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Vetter White Paper Edition

Product Lifecycle Management
Maximizing profit and leveraging innovation

Vetter Pharma International GmbH

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Introduction

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The cost of developing a new drug is continuously rising. Many other factors, such as stricter regulations and stronger global competition, are also creating major challenges. If a pharmaceutical company intends to increase its market share and return on investment, it must consider how to maintain a drug's profitability even after its patents have expired. Product Lifecycle Management (PLM) is a viable option for extending profitability, and there are several methods for approaching PLM effectively. What is crucial, however, is to plan for it early on, even, if possible, before the drug actually enters the market.

The key to successful Product Lifecycle Management is to create and evolve a proactive strategy for the product throughout its entire useful life, from its launch through to its long-term growth and acceptance in the market.

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Product Lifecycle Management
Maximizing profit and leveraging innovation

Lifecycle Management is an integral part of the success of any product. But in the pharmaceutical industry, it remains something of a special case. Rather than try and maintain their drugs on the market, many companies have until now relied on their ability to keep the pipeline filled with new products. But the number of new drugs has been declining, while development costs have been rising. More than ever, therefore, pharmaceutical companies have been turning to lifecycle management in order to differentiate their products. In other words, finally getting a drug on the market is no longer enough: keeping it there and managing its success is just as crucial.

This is where Product Lifecycle Management (PLM) comes in. Essentially, there are two kinds of markets, each demanding a certain approach. A first-in-class product entering a non-competitive market – i.e. without any other similar drug – will need to be launched quickly and efficiently. A simpler form of administration can be chosen, thus speeding up time to market and keeping costs down. Once the drug's patent runs out or more drugs enter the market, however, the market will become competitive. In that case, it will have to have certain qualities unique to it, like a special form of administration. That is one common version of PLM.

Figure 1 shows the options a pharmaceutical company has if it plans to launch a new product. The market situation is important for the Product Lifecycle Management.

Product Lifecycle Management

Situation product entering the market:	Options for pharmaceutical company:
Non-competitive market: • High need for medication • No competitive drug is on the market at the time of launch	• A first-in-class product needs to be launched as soon as possible • A company may opt for a simpler administration form in a first step, while at the same time working on an end-user friendly solution • Option for later PLM sustained release form and improved end-user handling, e.g. pen/auto-injector systems
Competitive market: • No high need for medication • Competitive drugs are already on the market	• The new product coming to market will have to have certain USPs such as a special administration form like pre-filled syringes • Option for later PLM sustained release form and improved end-user handling, e.g. pen/auto-injector systems

Figure 1: Options for launch of a pharmaceutical product

Maintaining a successful course

About a decade ago, longer-term PLM was something to which pharma companies devoted little time, once the drug was on the market and earning returns on investment. The preferred approach was to simply focus on the first launch and then turn attention to the next drug in the pipeline when the lifecycle of the first one ground to a halt. But times have changed dramatically. Today, there are fewer drugs coming to market, and major product patents that brought in large earnings will expire between today and 2010. Plus, product development costs have increased, so a pharma company has to draw the most out of drugs it already has on the market. This has given rise to carefully designed strategies elaborated well ahead of time to extend a drug's lifecycle.

A major Vision & Reality report by Capgemini published in 2006 suggests that no fewer than 90% of pharmaceutical industry executives said they believed PLM to be significant for the bottom line, and 60% predicted its importance would grow considerably by the end of the decade. Most of those interviewed for the report had a prime rule: it is crucial to have a clear concept early on if a company wants to be successful and maintain a larger piece of the market. PLM must also be deeply integrated in the entire process, which can save a great deal of money. The authors concluded that using legal loopholes or other measures to prevent competitors from entering the market is counterproductive. This is far more costly than robust PLM and the outcome is doubtful.

So how early is early enough? Some drug companies may well consider planning their lifecycle management in the preclinical phase. In other cases, relatively sudden changes on the market can force a quick rethinking of a drug's design. Around 2000, for example, a discussion arose in the U.S. over lowering costs for Medicare by providing patients with larger pills, that they then had to break in two in order to get the right dose. This meant less packaging, but there was a problem with actually breaking pills, in two with enough precision to produce two exact doses. After considerable research – and discussion – it was determined that some drugs did not require such precision and could therefore be packaged in a larger tablet form with a simple breaking line. Others required different solutions. The point is: a proper Product Lifecycle Management concept might have forecast the need for breakable tablets in good time, and a pharma company producing that medication would then have been ahead of the competition.

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PLM options

Generally speaking, there are several approaches to PLM that can be combined depending on need.

Developing new markets
If a drug is being released to a limited market, extending it to other markets is of course the next logical step. This may require passing regulatory barriers or forming alliances with other companies.

Looking for new applications
Sometimes a particular drug will have more than one indication allowing it to be targeted at a completely new market. Some drugs, for example, began as treatment against angina pectoris and were later used to treat high blood pressure. Antidepressants, too, have been subject to indication expansion.

Redesigning the product
Reformulation, as the process is known, involves essentially changing an existing drug to make it more attractive to users and to make it more competitive. The tablet industry, which makes up around half of the entire market, has several options available. The use of color-coding can improve the practicality of a tablet and make it safer to use: e.g. stronger doses are in red, weaker ones in green. A hard-to-swallow tablet can be either coated to make it easier to ingest, or ground up and placed into a capsule. And time-release options mean that the patient only needs to take a tablet once a day. Even adding a flavor to some "bitter pill" can improve its market position.

In the case of injectable drugs – currently about 25% of the entire market – reformulation would involve the process of changing a lyophilized drug, for instance, to a liquid formulation or sustained release formulation. However, drug companies must be sensitive to proper launch timing and competitive pricing for a reformulation to be successful. In addition, they must keep in mind at all times the major limitation facing reformulations: they are only commercially viable if they add significant value to the treatment of a medical condition.

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Comfort for the user

A drug's delivery system plays a vital role. To improve in this field requires imagination and technological creativity and skill, at times. It also requires deep awareness of the market and the trends in the market. Knowing who is using the drug, for example, is a key to understanding what to do with the drug. The current trend towards increased homecare tells the pharmaceutical industry to package its drugs in a more patient-friendly manner. With tablets and other delivery forms, the options are fairly simple. In the case of injectables, however, the situation is a little more complex. A company might launch a drug in a vial/diluent system and then change to an innovative end-user-friendly application system such as a prefilled syringe or a cartridge/pen or dual-chamber system (for lyophilized drugs). With the dual-chamber syringes – ideal for sensitive formulations – a drug can be lyophilized and packaged with its diluent, permitting the end user to reconstitute and administer the drug. The system is highly convenient and allows for far greater precision in dosing, and increased yield exploitation due to reduced overfill, which results in a clear added value. A drug that is established on the market in vials can be repackaged in this modern and user-friendly system quite affordably. This decision can be made very early and preparations can then be met during the packaging phase already to facilitate and speed up filling procedures later on.

Keeping an eye on developments

As mentioned above, effective PLM does require imagination and creativity, but it also means that a company should be aware of the trends in the market. Is the use of pre-filled syringes on the rise, for example? Is a drug going to be used a lot in a mobile situation? Who is the target group of this particular drug? These are just some questions to consider. General information such as demographics and our aging society can be a powerful hint as to what will be the next lifecycle of a product: homecare and self-care. Diseases such as rheumatoid arthritis and diabetes are increasingly requiring patients to administer drugs themselves. Auto-injectors and pen injectors are quite naturally growing in popularity, and they are filled using a syringe/cartridge. The market even provides dual-chamber cartridges for lyophilized products that function in a similar manner to the dual-chamber syringes described above.

PLM basics: a head start and a long view

In the final analysis, Lifecycle Management must be made into an integral part of any drug's development. PLM should therefore begin far earlier on in the process with research into trends and the possibilities to increase the drug's competitiveness. Considerations when a patent runs out on a drug are definitely too late. When the drug is relaunched, it will have to be even more recognizable, better looking and, above all, more user-friendly and, if possible, more effective. Clearly, the latter two are crucial to the user target group. So, prepared with a robust PLM concept and schedule, pharmaceutical companies these days can look to the future with optimism.

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Based on an article first published in Contract Pharma, Rodman Publishing, USA September 2007

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