

NICHOLAS PIRAMAL INDIA LIMITED



Nicholas Piramal is one of the largest pharmaceutical companies in India that has successfully positioned itself as a custom manufacturer for global companies.

Background

Nicholas Piramal India Limited (NPIL) came into existence in 1988 when the company Nicholas Laboratories was acquired from Aspro Nicholas by the Mumbai-based Piramal family. In 1991, NPIL commissioned a new manufacturing plant to add to the existing two plants, which were small and considerably outdated. The new plant was built to comply with US FDA standards to allow NPIL access the huge generics market in the US as well as increase its credibility with potential partners in order to attract post-GATT product licensing agreements.

Over the years NPIL has grown to become a market leader in the Indian pharma industry through a series of well-managed acquisitions, mergers and alliances. The first acquisition was that of Roche Products in 1993, with NPIL retaining the right to manufacture and distribute all existing and new Roche products under the Roche brand name. The second acquisition was that of Boehringer Mannheim India, subsidiary of Boehringer



Mannheim AG (BM) of Germany, in 1996. This gave NPIL access to all research products of BM Germany, for launch in India in the areas of pharma, diagnostics as well as biotechnology. Some of the major acquisitions made by the company thereafter include Hoechst Marrion Roussel's Research Centre, Rhone Poulenc India Ltd., ICI India Ltd.'s pharma division and Boot's OTC brand Lacto Calamine.

The company's strategic intent has been to position itself as a partner of choice for global drug companies that want to leverage India's low manufacturing cost advantage. Its core strength lies in its joint ventures and alliances with some of the key global players in the industry which include F. Hoffmann-La Roche Ltd (Switzerland), Allergan Inc. (USA), Boots Plc (UK), Gilead Sciences (USA) and Cheissi (Italy).

Company	Products	Established	Founder	Distribution	Production plants
Nicholas Piramal	Pharmaceuticals	1988	Piramal family	India, Americas, Europe, Asia, Australasia, Africa	India, UK, Canada



NPIL has formed a joint venture with Boots named Boots Piramal Healthcare Pvt Ltd, for over-the-counter (OTC) products. NPIL has 49 per cent stake in this venture, which markets and distributes NPIL's OTC brands like Polycrol, Lacto Calamine, Saridon, Strepsils and Clearasil. Another important alliance is with Allergan India, in which NPIL has 49 per cent stake. Its product range is targeted at the ophthalmology market for diseases like glaucoma, ocular surface disease/dry eye and introducing new surgical products (particularly small incision cataract surgery).

NPIL has a 100 per cent stake in two pathology laboratories - NPIL Diagnostic Laboratories Pvt. Limited (Kolkata, West Bengal) and Dr. Phadke Pathology Laboratory & Infertility Centre Pvt. Limited (Mumbai, Maharashtra). These labs offer a wide range of pathology investigation tests, which include immunology tests, haematology, microbiology, infertility investigations and histopathology examinations.

The company's promoters, the Piramal family, hold the majority stake in NPIL (50.4 per cent). The next largest shareholder is the Indian public (with 13.1 per cent stake) followed by foreign institutional investors (with 13.2 per cent stake). Foreign companies, domestic financial institutions, private corporate bodies and non-resident Indians hold the residual shares.

Products and brands

NPIL has business expertise in the areas of bulk drug manufacture for domestic and export markets, speciality labs and chemicals and formulation development. Formulations constitute more than 65 per cent of gross sales. Details of the products are as follows:

- **Domestic Formulations business:** These include products in various therapeutic categories – analgesic / anti-inflammatory, antibiotics, anti fungal, antihistamines, antiseptics, cardiovascular, central nervous system, diabetes, dermatology, endocrinology, gastro-enteritis, multivitamins / nutraceuticals, oncology, pulmonary / respiratory and trauma / emergency.
- **International Formulations business:** This focuses on anaesthetic and parenteral products used in operating rooms and critical care units. It currently manufactures and exports inhalation anaesthetic (Halothane and Isoflurane) and plasma volume expander (Polygeline). In addition, through a licensing agreement with AstraZeneca, NPIL also manufactures and exports Tetmosol, a monosulfuram soap, which is an anti-scabies in selected markets.
- **Diagnostics Division:** NPIL is the leader in the field of in-vitro diagnostics with its state-of-the-art equipment and kits, in the fields of clinical chemistry, immunology diagnosis, haematology diagnosis and rapid diagnostics. It also offers diagnostic tools in the fields of diabetes care, cardiac care and urinalysis.
- **Vitamins and fine chemicals:** NPIL is a leading supplier of vitamins and fine chemicals used extensively in human and animal nutrition and health businesses.

NPIL owns some of the well-known brands in the

pharma business. Its top 10 brands, Phensedyl, Haemacel, Stemetil, Gardenal, Pentids, Tixylix, Phenergon, Paraxin, Sorbitrate and Gentylin contribute around 29 per cent of its revenues.

Financial Analysis

Sales of the company grew at a CAGR of 21.5 per cent between 1999 and 2005 to reach a level of USD 317 million. A slowdown in sales was observed in 2005 due to several reasons – introduction of MRP (maximum retail price) based excise duty, chemists' boycott of Psychotropic and Narcotic drugs and replacement of sales tax (averaging about 9 per cent across most states in India) with Value Added Tax (VAT) of 4 per cent. This led to significant down stocking by trade channels to clear out high tax bearing inventory before the end of the financial year. Net profit in 2005 was USD 23 million. Operating margin and net margin were 20.2 per cent and 7.2 per cent respectively in 2005.

NPIL's contribution in making "Made in India" global

In the global markets, NPIL has prepared an export plan with a difference. It has positioned itself as a high-end contract manufacturer for bulk drugs and formulations for renowned global companies and does not operate in the early-to-market generics market. This strategy is quite different from that of its peers, which are currently in a race to export generic versions of patented drugs to be sold in developed markets. It has ensured that NPIL does not cross the path of multinational research-based companies by launching generics. The company concentrates only on high-end products, which are more complex and difficult to manufacture. However, it is open to marketing "grandfather" generic molecules - products whose patents have long expired in the developing and non-regulated markets.

Global sales currently constitute 21.4 per cent of gross sales. They include sales of niche and "late-to-market" generic active pharmaceutical ingredients (API) to European regulated markets as well as some unregulated markets. NPIL also exports select formulations such as Halothane and blood plasma expanders.

The company's contract research and manufacturing services (CRAMS) business is witnessing growth and has already announced six contracts till date.

- **Agreement with Fortune 500 company (name of company and products not disclosed by NPIL):** This agreement is for manufacture and supply of various pharmaceutical products for sale in the US for an initial period of 5 years and renewable for another 3 years. It also has the option of being renewed on a year-to-year basis. The deal is estimated to be USD 15-20 million in size.



- **Agreement with Allergan Inc., USA:** This agreement is for the manufacture of two anti-Glaucoma APIs (Levobunolol and Brimonidine) for Allergan's world-wide requirements and is valid upto October 2011.
- **Agreement with AstraZeneca:** This is for the development of processes and supply of certain intermediates and APIs (names not disclosed). On successful product development, the two partners are expected to further negotiate the terms of the agreement for supply of products by NPIL.
- **Agreement with Advanced Medical Optics (AMO):** This is for exclusive supply of neutralising tablets and sterile FFS packs for AMO's world-wide requirements and is valid upto 2010;
- **Agreement with Hospital Products Company:** This is for exclusive sourcing partner for products across the value chain. The contract remains till 2010.
- **Agreement with Pfizer International LLC:** Under this agreement, NPIL will provide process

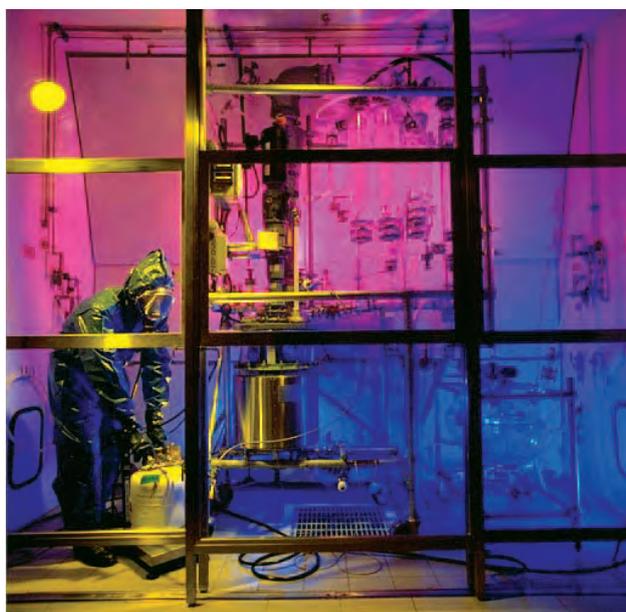
development and scale-up services to Pfizer's Animal Health Division from its facilities in India. NPIL will develop processes for Pfizer, and provide scale up batches for Phase Trials. The contract is valid till 2012.

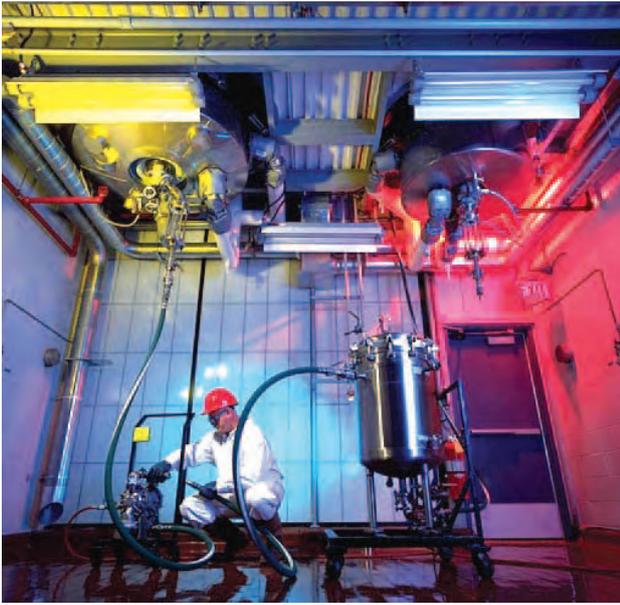
NPIL's 100 per cent subsidiary in the US, NPIL Pharma Inc serves as the front-end in its business development efforts for custom manufacturing for global companies.

NPIL recently acquired the manufacturing facility of Pfizer Inc. located at Morpeth, UK, which came along with a supply agreement till November 2011 totalling potential revenues above USD 350 million. This site is one of Pfizer's global, high-quality, integrated facilities having end-to-end production and supply chain capabilities that cover API's Finished Dosage, Packaging and Distribution. With the acquisition of this facility, NPIL has become the biggest supplier (in terms of spend) within Pfizer's Global Custom Manufacturing network with supplies to over 100 global markets.

The CRAMS business of NPIL has also been strengthened with the acquisition of Avecia Pharmaceuticals (UK) in 2005 for a consideration of GBP 11.8 million. Avecia Pharmaceuticals is a global custom manufacturing player focused on providing custom chemical synthesis and manufacturing services for the innovator pharmaceutical and biotechnology companies. This acquisition will not only add new clients to NPIL's portfolio but also give it access to critical technologies. NPIL's current CRAMS pipeline is expected to have peak sales of USD 110-130 million (including Avecia) by 2008.

To add to its portfolio of IA, NPIL has entered into an agreement with the US-based Minrad for exclusive distribution and marketing of a new generation of IA products (Isoflurane, Enflurane and Sevoflurane).





Prior to the Avecia acquisition, NPIL had acquired Rhodia's inhalation anaesthetics (IA) business in December 2004 for a total consideration of GBP 7 million. This acquisition gives NPIL access to the technology and state-of-the-art manufacturing facilities in UK and India, as well as the global sales and marketing rights for Rhodia's IA products - Halothane and Isoflurane. The company has given NPIL complete access to Rhodia's sales and marketing network of exclusive pharma distributors in over 90 countries – including the U.S., Europe, Japan, Australia and numerous emerging markets. This deal has given NPIL a strong growth platform in the global hospital/ critical care business.

These would be marketed exclusively by NPIL through dedicated distributors and marketing agents in the markets of Russia, Ukraine, Nigeria, Kenya, Sudan, Syria, Jordan, Iran, Egypt and Bangladesh. NPIL had earlier acquired the rights to Halothane, the only other major inhalation anaesthetic globally, when it took over ICI's Indian pharma business.

As a step towards creating a presence in the biotechnology space, NPIL has acquired a stake in BioSyntech, a Canada-based biotechnology company specialising in discovery and development

of therapeutic thermogels for regenerative medicines. This acquisition has given NPIL exclusive rights for marketing, sales and distribution of current and future products of BioSyntech for India, Pakistan, Sri Lanka, Bangladesh, Laos, Cambodia, Vietnam and Philippines. In addition, the companies have agreed to explore opportunities to collaborate for research and development with respect to future products of NPIL using BioSyntech's technological platforms.

Factors fuelling NPIL's global initiatives

NPIL's strategy of entering into long-term contracts with innovator companies for contract manufacturing and not engaging in patent challenges has helped it to become a partner of choice with many MNC pharma companies. It intends to partner the innovator through all stages of the CRAMS business, starting from custom chemical synthesis to contract manufacturing for on-patent and off-patent products. The company aspires to become a global leader in Custom Manufacturing across the Pharmaceutical Value Chain. In annualised terms, it is expected to have custom manufacturing revenues exceeding USD 200 million.

Even in the domestic market the company has positioned itself as a marketing partner for multinationals selling in India. In-licensing alliances of this nature are with

- Laboratories Pierre Fabre, France for derma cosmetics and dermatology products (brands Exomega and Kertyol-S)
- Genzyme Corporation, USA for viscose supplementation (brand Synvisc) for local treatment of pain associated with osteoarthritis
- Ethypharm, France for accessing technology for producing dispersible flash Paracetamol tablets
- Biogen Idec, USA for marketing Avonex, a leading life-saving therapy for Multiple Sclerosis, in India and Nepal



- Chiese Farmaceutici, Italy for Curosurf, a lung surfactant for premature babies with Respiratory Distress Syndrome (RDS)
- Eli Lilly & Company, USA for Dobutrex, an injectible drug in the Cardiovascular (CVS) therapeutic segment

Having built up a reputation of being a partner to large international companies for launch of their products in India, NPIL has leveraged this to become a contract manufacturer for the global markets. NPIL now has relationships with 7 out of top 10 global pharma companies.

Its strong research capabilities have backed its success in globalisation. In 2005 the company inaugurated its new 200,000 square feet R&D centre at Mumbai (Maharashtra), which is one of the largest, single-site pharmaceuticals R&D centre in the country. It has facilities to carry out new drug discovery, novel drug delivery technology, formulation activities and API process development. The R&D team has 500 scientists. The company also has alliances with academic institutions in India for discovering new targets to treat fungal diseases,

novel immunomodulators and new drugs to treat cancer and diabetes. Its lead molecule P276-00 for Oncology is in Phase I/II and two mono herbal products are in Phase II. By the end of the financial year 2006-07 NPIL expects four more candidates to be in human clinical trials.

The company's manufacturing facilities are accredited with several international agencies, which make it acceptable to global pharma companies. Its plant at Hyderabad (Andhra Pradesh) is the only one in India to have US FDA approval for the entire facility and is used for manufacturing APIs. It is also accredited and approved by MHRA (Medicines and Healthcare products Regulatory Agency) of UK, TGA (Therapeutic Goods Administration) of Australia and the European and Canadian Drug Authorities.

Its plant at Pithampur (Madhya Pradesh) has obtained ISO-14000 certificate from BVQI and is used for toll manufacturing by reputed companies like Allergan, Novartis, Solvay and IVAX for manufacturing of pharmaceutical finished dosage forms. The Pithampur plant is approved by MHRA,

MCC (Medicines Control Council) of South Africa and TGA. The plant at Thane (Maharashtra), used for manufacture of vitamins and fine chemicals, has obtained the coveted ISO – 9001 & ISO – 14000 certificates and also the SQF 2000 & HACCP Certification. Its Chennai (Tamil Nadu) facility is a cGMP compliant site dedicated for the manufacture of advanced intermediates.

Future plans

NPIL expects a rapid transformation in its business led by an exponential increase in export revenues in the next 2-3 years. The company has identified contract manufacturing as a focus area for future growth. The company is also looking at acquisitions in the USA and UK to build upon its capabilities in process development and manufacturing new molecules.

NPIL has also recently commenced production in a phased manner from its formulations facility at Baddi (Himachal Pradesh) in order to get benefits from the state government's policy of giving exemption from payment of excise duty for the first ten years.

Globalisation at a glance

- Exports of APIs and formulations made to various global markets
- Pioneer in custom manufacturing - positioned as "partner of choice" for global innovator companies
- CRAMS business made stronger with the acquisition of Avecia in UK
- Manufacturing facilities in UK and distribution network across 90 countries for inhalation anesthetics, obtained after the acquisition of Rhodia
- Inhalation anesthetics business made stronger through an agreement with Minrad, USA to market Minrad's products in several markets