

PRODUCT LIFECYCLE AND PORTFOLIO MANAGEMENT

There are many factors that influence a pharma company's survival. In today's competitive market, integrated product lifecycle and portfolio management will help support the drug company's strategy, thereby maximising company profitability, write Hans Hoogkamer director and Miriam Halpern Wernli of Actelion Switzerland.



Authors

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Expiry of blockbuster drug patents, short drug lifecycles, strong competition, heightened health authority scrutiny, rising development costs coupled with lower drug prices and the need for the latest technologies are putting tremendous pressure on today's pharmaceutical industry. Successful pharmaceutical and biotechnology companies of tomorrow must continuously develop and commercialise a portfolio of new drugs and indication extensions, thereby remaining competitive in the global drug market. Therefore, companies must efficiently manage their product portfolio to reduce the time-to-market and maximise return on R&D investment.

In the pharmaceutical industry, effective drug development comprises two main components: doing products right and doing the right products. While product lifecycle management is about doing products right, portfolio management is about doing the right products, as well as developing the right set of products to meet business needs, and deliver results.

Drug discovery and development

Target identification is the first step of the drug discovery and development process in which scientists search for a target or a particular gene sequence that they believe might influence the course of a specific disease (see Figure 1). An identified target

helps scientists develop compounds that might interact with the target to alter how it affects a biochemical pathway and, ultimately, the disease. Chemists develop compounds that may interact with that target. Using an automated robotics system, scientists may screen more than a million compounds to find a promising lead. Preclinical in vitro and in vivo experiments are performed with the selected lead compounds to gain information on mechanism of action, potency and toxicity profile.

A drug candidate enters development, once the initial safety profile is established, with phase 1 or proof-of-concept studies (see Figure 2). Typically, the drug candidate is administered to a small group of patients or healthy volunteers to verify the mechanism of action and to test if the new candidate is efficacious in human disease. These studies should evaluate a safe dose range and the metabolism of the candidate in the human body. In parallel, manufacturing processes are developed and a suitable drug product is formulated. Additional preclinical in vitro and in vivo experiments are performed to gain further data on mechanism of action. When a drug candidate is considered to be safe and promising, it enters phase 2 clinical trials involving a few hundred patients. The purpose of phase 2 is to establish the range of efficacious doses for a particular disease. If successful, the drug candidate enters phase 3 trials, which provide definitive information about the drug's effectiveness and increase the knowledge on its safety profile in large groups of patients. Large phase 3 studies may include over 10,000 patients.

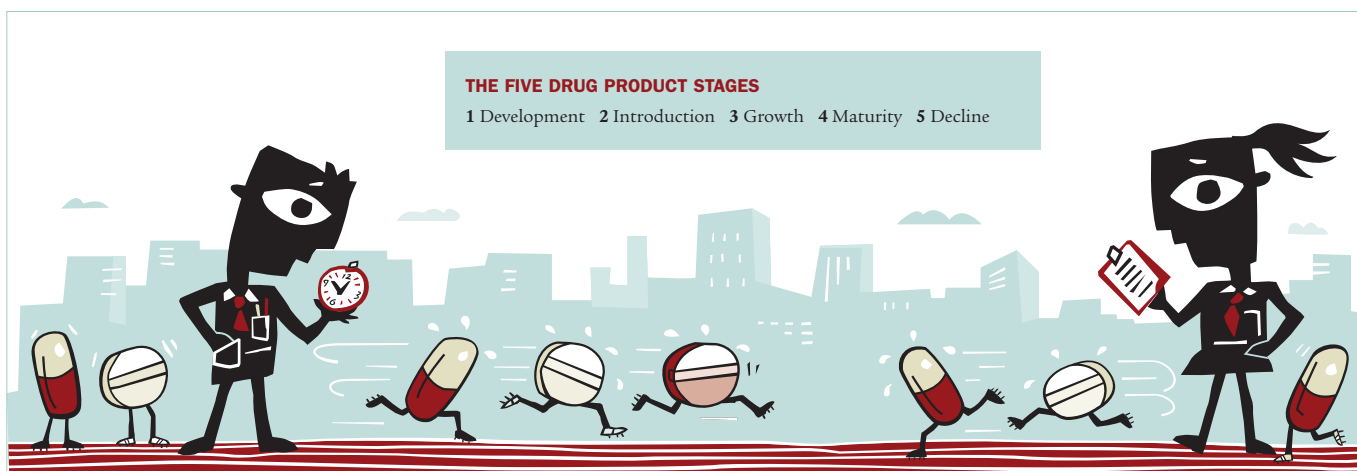
For the registration of the new drug, the results from all preclinical and clinical studies are collected and analysed together with the quality data and the description of the manufacturing process. All the material is compiled and subsequently submitted in an appropriate form to the regulatory authorities for review. If the regulators agree that the data proves the quality, efficacy and safety of the drug, a marketing authorisation is granted. From then on, a new drug can be made commercially available to patients.

Of approximately 10,000 new chemical entities discovered, only 100 drug candidates will enter clinical testing and only one of these will be approved. It is estimated that the average cost of bringing a new drug to market is \$800m, and the average length of time from discovery to patient is 15 years. Half of the costs are for compounds that were discontinued during their development process. For these reasons, drug discovery and development is considered a high-risk venture.

The pressure on the pharmaceutical industry will further increase over the next few years. Patent expirations and heightened regulatory scrutiny are among the challenges faced by the healthcare conglomerates. Major product patents will expire between today and 2010, with the total value of these products amounting to approximately \$100bn.

Integrating product lifecycle and portfolio

A product's lifecycle can be defined as a succession of stages: from early concepts to end of product life. A product's life is usually described by five distinct stages: development,



introduction, growth, maturity and decline. For medicines, the latter coincides with the expiry of the compound patent.

Product lifecycle management is the succession of strategies used by lifecycle management as a product goes through its lifecycle. Its goal is to maximise a product’s lifetime value through the integration of development and business strategies. In the pharmaceutical industry, one of the key objectives of product lifecycle management is to deliver a steady stream of new medicines coming through the R&D pipeline. The lifecycle process can be envisioned as a funnel, with early projects progressing from ideas through preclinical and clinical R&D to successful global product registration followed by local launches and commercialisation of the brand.

Product lifecycle management is tasked with making sure that medicines are developed for the global markets as efficiently as possible while maintaining high quality. Therefore, an interface with product development throughout the product’s lifecycle is essential. Product lifecycle management includes recognising and launching lifecycle expansions such as new disease areas or line indications, improved formulations and other extensions for the product, thereby creating an optimal brand value. Pharmaceutical companies therefore establish dedicated, multifunctional lifecycle teams consisting of all functional areas involved in the many drug development and marketing aspects (see Figure 3, overleaf). These teams coordinate development and business-related product activities across functions and regions, discuss and challenge scientific and business strategies, and are involved in problem solving of project-related issues.

Pharmaceutical lifecycle teams should be initiated during the early stages of the product’s life. They must be proactive and have patient focus always high on the agenda. These teams progress naturally from being development driven early on to becoming more business focused – market and commercially – when the drug matures.

Portfolio management is about making the right investment in the right products and finding the optimal products mix and product focus based on strategic priorities. It is also about

Figure 1. From discovery to a development candidate

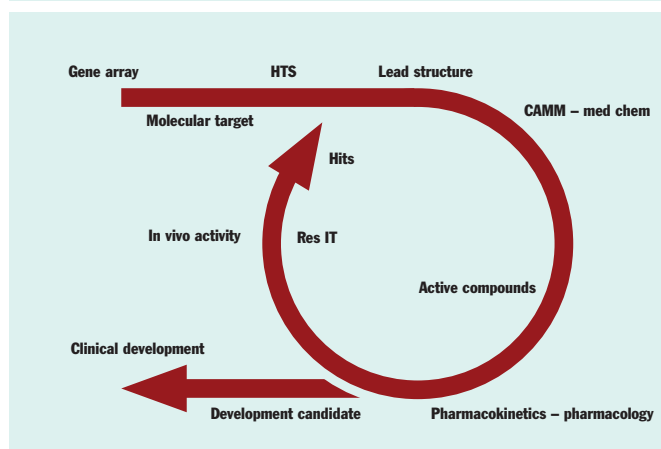
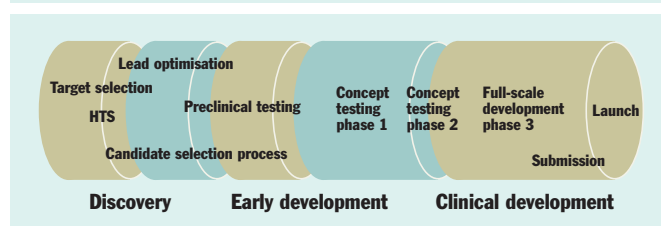


Figure 2. Candidates going through the drug development process



prioritising and selecting projects with the ultimate goal of sustaining a steady stream of new product revenue.

Portfolio management serves to shape, balance and prioritise all project opportunities (see Figure 4, overleaf). It can be envisaged as a matrix, where the whole set of potential products can be seen across different dimensions, such as fit with company culture, market opportunities and likelihood of development success. The dimensions may vary, but the goal is to array all product development activities and look at it in aggregate. Choices about individual projects can then be made focusing their effect on the portfolio.

Figure 3. Breakdown of a cross-functional life cycle team

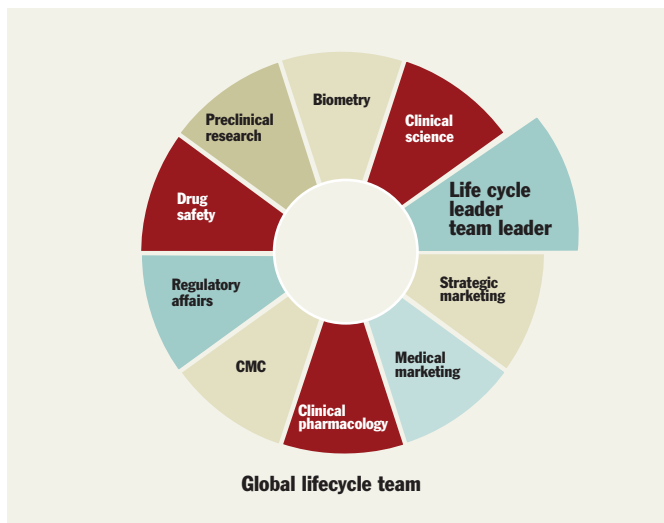
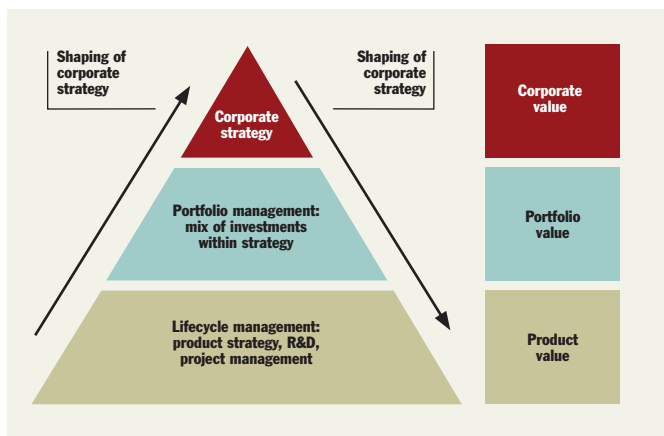


Figure 4. Portfolio management: a framework for corporate strategy and generating value



Integration of project lifecycle and portfolio management in pharma results in added value: this enables the proactive management of the portfolio by having timely and accurate cost, schedule, risk and benefit information available at many levels.

Portfolio management and corporate strategy

Establishing a strategic role for integrated product lifecycle management and portfolio management in any company is critical. Projects and products are important vehicles for achieving corporate objectives. There is a strong rationale to link portfolio management closely with corporate strategy to ensure that projects are prioritised to facilitate their implementation.

However, while portfolio management is often seen as a framework for solely implementing corporate strategy, it should also play a role in the shaping of corporate strategy. If corporate strategy is the blueprint by which the company intends to deliver shareholder value, then portfolio management represents the framework by which the company's corporate

strategy is implemented and developed. Therefore, the ability to effectively link portfolio management to the implementation and shaping of corporate strategy is key for future success.

Integrated process

Project portfolio management is an information-based process and this information resides in different places, in different forms, and is often difficult to obtain, maintain and manage. In responding to this need, it is key to establish a system that supports project portfolio management in the pharmaceutical industry. Such a system should facilitate the collection, integration, management, analysis, reporting, communication and changing of project portfolio information, including project, financial, resource and strategic information. The system is critical in supporting the portfolio and lifecycle management process and in providing the portfolio management and global lifecycle teams with information and tools to make informed recommendations and decisions. A system should be able to provide the following functions:

- Allow management of resource, cost and schedule information
- Drill down from portfolio to compound, indication and clinical trial levels
- Integrate strategic and operational information
- Have a rule-based setting of flags (for example, status alerts to allow managers to react to projects approaching cost, resource or time limits) and calculation of field values
- Aggregates' data at multiple levels (for example, cost data rolls up from indication to compound level)

If well designed and implemented, the system should support the need to:

- Align and prioritise products in the portfolio based on business strategy in order to maximise investment returns
- Maintain an optimum candidate pipeline portfolio by continuously reviewing, analysing, simulating and restructuring the portfolio in response to change
- Manage capacity by identifying products that are not aligned with the company's business strategy so that allocated resources can be redistributed among competing products to maximise performance
- Enhance visibility and clarity of the project portfolio allowing informed, real-time decisions to be made quickly

Potential gains

The benefits of an integrated product lifecycle management and portfolio management in the pharmaceutical industry enable companies to proactively manage the portfolio by having timely and accurate cost, schedule, risks and benefit information available at multiple levels.

A link with strategic objectives enables the company to regularly measure the alignment of ongoing and planned projects in the portfolio with corporate strategy. These benefits should result in a potential reduction of time-to-market of new medicines with improved quality to maximise profitability. END