

THE INDIAN DRUG DISCOVERY AND DEVELOPMENT PIPELINE

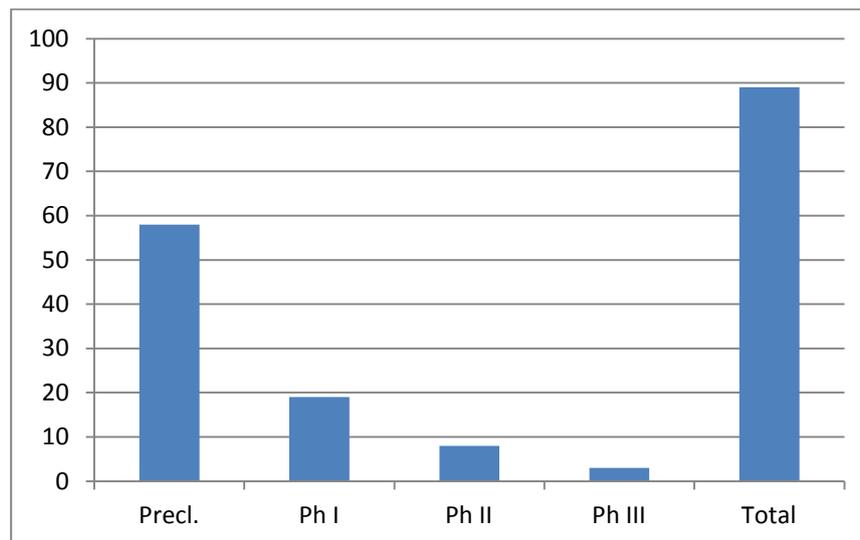
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In the late nineteen eighties, Indian pharma companies started in-house drug discovery activities, aiming at developing the country's first home-made drug. Pioneers like Ranbaxy and Dr Reddy's were joined by companies like Glenmark, Biocon, Piramal, Sun, Torrent and Wockhardt. More recent players include Advinus, Zydus Cadila, Suven and a number of much smaller start-ups.

In October 2011, the first drug developed - although not discovered - by an Indian company reached market approval from the Drug Controller General of India (DCGI): Ranbaxy's anti-malarial combination treatment arterolane/piperaquine. Arterolane is licensed from Medicines for Malaria Venture, and was initially discovered at the University of Nebraska (USA).

The need for a better understanding of the current drug discovery pipeline prompted this report. It is based on information available on company websites and in press releases. It includes about twenty companies that have reported in total almost ninety compounds in various preclinical and clinical development stages (Figure).

FIGURE: Indian R&D Pipeline: number of compounds in development





The most advanced small molecule drugs discovered and developed in India include:

- In clinical phase III studies: DRF 2593 (Balaglitazone), a PPARgamma agonist, for the treatment of diabetes and metabolic disorders (Dr Reddy's), and ZYH1, a PPARalpha/gamma ligand for the treatment of dyslipidemia (Zydus Cadila)
- In phase II studies: DRL 17822, a selective CETP inhibitor, for the treatment of dyslipidemia and associated cardiovascular diseases (Dr Reddy's), GRC 8200 (Meloglyptin), a DPPIV inhibitor for the treatment of diabetes (Glenmark), P276, a CDK inhibitor for oncology (Piramal Lifesciences) and SUN-1334H, an antihistamine for the treatment of allergies (Sun Pharma)

In addition, close to twenty compounds have been reported to be in phase I studies, and almost sixty molecules are currently at various stages of preclinical development.

The drug discovery and development process is long (>12 years from project initiation to the launch of a new medicine) and highly risky, with huge associated costs of bringing a new drug to the market. Few of the Indian companies have the financial stability to cover such costs and risks. This means that whereas the discovery stages are run successfully in-house, external partnerships with the required strong financial backing for the expensive clinical development stages are generally an integral part of Indian pharma's strategy.

Prominent licensing deals have been signed in particular by Glenmark, although several of the compounds failed later in clinical development. These include Oglemilast for the treatment of asthma/COPD with Forest/Teijin in 2005 (failed to meet the desired clinical targets in 2009), meloglyptin for diabetes with Merck in 2006 (development stopped in 2009) and GRC6211 for osteoarthritic pain with Lilly in 2007 (returned in 2008). More recently, Glenmark signed agreements with Sanofi on GRC 15300, an early-stage compound for the treatment of osteoarthritic pain, and GBR 500, a monoclonal antibody for anti-inflammatory diseases.

CONCLUSION:

The industry-wide declining productivity and increasing costs along the pharmaceutical value chain are putting a considerable pressure on the pharmaceutical industry, forcing it to explore options for improving performance by reducing costs and increasing productivity. Among the options, outsourcing and partnering are particularly well established approaches. The current Indian drug discovery pipeline offers attractive opportunities, as it illustrates that Indian pharma and biotech companies have proven their capability to build integrated drug discovery capabilities, and to drive molecules from the early discovery stage into development.

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More details on this report are available from:

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