pharmaphorum™
bringing healthcare together

German life science: difficult times, unusual strategies

In this article, Mariana Brea-Krueger explores some unusual strategies for pharmaceutical companies to consider, especially when the whole industry is currently being affected by the tough economic situation.

Germany leads the way in new legislation to curb cost in its national health insurance system (GKV). Demographically, the aging population is incurring much more healthcare costs per capita than a younger population and, therefore, causing the national health insurance budgets to be squeezed. According to the OECD of 2006, Germany ranks the lowest in per capita expenses among five European countries measured (Source: Bundesministerium für Gesundheit). Nonetheless, there is concern for balancing budgets and assuring that the national health system is affordable – the German Ministry of Health recently passed some cost-cutting laws that redefine the way business is done.

A second look at the German Ministry of Health data shows that the pharmaceutical industry carries 64.5% of the total value-chain for medicament expenditures when compared to the distributor / wholesaler, the pharmacy and the State.

With what may be interpreted as a certain amount of panic, two new laws were passed affecting pricing and reimbursement of new and generic medicaments. These are the German National Health System Change Laws of 2010 (GKV-Änderungsgesetz) and the Act on the Reform of the Market for Medicinal Products of 2011 (AMNOG). Among many things, the law forces all non-price-controlled new medicaments to offer a 10% rebate to the national health system over the existing 6% (Festbetrag and Hersteller-Zwangsrabatt). The AMNOG concept of control and review may create enormous bureaucracy and could end up costing the tax-payer more than it could possibly save. In a nutshell, the AMNOG permits launch of new drugs without pricing constraints during the first year only. In the second and subsequent years, a proof-of-superiority negotiation and debate over existing competitive medicaments begins that may adversely affect the price / profit of the product and require new clinical trials. What's still uncertain, is how to manage orphan drugs and drugs with no marketed competitors. The Ministry has assured that they will find a way. The fundamental problem for the industry is that Germany serves as a price-reference country for 22 countries. France, Spain, U.K. and Italy have also devised new systems that control their healthcare costs, but they will be watching Germany.

> ***"...the pharmaceutical industry may need to reinvent their mission statements..."***

Where does this leave the pharmaceutical industry given the profit-costing pressures on pricing and reimbursements, FDA and EMEA's increasing demands, patent expirations, "personalized medicine" reduction in sales size of blockbusters? Not to mention, an endangered biotech industry? They will need to downsize, but also reinvent themselves.

There are many healthcare areas that were by-passed by the pharmaceutical industry in search for bigger blockbusters, better and more prestigious science. The "same game" was continued. In order to compensate for the future squeeze on margins due to new pricing and reimbursement laws, etc., the pharmaceutical industry may need to reinvent their mission statements and review a multitude of old "off-limit" sectors, in search of a "new game". Such traditionally ignored sectors may provide revenues and profits to carry the traditional infrastructure. These could be, for example:

- Devices and equipment such as radiation therapies, in addition to cancer therapeutics;
- Patient and point-of-care diagnostics and companion diagnostics;
- Consumer health, nutritional additives, even baby foods;
- Women's health;
- Homeopathic medicines;
- Chiropractic aids;
- Acupuncture;
- Transfusion management;
- Orphan drug diseases.

What is right for each pharmaceutical company will vary. Companies will need new strategies and more importantly in-house entrepreneurs qualified to start and successfully operate this redefined life science business.

Potential same-game strategies

What new strategies could be developed for both big pharmaceutical, mid-sized and small operations to survive the aging population squeeze on pricing and reimbursement constraints? We believe that one way forward is to spend less on new biotech-to-pharma technologies and do more transactions with academia which the industry has started to do. Another way is to seek to "close-the-gap" in "unsolved" disease areas such as diabetes, cancer, rare or orphan diseases. Clearly disease sectors in which there are no or few competitors are potential strategic goal areas. Streamlining is necessary, but finding a less government-restricted life science sector in which the patient / consumer is willing to invest private monies in is one option. Alternative life science may be the next "gold rush".

Closing thought: How can pharma survive the squeeze on pricing and reimbursement constraints?

About the author:

Mariana Brea-Krueger is Managing Director and Founder of IMI Consulting GmbH .

Contact details:
IMI Consulting GmbH, Auf dem Amtshof 3, 30938 Burgwedel, Germany
Tel.: (+49) 51 39 99 18 0
Fax: (+49) 51 39 99 18 77
Email: mbk@imiconsulting.com
Website: www.imiconsulting.com

Reprinted with the kind permission of www.pharmaphorum.com

First published: 29th November 2012