

Life Cycle Management Strategies

The patent cliff and a reducing drug pipeline are the two biggest challenges faced by innovator companies today. With the expiry of blockbuster drugs and early entry of generics, the pharmaceutical industry has lost about \$157 billion in sales between 2010 and 2015. This is hampering the industry's ability to fund drug development programs. Until about two decades ago, most drugs had an effective patent life of about 17 years, but changes to regulatory requirements and challenges by generic companies has resulted in only about 7 to 11 years of market exclusivity for innovators' drugs.

To tackle the above challenges, and to keep the market success of a brand protected from generic competition, pharmaceutical companies are launching product line extensions through the 505(b) (2) NDA route. Line extensions account for around one-third of all lifecycle management strategies. An estimated 30 important line extensions are launched in the U.S. market every year.

Line Extensions A line extension is a variation of an existing product that is used to either extend a period of exclusivity or ward off market erosion by generic introduction through implementing a strategic advantage. The variation can be:

1. New Indications or Drug Repositioning

New indications hold tremendous value as they have the advantage of decreased development costs and decreased time to market than traditional discovery efforts, due to availability of previously collected pharmacokinetic, toxicology and safety data.

1. New Formulation or Drug Reformulation

- Reformulation of a drug uses the same active ingredient as the original drug, but the formulation is changed to improve compliance, reduce side effects, or improve efficacy. The reformulation approach has shorter approval times than new product development and typically receives protection through the new formulation patent. For example a pediatric formulation of an existing product gives it additional patent protection for six months.

- Reformulations include:

- Delayed, Extended and Modified Release Tablets, Chewable tablets, etc.
- Conversion from Injection into Oral Formulations.
- Conversion of a Lyophilized Presentation to a Liquid Presentation.
- Novel Drug Delivery Systems Formulations like Transdermal Patches, Liposomal Formulations, Depot Injections, etc.

1. Combination Drugs Combination drugs are prepared by combining the active ingredient of an approved drug with one or more other active ingredients to produce a single new product.
2. New Forms (Polymorph, Salts, etc.) of Existing Drugs Companies develop new products whose active ingredients are chemical derivatives of previously approved drugs. The FDA classifies these medicines as “new salts or esters.” Their development builds on the mode of action and pharmacology of the first-generation product.

Piramal Lifecycle Management Capabilities An increased focus on lifecycle management will help companies maximize product sales and better prepare a counter-generic strategy in the future. Product line extensions like new indications, combinations and reformulations, etc., give faster returns on the development spend than other product strategies. Successful line extension strategies have added millions of dollars in new revenue to existing products while opening up new opportunities for growth. Piramal Pharma solutions, with strong development and regulatory capabilities, can help customers to execute successful product line extension strategies.

Our facilities at Mumbai and Ahmedabad, India; Morpeth, U.K. and Lexington, Kentucky, USA offer the following special formulation development capabilities: • Pediatric and Geriatric Formulations. • Oral Solids. • Immediate and Modified Release Tablets. • Bilayer Tablets and Press-Coated (Tablet-in-Tablet) Tablets. • Chewable Tablets • Orally Disintegrating and Fast Dissolving Tablets. • Combination Drugs. • Novel Injectable Formulations such as Liposomes, Micro Emulsions, etc. • Conversion of One Dosage Form to Another — Injectable to Oral, Lyophilized to Liquid, etc.

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