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Why health economics is becoming ever more important in the industry

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Although the pharmaceutical industry exists to develop medicinal products to improve patient health, it also seeks to maximise profits by building the business. This is fundamental to satisfying shareholders and remaining competitive.

One of the greatest challenges is to augment product output in the face of increasingly limited investment resources. The situation is compounded by the stark fact that industry is investing twice as much in research and development (R&D) as it did 10 years ago, but is only producing two-fifths of the medicines it used to then.[1]

The need to identify and assess investment opportunities and minimise opportunity costs, has amplified the importance of health economics in fostering sound product development and strategic decision-making. The old adage that money talks rings true in the context of the changes taking place in modern healthcare.

A marginal business

It is widely acknowledged that the pharmaceutical industry is undergoing a paradigm shift as healthcare moves away from the old model of curative breakthroughs to one of preventive and “add-on” therapies.

The disintegration of the blockbuster model, where products achieve peak sales of $1bn or more, and the growth in generic products has forced down the profit margins associated with development of new pharmaceutical products.

To a large extent, this is driven by a narrowing of product pipelines and the shifting of clinical advances away from scientific absolutes in previously untouched disease areas to a more nuanced battleground of medicinal relativity. The role and importance of health economics to guide investment decisions is therefore growing.

Decision-makers are becoming more cost-conscious as healthcare budgets are subjected to increased scrutiny and resource pressures.

Demonstrating clinical safety, quality and efficacy is no longer enough. Cost-effectiveness must also be demonstrated as an intrinsic component of reimbursement. This lies at the heart of health economics and is a source of topical debate, especially in the UK.

Satisfying the watchdog

The UK is often cited as the pre-eminent example of using health technology assessment (HTA) for healthcare evaluation.[2]

The National Institute for Health and Clinical Excellence (NICE), which was founded in 1999 to counter geographical variations in healthcare and control costs, is the independent watchdog responsible for

recommending which drugs and treatments should be provided by the NHS.[3,4]

In recent times, the role and profile of NICE have increased. Well publicised controversies and damning media headlines over Alzheimer's disease and NICE's strictures on who can be prescribed donepezil and oncology drugs, such as trastuzumab, have catapulted the institute into the spotlight, while the fact that there has been a parliamentary inquiry into NICE has accentuated the importance of decisions pertaining to NHS drug availability.[5, 6]

From an industry perspective, the entrenchment of formal economic evaluation and the increasing emphasis on cost-effectiveness makes NICE a key element of the pharmaceutical industry equation, not least given its international reach.

Keeping abreast of the changing requirements for getting NICE approval is vital for developing appropriate strategies to maximise reimbursement opportunities.[6]

Health economics and the product pipeline: backing the winner

Although health economics has traditionally played an end-stage role in the wider milieu of pricing and reimbursement decisions, applying the principles is increasingly important during product development.[7]

This is particularly the case in the context of the disintegration of the blockbuster model and the marginalisation of product differentiators as scientific advances confer diminishing returns. Backing the winner and investing wisely are imperatives in the new medicines market. Speculative punts and clinical flutters cannot be justified when apportioning tightly constrained budgets and assuaging shareholder demands.[1]

It is from this premise that the use of health economics from the start offers strategic advantages for efficient allocation of scarce R&D resources and ensuring a steady flow of winners through the product pipeline.

With the increasing attention being paid to drug pricing and NICE decisions, getting the economics right is as important as demonstrating clinical efficacy. This can focus attention on blockbuster or profit-maximising potential, while reducing the pursuit of unprofitable and cost-ineffective pet products.[7]

Companies that understand this reality will benefit most in a more competitive but narrow international market.

Don't forget the politics

The pharmaceutical industry is a unique economic sector for one striking reason: it deals with people's health. For publicly funded healthcare systems such as the NHS, the reality and importance of politics is central to a clear understanding of the prevailing policy environment.

Although elected representatives acknowledge the centrality of NICE as a decision-maker, gone are the days of leaving it to the experts: the recent parliamentary inquiry into NICE by the Health Select Committee exemplifies this point with the HSC showing new interest in these matters.[5, 8]

This political shift in focus is as much the result of the political imperative — the need to respond to voter and patient concerns — as it is about health economics.

Although spending on medicines accounts for only 10 per cent of healthcare spending, a survey showed that 97 per cent of people thought the figure was 1 per cent or more, while 63 per cent of people thought the figure was between 40 and 79 per cent.[1]

Pricing arrangements and reimbursement deals are an easy target for politicians. Patient demands for improved healthcare are at an all-time high.

Increased scrutiny combined with a political desire to rein in overall drug spending points to sharper and tighter economic evaluation on the grounds of cost-effectiveness and hence the need for pharmaceutical companies to demonstrate product value.

This has clear implications for the design of clinical trials and the possible employment of subgroup analyses. Companies will need to improve the way they handle the reality of incomplete or missing data by using evidence-pooling techniques, such as meta-analysis where appropriate.

Pricing and reimbursement

Spiralling healthcare costs and tighter budgets have impelled modern governments to place additional emphasis on allocating scarce resources efficiently and effectively. The pricing and reimbursement of pharmaceuticals is an area where the Government wants more for its money.

In the UK, about 10 per cent of the NHS budget — roughly £11bn per year — is spent on medicines. Of this, around £8bn is used to buy branded products.[7]

Despite spending being lower than that of our European counterparts, national decision-makers are paying increasing attention to the way in which drugs are reimbursed.

The Pharmaceutical Price Regulation Scheme (PPRS) is the voluntary agreement between the Department of Health (DoH) and the Association of the British Pharmaceutical Industry under which companies negotiate reimbursement on sales of branded drugs to the NHS every five years.

The scheme has been running since 1956 (formerly the Voluntary Price Regulation Scheme), but has recently been the subject of growing scrutiny and debate.[7]

The workings of the PPRS are complex. In essence the scheme encompasses two key elements: profit controls, which set a maximum level on company profit earning; and price controls, which provide the industry with some freedom to set initial prices for new medicines but with subsequent restrictions.[9]

Advocates argue that the PPRS has facilitated the sustained retention of UK-based pharmaceutical companies, fostering the appropriate mix of incentives between investment in R&D and profit-making.[10]

The PPRS offers the pharmaceutical industry a degree of certainty over drug pricing even when price cuts occur in renegotiations. It enables companies to predict revenues over a five-year period and therefore provides a stable medium for long-term investment.

Opponents contend that the scheme is arcane, serving the purposes of the industry rather than delivering value for money to patients and the NHS.[11]

A recent Office of Fair Trading report into UK drug pricing has recommended replacing the PPRS with value-based pricing.[9]

The report argues that the PPRS does not optimise value for money for taxpayers, incentivise R&D and innovation, or assist the efficient uptake of new medicines.

Despite the OFT recommendation, the PPRS was renegotiated in early 2008 and finalised at the start of this year. The headline changes included an interim price freeze activated between 1 September 2008 and 31 December 2008, the introduction of a price cut of around 6 per cent starting in 2009, and measures to link the price of out-of-patent branded medicines to the prices of equivalent generics from 2009.

The new deal also includes scope for flexible pricing and “patient access schemes” which build on the principle of risk sharing.

The DoH has also outlined statutory proposals to control the price of branded medicines. These involve the reduction of price modulation as enshrined in previous schemes. The measures apply to any company not participating in the new PPRS.

The DoH expects the changes to deliver savings equivalent to a price cut of 5 per cent, with the new arrangements to be reviewed within a year.[12]

However, as healthcare budgets come under greater scrutiny and governments wise up to the importance of inculcating the shared principles of cost-effectiveness and value for money in pricing and reimbursement decisions, it is likely the PPRS will evolve or become obsolete. Instead, a system of drug pricing envisaged by the OFT is likely to gain momentum.

Hedging your bets: risk-sharing

Risk-sharing schemes are likely to increase as governments seek to maximise value for money. Indeed, Shadow Health Secretary Andrew Lansley recently wrote in a national newspaper: “We should encourage the NHS to use new medicines that are clinically effective, and agree subsequently to pay the drugs companies according to the therapeutic benefit. In other words, drugs companies should only be paid according to the benefits that a drug brings to patients.”[13]

This article heralded the benefits of risk-sharing schemes.

An example of risk-sharing can be seen with Janssen-Cilag's Velcade, which costs about £18,000 per patient per year. The drug has been approved by NICE on the basis that if patients show a "full or partial response" to the treatment, the NHS will fully reimburse. However, if patients show "no to minimal response", Janssen-Cilag will pick up the bill.

For certain disease areas, this system of risk-sharing is likely to expand, given the clear advantages to healthcare payers. Governments will only pay in full for medicines where there is demonstrable clinical and cost-effectiveness.

As Allen Roses, Glaxo-SmithKline's worldwide vice-president of genetics, commented in 2003: "The vast majority of drugs — more than 90 per cent — only work in 30 to 50 per cent of people."[14]

Increasingly, governments will want to ensure, where possible, that they are only paying for the 30 to 50 per cent of cases.

The road ahead: a new order?

The pharmaceutical industry is undergoing fundamental change as a direct consequence of shifting imperatives and the diversion of strategic and operational activities.

The increasing prominence and authority of advisory bodies, such as NICE in the UK, has reinforced the need for companies to demonstrate product cost-effectiveness in addition to clinical efficacy. That is where health economics can play a key role.

Companies need to continue investing in global health outcomes and health economics capabilites to improve forward-thinking and health economic planning. It is essential to develop a clear understanding of what business strategies are needed to maximise profit and ensure prudent product selection throughout the pipeline.

Innovative methods to assess product value are important. Being cost-effective is the new gold dust of pharmaceutical product development.

Stuart Carroll, BA, is a health economist.

Ross Carroll, MRPharmS, is a medical information pharmacist for Abbott Laboratories

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