

herapeutic area leadership was once defined simply by who had the biggest and best drug for that condition; the level of 'leadership' could usually be measured by sales figures, but times have changed.

Individual products are still undoubtedly the most important factor, being a therapeutic area leader now often entails allencompassing, holistic involvement and investment in that field leading to rich product portfolios - which in turn can bring tremendous benefits to pharmaceutical companies as well as those they serve. As a result, the drive to therapeutic area leadership is becoming increasingly competitive.

'Many therapeutic areas have a 'leader' based on continuous product innovations'

Therapeutic area leadership can provide advantages across the entire life cycle, from better access to superior R&D projects through in-licensing and partnering, to superior long-term relationships during commercialisation. In this article we look at some of

the current trends in therapeutic area leadership, examine which companies are currently making the major moves, and assess how a long-term leadership strategy can be commercially invaluable.

Long-term product innovation has been the key to leadership

Many therapeutic areas have a recognised pharmaceutical 'leader' based on continuous product innovations over many years. A good example is Novo Nordisk, which describes itself as "a global healthcare company with 90 years of innovation and leadership in diabetes care". Over this time, the company has amassed significant heritage in the area through its wide portfolio of diabetes products, and commands more than 40% of the insulin market. Similarly, Roche prides itself on being "the world's leading provider of cancer care products", a situation that looks set to continue for many years; in 2012 it surpassed \$25bn in sales and its top-selling cancer drugs (Rituxan/ MabThera, Avastin and Herceptin) were all amongst the top 10 pharmaceutical products in 2013.

In both of these situations, the leadership position has been attained because the companies have been genuine innovators in their respective areas and have established an impressive portfolio of differentiated products. But it does not mean that either company's leadership position can be taken for granted - Novo Nordisk is under strong pressure from Sanofi with its dedicated diabetes business unit, and Roche is being pursued by a myriad of competitors attracted by the fast-growing oncology market. There are opportunities for companies to stake a claim.

Leadership beyond the pill or vial

Both Novo Nordisk and Roche have identified the need to expand 'beyond the pill' (or vial for biologics) in their respective areas of leadership, and they are providing solutions throughout the patient pathway. These solutions can be in partnership with other stakeholders and may extend beyond one individual product to cover an overall product portfolio; for example, Roche's HER2 companion diagnostic - the HER2/ neu (4B5) Rabbit Monoclonal Primary Antibody assay marketed by its subsidiary Ventana - used to detect breast cancer patients eligible for Herceptin, Perjeta and Kadcyla.

In addition to its proprietary leading-edge delivery solutions, Novo Nordisk offers webbased patient management tool NovoTrack to assist both patients and their healthcare teams - which is not specific to the company's portfolio, but rather aims to assist all patients living with the particular condition; such a tool inherently communicates leadership.

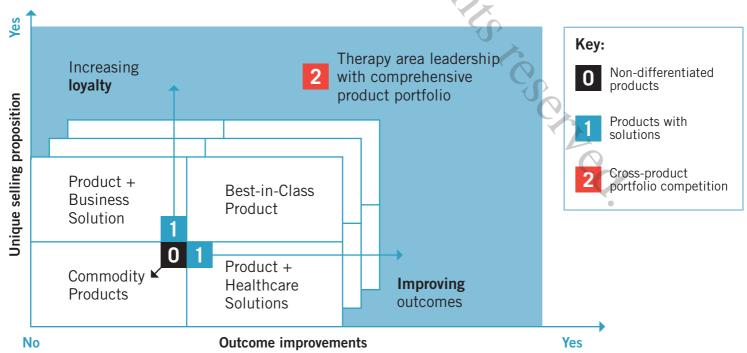
Whether they are currently leaders in their field or not, pharmaceutical companies should complement their specialty products with healthcare solutions to improve outcomes over gold standard of care, such as companion diagnostics, dosing guides or adherence tools. In addition, pharmaceutical marketers can build the foundation of a unique selling proposition on various business solutions with the objective to increase customers' loyalty; for example by helping healthcare providers to de-bottleneck their infusion capacity constraints or collaborating with private payers to create novel insurance policies.

Over time, the combination of a comprehensive product portfolio and differentiated healthcare and business solutions should lead to therapeutic area leadership, similar to those enjoyed by Novo Nordisk in diabetes and Roche in oncology (see figure 1).

Current trends consolidated focus to drive leadership

A common trend in the pharmaceutical industry at the moment is consolidation of focus - many companies





are choosing to play to their strengths, where in the past they would have sought to expand into more and more therapeutic areas. Much of this consolidation is happening through mergers, acquisitions and divestitures, and the jostling for position is becoming more noticeable.

Novartis recently announced a \$20bn deal with GlaxoSmithKline focused on creating businesses capable of competing as leaders in their fields, enabling the company to further boost its already strong oncology business with more than \$10bn revenues in 2013. GSK meanwhile is strengthening its leadership position in two additional areas, by taking over Novartis' vaccines business and having the majority stake in their newly-formed consumer healthcare joint venture - building on the experience of its landmark ViiV joint venture, created with Pfizer in 2009 to focus on HIV, and expanded in 2010 to include Shionogi.

It is not just the big guns either - mid-sized players, such as Gedeon Richter, are making a move. Gedeon Richter has undertaken a series of deals to strengthen its women's health franchise, for example by acquiring PregLem's reproductive medicine and Grünenthal's contraception business in 2010. Meanwhile Biogen Idec's is the leader in multiple sclerosis (MS) since launching

the first interferon beta 1a Avonex in 1996 in the US, re-launching Tysabri in 2006 after a market withdrawal and reshaping MS with its highly successful Tecfidera launch 2013. There are many other examples of mid-sized companies staking a claim for therapeutic area leadership, including Genzyme, Gilead and Shire.

What are the benefits of therapeutic area leadership?

Therapeutic area leadership can bring significant benefits for pharmaceutical companies. Leadership engenders a sense of expertise and trust in the given area, which can speak to being both a genuine innovator and a 'safe pair of hands'. On the commercial side, it provides a company with larger degrees of freedom to compete against its competitors still focusing on individual products, extending the value by becoming a onestop-shop for patients, healthcare professionals, providers, payers and/or other stakeholders. Leveraging synergies across the product portfolio is particularly relevant, for example through deeper and more intensive collaborations with opinion leaders globally and at the national level due to a continuous stream of novel products. Other healthcare professionals are also willing to collaborate more and engage longer with companies perceived as

in some cases in up to 30-50% more time with prescribers.
It can also make worthwhile the investment into solutions

therapeutic area leaders - resulting

It can also make worthwhile the investment into solutions which work across a range of products, magnifying the competitive advantage further with each additional drug, as already implemented successfully by Roche with its various companion diagnostics in oncology, and by Biogen Idec with its provision of MS patient services.

Therapeutic area leadership also gives a company more scope to look beyond the sales rep model on the ground, utilising key account management (KAM) practices to concentrate on improving stakeholder interactions within the overall therapy area to reduce healthcare inefficiencies, creating privileged relationships and erecting entry barriers with physicians and/or providers.

Identifying opportunities around therapeutic area leadership

The opportunities for therapeutic area leaders are great. Based on our project experience we have put together a set of questions we go through with our clients when re-designing their commercial models to maximise their advantages from therapeutic area leadership (see table 1).

Overall, we believe the current level of competition around therapeutic area leadership is arguably leading to even stronger and more sustainable leadership, because emerging leaders can maximise the value of individual products much better than their competitors in the past, similar to the evolution in many medical devices segments, such as orthopaedics, dental implants and imaging. Therefore to be a current therapeutic area leader is very beneficial. But companies on the cusp of potential leadership, with all the potential new opportunities that entails - will find it even more rewarding.

Andrea Sobrio is managing partner, Aleksandar Ruzicic and Meike Wenzel are partners, at specialist healthcare consultancy Executive Insight. Email: a.sobrio@executiveinsight.ch, a.ruzicic@executiveinsight.ch and m.wenzel@executiveinsight.ch

'Therapeutic area leadership gives a company more scope to look beyond the sales rep model'

Table 1: Key questions for therapeutic area (TA) leaders on commercial degrees of freedom

- How will you leverage synergies as a TA leader across the portfolio that your competitors cannot?
- Which unique healthcare and/or business services truly differentiate you as a TA leader?
- What novel commercial model(s) will reshape the market in your favour as the TA leader?
- Where can you create novel commercial roles your competitors do not have the critical mass for?
- Who can you interact with through unmatchable capabilities and/or resources as a TA leader?