COMPLEXITY AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY

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Companies in the pharmaceutical sector are facing increasingly turbulent conditions in their relations with other companies and with policy makers, regulators, and members of the public. On top of the usual uncertainty about which research areas are going to lead to the next big breakthrough - what will work and what won't - there are many new issues that could affect the future of the industry. These include how to bring radically new types of product, such as biotech and genomics drugs, or stem cells, to the market; a changing regulatory environment; the impact of health service purchasing policies and other market-related factors, and public/stakeholder acceptance of new drugs and medical procedures. No single factor is likely to cause a seismic shift in the industry, but a combination of circumstances in an unexpected sequence could lead to major shifts in the balance of power and competitive advantage within the life science sector.

The highly innovative and successful pharmaceutical industry is perceived to be a major platform for economic growth, national and global competitiveness and for improving quality of life in many developed and emerging economies – particularly India and China. It is the only route available to develop new products from the huge and increasing public, charitable and private investments in the generation of new knowledge from genomics and related fields. Yet, in the press coverage, good-news stories about the benefits of new drug therapies are increasingly undermined by bad-news stories and claims of unethical practices.

A huge internal challenge facing the sector is the increasing difficulty and cost of discovering new blockbuster drugs and sustaining healthy development pipelines. This is a straightforward problem of 'maturity'. The products that are easiest and cheapest to develop – and have the largest potential markets – have already been produced and are probably off-patent or nearing that point. This makes it harder to find new drugs that can compete on safety and efficacy grounds and can be sold for a high enough price to sustain profitable growth. For a time, this problem was forestalled by innovation in discovery techniques and instrumentation, for example, combinatorial chemistry and high throughput screening linked to new biotechnology approaches for targeting potentially active molecules (Ratti & Trist, 2001). However, such techniques may now be nearing their limits.

These are important drivers of the twin tendencies toward (i) mergers of large multinationals and their acquisition of smaller companies (Danzon et al, 2004) and (ii) outsourcing by multinationals of many of their core research and development functions (Crossley & Kordel, 2002).

Other challenges within the sector come from emerging Asian-based multinationals with strategies founded on building a competitive position in high value-added innovative drugs from a starting base in commodity drugs – a very different approach from that pursued by today's dominant companies.

Some new developments in the life sciences could now begin to undermine the dominant blockbuster drug model of success employed by big pharma companies. The success of most blockbusters depends on their being taken by large numbers of people over long periods of time. If, as is claimed, we will be able to cure major diseases such as diabetes, heart disease, Parkinson's disease and arthritis, this will remove some major blockbuster targets from the current repertoire of pharmaceutical companies. Pharmacogenetics may also allow a more targeted approach to drug prescribing, which again implies niche, rather than blockbuster, markets.

These internal challenges for the industry could change the relationships among companies, knowledge providers, policy makers and markets, leading to radically new models for success and profitability in health care and drug development.

Factors external to the industry are also causing an increasingly turbulent operating environment. For example, there are uncertainties about the nature of future regulatory systems. If pharmacogenetics, as is being predicted, lowers the regulatory hurdle for new drugs targeted to niche markets, this could enable smaller companies to take new drugs through to stage three clinical trials and compete directly with multinationals in the market place.

We have seen several withdrawals of blockbuster drugs recently, either due to the emergence of unsuspected side effects or, even more seriously for the industry, after accusations of concealment of negative results from clinical trials. Another major external challenge to the industry comes from public and government demands for cheaper drugs. Adding to pressure from developing countries for cheaper drugs for AIDS, malaria and tuberculosis, European governments are proposing to make reductions in their drugs budgets and poorer patients without health insurance in the United States are successfully putting pressure on companies to reduce prices (and hence profits).

Some of these factors are already beginning to undermine public trust in the industry. Pressure groups are emerging with principled objections to high-tech, expensive medicines, favouring instead greater public investment in traditional health care and disease prevention. Such groups are currently counter-balanced by patient groups campaigning for new technology-based treatments, but a series of accidental events that undermines the trust of patient groups in the industry could lead to a wide range of public groups joining a coalition opposed to life-science-based medicine (Tait, 2001).

No single event or outcome is likely to have a path-breaking impact on the current balance of the industry or the strategies of the companies involved. However, a combination of innovation-based challenges to the blockbuster drug model, perceived regulatory failures, failure of public trust in the pharmaceutical industry, and lack of clarity in policies for regulation of new technology and in their presentation, could trigger major and rapid change.

It is unrealistic to expect any innovation path to continue for ever, and new knowledge is often the most important stimulus to change, as is happening with life sciences in the pharmaceutical sector. Companies themselves have a major role to play in guiding future change, but to do this successfully they will need managers with an unusual breadth and clarity of vision. As John Kay (2004) has commented, "If you want to go in one direction, the best route may involve going in the other … goals are more likely to be achieved when pursued indirectly. … Obliquity is relevant whenever complex systems evolve in an uncertain environment and whenever the effect of our actions depend on the ways in which others respond to them." (Kay, 2004, pp. 17-21)

Public stakeholders are also being encouraged to expect to have more influence - at an earlier stage in the innovation process - in the direction taken by new innovation pathways (Wilsdon and Willis, 2004). At the same time, the way policy makers and regulators set the environment for the promotion of innovation and its regulation, and how they manage the interplay between public desires and commercial realities, will play a major part in the direction taken by new innovation pathways and in the smoothness of the ride.

These issues are the subject of a major international conference on *Evolution of the Life Science Industries* being held in the Edinburgh International Conference Centre, 23rd-25th February, 2004 (www.innogen.ac.uk)

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