

## Drugs and Devices - A Winning Combination?

Combining drugs and medical devices is not a new concept. Long before the development of drug eluding coronary stents, dedicated medical devices such as respiratory inhalers have helped make drugs more efficient and safe. Even though the benefits of a drug / device combination are clearly evident to clinicians and patients, significant cultural barriers still prevent the industry from developing a vast array of applications: drug delivery, drug potentialization, smart dosing, etc. The medical device players remain entrenched in their engineering-centric view and do not think enough about clinical outcomes, while the pharmaceutical players focus on chemistry and the disease stage and often lose track of what devices can achieve today.

This issue of TMTG's Minute tries to illustrate how the product development thinking can be changed to promote better synergies between a molecule and a device, rather than polarize the debate on antagonistic views. Specific examples in the cardiovascular and respiratory fields show the great promise that drug / device cooperation offers.

## COUNTRY SNAPSHOT: The Polish Market

### Healthcare Spending:

- Portion of GDP: 6.4% (GDP per capita: €7,040 – Healthcare spending per capita: €450).
- Payers: Compulsory contributions by citizen account for €11.8 billion and represents a burden of 9% on individuals' incomes. The public national budget for healthcare accounts for €2.6 billion and private spending is estimated to be between €5.9 billion and €7.7 billion.

### Market Structure:

- Hospitals: 589 public hospitals including 41 university hospitals (average 280 beds); 153 private hospitals (average 50 beds). The total number of beds in the country exceeds 176,000.
- Physicians: 76,000 out of which 80% are specialists; representing 4.7 physicians per every 1,000 patients.
- Nurses: 37,000 representing 2.3 nurses per every 1,000 patients.
- Imaging equipment: 600 mammography units, 300 CT scanners, 70 MRI units, 70 gamma cameras, 1 PET unit.

### Key Attributes:

- Healthcare services costs are regulated by law when provided by institutions under contract with the NFZ (National Fund for Health). The NFZ is funded by patients paying 9% of their income to the ZUS (Polish Social Insurance Institution).
- The 16 provinces (voivodeships), 379 counties (Powiats) and the 2478 municipalities (Gminas) can dedicate part of the taxes that they collect to fund healthcare equipment acquisitions.

### Trends in Healthcare:

- Only 1 out of 20 Polish citizens receives care from private healthcare institutions. However, private health expenditures increased by 38.6% between 2003 and 2006 while spending on public health care increased by only 25.5% during the same period.
- The number of private care institutions rose to 153 facilities in 2006 from 72 facilities in 2003. Premiums collected by private insurers reached €140 million in 2007.

Sources: Polish Central Statistical Office (GUS), World Health Organization, Polish Ministry of Health, 3rd International Health Summit, The Marketech Group 2008

## CASE STUDY: Launch strategy for Peripheral Arterial Occlusive Disease (PAOD) device

- The Company: The medical imaging business unit of a large European conglomerate is trying to diversify its activity and is thinking about launching new medical devices dedicated to interventional imaging.
- The Challenge: Evaluate operational marketing elements and sales channels in order to launch a PAOD treatment device and optimize the chance of success. In addition, the client requested a strategy for branding and distribution.
- Our Solution: A series of qualitative interviews were conducted in 5 countries with specialists involved in the treatment of PAOD. A quantitative survey and perceptual map allowed the values of "brand and distribution channels" to be validated for the launch of the new device.
- The Impact: The MarkeTech Group first validated the market opportunity, then quantified the market country by country and finally, suggested the best approach in terms of distribution and branding (brand stretch vs. new brand).



To find out what The MarkeTech Group consultants can do to put the latest planning and technology services to work for you, visit our Web site at [www.themarketechgroup.com](http://www.themarketechgroup.com)  
USA: +1 (530) 792-8400, EU: +33 (0)2 41 88 41 44

# HOT TREND

## of the Quarter: Drug Developer's View on Combination Therapies

*Dr. Claude Bertrand, Global Vice President of respiratory and inflammation research area, Discovery, AstraZeneca*

**Q:** Where is innovation the most relevant today, in the drug or in the delivery system? Do you think one is more important than the other?

**A:** I don't think one is more important than the other. Referring back to some of the work we have done at AstraZeneca, prescribers and patients tell you that about 70% of innovation comes from the drug and 30% comes from the delivery system. Obviously, there are different situations. When you have a drug at the end of its lifecycle and you believe that significant improvement can be made on the delivery system, then this will bring innovation to the delivery system. But, in most cases we are trying to be innovative with the molecule as well as with the delivery system.

**Q:** Is there a specific development path? Are they developed in conjunction or is the drug developed first?

**A:** They are absolutely developed in parallel. That is a key to success. You have to concentrate on the disease and the biological activity you are trying to get to through the mechanism of action being targeted. If your mechanism of action is for COPD (Chronic obstructive pulmonary disease), then it is going to be a different device, versus if it is for asthma or if it is for cystic fibrosis, because the morphology and the anatomy of the lungs look very different. The mechanism of action you want to tackle could be in a different place and the patient you are targeting could be very different. For example, in asthma, if you deal with kids you must have a very different device than if you deal with the elderly, who will have trouble dealing with the technical aspects of the device. If you are dealing with COPD, you have to go deeper in the lungs compared to asthma which is mostly targeted in large airways.

**Q:** Within a very competitive environment where generics are gaining in importance, could improved delivery systems be a protection against market share loss?

**A:** It is not about marketing, it is about what patients, payers and medical professionals want. If you manage to get something that fulfils unmet medical needs, then you will win, but obviously not at any price.

When you look at data and clinical reports, it's a mix of the efficacy of the drug, how efficient your device delivers the drug to the target and how patients are, or are not, compliant using the device and the drugs in that device. The composite of all the data will tell you if your product is more efficacious than a competitor's product. And that's as true for generics as it is for your branded product.

**Q:** Will new combinations of drugs and delivery systems help gain new indications and new patients?

**A:** Yes. In the US we have seen that with Advair™ and Symbicort™. If you look at both products, they are a combination of very old mechanisms of action, but they clearly had an incredibly large penetration in the market place. There is nothing innovative in the mechanism, but the innovation is in combining both molecules into one device. Now that sounds simple on paper, but the only two companies in the world that have done this so far are AstraZeneca and GSK. It's definitely a very successful product and it's not because of marketing. It does something for patients, which having those two molecules in two separate devices cannot achieve. We now have plenty of Phase 3 clinical trials to show that adding two molecules in the same device is more efficacious than having two drugs in two different devices.

Take elderly patients, for example: They are not going to carry two, three or four inhalers in their pocket. If you can start combining things that we know work and will work better when associated and at the same time increase patient compliance, the overall efficacy in a Phase 3 trial will absolutely be outstanding. We just have some studies coming out where we combine three drugs. The next challenge is: will we be able to put those three mechanisms into one device and have a triple combination?

*For More Information about AstraZeneca, please visit <http://www.astrazeneca.com/>*

*Long version of this interview: [www.themarketgroup.com/minute/tmtg-min23-bertrand.pdf](http://www.themarketgroup.com/minute/tmtg-min23-bertrand.pdf)*

## ON THE HORIZON: Combining Devices and Drugs: CVD

### HIGHLIGHTS

- According to the American Heart Association, over 80 million Americans were diagnosed with cardiovascular diseases (CVD) in 2005 and treated with an estimated 6,989,000 inpatient cardiovascular operations.
- An estimated 17.5 million people died worldwide from CVD in 2005, representing 30% of all global deaths. By 2015, almost 20 million will die from CVDs.
- In 2002, the US Food and Drug Administration established the Office of Combination Products (OCP) to handle drug-device, drug-biologic and device-biologic products.
- Johnson & Johnson (Cypher™), Boston Scientific (Taxus Liberte™), Medtronic (Endeavor™) and Abbott (Xience V™) have all launched drug delivering coronary stents to battle CVDs.

### AT STAKE!

- Drug development companies need to understand how better engineered medical delivery devices can enhance efficacy of the drugs and deliver the same drug to different parts of the body to enhance drug metabolism.
- To stay ahead of the medical technology development curve, drug and device manufacturers need to develop products in conjunction.

### SO WHAT?

- MedTech companies need to consider the interaction of the drug with the device in addition to the mechanical design and functionality of the primary device.
- Older technology and molecules could renew their products by combining the delivery model for increased efficacy and patient compliance.

Sources: WHO Fact sheet N°317 – February 2007 <http://www.who.int/mediacentre/factsheets/en/>

## THE ASSOCIATE CORNER: Compliance Increases Savings

From a clinical value standpoint, combining molecules and devices achieves the objective of improved drug delivery. One of the many benefits is better patient compliance, which can lead to significant savings for the healthcare system.

Compliance seems to be the medical-economic cornerstone of drug and device combination. Among the causes of lower efficiency of combination products seem to be insufficient therapeutic education related to usage.

In today's environment, innovation is too often perceived as a cost rather than a benefit. Market "game changers" are often the only innovations recognized by regulatory authorities and incremental enhancements struggle to gain full credit for the improvements they bring. Moreover, compliance is hard to evaluate and it is sometimes mandatory to observe a six month wash-out period in order to assess a new device's impact on patient compliance.

Therefore, even if improvements are recognized by the authorities, which is already difficult, the way to maximum benefits for the healthcare system is to increase patient compliance with better therapeutic education.

*Alexandre Vainchtock is a pharmacy graduate and a healthcare economics specialist. He is the co-founder of the HEVA Company, a consulting group focusing on the analysis of the French hospital environment for the healthcare industry. For more information, please visit: <http://www.hevaweb.com>*