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How to Sell a Drug Before it is Approved

By **John Mack**

Pharmaceutical marketers can generate significant interest in a drug before it is officially launched. This is often done by supporting educational CME programs for physicians, employing key opinion leaders, sponsoring satellite symposia at major medical meetings, and publishing clinical trial results.

However, did you know that you can also sell a drug before it is launched? Dr. Gene Emmer, President of Med Services Europe B.V., an Amsterdam-based consultancy focused on sales, marketing, and business development for the medical industry, advises his start-up, cash hungry, biotech companies to consider if a European "named patient program" might be an option.

A named-patient program allows physicians and their patients access to drugs which have not yet received approval for marketing by national health authorities. The drug must be used to meet the needs of an individual patient where a licensed alternative therapy is not available or is not suitable for the patient.

"European Named Patient Programs, like US compassionate use programs, offer physicians access to pharmaceuticals which have not yet been licensed" explained Dr. Emmer, "However, there is one important difference: in Europe an unlicensed drug is often purchased by National Health Systems." This presents drug-makers with an opportunity to generate revenues while development is still in-progress.

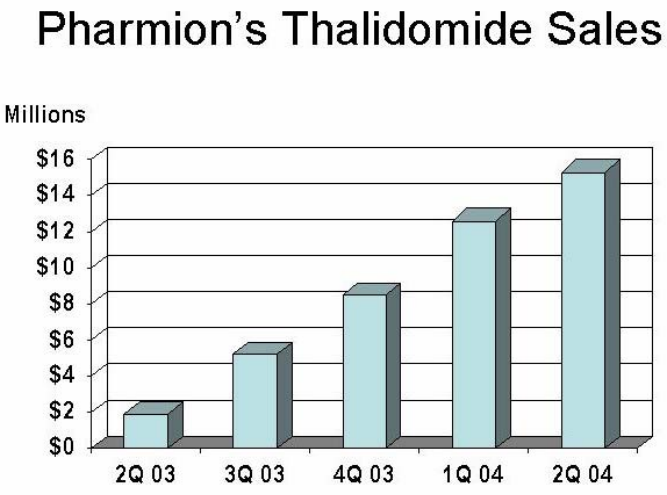
Most often, drugs that are commonly demanded by physicians and patients before they are approved for sale are those drugs that treat rare and/or fatal diseases. A case in point is Erbitux, the colon cancer drug developed by Imclone Therapeutics. Following reports in 2000 of the company's research, Imclone began receiving hundreds of calls a day requesting "compassionate use" the drug, which was then known as C225.

Generating pre-launch demand can help get your product off to a fast start after launch, but demand could be so high that it may upset your launch plans. If appropriate, a structured named patient access program may be a good way to manage the demand and make some sales as well.

Significant Revenues Are Possible

The additional revenues can be considerable. For example, a source at Pharmion, a US based company focusing on Oncology and Hematology reported dramatic increases in its Thalidomide sales from $1.9 million in 2Q '03 to $15.3 million in 2Q '04, primarily due to named patient sales in Europe for Multiple Myeloma (see Chart below). Thalidomide sales accounted for approximately 75% of Pharmion's total revenues for the first half of 2004, according to company sources, and were generated while the product awaits marketing approval for this indication. Before receiving European Marketing Approval, Shire's Argylin® for essential thrombocythaemia generated about 5% of its total sales from its European named patient program.

"We are pleased with the compassionate use and named patient sales growth we experienced for thalidomide," said Patrick Mahaffy, Pharmion's president and chief executive officer. Net sales growth for the first quarter of 2004 was primarily



driven by increased named patient sales of thalidomide, which have grown steadily since sales commenced in the second quarter of 2003.

Other Benefits of Named Patient Programs

A named patient program can speed uptake after official launch. Physicians, who have had experience before launch, via clinical trials or named patient programs, often become early adopters and references for other physicians once the drug is freely circulating.

Named patient programs, like US compassionate use programs, can increase good-will toward the company because they simplify the process of gaining access for patients in critical need. Smaller companies often can not afford the administrative time and costs of shipping drugs around the world before launch. This can lead to frustration and resentment towards a company that many physicians will remember long after a drug is officially on the market. Creating a formal channel eliminates the unfortunate need of denying requests and risking ill-will later.

A named patient program should be considered an important part of a pre-launch program. It increases awareness to a pharmaceutical's existence, creates excitement, generates good-will and speeds penetration of the product after launch. In this age of the Internet and patient empowerment, you cannot underestimate the power of the patient to drive awareness of and demand for your product.

A named patient management program also can provide valuable market research data including feedback from both physicians and patients. This vital pre-marketing data can be used to support the drug's approval.

Named patient and compassionate use programs also can help identify early adopters to target for post-launch marketing activities. In addition, information about the patients, including number of patients, can be helpful in forecasting.

Communication Yes, Marketing No

While physicians are used to simply writing a prescription and being done with it, named patient programs require paper-work that some find tedious. Therefore the pharmaceutical company needs to create an appropriate communication plan and work closely with the targeted medical community to keep them informed and simplify the process.

If one of the objectives is to generate revenues, setting up a named patient program is just the beginning. In order to achieve success, physicians need to be aware of the product and what they need to do to get it. Typical methods of informing physicians, such as detail aids and ads, may not be appropriate because a license is necessary to market a drug.

However, in many countries, a sales rep will be allowed to inform the doctor that the drug is available on compassionate use. In many cases, the rep will be able to give a scientific journal article and a telephone number to the doctor without it being considered promotion. In some countries, the rep can pre-market with an unbranded journal article. When asked by the doctor about availability, the rep will be able to give contact information or ask the doctor if he or she would like to receive a request form. "There are many approaches to this issue," suggests Dr. Emmer, "and it must be discussed in detail with a local medical advisor/regulatory expert."

European Marketing Expertise Required

Some companies may choose to hand the management of program over to a third party company that has experience with managing and handling named patient programs.

If you do not have an experienced European marketing group, an organization that is familiar in sales and marketing of pharmaceuticals in Europe can help you to maximize participation in the named patient program. A communication plan, if properly developed and implemented can increase product awareness, but communication concerning an unlicensed product must be done appropriately.

According to Dr. Emmer, your communication plan should ensure that your entire target group is fully aware of the product AND the program, knows what needs to be done to take advantage of the program, and has an advocate available to guide them through the process.

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