidding on large tenders from UNFPA and USAID. Its product portfolio, which includes phasic and third-generation OC formulations, is indicative of an interest in more-developed markets. Cipla's business model is to establish and build strong marketing partnerships with local businesses. Unlike contract manufacturers, Cipla markets branded generics that are sold on commercial markets.

Other large Indian manufacturers, such as Ranbaxy, Dr. Reddy, Cadila, and Torrent, have strong local and international generics businesses, but none of them carry hormonal contraceptives.

4.3 SOCIAL MARKETING AND PUBLIC-SECTOR DISTRIBUTION

CSMP was launched in 1987 and modeled on the existing social-marketing scheme for condoms. The DOFW encourages and supports SMOs in marketing OCPs and IUDs, in addition to condoms, to lower-income and hard-to-reach population groups. As part of CSMP the government procures condoms and pills from the manufacturers and resells them to SMOs at subsidized prices. There is no subsidy for IUDs and ECs. While the government procured ECs in 2003, it is not distributing them and injectables are not part of the program. The scheme is illustrated in Figure 2.

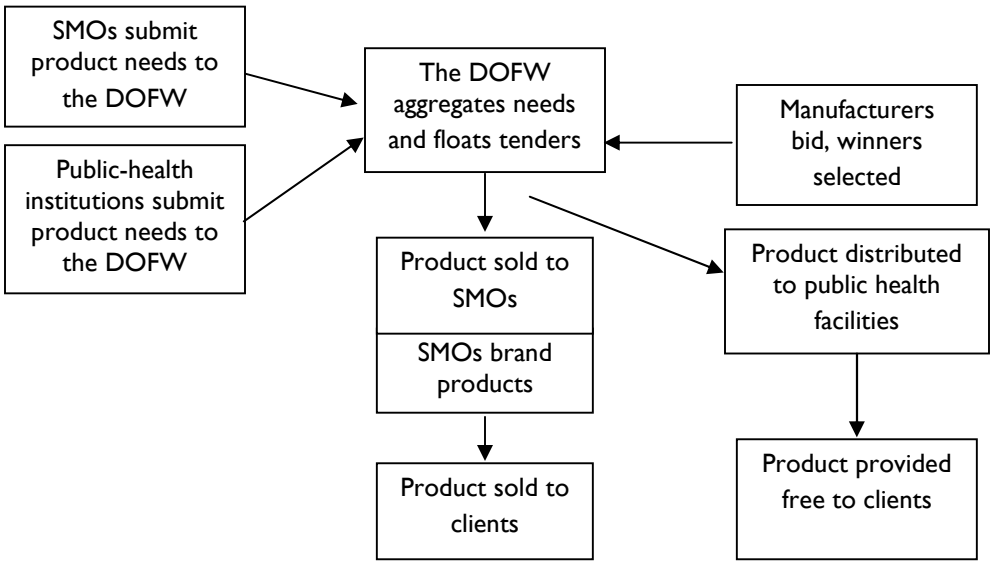
Until 2003 the government also procured APIs from bulk manufacturers and gave them to Indian contraceptive manufacturers for processing and formulation. Since 2003, however, these contraceptive manufacturers have been procuring the APIs themselves.

Participating organizations sell OCPs through private pharmacies, nonprofit clinics, and other licensed outlets. The products are Schedule K ones, meaning that they may be sold over the counter. Compared with similar products R&D companies market, the SMO products are cheaper, making them affordable to larger segments of the population.

Due to India's size, SMOs tend to focus on selected regions and states. Some SMOs, such as PSI, Janani, and the Family Planning Association of India, also operate chains of clinics that offer an array of reproductive-health services, including counseling, sexually transmitted infections diagnosis and treatment, and HIV/AIDS programs.

The DOFW also runs a program that provides OCPs (*Mala N* brand) and IUDs through public health facilities. Free products are available to anyone on request. For the 2002–2003 fiscal year, the public sector made available 57.4 million cycles for free distribution through public health facilities and 47.8 million cycles for sale through SMOs.

FIGURE 2: THE CONTRACEPTIVE SOCIAL-MARKETING SCHEME



Illustrative cost chain for OCPs marketed through SMOs:

1. The DOFW buys OCPs from manufacturers at Rs. 3.55/cycle
2. An SMO buys OCPs from the DOFW at Rs. 1.60/cycle
3. The SMO buys its own packaging with a government subsidy of up to Rs 0.35/cycle
4. The SMO receives a promotional subsidy from the GOI of Rs. 0.25/cycle sold

4.4 THE MIDDLE MARKET

During the assessment, manufacturers and marketers discussed the concept, existence, and viability of a middle market. In the middle market, a product's price would be affordable and commercially viable.

The basic issue is whether a commercially viable market exists between the market for high-priced MNC products and the market for low-priced SMO and government products. There is no new product proposition; that is, products geared towards the middle market will not differ from low-priced brands. Instead, the creation of a middle market is an exercise in positioning and branding (that is, creating a product image that is attractive to a certain segment of the population).

All interviewees agreed that the customer base for a middle market would have to be drawn from the subset of consumers who already purchase low-priced products. The upper-stratum market, which MNCs' high-priced products dominate, already is taken. From a public-health perspective, a shift in demand from the high-end market would do nothing to increase use, reach, or sustainability. Instead, middle-market consumers would be existing users of SMO and public-sector products who are willing and able to pay for their contraceptive products. They likely would be in the middle class, with some upwards mobility and aspiration. These consumers are likely to be educated and urban.

The idea of developing a middle market in India is not new. German Remedies reported at least one previous effort to launch a lower-price commercial product (Rs. 17 per cycle), but found that demand did not materialize. The current two-level stratification of the market creates a substantial barrier to feasible commercial ventures. To be commercially viable, products would have to be marketed at higher prices than those charged for SMO brands. Schedule H would then regulate those products, however, thereby classifying them as prescription drugs and triggering promotional restrictions, high-marketing costs, and limited reach. At the same time, a new entrant would compete with low-priced, quality products that are not only subsidized, but that also can be advertised to the public and sold over the counter.

Most companies interviewed for this assessment felt that launching a product that targets the middle market would pose considerable risks and require sustained investment for several years to ensure success. Most question whether a commercially viable middle market even exists. Free and subsidized products stifle the development of private commercial markets. While most companies would venture into a commercial-marketing effort if they were provided with resources, none seemed inclined to invest their own resources in doing so. One exception is Phaarmasia, which recently introduced a commercial OCP, *Ovipause*, that will compete directly with Wyeth's *Oral L* (levonorgestrel 0.15 mg + ethinyl oestradiol 30 mcg) at the lowest end of the commercial segment. *Ovipause* sells for approximately Rs. 55 per cycle. (As a comparison, the most expensive social-marketing brand is priced at Rs. 5 per cycle.)

Another exception is Contech Devices. Contech pursues tenders and institutional business, but also markets its IUDs and a brand of OCPs (*Marilyn*) in the domestic commercial market. Even though *Marilyn* has the same composition as Schedule K products (and, therefore, could be sold over the counter), the company has chosen to market it through doctors on a prescription basis. Contech is pilot marketing the product in a few cities in the south. Contech Devices sells *Marilyn* to health care providers at Rs. 35 per cycle and to end users at Rs. 42 per cycle This effort, though limited in scale, attests to Contech's interest and initiative in supplying contraceptives to the middle market. Most importantly, Contech is engaged in the effort with its own resources.

5. INDIAN MANUFACTURERS IN THE ANE REGION

During the past several years, Indian generic-contraceptive manufacturers have developed an international presence, usually through tenders issued by multilateral and bilateral agencies, ministries of health, and international-development organizations. Consequently these manufacturers contribute to the supply of quality, low-cost contraceptives in developing markets.

5.1 CURRENT EXPORT ACTIVITIES BY INDIAN MANUFACTURERS

Companies interviewed for the assessment were asked to discuss the opportunities and challenges they face in exporting their products, both commercially and through tenders. Because contract manufacturing is competitive, companies were reluctant to provide details about the extent, depth, and success of their efforts. They did offer similar perceptions and experiences, however, regarding the international business.

- Pregna and SMB Corp. have a high level of international sales of IUDs through institutional tenders. Pregna enjoys a close partnership with a commercial distributor in Iran. Other commercial-export opportunities are limited and usually are triggered by an inquiry from an in-country distributor.

- HLL's exports totaled about $3 million in FY 2003–2004, but condoms and blood bags represented the overwhelming share of those exports. HLL also hopes to gain international acceptance for its once-a-week, non-steroidal brand, *Saheli*, which is sold through commercial distributors.

- Contech Devices' main markets for IUDs are Egypt and Turkey. In the ANE region, it markets in Singapore, Malaysia, and Micronesia and is attempting to enter the Philippines. It holds registration in an additional four to six countries and supplies some African countries through UNFPA. The company also supplies OCPs to a number of countries through commercial channels in Colombia and Brazil and through the public sector in Turkey and Bangladesh.

- Famy Care has the strongest profile in the international marketplace by manufacturing several OCP formulations according to customers' specifications. In the past few years, it has aggressively and successfully bid on several international institutional tenders from the UNFPA, the World Bank, ministries of health, and SMOs. Institutional business through tenders makes up the vast share of Famy Care's sales. The company has submitted dossiers to about 30 countries, including Bangladesh, Sri Lanka, Myanmar, and Cambodia in the ANE region.

- While Phaarmasia is trying to collaborate with distributors in several countries, it has yet to enter the export market and is seeking registration with the UNFPA.

Experience in their own market has shaped the perception of Indian manufacturers when it comes to exporting their products to other developing countries. These companies perceive, accurately or not, that ANE countries present similar market conditions, with MNCs' brands dominating the high end and

free or subsidized products dominating the low end. They typically do not have access to market research, nor are they inclined to initiate it.

While all Indian manufacturers expressed interest in serving international markets, it is almost exclusively limited to supplying institutional buyers or supplying distributors responsible for in-country marketing and distribution. With the exception of Famy Care, companies engage in limited efforts to identify and develop markets on their own or to seek out distribution and marketing partners. When these efforts do happen, it is largely in response to inquiries from foreign agents and importers.

Market-development costs (travel, distributor search and development, registration, and so forth) are high and companies perceive markets as small with unattractive pricing. They also point to the perceived high risk and small potential for market development. As with the domestic market, most companies would venture into a commercial-export marketing effort with donor or government support, but none are willing to invest their own resources.

Several companies noted that they are involved in registering products outside India. It is unclear whether these companies are responding to tender requirements by providing documentary support to a local importer or deliberately engaging in market prospecting.

5.2 STRENGTHS AND LIMITATIONS

The following observations focus on manufacturers of generic contraceptives in India. Manufacturers not involved in the production of contraceptives may have different skills.

MANUFACTURING CAPACITY

Indian contraceptive manufacturers produce many formulations of hormonal contraceptives. Famy Care, for example, exports a variety of OCPs, including triphasic pills, cycles with placebo pills, and EC pills. Other companies also have produced EC pills, and HLL produces a non-steroidal pill with the name *Centchroman*. IUD manufacturers are experienced in producing the basic Cu380T IUD and variations of that product. There is no reason to believe that Indian manufacturers cannot meet product needs in terms of formulation, packaging, and design. Although it is a small group of small companies, they all have a substantial amount of free capacity and additional capacity could be added quickly.

COST CONSIDERATIONS

Indian companies have a strong incentive to drive down costs because winning a tender is predicated on low prices. The manufacturers interviewed for this assessment all discussed costs and efforts to improve efficiencies. Indian producers do not necessarily have a cost advantage over MNCs, which can spread production costs through large product portfolios. Western-based suppliers are not always interested in responding to individual government tenders for all ANE countries. Indian contract manufacturers, however, are focused on expanding this type of business and are poised to become suppliers of national family-planning programs in the region. Famy Care, for example, has replaced Wyeth as the principal supplier of OCPs to the government of Bangladesh.

Commercial markets present a different cost structure than the tender business. Commercial prices include manufacturing, importation, clearance and inspection costs, as well as importer, wholesaler, and retail margins. Trade margins compose a significant proportion of the final product costs, often 50 to 80

percent). Thus, importation, marketing, and distribution costs may exceed manufacturing costs. Indian manufacturers, however, still may have an advantage over commercial markets because they tend to have lower overhead and marketing costs. The difference in the price of products MNCs market and those generics companies market is largely a matter of corporate strategies. Commercially sold R&D brands have high-profit margins that support drug development. MNCs also tend to target high-end consumers for whom price is less of a factor. As a result, generic companies willing to market products commercially may be able to do so at a lower cost, which should be reflected in consumer prices.

QUALITY ISSUES

Regular and stringent product testing by the Indian DOFW and international institutional buyers has resulted in high quality standards at Indian OCP plants. Each brand produced for an SMO or the public sector is tested at the manufacturers' in-house testing labs and subsequently offered for evaluation at a government-approved testing laboratory. These government-contracted laboratories test samples from each batch at the production site per parameters in the national drug rules. This procedure is specific to government procurement and addresses regulatory-enforcement concerns that often arise in developing countries. Four IUD companies (Pregna, SMB Corp., Famy Care, and Contech Devices) have supplied UNFPA, various ministries of health, SMOs, and other international institutional buyers. With respect to OCPs, Famy Care has supplied UNFPA, PSI, DKT, Marie Stopes International, and ministries of health through international tenders. These organizations follow strict quality-control and testing procedures.

All Indian contraceptive manufacturers comply with GMPs and other protocols and have earned international certifications. The SMOs interviewed for this assessment reported that they had not experienced any quality issues recently with Indian-made products. The only OCP brand not supplied directly to the government, but marketed on commercially is Contech Devices' *Marilyn*. The laboratory testing of six samples of *Marilyn* through Family Health International's Product Quality and Compliance Division resulted in a passing score, indicating that the product meets the U.S. pharmacopoeia criteria for this product formulation.

The notion that Indian OCPs and IUDs are inferior products is a perception—not a reality. Pervasive doubts about the quality of these products, however, may limit the extent to which they can be used in family-planning programs or sold in commercial markets outside of India.

BUSINESS MODEL

The business model many of India's generics manufacturers adopt is contract manufacturing. These companies see themselves as manufacturing products for others to market and distribute. As a result they are reluctant to market their own brands commercially, but will invest instead in exploring opportunities in the international tender business. Several manufacturers have leveraged their DOFW business and the economies of scale it provides to bid on international tenders from ministries of health, the UNFPA, the World Bank, development organizations, and others. Institutional business requires little marketing efforts apart from participating in the bidding process and it poses little risk.

Companies that possess the capacity and willingness to market their own brands, however, typically find more-lucrative opportunities in other product categories. Because R&D companies dominate the high-end commercial markets and are likely to continue doing so, Indian labels are most likely to compete directly with free and deeply subsidized products. The availability of these products and the fact that they are sold through commercial outlets makes it difficult to market new brands at commercially viable prices.

MARKET ACCESS AND REGISTRATION

A variety of issues may hinder market access, such as high import duties, adherence to local quality regulations, requirements for clinical trials, complex distributor or agent contracts, preference for local manufacturers, exchange regulations, and lack of access to foreign currency.

One of the major barriers to entering a foreign market is registration. Typically, the process takes at least six months and often more than a year. Some countries do not accept clinical studies performed elsewhere or require additional ones. These requirements subject the manufacturer to significant efforts and expenses. As a result, Indian manufacturers are reluctant to seek registration in countries with perceived limited potential for profits. Bidding on international tenders also requires the completion of product registration in-country before the first order is delivered. Because of the time required to register products, some manufacturers have begun to initiate registration in countries where they see potential opportunities for large government or donor contracts.

6. CONCLUSIONS AND RECOMMENDATIONS

During the past decade, Indian pharmaceutical manufacturers have demonstrated their ability to supply quality, low-cost, generic hormonal contraceptives and IUDs in large quantities. These manufacturers are major entities in the Indian market because they supply the products government and social-marketing programs distribute. Their contribution to a more-sustainable approach to product supply, however, is predicated on creating real market opportunities for them.

Similarly Indian manufacturers can become major suppliers to other countries as long as demand for products in these countries can be translated into viable market opportunities. Increasing the role of these manufacturers abroad can be achieved through international procurement programs and, for a select group, through public/private or fully commercial partnerships.

INTERNATIONAL PROCUREMENT

Contraceptive manufacturers are pursuing bidding opportunities outside of India and are likely to be global players through government-funded programs and the UNFPA. These manufacturers can supply social-marketing and public-sector programs outside of India at prices that may be cheaper than what R&D companies offer and with more-flexible conditions. Increasing the participation of Indian manufacturers in international tenders may involve streamlining product-registration processes and disseminating information about upcoming tenders. Indian manufacturers are not expected, however, to become regular suppliers of USAID programs because they do not have, and are unlikely to seek, FDA approval. In addition, USAID must grant preference to U.S. suppliers when they bid on tenders.

Indian manufacturers also can supply low-cost commodities that help social-marketing programs reduce their dependency on USAID or government-donated products. These manufacturers may even market commercially sustainable brands. SMOs have been procuring condoms from Asian manufacturers for years but are now seeking new hormonal contraceptive suppliers in India, Thailand, and Indonesia.

DEVELOPING COMMERCIAL MARKETS

In India developing a commercially viable middle market has proven discouraging. The availability of low-price, government-supported and -endorsed products is a deterrent to commercial companies. While past category-promotion efforts have increased the market, they have not changed its structure and dynamics. Without a change in market conditions, it is unlikely that India will experience a sizeable shift to commercially viable products.

Internationally, whether a country can develop a commercially viable middle market and Indian manufacturers can supply it depends on that country's situation. Where SMOs and government programs distribute subsidized or free products on a large scale, they may prevent the development of sustainable markets. According to opinions representatives of companies interviewed for this assessment expressed, these programs are a major barrier to entering markets at commercially viable prices. The customer base for a middle market will have to come from users who are willing and able to

pay market prices for contraceptive products, but are currently obtaining free or subsidized products. Market building strategies may include phasing out free and subsidized products, targeting them more effectively, or introducing mid-priced products in partnership with SMOs.

Fully commercial partnerships between Indian manufacturers and distributors are possible, but they are unlikely to involve contract manufacturers. Commercial distributors prefer to work with manufacturers that have large portfolios of complementary products and can provide marketing support. Contract manufacturers, with their limited range of unbranded generic products, are unable to spread their marketing and distribution costs and, therefore, have difficulty supporting the distributor.

India, however, is home to large generic manufacturers with extensive product portfolios and marketing capability. Their involvement in the commercial distribution of low-priced contraceptives is predicated on motivating them to produce or procure contraceptives in the first place. Regrettably market distortions specific to contraceptive supply in India and the region have discouraged them from marketing this class of products. Should market conditions change, these large companies may be instrumental in supplying the developing world's need for quality, low-cost contraceptives.

Even large established Indian generics manufacturers, such as Cipla, need to find in-country marketing and distribution partners with distribution capacity, complementary products, and contacts. Several companies mentioned the difficulty identifying and screening reliable marketing partners in other countries. Commercial partnerships can be encouraged by making market-research information available to Indian manufacturers, identifying distributors and agents, and introducing Indian companies to potential partners.

ANNEX A: SELECTED INDIAN LAWS AND POLICIES

Selected laws, policies, and regulations relevant to pharmaceutical manufacturing and marketing in India:

- The Drug Policy of 1986 (revised in 2002) is available at http://chemicals.nic.in/pharma4.htm (accessed March 13, 2006).

- Patent regulations. On March 23, 2005 India adopted international patent-protection standards (up to that point it did not recognize international patents and agreements) is available at http://www.patentoffice.nic.in/ipr/patent/patents.htm (accessed March 13, 2006).

- The Drugs and Cosmetics Act of 1940 (and later amendments). An overview, historical review, and details of this law and other ones are available at http://www.cdsco.nic.in (accessed March 13, 2006).

- The Drug Price Control Order of 1995 regulates the prices of some drugs (currently 74 formulations). Details about these drugs are available at http://nppaindia.nic.in/drug_price95/txt1.html (accessed March 13, 2006).

- The Drugs and Magic Remedies Act of 1954, which regulates advertisements, is available at http://www.indialawinfo.com/bareacts/druma.html (accessed March 13, 2006).

- To import a pharmaceutical product, it must be registered with the Drug Controller General of India in New Delhi. Information on doing so is available at http://www.cdsco.nic.in (accessed March 13, 2006).

- The most important regulatory body for pharmaceuticals is the Central Drug Standard Control Organization. Information on this entity is available at http://www.cdsco.nic.in (accessed March 13, 2006).

ANNEX B: ORGANIZATIONS CONTACTED

Interviews for this assessment, some of which were confidential, were conducted with one or more individuals from the following organizations:

MANUFACTURERS

- Cipla
- Contech Devices
- Famy Care
- German Remedies
- Hindustan Latex Ltd.
- Indian Drug and Pharmaceutical Ltd.
- Pfizer
- Phaarmasia
- Prabhu Global Exports
- Pregna
- SMB Corporation
- Strides Arcolab
- Torrent Pharmaceuticals
- Win-Medicare

NONPROFIT ORGANIZATIONS

- DKT/Janani
- IntraHealth
- IPAS
- PATH
- Population Services International
- Private Sector Partnerships-*One*

ANNEX C: RESOURCES

Carter, E. 2005. Pre-Qualification Assessment Famy Care Limited, Unit II—Oral Contraceptives. Sarigam, India.

Department for International Development (DFID), 2005. *Increasing People's Access to Essential Medicines in Developing Countries: A Framework for Good Practice in the Pharmaceutical Industry.* A UK Government Policy Paper. London: DFID.

Holmes, K. 2005. *The Indian Pharmaceutical Market: Challenges and Opportunities*. Princeton, NJ: Espicom.

Joshi, H.N. 2003. Analysis of the Indian Pharmaceutical Industry, with an Emphasis on Opportunities in 2005. *Pharmaceutical Technology* January.

Program for Appropriate Technology in Health (PATH). 1994. *Issues to Consider in the Production of Hormonal Contraceptives*. Geneva: World Health Organization (WHO).

Stanback, J. 1997. *Perspectives on Local Manufacture of Contraceptives in Developing Countries*. Arlington, VA: PROFIT Project.

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