Improving focus

Outsourcing can allow pharmaceutical companies to concentrate more on their core business, if they plan carefully and contract with the right partner, write Jo Pisani and Graham Pascoe of PricewaterhouseCoopers LLP.

The past few years have been challenging for the pharmaceutical industry, with a continuing decline in total shareholder returns. There is a scarcity of drugs with 'blockbuster' potential in R&D pipelines to offset impending patent expiry of current blockbusters, the impact of development delay or failure, and a return to long US Food and Drug Administration (FDA) approval times. In addition, pharmaceutical companies (pharmas) have faced high-profile operational issues, scrutiny of corporate governance and cynical reactions of the stock markets to mega-mergers. Some examples of these issues are:

- Lean R&D pipelines and rising costs have increased the focus on improving effectiveness. Ten years ago, profit followed scale; a solution was to merge or acquire. Tomorrow, promised merger synergies will not be sufficient to meet investors' expectations.
- There has been increased licensing activity to plug gaps in the product portfolio, with licensing deals increasing in value and changing structure.
- Low valuation of the biotech industry means that the sector seems ripe for merger activity, yet there has been little sign of this. 'Egos' may be the block, but it is only a matter of time before investors insist on biotech mergers to spread risk and reduce costs.
- Payor pressure on drug prices has increased, together with calls for improved access to medicines for the developing world.
- There has been an increased supply risk; the FDA recently levied the largest fines ever for good manufacturing practice (GMP) violations, and is now evaluating its inspection process. A worldwide shortage of biotech manufacturing capacity will limit the potential of many new drugs in the medium term, and 'at risk' capacity commitments will have to be made while new products are still in Phase II or III.

Adapting to a new business model

According to the futurologists[1], several changes will take place. The new pharmaceutical model must:

- Shift from chemical-based small molecules to biological-based large molecules (proteins, antibodies)
- Put clear emphasis on early validation of targets
- Provide better disease segmentation to understand differences among patients, resulting in developing drugs targeting sub-populations with specific disease states
- Create drugs that have a disease-modifying rather than just a symptom-modifying impact
- Shift to a more holistic service rather than drugs only, providing diagnosis, treatment, monitoring and patient support

The industry must manage these operational issues and make the transition to the new business model while under the investor spotlight on maintaining earnings per share growth. This all adds up to a complex management problem to decide where best to place its resources for maximum return on investment (ROI).

> A major reason why some outsourcings fail is that management abdicates responsibility

Managing complexity through outsourcing

A rational reaction to this changing environment is to focus on core competencies (R&D and marketing), improve ROI by reaping the benefits of economies of scale for back-office functions and implement supply strategies that minimise risk and improve asset utilisation. Clearly, this changes the dynamics of the relationship with outsourcers.

For example, contract research organisations (CROs) traditionally provide an offer based on fee for service. There is now potential for CROs to step up to become strategic partners in bringing drugs to market and maximising their value. Factors such as slow patient recruitment or poor patient screening can have a major impact on the success of late-stage clinical trials. CROs can leverage their knowledge to improve recruitment processes and avoid the risk of delay. These skills can then be translated into monitoring the performance of marketed drugs and facilitating in-market trials.

Also, in the past, contract manufacturing organisations (CMOs) were used as 'swing capacity' to absorb short-term peaks in production demand with capabilities that were bought as a commodity. Nowadays, successful pharmas regard their CMOs as strategic long-term partners for three reasons:

- **Sale of under-utilised assets to CMOs.** As pharmas merge, and blockbuster drugs near the end of their commercial lives, pharmas are finding themselves with under-utilised assets that undermine return on capital employed. A popular strategy has been to sell manufacturing facilities to a CMO which can then increase asset utilisation by bringing in additional products and thus offer attractive long-term supply terms to the original owner of the facility.
- **Near-term capacity crunch for biopharmaceutical products.** A worldwide shortage of biotech manufacturing capacity will limit the potential of many new biotech drugs over the next five to six years, and some biotech companies will struggle to match supply with demand. Some CMOs have recognised this opportunity, and are installing flexible biotech capacity.
- **Increased operational risk.** Following its recently levied fines for GMP violations, the FDA is now evaluating its inspection process for manufacturing to include advanced manufacturing technology and biologics. pharmas will increasingly find themselves having to manage new technologies to produce new products, or simply to remain competitive. This will create opportunities for CMOs that manage supply chain compliance effectively, particularly for innovative processes.

Moreover, contract sales organisations (CSOs) are moving from being rented sales forces to strategic partners that provide access to market insight, specific skills to sell specialised products, and complex selling propositions (for example, integrated offers with diagnostics, and so on). Access to patient information can provide pharmas with significant market insight and additional data to support efficacy and side effects, and yet pharmas cannot collect this directly from patients. CSOs can act as middlemen, aggregating data to pass on to the pharma while respecting patient confidentiality.

Finally, there are well-established business models for outsourcing back-office functions such as HR, finance and IT, and this is a recognised source of cost reduction.

In addition, there is a proliferation of many other outsourcing offers such as marketing and regulatory services that will increasingly provide pharmas with alternatives to developing in-house expertise. Consequently, there is an increase in outsourcing activity in Europe, in terms of the size of deals, their complexity and cross-border nature.

Defining outsourcing

There are two types of outsourcing that pharma businesses can employ:

- **Strategic outsourcing** is perhaps the most fruitful type. It enables the pharma to work in partnership with the provider in a way that will mutually benefit their businesses. This means that the service provider will be able to offer 'best-of-breed services' across areas that will enable the pharma better to face the marketplace. These strategic deals are typically seen in contract manufacturing and back-office functions.
- **Tactical outsourcing** is normally driven by cost reduction and the desire to reduce pain and problems that the company is experiencing with various activities in house. These are usually services focusing on areas such as facilities management and security, which companies have never undertaken themselves and are not likely to in the future.

Once the decision is made to outsource, pharmas have to establish the main business drivers behind the decision. It is not unusual for outsourcing to fail because there has been a disconnection between what senior managers want and what is actually in the contract.

> Strategic outsourcing enables the pharma to work in partnership with the provider in a way that will mutually benefit their businesses

In a good outsourcing arrangement with a customer-focused service provider, the contract should normally 'stay in a drawer gathering dust' while the outsourcing is carried out, based on service level agreements that are used as working and dynamic documents.

It is essential that outsourcing contracts have simple and clear objectives; outsourcing deals succeed when the objectives are clear and understood by both the service provider and the outsourcer.

One of the main factors, all too commonly forgotten in the business world, is that outsourcing contracts are essentially based on trust and people. The choice of outsourcing partner is important. Just because pharmas get the best cost savings with a particular service provider does not necessarily mean that it is the right service provider. It is not a perfect world – something will go wrong at some point during the lifetime of an outsourcing contract. How problems are to be resolved is a critical factor. That is why trust and people management are essential in any outsourcing contract.

All too frequently, the most neglected area in outsourcing deals is service management. When services are handled in house, they are often run as a monopoly under single management. Suddenly, when an outsourcing deal has been struck, that manager becomes the customer. This means that he or she often has more power, but in a very different way. Adapting and managing the relationship with the service provider is crucial.

This new customer has the ability to drive through changes a lot faster than as an in-house manager. He or she will have a service level agreement as well as a contract, thus gaining more control in some areas but losing control in others. Day-to-day services may be run by another company, but the manager now has more power to determine what should be done as laid out in the service level agreement – and has more responsibility.

How outsourcing arrangements are put into practice varies from contract to contract, although each arrangement has its core elements, such as: objective setting and business case; service provider selection; contract negotiation; service management; and constant monitoring of how the arrangement is working.

Managing expectations

Outsourcing is often based on the proposition that it enables an organisation to reduce costs. However, all too frequently, cost reduction is still a far-away dream for many companies. Service providers do have the expertise, scale and processes, but they are not magicians, and the ability to reduce costs is not as easy as some companies imagine. Service providers are often faced with the same problems the company has tried to address for many years, and it is often unrealistic to expect them to change entrenched ways of working overnight. This is particularly true in the contract manufacturing area where pharmas often sell an under-utilised manufacturing plant with the expectation that the new owner will be able to fill it quickly with additional products, thereby improving cost of goods. In reality, it can take time to find additional products that are compatible with the current portfolio, and to manage the technology transfer process.

From the outset, companies must be clear about what they want to achieve. If they are not, this may cause confusion and, perhaps more importantly, the main objectives will not be met. A major outsourcing contract is very similar to a disposal of part of the business, except that outsourcing contracts usually last between three and ten years – it is important to get it right.

A major difference is the element of business risk that is involved with outsourcing, and this can be one aspect that makes companies decide against outsourcing. This is particularly the case in pharmas, where risk management is key. A company planning to outsource should have thought through the mechanics and consequences clearly, and identified the business risks involved. If a company fails to do so, the outsourcing agreements can, in retrospect, seem one-sided.

Meeting expectations

The key to good relationships is for both parties to have a mutual understanding of what is required at each phase of the life cycle of the outsourcing arrangement. A major reason why some outsourcings fail is that management abdicates responsibility. Once a contract is made, it views the operation as detached from the core business and seems to believe that it does not need to stay involved. This is a high-risk strategy. The operation is still management's responsibility – outsourcing is just a different way to manage it.

Effective outsourcing will distinguish the winners

Given the short-term challenges that the pharmaceutical industry is facing, it is clear that there will be an increase in the number, breadth and depth of outsourcing relationships. The pharmaceutical industry has the luxury of lagging behind a number of other industry sectors in developing the role of outsourcing and can, consequently, learn from their experiences.

There is no doubt that outsourcing can have significant benefits for business, but only if companies manage the transition properly and acknowledge the ripple effect that outsourcing will cause. Outsourcing has a role in many pharmas; indeed, the majority are probably already engaged in this activity. If companies plan carefully and contract with the right partner, outsourcing can allow them to focus more on their core business. ■

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[1] 'Pharma 2010: the threshold of innovation'. IBM Business Consulting Services 2002.

AUTHORS

Jo Pisani is an assistant director in the valuation and strategy pharmaceuticals team of PricewaterhouseCoopers LLP (PwC), where she assists clients in evaluating their strategic options within R&D, supply chain and sales and marketing. She has 13 years' industry experience with GlaxoSmithKline and BP. Before joining PwC, Pisani spent three years with Booz Allen Hamilton, a strategy management consultancy, where she focused on strategic issues in the pharmaceutical and energy sectors. She holds an MBA from Warwick Business School.

Graham Pascoe is a partner based in the London office of PwC. He specialises in providing advice to clients, providers and financiers on all aspects of the outsourcing process.

For further information, please contact PwC on tel: +44 20 7804 3744, Jo Pisani on email: jo.pisani@uk.pwc.com or visit the company's website: www.pwc.com/pharma