

PHARMA BETS ON SUCCESS IN ONCOLOGY

Innovative, effective, but premium-priced, therapies are reshaping approaches to cancer treatment and outcomes. **Graham Lewis** of IMS Health reviews a market where an ever widening array of effective options has stakeholders impressed with success rates but growing increasingly concerned about costs.





Author

Graham Lewis is vice president of global strategy for IMS Health, with a primary focus on strategic issues in the pharmaceutical industry including geographical growth opportunities, mergers and acquisitions, portfolio planning and forecasting. He has worked extensively in oncology, from early-stage compound evaluation through market assessment, strategic planning and business development.

Of all the key pharmaceutical business sectors, oncology is currently the most significant for all the stakeholders involved. Thanks to an accelerating surge in the quantity and effectiveness of new products for cancer, combined with the effects of improved screening rates and an ageing population, this \$35 billion global market is growing at three times the rate of the overall market, and cancer treatment is the single most important therapy area driving global pharma growth.

The widening range of enhanced treatment options has seen the number of patients on chemotherapy increase – by 17% in the US in the last two years alone. With over 40 new oncology compounds expected to reach the market by 2010, this exceptional performance is set to continue. IMS forecasts 17–20% annual growth through this period, making oncology by far the largest single pharmaceutical franchise in value terms by 2010.

This projected growth will be fuelled by increasing use of targeted therapeutic agents introduced over the past ten years, by new innovations coming to market for the first time and by the transformation of therapeutic options for some previously intractable cancers. These will include vaccines for prevention on the one hand and effective maintenance therapy on the other. The use of oral medications will expand.

At the heart of these developments is the industry's substantial investment in oncology R&D programmes. The oncology pipeline is the richest in terms of numbers and potential of all the therapeutic categories, with nearly 2,000 individual molecules being investigated in pharmaceutical industry laboratories and clinical departments around the world. There are 95 compounds in late-stage development alone – either in Phase III clinical trials or awaiting regulatory review. If the average annual launch trend of 30 new pharmaceuticals across all disease areas over the last three years continues, oncology molecules will account for almost one-third of all new products launched between 2007 and 2010.

KEYS POINTS

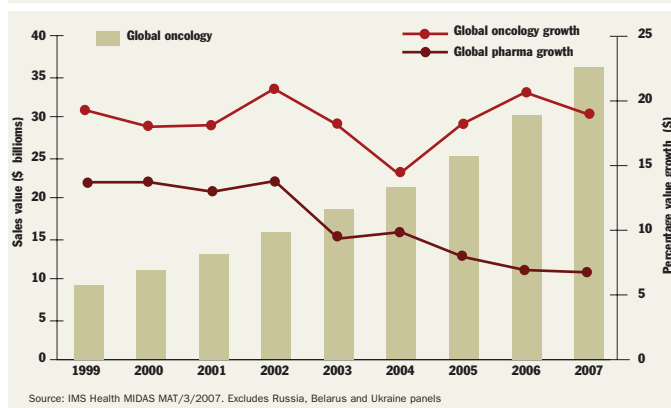
- The pharmaceutical industry is producing increasingly effective therapies for the treatment of cancer.
- As a result, the market for new cancer therapies is growing three times faster than the overall market.
- The efficacy of individual cancer therapies must be clearly demonstrated as the financial burden on healthcare providers grows.

Targeted therapies

Much of the growth can be attributed to targeted therapies, sales of which reached \$13 billion in 2006 compared with \$1.3 billion in 2001. These products continue to be the focus of heavy investment by established players and new entrants alike, and currently account for 50% of the oncology molecules in late-stage development.

With solid tumours, most new research is directed towards small molecule receptor inhibitors and neutralising antibodies of one or more of the VEGF, EGFR, TKI and HER2 proteins. The majority of these approaches target key processes of cancer cells – either in preventing cancerous cell growth, reproduction or both – while others target apoptosis, or programmed cell death. In leukemias they work by boosting the immune system or selectively targeting cancerous cells with

Figure 1. Oncology is growing at three times the rate of global pharma.



antibodies or receptor blockers. All of these targeted therapies have many potential applications within (and sometimes beyond) the cancer space, giving pharmaceutical companies a strong incentive to broaden the focus of their research beyond different stages of the same disease type to new disease areas.

Many of the molecules in late-stage development are being evaluated for a range of potential oncology indications. Some cancers with significant unmet needs are the subject of intensive focus. There are more than 20 molecules in late-stage development for breast and pancreatic cancers, and more than ten for non-Hodgkin's lymphoma, prostate cancer and malignant melanoma. New molecules are also in development for other cancers that still offer significant potential, including advanced lung cancer, gastrointestinal cancers and esophageal cancer.

Added to this is the ongoing research into follow-on indications for products that are already approved and available for other tumour types. These investigations include more than 230 potential new indications for molecules already available to physicians. Even if only one-third of these indications is ultimately approved, treatment options will be enormously expanded for many tumour types over the next ten to 20 years.

Pharma commitments

Several large pharmaceutical manufacturers have committed more than 20% of their late-stage pipeline projects – complete with the inherent risk – to oncology. Some of these companies have little or no prior experience in the cancer therapeutics field. Currently, just ten corporations account for 75% of global oncology sales (defined as anti-cancer therapeutic drugs, including vaccines) and their goal is to remain in the premier league despite likely incursions from a plethora of new players. Amgen and Merck KGaA entered the oncology therapeutics market in 2006, and GlaxoSmithKline will follow in 2007/08 with two new molecules, one of them a vaccine for the prevention of cancer. All three of these corporations rank among the top ten global pharmaceutical players.

Mounting pressure

Against the promising outlook for oncology and an anticipated explosion of anti-cancer approaches and technologies, there are already growing pressures, driven

Figure 3. Oncology is the single most important therapy area driving global growth.



by increasing competition, changing patient demographics and the need for a reconfiguration of cancer care delivery. In Europe and North America, approximately 75% of all sales of anti-cancer agents are for therapeutics

introduced in the last ten years. The strain on national budgets is beginning to show, and the situation is likely to get worse. On their current projected trajectory, oncology therapeutics, not including supportive care agents, will represent just under 10% of global pharmaceutical sales by 2010.

Until recently, policymakers reacted more to the benefits of the new oncology technologies rather than the costs. Health economics research was still in its infancy when the surge began, regulators took a fairly relaxed view of product pricing and, since most of the products have emerged from biotech, with its complex and expensive manufacturing processes, high prices for new products have become the norm. However, the pressure on payers is clearly changing market dynamics.

There is already debate regarding the future funding of cancer treatment, and this is likely to intensify as the overall costs of cancer care continue to rise. In the EU, health authorities have already been restricting access to certain populations as a means of controlling drug budgets, and widespread disparities in access to innovative cancer therapies are apparent among different European countries. Payment by results is a concept being explored and implemented in a few markets in Europe. In the US, payers are still recommending 'appropriate use' rather than applying restrictions, but they may well follow the EU's lead in time. Already, Medicare has proposed limitations on reimbursement for the use of erythropoietins in cancer patients.

Figure 2. Oncology will outgrow the market and become a dominant therapy area by 2010.

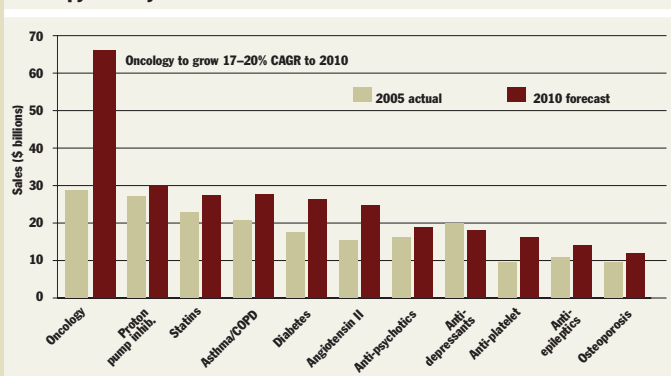
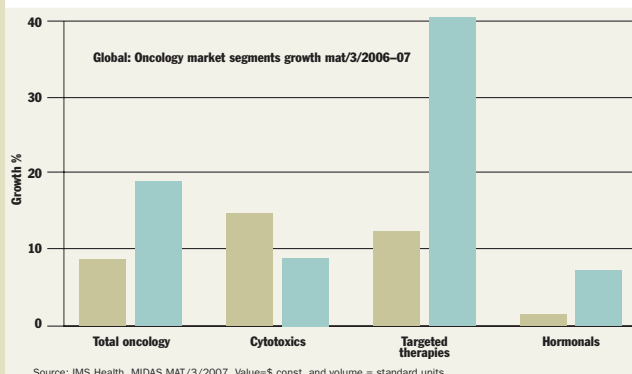


Figure 4. Targeted therapies are the largest contributor to growth.



At the same time, patients are emerging as important stakeholders as they take charge of their health and demand greater access to therapies that will improve or prolong their lives. Their power to influence regulatory approvals and market access decisions, and sway prescribing behaviour will only increase.

As the challenge deepens, it will be vital for pharma to develop drugs that can match the aspiration of patients, meet with the approval of healthcare professionals and enable policy makers to balance access with affordability.

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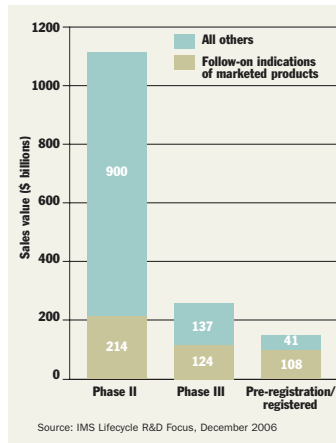
Some academics – and an increasing number of payers – believe that more must be done to improve the predictability of outcomes in different patient cohorts, thereby avoiding the use of expensive therapies in potentially unresponsive patients. More sophisticated diagnostics are urgently needed to assist the appropriate selection of effective therapies and support the utility of the many targeted therapies nearing the market.

Generic competition

A source of respite for payers is that several current blockbusters may lose patent protection by 2010 – including Taxotere, Arimidex, Gemzar and Camptosar among others – with a combined value of about \$5 billion in the seven key markets. IMS forecasts that about 30% of 2006 oncology drug sales will be subjected to generic competition during this period.

While this will offer some short-term budgetary relief, it will also significantly impact the value proposition of many current drug combinations, and potentially increase the combined use of some older agents with newer biological therapies. Thus, the savings from ‘genericisation’ are likely to be more than offset by the rise in volume usage of combination therapies

Figure 6. Oncology is also driven by follow-on indications in the late-stage pipeline.



that include older and newer products. This is an important consideration, since the great majority of cancer treatment protocols are based on drug combinations, and recent and future innovations do not suggest that this pattern of treatment will change significantly.

The need for differentiation

As the choice of treatments in oncology grows, it will become harder to develop and launch new molecules. Competition is already intensifying as the market

becomes increasingly well served with new options. Higher levels of performance will be demanded in terms of remission and survival for a drug to qualify for reimbursement or even to sustain the launch price over time. To achieve premium pricing or avoid disadvantaged access, cancer products will need to demonstrate improved outcomes relative to competing products using the metrics that matter most to each stakeholder. If the National Institute for Health and Clinical Excellence (NICE) is the bellwether, then health economics will become increasingly important to the process of justifying access and uptake, making the ability to clearly demonstrate the clinical and economic value of cancer therapies with targeted effects on specific forms of cancer critical to progress.

Growing competition will give payers the leverage they need to strengthen their technology assessments, re-evaluate current concepts of value and strengthen access barriers, severely testing the industry’s strategic foresight and operational prowess. Companies will need to think about where they launch, the sequence of successive launches and the way their products will be differentiated from others. Savvy indication strategies, strong price support and effective management of all stakeholder needs will be key to continued success. **END**

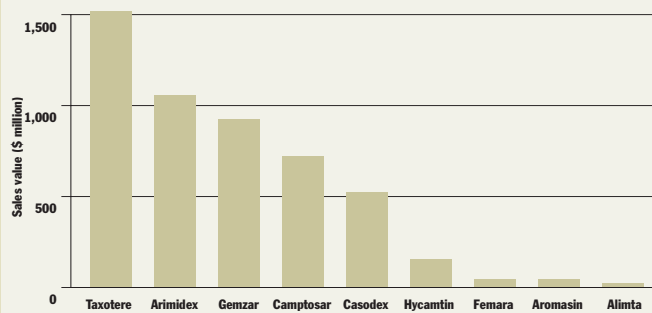
Figure 5: High-incidence tumours dominate near-term pipeline.

Exceptions are renal and pancreatic

Tumour type	Phase III	Pre-reg/reg	Phase II reg % of projects
Breast cancer	15	8	6.6%
Pancreatic cancer	18	10	5.2%
NSCLC	13	3	4.6%
Non-hodgkin's lymphoma	13	3	4.6%
Prostate cancer	8	7	4.3%
Melanoma	11	1	3.5%
Ovarian cancer	8	1	2.6%

Source: IMS Health R&D Focus, December 2006

Figure 7. Generic competition exposes \$5 billion of 2006 revenues by 2010.



Source: IMS MIDAS Market Segmentation, Rx bound ethical market, MAT Dec 2006