

# Perspectives on Life Sciences

Autumn 2009





# Foreword

**At the end of this year, when senior executives reflect on 2009, many will do so with a sense of relief that it's over and a hope that 2010 will be different. In the life sciences sector, however, leaders will often have reason to feel more positive than most about the past year's achievements.**

2009 has been a curious year for the entire sector. The economic crisis didn't seem to hit life sciences companies (biotechs aside) as hard as many others: strategic M&A activity – as opposed to the reactive deals done in the financial services sector – grew, investment in R&D continued, and so on. The outbreak of H1N1 swine flu created opportunities for some pharmaceutical and healthcare companies to enhance their public relations by being seen to come to the rescue of the population (whilst simultaneously building revenues). Most companies did cut costs, but often the crisis allowed them to expedite cost reduction plans that were already in place.

Many life sciences companies, then, have enjoyed a reasonably successful 2009, but in the current climate there is understandable anxiety about what lies ahead. In this Autumn 2009 issue of *Perspectives on Life Sciences*, we look at some market trends that have been in the news this year, and consider how life sciences companies can get themselves ultra-fit to tackle the opportunities they represent, while dealing with the other challenges that 2010 will doubtless bring.

I hope you enjoy reading this issue and as always, I welcome your perspective.

Finally, I would like to extend a special “thank you” to our many readers who shared feedback after the last issue. It was great to hear how popular the articles were. Thank you also to those who suggested articles they would like to see in the future – you will find some of these in this issue.

**Tim Dulley**  
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Tim Dulley

# Synopsis of Articles

## Part 1 Industry trends

### **Biofuels**

*By Matthew Whitson & Gabriel Vergniaud*

For around a decade, biofuel production has provided agribusiness with an additional revenue stream based on its existing products. However, mainstream biofuels are coming under fire over their costs and their alleged impact on food supplies and the environment. A second generation of biofuels, from sources such as plant cellulose and algae, is intended to overcome these objections. For agribusiness, however, this may be a harder market to crack because specialist products are likely to be needed and there is a broad diversity of potential sources. Companies will want to be assured of the long-term viability of the fuels before investing too heavily.

### **Biosimilars**

*By Colin Walsh & Shankar Balakrishnan*

Biosimilars – which, in many ways, can be considered generic versions of biological drugs – have the potential to help payers control costs in this fast-growing area of healthcare spend. First, however, two inter-related issues need to be resolved: the extent to which their manufacturers need to repeat non-clinical and clinical regulatory studies, and the period of exclusivity that innovators should enjoy. If governments can steer a middle course, then innovators should be able to achieve acceptable rewards while biosimilar manufacturers are also able to deliver the hoped-for cost benefits to payers and patients.

### **Emerging Markets**

*By Tim Dullely & The Strategic Insights Team (Suday Karkera)*

With sluggish growth in traditional markets, pharmaceutical companies are increasingly interested in the relatively buoyant emerging markets such as India and China. While pharmaceutical companies have been active in moving development and production activities to these countries, most have yet to exploit their full potential as consumer markets. Successfully entering these markets necessitates thinking about their individual characteristics, with special attention to Intellectual Property protection and pricing. There is a range of business models to choose from, but adaptation to local requirements is critical if significant market share is to be achieved.

### **Pandemics**

*By Colin Walsh & The Strategic Insights Team (Prachi Chowdhury)*

The current H1N1 outbreak is the latest pandemic of many, and we can learn from earlier ones. While the initial occurrence of a pandemic is impossible to predict, once a pandemic starts then a relatively mild first wave is likely to be followed by one or two further waves that are more severe and affect different segments of the population. With this pattern in mind, governments need to manage their message to the public carefully to make sure that people do not become deaf to the warnings at the very moment when they need to take most notice.

## Part 2 Management issues

### Accelerated Execution

*By Tim Dulley & Tom Swanson*

Even high-profile programmes within life sciences companies often fail to deliver value as fast as management would like. Causes include gaps in capability, lack of clarity of outcomes, poorly articulated or tested assumptions, and slow decision-making. Behind these problems lies the fact that existing tools and disciplines for programme management cannot always cope with the increasing complexity of the business environment. Capgemini's Accelerated Execution approach homes straight in on potential problem areas and helps the team put things right without disrupting the programme.

**Note:** Tom is a Senior Vice President in the Global Life Sciences team. He is one of the creators of Capgemini's Accelerated Execution Framework and is a recognised expert in this field.

### Procurement

*By Jim Abery & Hamish McKechnie-Sharma*

Procurement functions in life sciences companies are under growing pressure to save money, partly in order to safeguard R&D spend during the downturn. However, a recent survey shows that current initiatives to improve procurement tend to be piecemeal and to over-emphasise short-term savings. Meanwhile, long-standing challenges (such as spend visibility and effective use of eProcurement) have yet to be successfully tackled. Companies that can break out of this pattern can win competitive advantage.

### Cost Reduction

*By Tim Dulley & Matthew Whitson*

The greatest challenge for cost reduction programmes often lies not in knowing what to do, but in finding a meaningful, sustainable way to do it. This vital "how" question should ideally be confronted in the initial phase of the programme, through an analytical process that goes further than the traditional "top-down" calculations. The answer must take account of the emotional and political, as well as the rational, dimensions if the programme is to succeed.

### Marketing Maturity

*By Matthew Whitson & Adrian Howells*

In the current climate, marketing teams must create more value from fewer resources, and industry trends mean that the pressure is only going to increase. The Marketing Maturity model allows companies to assess their fitness for the task, and pinpoint areas in particular need of attention; customer-centricity is the hallmark of maturity. By focusing on six specific areas of marketing, companies can then break their journey down into manageable steps. This approach has emerged from experience in other industries, such as hi-tech and Fast Moving Consumer Goods, and pharmaceutical companies can benefit from their experience.

### Key Account Management

*By Colin Walsh & Adrian Howells*

Key Account Management (KAM) is an effective way for pharmaceuticals sales to respond to the rapidly-changing marketplace. As other industries have found, addressing the growth of an increasingly complex stakeholder environment requires a more targeted approach, which KAM provides. In the case of the pharmaceutical industry, KAM is complex to set up. Realising its full benefits requires a mindset change in terms of customer relationships, plus far-reaching internal changes. However, KAM promises a more co-operative relationship between pharmaceutical companies and healthcare decision-makers, ensuring both sides deliver more with less.

### War Gaming

*By Karin Olivier & Hanne Buus van der Kam*

Success in exploiting new and existing products can be threatened by lack of competitive insight, yet this is an area that many companies tend to neglect. War gaming is an excellent tool for testing and refining strategy by dynamically simulating likely competitive situations. The exercise provides insights to shape strategic decisions, and at the same time participation improves cross-functional alignment around those decisions. Careful preparation and facilitation are vital for success.

**Note:** Hanne is the Global Life Sciences Sector Lead and has extensive experience across the sector especially in sales and marketing and in war gaming.

# Biofuels

**Biofuels have become an important business segment for agribusiness, but question marks hang over their future. Will second-generation biofuels present the answers?**

At the turn of the millennium, biofuels were heralded as having the potential to reduce society's reliance on crude oil – an attractive proposition for governments faced with a limited supply of fossil fuels and a growing demand for energy, particularly those like the United States and Brazil whose demand for oil far surpasses their own supply capabilities. The higher production costs of biofuels were offset by their alleged “green” credentials. Global production has been accelerating rapidly for almost a decade: output of bioethanol tripled between 2000 and 2007, while biodiesel increased by a factor of 11 over the same period<sup>1</sup>.

The problem facing governments is the continued increase in demand for energy. The International Energy Agency predicts that world primary energy demand will grow by 1.6% per year on average up to 2030: that is a growth of 45% from 2006<sup>2</sup>. This means that global demand for oil will increase from 85m barrels per day in 2007 to 106m barrels per day in 2030. As reserves decrease and become more difficult to access, prices will rise and all governments will come under increased pressure to provide alternatives.

For agribusiness, the growth in biofuel production has presented an attractive and profitable income stream that features heavily in companies' strategic growth plans. However, ten years on, serious doubts are being cast on the future viability of “first-generation” biofuels – those produced from arable crops. This

article examines the key themes in this debate, presenting our view of the future for liquid biofuels and their likely impact on agribusiness.

## Biofuel production

There are two main types of liquid biofuel. The first is ethanol-based, and is produced from fermenting sugar and starch from crops such as corn, wheat and sugar cane before blending with gasoline. The second type consists of vegetable oils produced from soya bean, rapeseed or palm trees, which are blended with diesel to form biodiesel. The percentage of total volume represented by biofuel in both bioethanol and biodiesels ranges from 5% to 85%.

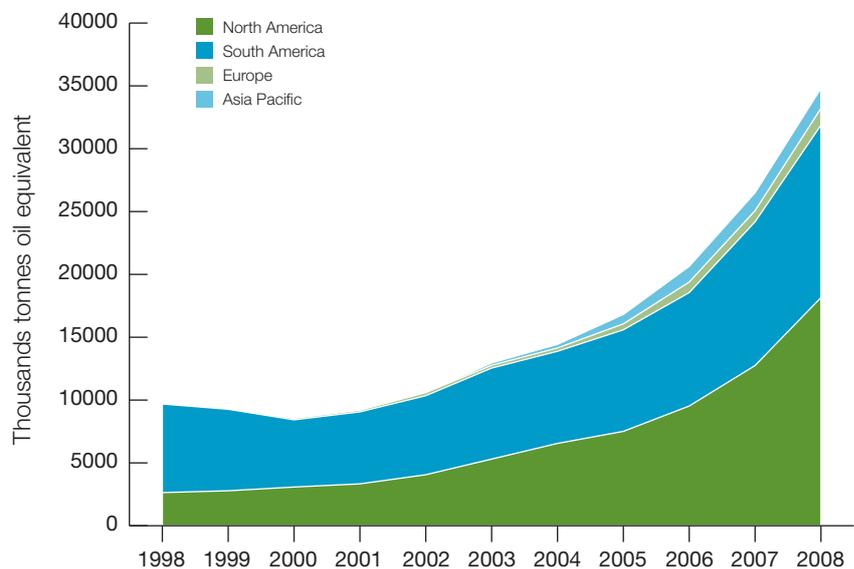
As figure 1 shows, commercial production of biofuels started to take

off in 2000. Production levels at this time were 18bn litres, of which 96% was ethanol. Production centred in the U.S. and Brazil. Ethanol production reached 64.5bn litres in 2008, with 22bn litres made in Brazil alone, where about 75% of light vehicles can run on a 15%-85% gasoline-ethanol blend<sup>3</sup>.

The biggest producers of biodiesel are the United States and Europe. Southeast Asian countries, such as Indonesia and Malaysia, are rapidly increasing their production.

Growers of these “first generation” biofuels represent an appealing market for agribusiness because they use broadly the same fertilisers, pesticides, fungicides and so on as are used in growing food crops. The risk for agribusiness companies getting

**Figure 1. Worldwide production of fuel ethanol between 1998 and 2008**



Source: BP Stats 2009

**Despite almost a decade of investment and stimulus, and the dramatic increase in production, ethanol and biodiesel remain marginal products as a proportion of total worldwide fuel consumption.**

into this market is relatively low because there is no need to develop products specifically pitched at the biofuel market.

#### **Questioning biofuel viability**

However, despite almost a decade of investment and stimulus, and the dramatic increase in production, ethanol and biodiesel remain marginal products as a proportion of total worldwide fuel consumption, partly because of the limited availability of blends for use with conventional engines, especially in the United States. According to the Food and Agriculture Organization of the United Nations<sup>4</sup>, biodiesel's share of the diesel market will rise to only 2.6% by 2017 (from 1.5% in 2008), while ethanol's share of the oil market will rise from 5.5% in 2008 to 7.6% in 2017. This limited penetration after almost 20 years of investment raises serious questions about the return on investment from biofuels.

Part of the problem is governments' failure to stimulate demand. Outside a few countries, notably Brazil, which are strongly motivated to reduce expenditure on conventional fuels, governments have not offered adequate incentives to oil producers or consumers to switch to biofuels.

Aside from their acceptance by consumers there are three other questions that need to be resolved if biofuels are to fulfil their initial potential. Can they offer a cost-effective alternative to crude oil? Can they be produced on the required

scale without threatening food supplies? Is their environmental impact acceptable to an increasingly "green" global audience? By answering these questions we can build a view as to whether biofuels justify the considerable investment and support that governments have offered to date.

#### **Are they cost-effective?**

In Asia there are biofuels that provide a cheap alternative, but in the western world Brazil's ethanol production from sugar cane is currently the only significant biofuel that is cheaper to produce than U.S. gasoline<sup>5</sup>. U.S. corn ethanol would be more expensive than crude oil without government subsidies. Even today's drastically increased oil prices<sup>6</sup> are matched by high crop prices because of the well-publicised global food crisis. In January 2009, U.S. ethanol was at \$1.81/gal against \$1.86/gal for gasoline<sup>7</sup>.

Biodiesel has a similar profile against traditional diesel. Historically, biodiesel prices have remained above traditional diesel prices, with biodiesel B20<sup>8</sup> costing \$2.67/gal in January 2009, against \$2.44/gal for conventional diesel<sup>9</sup>.

#### **Do they impact food supplies?**

The FAO has stated that despite the increase in world cereal production in 2007, a significant drawdown of cereal stocks was required in order to meet demand in 2008<sup>10</sup>. It estimated that during the same year, 2% of the world's available arable lands were being used to grow crops for biofuels<sup>11</sup>.



<sup>1</sup> "Water in a Changing World", The United Nations World Water Development Report 3, p111

<sup>2</sup> "World Energy Outlook executive summary", IEA, 2008

<sup>3</sup> "ANZ Industry Report: biofuels", ANZ, Oct 2008

<sup>4</sup> Hooegeeveen, J. et al. "Increased biofuel production in the coming decade: to what extent will it affect global freshwater resources?", *Irrig. and Drain.* 58: S148-S160, 2009

<sup>5</sup> ANZ, op. cit.

<sup>6</sup> According to IEA, crude oil import prices will average \$100 per barrel (in real year-2007 dollars) over the period 2008-2015, rising to over \$120 in 2030

<sup>7</sup> US Department of Energy, "Clean Cities Alternative Fuel Price Report", January 2009

<sup>8</sup> 20%-80% biodiesel-diesel blend

<sup>9</sup> US Department of Energy, op. cit.

<sup>10</sup> FAO global cereal supply and demand indicators, no. 2, April 2008

Using arable land for biofuel crops instead of food is one of many factors that increase pressure on commodity prices, with obvious implications for both developed and developing economies. Projections from the International Food Policy Research Institute suggest that the number of food-insecure people in the world would rise by over 16m for every percentage increase in the commodity prices<sup>12</sup>.

### Are they environmentally friendly?

If we accept that first-generation biofuels are more expensive than traditional products and that they may increase pressure on already stretched food supplies, then their main supporting argument must be their environmental credentials. Initial reports suggested that greenhouse gas emissions from biofuels were up to 25% less than traditional equivalents<sup>13</sup>. This included the farming process, agrichemicals production, machinery, transport, processing and finally burning. This consideration has been a contributing factor to the support offered by governments, especially in developed countries.

However, the key element that until recently was missing from these calculations was land-use changes (such as the clearing of rain forests in Latin American countries to free up land for biofuel production). When land-use change is taken into account then it is suggested that biofuel production may have released 17 times the greenhouse gas emissions that were saved by replacing traditional fuels<sup>14</sup>. The U.S. Environmental Protection Agency has begun an investigation into greenhouse gas emissions produced across the biofuel life cycle, which may result in a change of strategy in one of the largest producing nations.

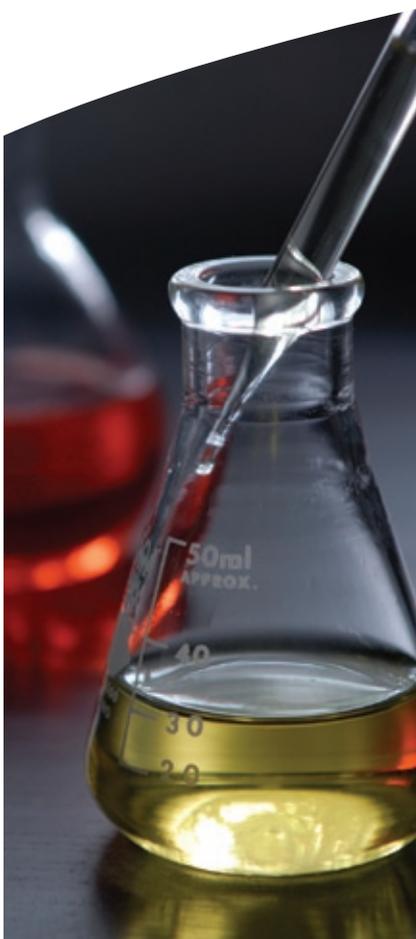
### A new generation of biofuels

Some governments are already rethinking the nature of their support for biofuels. The EU Parliament agreed to reduce its mandatory biofuel consumption targets from 5.75% by 2010 to 5% by 2015, and to specify that at least 20% of the 2015 target and 40% of the 2020 target must be from “non-food and non-feed competing second generation biofuels and/or from green electricity or hydrogen sources”<sup>15</sup>.

Despite these moves, overall government support for biofuels remains generally strong, especially in developing countries. The biggest biofuel producer, Brazil, has set its ethanol consumption target to 60% of all transport fuel by 2020, from 37% today. This raises serious questions about the potential environmental impact, given the possible requirement for land use change to accommodate a near doubling of consumption.

China’s target is 15% of transport fuel by 2020. However, when setting this target, the Chinese government simultaneously announced an expansion of “second-generation” biofuel production<sup>16</sup>. Second-generation biofuels are produced from plant material whose production does not impact food supplies, such as cellulose from grass, woody plants or otherwise unused parts of food plants, or oil from algae or from jatropha trees (which can be grown on poor land). In some cases plant genres that have not been commercially exploited to a significant extent before may be suitable for biofuel, jatropha being an example.

There is already activity in several of these areas. Biotech companies have stated that they are ready to commercialise cellulose-made biofuels, whose output could surge from zero at present to 1bn gallons by



2013<sup>17</sup>. Other companies are working on making ethanol with blue-green algae, feeding it carbon dioxide and farm animal waste or seaweed. China announced it will plant 13m hectares of jatropha trees by 2010, with potential to produce around 6m tons of biodiesel a year<sup>18</sup>. Other areas of research include yeasts that can ferment biomass materials directly into ethanol, which could drastically reduce the cost of production<sup>19</sup>.

### Second-generation biofuels and agribusiness

The likelihood of first-generation biofuels providing a viable long-term alternative to crude oil is decreasing, but second-generation fuels show promise. What are the implications of this situation for agribusiness?

Demand for current products such as fertilisers and pesticides will be sustained by the need to maximise crop yields, whether they are produced for biofuels or food purposes. Production of first-generation biofuels can be expected to continue for the foreseeable future, certainly in countries like Brazil which are already heavily committed to them.

However, if second-generation biofuels are proved to present a more cost effective and environmentally friendly alternative, future requirements for agribusiness products may not be so closely linked to companies' current portfolios. Companies may need to consider producing biofuel-specific products – perhaps GM seeds that are disease-resistant and high-yielding, or pesticides and fertilisers specific to plants that in some cases have never been commercially cultivated in significant enough volumes before. Companies will need to make strategic decisions about how much, and when, they want to invest in research and development of products in this area, given the

opportunity cost of doing so and the uncertainty of future returns. One potential strategy is to wait for smaller companies to prove the technical and commercial viability of specific products and then acquire them; this option could be an attractive one since the strong growth of agribusiness in recent years means that the industry leaders have the cash to make acquisitions.

There is compelling evidence to suggest that first generation biofuels have limitations that will prevent them from fulfilling their initial potential. The future of liquid biofuels will therefore depend firstly on the emergence of second-generation alternatives that can meet increasingly stringent global requirements especially in their environmental impact. If they do, then the onus will fall to governments to use regulation and tax incentives to stimulate research into, and commercialisation of, the fuels and – equally importantly – to stimulate consumer demand for compatible products (such as cars with biofuel-consuming engines).

In the long run, the world must find an alternative to fossil fuels, and so the likelihood is that there will be a steadily growing demand for some form of biofuel, initially to blend with oil or diesel and eventually to replace it. That will represent an opportunity that agribusiness cannot afford to miss.

**The likelihood of first-generation biofuels providing a viable long-term alternative to crude oil is decreasing, but second-generation fuels show promise.**

<sup>11</sup> ANZ, op. cit.

<sup>12</sup> Faisal, A.M., "Biofuel - A Threat for Food Security and Environment", UNDP, March 2008

<sup>13</sup> ANZ, op. cit.

<sup>14</sup> ANZ, op. cit.

<sup>15</sup> *The Guardian*, May 2009

<sup>16</sup> ANZ, op. cit.

<sup>17</sup> *British Business Monitor*, May 2009

<sup>18</sup> "Fuel from forests is new clean energy goal", *China Daily*, 8 February 2007

<sup>19</sup> ANZ, op. cit.

# Biosimilars

**The generics of the biologics world offer potentially sizeable cost benefits to payers – but first some conflicts must be resolved**

**Biosimilars may present an opportunity to tackle the twin, and often opposing, challenges of improving the quality of, and access to, healthcare while delivering substantial savings.**

Faced with recessionary pressures, ageing populations, and increasingly expensive therapies, governments are redoubling their efforts to contain healthcare costs. Biologics present special challenges to these initiatives. Chronic conditions such as diabetes and catastrophic ones such as cancer represent the fastest growing areas of healthcare spend. The most effective ways to treat these conditions is increasingly through novel biologic drugs, and these don't come cheap. Treatment for breast cancer using Avastin – a blockbuster modern biologic therapy – costs around \$92,000 per year in the U.S<sup>1</sup>.

Biosimilars could potentially play an important role in the treatment of these conditions. By reducing the cost of cutting-edge treatment, biosimilars may present an opportunity to tackle the twin, and often opposing, challenges of improving the quality of, and access to, healthcare while delivering substantial savings.

However, there are two important issues that need to be addressed with respect to biosimilars, and the way they are resolved will shape the competitive landscape for drug manufacturers for years to come. The first concerns testing and the second the period of exclusivity.

## **How much retesting is necessary for approval of biosimilars?**

The first of the two issues under debate, testing, relates to a critical difference between generics and biosimilars. A generic is

bioequivalent to – and hence clinically interchangeable with – the corresponding innovator product. A biosimilar, on the other hand, is “similar” to the innovator product in terms of composition, but is not necessarily clinically interchangeable with it (hence the term “biosimilar”).

This difference has far-reaching implications for testing and validation. The manufacturer of a generic drug is allowed to use the test data on the basis of which the original product was approved<sup>2</sup>. Provided laboratory analysis confirms that the two drugs are identical, the generic's safety and efficacy can be assumed based on the data for the original drug.

On the other hand, because biologic drugs are produced from living cells and the innovator's manufacturing processes are not specified in the patent, it is almost impossible to replicate a biologic drug exactly<sup>3</sup>. Consequently, demonstrating therapeutic equivalence for biosimilars is not a straightforward matter. In contrast with generics, therefore, laboratory analysis of a biosimilar product is insufficient to ensure its safety and efficacy.

This difference has regulatory, scientific and commercial implications. The ability to reduce the need for clinical trials by referring to the original product's data is fundamental to the strategy of low-cost generic players. If biosimilar products have to undergo more extensive clinical trials, it will greatly

diminish their cost advantage over the innovator products.

At the extreme, a biosimilar that does not make reference to the originator's data package in some form, but instead requires a full package of non-clinical and clinical trials, is not truly a biosimilar but a competing branded product, analogous to a "me-too" drug rather than a generic. If you could not refer to the originator's data package, the development costs would be similar to any other original product and there would be a limited commercial opportunity, unless the biologic had some clinically relevant differentiation.

Outside the U.S., possible ways forward on approval of biosimilars are emerging. The EU has taken a lead in this area by publishing overarching guidelines; it has already approved biosimilars in six product classes through an abbreviated pathway. It has adopted a case-by-case approach to determine what clinical and non-clinical data is needed to establish comparable effectiveness, quality, safety and efficacy to the reference product.

This case-by-case approach is probably the most viable in such a complex field; however the biologics involved so far have been at the lower end of complexity, so the challenges in moving to more complex monoclonal antibodies and large proteins have yet to be dealt with.

#### Period of exclusivity

The testing issue just discussed is the first of two debates currently raging in the U.S. around biosimilars. A second, closely related, debate concerns the period of exclusivity that should be granted to the originator product (effectively, the question of how long it should be before the biosimilar manufacturer can refer to the data submitted by the innovator product company).

The period of exclusivity is critical for the industry as this is when it is able to recoup its development costs. After this period competition is likely to increase and prices to fall, so revenues are much less certain. Clearly, from the innovators' point of view, there is little motivation to innovate unless regulators require significant non-clinical and clinical studies for registration of a biosimilar, or there is a substantial period of exclusivity unrelated to the patent. But from the point of view of payers and biosimilar manufacturers it is desirable that the biosimilar becomes available as soon as possible.

Proponents of biosimilars in the U.S. (such as Representative Henry Waxman, who has put forward a bill in this area<sup>4</sup>) are suggesting an exclusivity of five years after approval, President Obama is supporting seven years, and the pharmaceutical industry is lobbying for 12 to 14 years. Given the complexity of patenting biologicals and the typical time to delivery, any of these measures would extend the period of exclusivity beyond that given by the patent. The U.S. Congress is expected to vote on this issue in September as a part of Obama's healthcare reforms.

The interaction of the specific period of exclusivity for biologics and the patent is a complex matter, and one to which we plan to return in a future edition of *Perspectives*. For one thing, patent laws differ between Europe and the U.S. For another, there are still questions about what exactly will be covered by a defined period of exclusivity: with biologics you cannot clearly define the substance in the way that you would for a conventional molecule, and so a broader definition in terms of function or structure may need to be used, extending the scope of exclusivity beyond that intended.



### Countering some objections to biosimilars: cost and trust

We are hearing arguments that the potential impact of biosimilars may not be as large as expected, depending on the decisions made about the issues discussed above, exclusivity and retesting. For one thing, it has been argued that the cost advantage is not as important as it appears. Biologics tend to be more complex to use and are typically administered in a clinical or hospital setting: in these environments the relative prices of the pharmaceuticals are not so transparent and are not the major driver of usage that they are in a primary care setting.

In addition to the cost question, there are also trust issues which do not arise with generics: with anything other than a very simple biosimilar, judgments have to be made about the extent of retesting that is required, and if the wrong decision is made the impact on patients could be serious. For this reason it has been argued that there could be a "trust deficit" on the part of both prescribers and patients towards the adoption of biosimilars.

At first sight, the early progress of some biosimilars might seem to bear out the doubts about cost and trust. Omnitrope, a biosimilar for hGH (human growth hormone), registered a tepid \$4m annual sales in 2007 in the U.S. and was priced 30% below the price of the innovator drug<sup>5</sup>.

Despite the reservations, we believe that biosimilars cannot be ignored. The potential cost advantages are, in reality, far from trivial, and will become more attractive with the anticipated explosive growth and adoption of biologics. The current consensus is that the prices of biosimilars will generally be 20%-30% lower than those of the corresponding innovator products<sup>6</sup>. 30% may sound modest compared with a 90% saving from generics, but given that a biologic treatment for metastatic cancer can cost as much as \$200,000 a year, a 30% price saving amounts to much more than a 90% savings on a drug that costs \$1,000.

Turning now to the trust argument, people will accept some level of risk in return for a cost saving, as we can see from the rise of medical tourism. In return for a 60-70% saving in out-of-pocket expenses, patients from developed nations have proved willing to travel to developing countries for complex treatments such as bypass surgeries and angioplasties etc. Moreover, despite some legal and commercial risks, insurers are willing to fund overseas treatment for policy holders. In much the same way, the savings available for biosimilars will probably overcome the trust issues, provided no horror stories emerge.

today, but it cannot be assumed that more complex ones will be equally successful and trouble-free.

For developers of both original biologics and biosimilars, communication with regulators is going to be vital. In particular, in the absence of universal guidelines, biosimilar developers need to talk to regulators as early as possible in the development cycle to find out what their stance on approval of a given product is likely to be. Without this knowledge, the risk attached to development of biosimilars is unacceptable, since unexpectedly onerous approval procedures could destroy the business case for the drug.

### Conclusion: a balancing act for legislators

To summarise the two points of view on biosimilars, governments and patients want to see a vibrant biosimilar sector driving down the cost of expensive biologic agents; a relatively short period of exclusivity would accelerate this process, as would the ability to reuse some of the trial data. For innovators, however, longer periods of exclusivity are required to allow them to recoup their research and development costs. If the period of exclusivity is very short, the commercial viability of biological molecules might be lost, halting this exciting area of research.

The biosimilar-related decisions to be taken by various legislative bodies in coming months will determine a big part of the industry's future for at least the next couple of decades. Since governments are strongly motivated to control the cost of medication, they are likely to promote the growth of biosimilars. As far as patients are concerned, we believe that a proportion of the patient population will consider that the risk attaching to biosimilars is acceptable at the outset. However, what will drive the long-term success or failure of biosimilars is experience. Results have been encouraging in the case of the simple biosimilars available

<sup>1</sup> "F.D.A. Extends Avastin's Use to Breast Cancer", *New York Times*, 23 February 2008

<sup>2</sup> Eshoo, A.G. "Pathway for Biosimilars Act – Protecting Patients and Innovation", George Washington University, 23 September 2008

<sup>3</sup> Eshoo, op. cit.

<sup>4</sup> The Access to Life-Saving Medicine Act HR 1038

<sup>5</sup> "European Biosimilars' Market Performance Mirrors US Legislative Progress: Slow but Steady", The RPM Report

<sup>6</sup> Grabowski, H. et al. "The Effect on Federal Spending of Legislation Creating a Regulatory Framework for Follow-on Biologics: Key Issues and Assumptions", White Paper, August 2007

# Emerging Markets

## Could better penetration of countries like India and China help multinational corporations (MNCs) to sidestep difficulties in their traditional markets?

**Pharmaceutical companies have been quicker to capitalise on these countries' advantages as environments for low-cost development and production than they have been to exploit their possibilities as consumer markets.**

In pharmaceutical companies' traditional markets, growth is sluggish or worse. IMS Health has forecast that pharmaceutical sales in the U.S. will decline by between 1 and 2% in 2009, and that over the next five years Compound Annual Growth Rate (CAGR) will be flat; France, Germany, Italy, the UK, Spain and Japan, meanwhile, are expected to show only low to medium single-digit CAGR over the next five years<sup>1</sup>. In the U.S., growth is dampened by cost-conscious payers and by cash-strapped consumers who are experiencing difficulty in meeting the costs of co-payment and branded OTC drugs. In other countries, governments are introducing cost containment measures like reference pricing, promotion of generics usage, and stricter cost-benefit analysis.

The picture looks very different in the seven emerging markets of China, India, Brazil, Russia, South Korea, Turkey and Mexico. IMS predicts that in 2009 more than half of global market growth will come from these, and that they will continue to contribute 40% of growth on average until 2013<sup>2</sup>.

So far, pharmaceutical companies have been quicker to capitalise on these countries' advantages as environments for low-cost development and production than they have been to exploit their possibilities as consumer markets. It has been estimated that only a third of new chemical entities have reached the emerging markets in the past decade, even though they represent

a potential market bigger than the EU<sup>3</sup>. Now, however, we are seeing a buzz of activity as pharmaceutical companies recognise that emerging markets could help them to weather the current hard times.

### **Growth drivers in emerging markets**

Why are these markets becoming so attractive? Most of the economies in question have been growing fast, and so there is more to spend on healthcare, both individually and at national level. For example, the Chinese government has announced a major healthcare reform programme to improve basic medical care, and it plans to invest around \$125bn in the next three years<sup>4</sup>.

The nature of these economies' expenditure is also changing. Rapid urbanisation has shifted disease patterns from acute infectious diseases to chronic lifestyle diseases like diabetes, obesity and cardiovascular ailments<sup>5</sup>. These trends make the countries' needs more amenable to treatment with western products, and the relatively high cost of therapies for these diseases is expected to boost the overall growth of the market.

### **Special challenges to consider**

While the opportunities for pharmaceutical players in emerging markets are huge, there are also special challenges, particularly with respect to weak Intellectual Property (IP) protection and tight pricing control.

Although India is in the process of improving its IP protection, for example with the 2005 Patent Act, issues remain. Rejections of patent applications for Novartis's Glivec, Eli Lilly's Forteo and AstraZeneca's Iressa suggest that the level of patent protection is not yet comparable with that in developed markets<sup>6</sup>. In China, too, Pfizer and GSK suffered setbacks when the government invalidated the patents on Viagra and Avandia.

There are IP-related questions to be resolved in most emerging markets, and companies may feel they should wait for IP protection to be strengthened before launching their more innovative products there. However, any country that wants to foster a thriving pharmaceutical industry is likely to provide that

protection in the long run, and there is evidence that some companies feel that in India, at least, IP protection is becoming adequate, as we shall see below.

Governments in emerging markets are seeking to force down drug prices in a variety of ways. Turkey has introduced a strict reference pricing system. China is cutting the prices of reimbursable drugs. In India the Drug Pricing Control Order sets price ceilings for more than 70 essential drugs.

Given these price pressures, pharmaceutical companies now have to choose between premium pricing and market penetration pricing strategies. GSK has now adopted a new strategic approach to pricing

in least developed countries, where prices of newly approved medicines will be determined on a country-by-country basis. The company is exploring different pricing options, including price-volume strategies and tiered pricing models whereby products will be priced differently for public and private health sectors. In the Philippines, GSK has reduced prices on 28 of its products by 30-60%, and this led to a 15-40% rise in sales volumes in three months<sup>7</sup>. More specifically a 60% reduction in its Cervarix vaccine against cervical cancer led to a 14-fold volume increase in eight months<sup>8</sup>. This "differential pricing" may be a way for companies to get a firmer foothold in a price-sensitive, generics-driven market like India, where a few companies, including GSK and

**Table 1. MNC business models in India**

	Indian Model	Global Model	Hybrid Model	Niche Model
<b>Leadership objective</b>	• Market leadership	• Therapy leadership	• Therapy leadership	• Therapy leadership
<b>Product portfolio</b>	• Broad portfolio (10 therapy areas, 100+ brands) with products catering to the Indian market • Skewed towards acute/mass market therapies	• Product portfolio usually mirrors global portfolio (3-5 therapy areas, 25-50 brands) • Most often focused on chronic/lifestyle therapies	• Balanced portfolio with a mix of global patented products (3-5 therapy areas) and legacy Indian products (3-5 therapy areas); 75-100 brands • Mix of chronic and acute therapies	• Narrow portfolio (2-3 therapy areas; <25 brands) of legacy mass market products catering to the Indian market
<b>Scale of operations</b>	• Fully integrated model from R&D to sales and marketing • Large distribution network across all geographic tiers • Large coverage of physicians across multiple specialities and across all geographic tiers	• Operations range from manufacturing to sales and marketing • Large distribution network in towns • Coverage limited to super specialities in metro cities	• Fully integrated model from R&D1 to sales and marketing • Large distribution network across all geographic tiers • Segmentation of physicians varies based on therapies i.e. super specialities targeted for chronic therapies (urban focus) GPs for acute therapies (urban+rural)	• Operations range from manufacturing to sales and marketing • Distribution network is small, limited to towns • Physician coverage is very specific to the portfolio and limited to towns only
<b>Other sources of revenue</b>	• In-licensing across broad range of therapies • Exports of bulk formulations • Clinical data management and support services	• None	• None	• None

Source: Capgemini research

Merck, have already started selling certain products at prices far lower than those prevailing elsewhere.

### Four business models for emerging markets

Pricing, of course, is only one of many decisions that companies need to make to succeed in emerging markets. Table 1 describes four business models that MNCs have adopted in India.

GSK, Pfizer and Novartis have adopted the Indian model with the aim of attaining market leadership. To date these companies have mainly kept to an India-adapted portfolio, in which their blockbuster patented drugs are conspicuous by their absence. However, with the tightening of the regulatory

environment, all three companies have announced plans to market new patented products in India and are moving towards a more Hybrid model: as table 2 shows, GSK will be launching six patented brands there in 2009-2010.

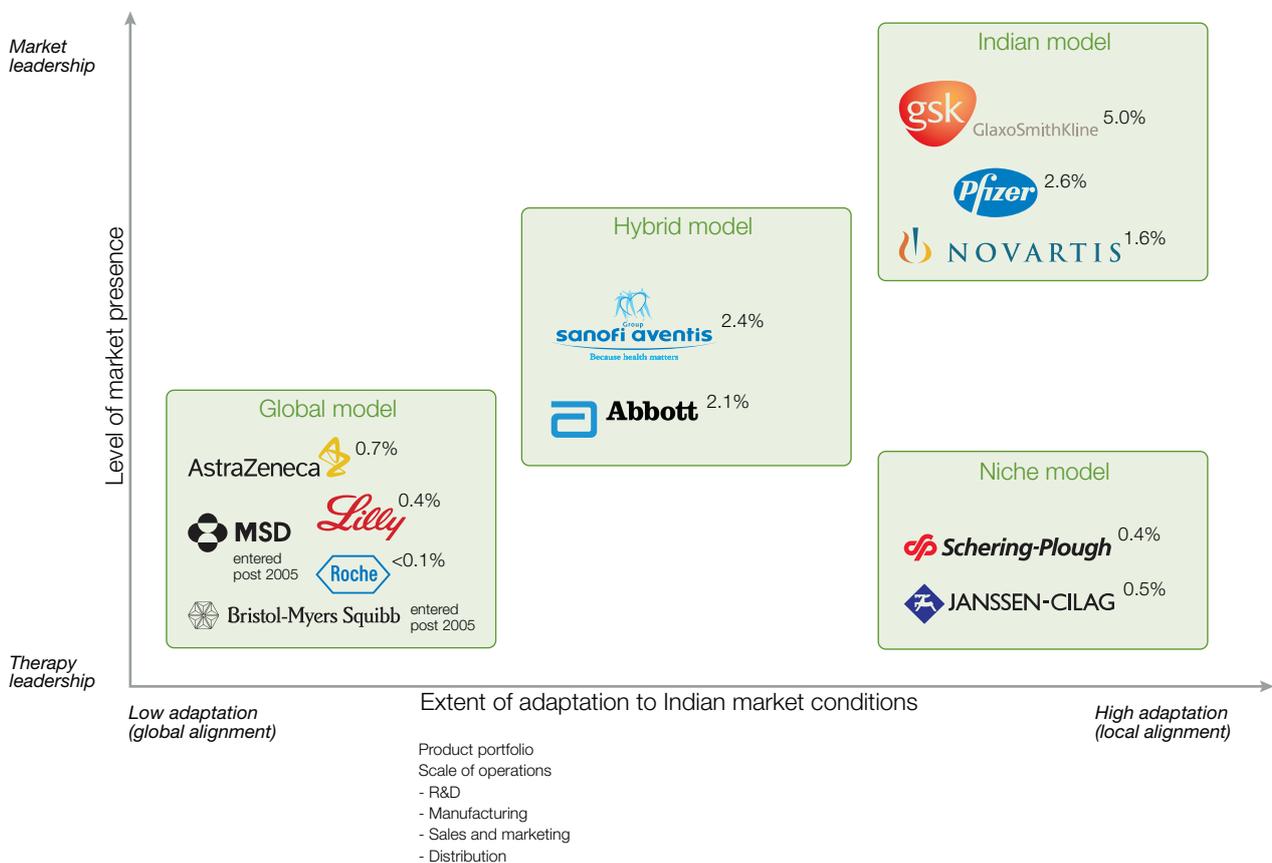
Other MNCs like Lilly, Roche, BMS and Merck (all of which have entered India recently, following the 2005 Patent Act) have adopted a Global model from the outset, bringing their global products into the Indian market. Unlike the market leaders, however, they focus on a couple of key therapeutic areas and a relatively narrow product basket.

Currently, many MNCs are seeking to strengthen their presence in the Indian market. Low stock valuations

and market potential have prompted many companies to increase their stakes in, or even de-list, their local arms. In March, Novartis, which currently has a 52% stake in its Indian arm, announced a plan to increase that stake to 90%, the threshold that has to be reached before de-listing. Shortly afterwards, Pfizer announced that it too aimed to raise its stake in its Indian arm, from 41% to 75%.

Among MNCs that have adopted the Indian or Hybrid business models, the majority have established local drug development support units. GSK has set up a Clinical Operations group in India to carry out studies in areas including cancer, depression, schizophrenia, diabetes and leishmaniasis. It has also established

Figure 1. Two dimensions of the business model: presence and adaptation



Source: Capgemini research; ORG IMS. NOTE: The examples in each business model are representative and do not include all MNCs operating in India; values in brackets represent companies' 2007 share of the Indian pharmaceutical market.

**Table 2. Launch of global patented products by GSK in India**

NCE	Therapy	Acute/chronic	India launch
Carzec	Cardiovascular	Chronic	2007
Arixtra	Cardiovascular	Chronic	2007
Inflapen	Analgesic	Acute	2007
Zemetril	Anti-infective	Acute	2007
Tykerb	Oncology	Chronic	2008
In-licensed Cardio-vascular	Cardiovascular	Chronic	2008
Rotarix	Vaccine	Acute	2008
In-licensed Critical care	Critical care	Chronic	2009
Cervarix	Oncology	Chronic	2009
Allermist	Respiratory	Acute	2009
Infanrix Hexa	Vaccine	Acute	2009
Eltrombopag	Thrombocytopenia	Acute	2010
Synflorix	Vaccine	Acute	2010

Source: GlaxoSmithKline Pharmaceuticals Limited

#### Tie-ups with local generic manufacturers

Many MNCs are acquiring, or entering into alliances with, local generic companies to gain entry into emerging markets or to access low-cost manufacturing facilities. Recent or current deals include those between Pfizer and Hyderabad-based Aurobindo Pharma, GSK and South Africa's Aspen Pharmacare, and GSK and Dr. Reddy's Laboratories in India. Sanofi Aventis has been among the most acquisitive firms in this area, with Czech company Zentiva, Brazil's Medley, and Mexico's Kendrick Farmaceutica among its purchases.

a Global Drug Development support centre with Tata Consultancy Services, to “expand capacity in response to increased efficiency demands, leverage the high-quality talent pool in India, and benefit from cost and process improvements”<sup>9</sup>.

Most of the work of Pfizer's Clinical Research group is concerned with phase II and III studies for the global R&D team, the rest supporting local registration, launch and marketing. In contrast, Novartis's Indian development centre was established in 2007 to meet “global data management needs” rather than to do research. The company has commented that it “will think of doing high-end R&D work in India only when the patent laws are made totally compatible with WTO [World Trade Organization] norms”<sup>10</sup>.

Pharmaceutical companies will choose different models for different countries, but to make significant inroads into a given market the companies will need, one way or another, to establish a sizeable presence. That may mean investing in R&D or other facilities in the target country, and perhaps doing deals

with local companies (see sidebar). The other prerequisite for gaining significant market share, as suggested by figure 1, is to adapt to local requirements, and it is to this topic that we turn next.

#### Conclusion: the key to success is adaptability

At first, companies tended to regard emerging markets as second-tier markets, and simply tried to re-use their existing business models there. This could explain why most failed to establish a significant position in Japan, the world's second-largest pharmaceutical market, where only three of the top 10 companies are from outside Japan, and the top four companies are all domestic ones<sup>11</sup>.

The key to success in emerging markets is adapting to local requirements. Despite some similarities, each individual market has its own opportunities and challenges. Companies that want to penetrate these markets will need to take time to understand their differences. They will have to create appropriate local sales and marketing channels, and build key relationships with local businesses and government entities. Equally imperative is a tailored strategy for managing the business environment and its risks.

It may sound like a lot of work, but pharmaceutical companies that put the effort in could find themselves sailing past the crisis in their traditional markets.

## Discovery and research operations in China

In China, too, many MNCs have recently either started or scaled up operations in basic drug discovery and research processes, as shown in table 3.

**Table 3. R&D expansion by MNCs in China**

Research activity	MNC	Details
Discovery research	Eli Lilly	<ul style="list-style-type: none"> <li>Opened its R&amp;D headquarters in 2008 to collaborate efficiently with its local R&amp;D partners</li> <li>Shanghai ChemExplorer, PharmExplorer and BioExplorer for basic research</li> <li>Wuxi AppTec, a pharmaceutical firm based in Wuxi, Jiangsu, which provides drug discovery to manufacturing services</li> <li>Chinese medicine firm Hutchison MediPharma to develop anti-cancer drugs targeted at the global market</li> </ul>
	Sanofi	<ul style="list-style-type: none"> <li>Established a strategic partnership with the Shanghai Institutes for Biological Sciences (SIBS) – a subsidiary of the Chinese Academy of Sciences, representing eight leading institutes active in life sciences for basic discovery research in the field of biotechnology in 2008</li> </ul>
	AstraZeneca	<ul style="list-style-type: none"> <li>Opened Innovation Center China research facility in Shanghai that will focus on translational science by developing knowledge about Chinese patients, biomarkers and genetics in 2007</li> </ul>
	GSK	<ul style="list-style-type: none"> <li>Launched a new R&amp;D centre in Shanghai focused on neurodegenerative disorders in 2007. The centre directs global discovery and development activities from drug-target identification to late-stage clinical studies, and collaborates with various research institutions</li> </ul>
	Novartis	<ul style="list-style-type: none"> <li>Set up a core R&amp;D facility in Shanghai in November 2006 with focus on infectious causes of cancer endemic to China and Asia</li> </ul>
	Roche	<ul style="list-style-type: none"> <li>Set up a wholly-owned R&amp;D centre in China in 2004 focusing initially on medicinal chemistry and parallel synthesis (Roche's own brand of combinatorial chemistry) experiments</li> </ul>
	Novo Nordisk	<ul style="list-style-type: none"> <li>Established a R&amp;D centre in 2002 focused on biotech. The centre's main research area is therapeutic protein discovery and development, with the current focus on technology development and application for protein expression and purification.</li> <li>The three main units of the centre are for research in molecular biology, protein chemistry and cell biology.</li> </ul>
Clinical trials and clinical data management	Sanofi	<ul style="list-style-type: none"> <li>Established the China Clinical Research Unit – R&amp;D centre 2005 in Shanghai for executing global clinical trials</li> <li>Set up a Biometrics Center in 2008 in Beijing to support global and local trials in both pharmaceuticals and vaccines development</li> </ul>
	Roche	<ul style="list-style-type: none"> <li>Opened its Pharma Development Center in Shanghai, China, in October 2007, focusing on the development of compounds for oncology, autoimmune and metabolic diseases, and anaemia therapies for both China and global development</li> <li>It has facilities spanning all the phases of clinical development, from innovative early exploratory clinical development to late-stage clinical development programs and regulatory filings</li> </ul>
	Pfizer	<ul style="list-style-type: none"> <li>Set up a new Research and Development Center in Shanghai in 2005. It provides input to study design, data management and statistical analysis for global clinical trials. Additionally, it provides support for training in internationally-recognised Good Clinical Practice standards to Pfizer colleagues in China as well as other Pfizer operations in Asia</li> </ul>

Source: Capgemini research; Datamonitor

<sup>1</sup> IMS, "IMS Health Lowers 2009 Global Pharmaceutical Forecast to 2.5-3.5 Per Cent Growth", press release, 22 April 2009

<sup>2</sup> IMS, op. cit.

<sup>3</sup> "Pharma's New World Order", Royal Society of Chemistry, 5 June 2009

<sup>4</sup> "China unveils health-care reform guidelines", Xinhua News Agency, 6 April 2009

<sup>5</sup> Datamonitor, Emerging markets series: "Benchmarking key countries Brazil, Russia, India, China and Turkey", December 2007

<sup>6</sup> Datamonitor, op. cit.

<sup>7</sup> Jack, A., "GSK to cut prices in emerging markets"- *Financial Times*, 11 June 2009

<sup>8</sup> Breuer, T. (Senior Vice President Global Clinical R&D & Chief Medical Officer, GSK Biologicals), investors' presentation: "Delivering a unique vaccines pipeline", 5 August 2009

<sup>9</sup> GlaxoSmithKline establishes Global Drug Development support centre with Tata Consultancy Services", press release, 29 March 2007

<sup>10</sup> "Novartis to ramp up India development centre", *Business Line*, 31 January 2008

<sup>11</sup> IMS Japan, JPM, 2008/3 MAT

# Pandemics

## When dealing with a flu pandemic, governments and healthcare organisations seem to be damned if they do and damned if they don't

As the novel influenza A (H1N1) virus continues its spread across the world, healthcare organisations and governments have put in place preparations for a pandemic. Inevitably, these actions have triggered concern, and even alarm, amongst the public. At present, too, their approach has been coming in for accusations of being unnecessarily heavy-handed, since the burden of disease appears to be less than initially feared. The perception of risk in the general population is exaggerated, as the press take up this emotive subject and report it extensively.

While avoiding causing unnecessary disquiet, these authorities need to cater for the current needs of patients and to anticipate the possibility that the virus might mutate into a more virulent form – a very difficult balance to strike.

In this article we look at previous pandemics to see what we can learn from them, before considering how the handling of the current pandemic may affect the ease with which future episodes can be managed.

### “Swine flu” and other pandemics

First, let us take a brief look at the current outbreak of H1N1 flu. It is caused by a new reassortment of earlier strains, though opinions differ as to which. Early analysis by the U.S. Centers for Disease Control and Prevention (CDC) identified four component strains: one endemic in humans, one in birds, and two in pigs

(hence the name “swine flu”)<sup>1</sup>, though its exact makeup has subsequently been disputed.

The disease was first identified in Mexico and nearby areas of the U.S. Several hundred cases quickly came to light, including some fatalities<sup>2</sup>. The virus spread to Europe and beyond until in June, the World Health Organization (WHO) raised the level of influenza pandemic alert to phase 6<sup>3</sup>, meaning that it was now regarded as a full-blown global pandemic.

Flu pandemics are nothing new. There have been three earlier ones in the 20th century, the worst of which started in Spain in 1918–1919; worldwide it is estimated to have infected as many as 40% of the population and to have killed 50m or more. 1957's Asian flu pandemic was identified and dealt with relatively rapidly, which may be partly why it was less severe than Spanish flu. Nonetheless it killed about two million worldwide. The flu pandemic of Hong Kong in 1968 was the most recent, with mortality of between one and three million<sup>4</sup>.

While there have been no actual pandemic outbreaks since 1968, some disease outbreaks have triggered fears of pandemics. In 2003, almost a thousand deaths resulted from a Severe Acute Respiratory Syndrome (SARS) outbreak. Several avian flu outbreaks in South-East Asia have also caused significant mortality<sup>5</sup>.

### Learning from past pandemics: the wave pattern

There has been no regular pattern in the occurrence of pandemics, making it extremely difficult for experts to predict the next one. Nonetheless, there are useful lessons to be learned.

Importantly, past pandemics have tended to unfold in waves, most often two or three of them, with a time lag as long as five years between the first and last waves. The Hong Kong influenza pandemic occurred in two waves in 1968 and 1970; the 1957 Asian flu pandemic was followed by two further waves in 1959 and 1962. People infected during the first wave of a pandemic gain immunity so that they are typically not affected by subsequent waves, but age groups and geographies not affected by the first wave are likely to catch it later.

It has also been noticed that subsequent waves tend to be significantly more severe in terms of both morbidity and mortality. Experts have not yet been able to pinpoint the exact reasons for the pattern of multiple waves, or explain the differences in morbidity and mortality levels between the waves. Nevertheless, knowledge of the wave phenomenon should help health authorities to prepare for successive waves.

### The modern world accelerates the spread of disease

The population density of modern societies makes it easier for diseases to spread, particularly through towns, where there is more frequent social contact. The fact that people

### The economic impact of pandemics

The World Health Organization estimates that the annual economic costs of pandemic influenza could rise as high as around 8% of GDP depending on the percentage of the population affected<sup>7</sup>. The more obvious impact arises from death and inability to work through illness. However, even more important from an economic point of view are “avoidance behaviours” such as reducing travel or avoiding visits to crowded places such as shopping centres and public events. According to World Bank estimates, these avoidance behaviours will actually account for nearly two-thirds of the financial damage arising from a pandemic<sup>8</sup>.

continuously travel to and from the towns means both that they are likely to see the first occurrences of infection and that they are likely to act as “hubs” for its dissemination<sup>9</sup>.

Demographic change also means that modern societies have a growing number of people who have weakened immune systems, and hence are more susceptible to infection. These include the elderly and those undergoing surgery, transplantation or chemotherapy. This profile makes today’s population more susceptible to infection, as do a number of chronic conditions that are becoming more common in today’s society, such as cardiovascular disease and asthma<sup>10</sup>. Not only do these conditions increase the proportion of the population that is likely to be more seriously, and sometimes fatally, affected by the infection, but they could also increase the rate of spread.

A factor which has received a great deal of attention during this pandemic is the rapid global spread of the disease driven by the high levels of air travel. Initial attempts at containment proved ineffective because, by the time the severity of the condition was understood, aircraft had spread the virus across the globe.

All these factors could conspire to make this pandemic harder to contain than previous ones, although the medical means available to counter it are undoubtedly better than ever before.

### Conclusion: managing the message

The major unknown in planning and management of the pandemic is the likely future course of H1N1. Will it remain as a relatively mild flu, causing significant illness without the death toll of earlier pandemics, or will subsequent waves bring increased severity and mortality?

Clearly, governments and healthcare organisations have no way to answer this question at present. However, given the potential economic and social impacts of the worst case scenario, they must in any case take action to raise awareness of the disease, while preparing to deal with its effects. The difficulty of spreading the word is that, human nature being what it is, global populations will increasingly ignore the warnings if that worst case scenario doesn’t arise within their attention span. It is important to have the active participation of the world’s populations as a major lever to contain the speed of transmission and its physical spread.

The waned nature of the previous pandemics may also provide us with an opportunity. Delays in the isolations and large-scale production of the vaccine will mean that only the very vulnerable will be vaccinated during this initial wave. However, the gap between this wave and any subsequent waves will provide an opportunity to conduct a more widespread vaccination programme.

Nonetheless, unless we can steer the right course between alarmism and complacency, the real legacy of H1N1 could be an outbreak of apathy and scepticism across the world’s population. The one thing we can be sure of is that sooner or later a really virulent pandemic is bound to emerge, whether as a later wave of this one or from a completely different infection. If officialdom is seen as “the boy that cried wolf”, the world’s populations could be deaf to warnings at the very moment when they really need to take notice.

<sup>1</sup> “Deadly new flu virus in U.S. and Mexico may go pandemic”. *New Scientist*, 28 April 2009

<sup>2</sup> WHO, “Influenza-like illness in Mexico and the United States”, 24 April 2009

<sup>3</sup> WHO, “World now at the start of 2009 influenza pandemic”, Statement to the press by WHO Director-General Dr Margaret Chan, 11 June 2009

<sup>4</sup> Directorate-General for Health and Consumer Protection European Commission, “Flu pandemic preparedness”, July 2006

<sup>5</sup> Directorate-General for Health and Consumer Protection European Commission, op. cit.

<sup>6</sup> Miller, M.A. et al, “The Signature Features of Influenza Pandemics — Implications for Policy” *NEJM* Volume 360:2595-2598, 18 June 2009, Number 25

<sup>7</sup> WHO, “Estimated economic impact of pandemic influenza”, graph in Chapter 3 of *World Health Report 2007*, p39

<sup>8</sup> CNN, “Pandemic equals economic pain”, 28 April 2009

<sup>9</sup> Risk Management Solutions, “Managing Influenza Pandemic Risk”

<sup>10</sup> WHO, “Assessing the severity of an influenza pandemic”, 11 May 2009

# Accelerated Execution

## Programmes often fail to deliver value as fast as life sciences companies would like, but there is a pragmatic way to get them back on track

John sits back in his chair, confident that the vital programme he has just kicked off will succeed in its aim of improving efficiency by 20%. He scans his mental checklist of critical success factors.

The programme goals are clear, specific and measurable; the plan is robust yet simple to understand; risk management plans are in place; there are no overlaps with, nor dependencies on, other priority programmes; all stakeholders are bought into the outcomes; the benefits tracking process is in place; the team are all dedicated full-time to the programme, and delighted to be; they are co-located in the one office, speak the same language and all fully understand the corporate culture in which they operate; all pigs are fed and ready to fly!... he comes back to earth with a jolt.

As we all know, the reality of most current life sciences programmes is quite different. We are increasingly finding that companies are unhappy with the way their programmes are conducted. Unsurprisingly, the main complaint is that the programmes are not delivering the intended benefits fast enough.

### Four top reasons programmes disappoint

The reasons are often evident once we start talking to the programme team. Even on make-or-break programmes, several serious threats to success have often gone unnoticed. We'll list the top four here.

- **Capability gaps.** The team's expertise is often patchy, and there may be no one with end-to-end experience of the lifecycle. In terms of specific programme management capability, training may focus on processes rather than actual capabilities, so that we encounter projects that have gone horribly wrong, but that have a nice tidy risk register which has been updated weekly without ever actually being used. Another problem here is that it is impossible in a rapidly-changing environment to create a process for every eventuality, and the lack of focus on capabilities leaves teams ill-prepared to deal with what is thrown at them.

- **Lack of clarity of outcomes.** Often the programme goals are rather abstract to begin with, and are forgotten weeks into the programme as focus shifts to delivery. At best, the focus is on a single numeric goal and does not bring clarity regarding other impacts. For example, teams do not visualise in any detail how the organisation will look to employees, customers and so on, as a result of the programme.

- **Poor articulation, testing and follow-up of assumptions.** This problem is related to the previous one concerning clarity of outcomes. When we ask the team what success for the product will look like, the answer often turns out to be based on impossible assumptions: in one case, to realise the projected sales level, more doctors would have had to be prescribing the product than

worked in the therapeutic field in question.

- **Slow decision-making.** Decisions often take longer than they should because managers do not have a full picture of the implications of the decision-making process. While the risks of making a decision based on imperfect information are usually apparent, it is often harder to see how far the programme will be delayed by waiting for additional information – or what that delay will cost.

These problems arise in part because companies' programme management techniques and tools have not kept abreast of evolving industry challenges. Big corporations now have more complexity to deal with in terms of scope and global reach of programmes, plus more uncertainty about the business environment. There is also more desire for pace – everything must happen faster. In addition, there is an abundance of programmes, many of which are taking place in parallel, with high levels of interdependency.

Companies typically have a large and challenging portfolio of programmes to manage, then. At the same time, the relentless focus on company financial results means that programmes are rapidly started by the company leadership without adequate time to prepare, and without the amount of resources they ideally need. Programme plans and risk management plans are often done for the sake of being done, rather than for the value they can add.

**The 18 components of the AEF have been refined through collaboration with life sciences companies as many are quite new to this sector.**

**A needs-driven solution**

How can companies raise their game to cater for this new more complex world – and in particular how can they improve the chances that programmes (whether new or already in progress) will complete within the intended timescales?

This is what Capgemini’s Accelerated Execution Framework (AEF) is about. It’s a comprehensive and balanced set of tools and disciplines to correct problems arising on programmes that are already running, or to set new programmes off in the right direction. Figure 1 shows the components of the framework, including the 18 modules containing these tools and disciplines, together with the journey support framework that helps a team to select and apply them in a systematic manner.

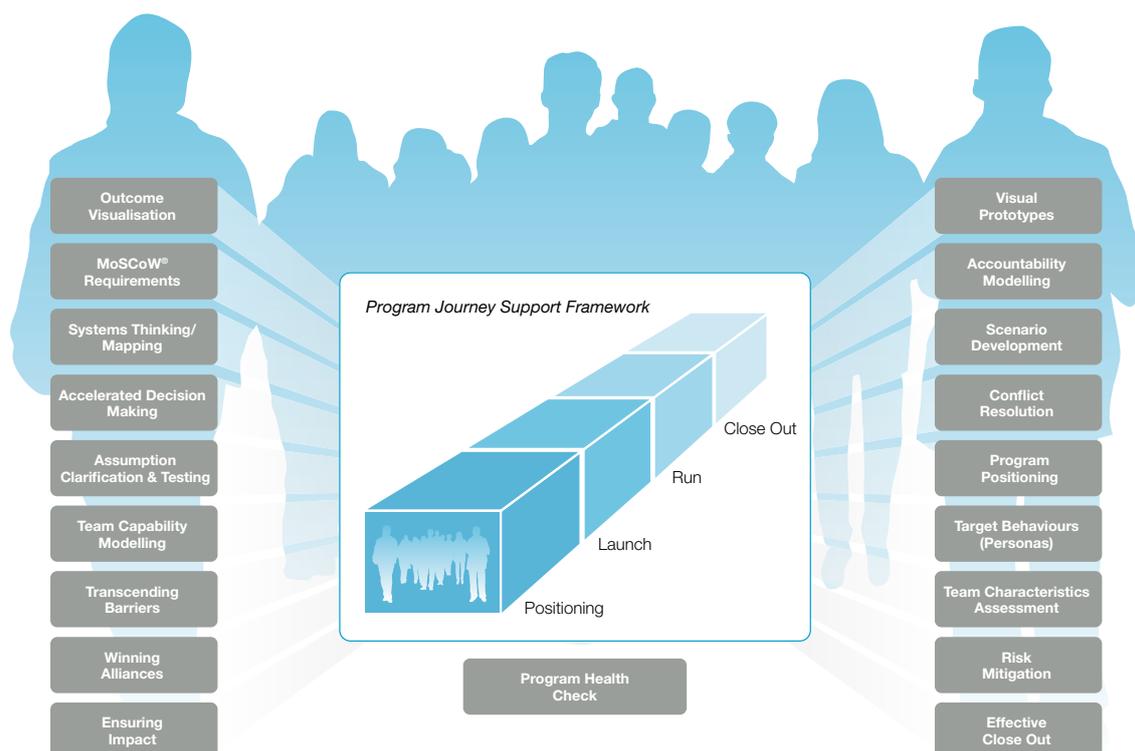
The 18 components of the AEF have been refined through collaboration with life sciences companies as many are quite new to this sector. They build on approaches from other

industry sectors that have already developed mature programme and change management techniques, such as design, new ventures and software development.

Over time we have found that these 18 elements are the ones that programmes need. Of course, a single programme will not use all 18. A rapid diagnostic phase allows us to sit down with your team and identify which elements are relevant to your specific situation. We help you apply any new tools and disciplines one or two at a time, so that benefits can be obtained rapidly without overburdening the team. No classroom training is needed; all learning is on-programme.

In building the AEF, we recognised that all sizeable organisations already have their own established approaches and tools for programme management and change management. Our approaches and tools are designed to supplement rather than to replace these. If you already have

**Figure 1. The Accelerated Execution Framework**



the necessary tools available in a given area, the diagnostic phase and framework will highlight ways to use them more effectively.

### Commonly-used modules

The AEF modules that are most often needed, in our experience, are those that deal with the issues that, as discussed above, commonly pose problems for major programmes – namely capability assessment, outcome visualisation, assumption testing, and decision-making.

The **team capability modelling** tool allows a team to assess what additional knowhow it needs to succeed. Having pinpointed any gaps, the team can fill them by bringing in additional people or by drawing on other sources of advice and experience. For example, in one company we positioned some of the executives as programme coaches, a role in which they made a significant practical contribution.

The **outcome visualisation** tool helps the team to articulate its vision of success to the point where it is clear and unambiguous, while the **assumption clarification and testing** tool (drawn from the world of venturing) allows it to evaluate the implied assumptions on which this vision is founded, so avoiding costly mistakes.

Finally, the **accelerated decision-making** tool helps stakeholders to think more about what decisions need to be made when. In particular, they become conscious of the costs of delay, and can offset them against the risks of making a decision based on incomplete information. (The tool includes a charting capability that displays the diminishing returns of waiting for more information – something that companies often underestimate, with potentially disastrous impact on programme schedules and costs.)

### Conclusion: try it for yourself

All these tools, and the overall approach, have been designed with today's changing business environment in mind, and to cope with the complexity, speed and proliferation of programmes in the typical organisation. To get a feel for how well Accelerated Execution addresses these needs, try evaluating a programme currently running within your own organisation in these three dimensions:

**1. Consider what it would take for the programme to succeed, and then honestly assess whether you have the capacity and capability to make this happen.** For example, in the case of a post-merger integration exercise, does your team have enough experience of transition management, or do you need to bring someone else in to handle this aspect?

**2. Test the clarity of the outcomes.** Do you really understand what the company will look like once the programme has completed and the benefits have been delivered? Answering this question may reveal that additional steps are required. For example, when creating a shared service organisation, companies may think they are freeing up the country Finance Directors from routine work to do more strategic tasks. But are the current FDs really able to make that transition, or do they need re-skilling or even replacing?

**3. Assess the level of complexity and uncertainty affecting the programme, and the team's ability to handle it.** For instance, if food prices rise beyond a certain point, then a given country's receptiveness to GM crops may increase. To anticipate changes like this, teams need to engage in "scenario thinking", and also to scan the regulatory horizon, not least by being as close to the regulatory authorities as possible.

By going through these three steps you will in effect be performing a simplified version of the diagnostic phase of an Application Execution assignment. The framework essentially provides a rapid way to pinpoint areas where your programme might go wrong, plus some tried-and-tested techniques to get things back on course.



# Procurement

**There are opportunities to be found amidst growing pressures on the procurement function**

**For many, savings targets have doubled from those that prevailed when we last conducted the Global CPO Survey, where these are now a necessity for survival.**

The pressure on the procurement function continues to grow exponentially. Within life sciences, this growth has been partly driven by the renewed push for companies to drive out costs in order to allow continued investment in R&D.

The importance and the difficulty of effective procurement are underlined by the findings of the third Global Chief Procurement Officer (CPO) Survey, which marks Capgemini's continued commitment to understanding the trends and issues affecting the procurement executive. With truly global participation, the intent of the Global CPO Survey is to provide executives with insight into both macro issues and focus areas so they may be better informed concerning the challenges they face and the decisions they make. This report is an abbreviated version of the full survey report titled *Global Chief Procurement Officer Survey 2009 - Responding to the Challenges of Economic Meltdown*<sup>1</sup>.

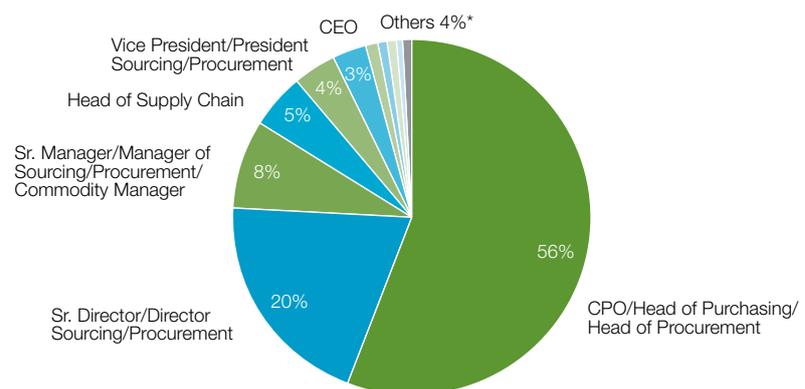
## Increasingly stretching targets

The majority of our feedback was received from the critical executives across the field of procurement, with most survey participants from sourcing/procurement functions and at CPO/director level or at middle management level. Across all industries, and importantly in life sciences, procurement executives have found they have increasing targets, altering focus areas and shortening planning time horizons. For many, savings targets have doubled from those that prevailed when we last conducted the Global CPO Survey, where these are now a necessity for survival.

## Short-term focus

When asked how the economic downturn was affecting the planning horizon for procurement activities and strategy, the majority of organisations highlighted it as a challenge to look beyond the short to the medium term. Given the uncertainties faced, this would seem

**Figure 1. Participants by position**



\*Others include – CFO, COO, Director of Logistics, VP Marketing & Technology



an understandable reaction. However the natural conclusion is to re-focus the behaviours and mindset on more tactical activities at the expense of longer-term strategic initiatives which, by their nature, take time to implement and deliver. What was prevalent in discussions was an overall shortening of the planning time horizon compared with the stable period of growth preceding the current economic slowdown.

The response to this focus appears to comprise short-term objectives in the main: top of the list of current initiatives for procurement is the tactical re-negotiation of existing contracts in an attempt to slash spend and reflect reduced demand. The other main activities being pursued target enhanced supplier management and raising the profile of procurement across the organisation. Even these can be tracked directly to short-term goals as opposed to more strategic, longer-term objectives.

One of the concerns we regularly encounter from company to company is that of unforeseen bankruptcies within the supply base. The fear is the unquantified effect this would have on downstream product and service provision. The response around supplier management therefore is far

more attuned to risk mitigation as opposed to the more traditional aims of development and innovation. Equally, the desire to raise procurement's profile can be traced back to a need to work better with stakeholders, internal customers, suppliers and end user groups to drive lower cost fit-for-purpose specifications.

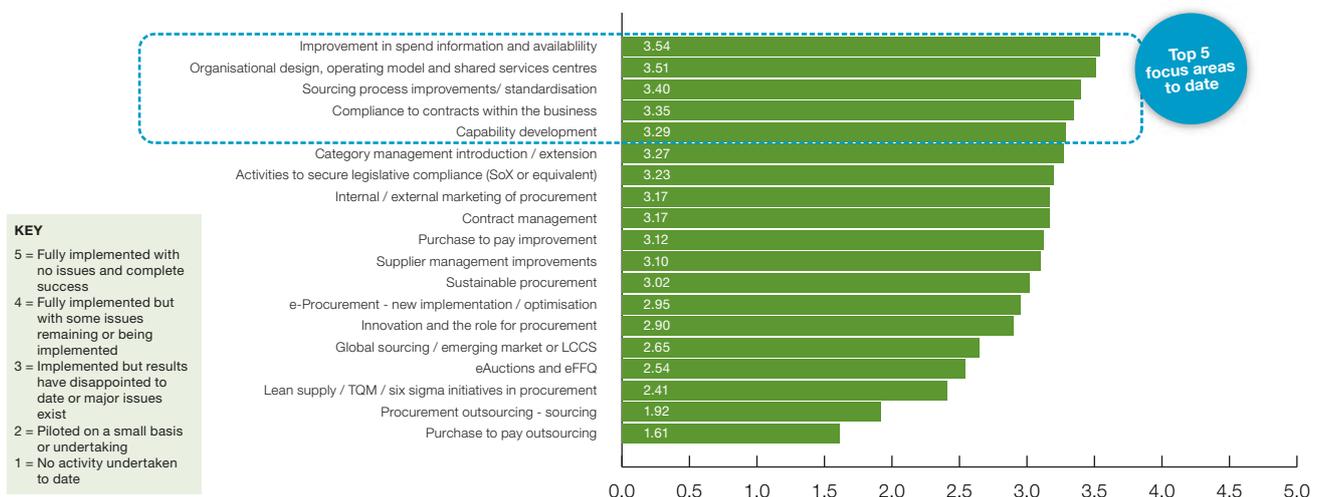
### Shift in procurement behaviours

We would conjecture that part of this is to move procurement behaviours from buying what is wanted to buying what is needed. All of these characteristics are consistent with the harsh environment procurement and organisations alike are currently operating in. These results are consistent regardless of industry sector or geography, and show the true nature and impact of the global economy. Even pharmaceutical-based companies, many of which had a long track record of investing heavily in headquarters buildings, are finding budgets for these slashed in an increasingly aggressive environment where continued existence is at the forefront of most executives thinking.

### The challenges

When turning our attention to areas of investment and improvement being pursued by CPOs, we see significant

Figure 2. Key focus areas to date for procurement



**It seems that while the problems are now well recognised, progress with resolving them is occurring at a slow pace.**

consistency with the themes from last year. The key findings include:

- Organisations continue to struggle to unlock the intrinsic value within IT solutions. More than 60% of respondents acknowledged that less than 20% of spend utilised eProcurement tools, despite significant investment made in technology.
- Perhaps connected to this, spend visibility remains a key problem and for the second year running is the top issue facing CPOs.
- Talent continues to be a front-of-mind issue and, along with the pressure for economic results, has become more acute for procurement functions struggling to execute effective strategies.
- Supplier management has come into focus as organisations recognise the risk of vendor failures within the supply chain.
- Organisational design continues to adapt to circumstance as respondents seek to balance end user intimacy with the need for control and consistency.

**Overcoming the challenges**

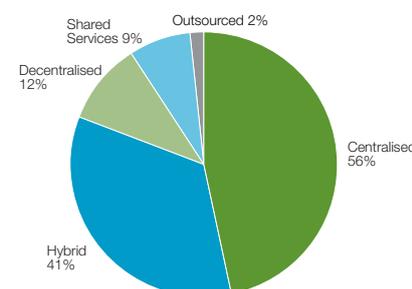
It seems that while the problems are now well recognised, progress with resolving them is occurring at a slow pace. One possible explanation for this is a common failure to see the integrated nature of such problems. Rather, activities are focused on solving what are seen as discrete issues leading to unsustainable solutions.

Our findings revealed a significant shift towards a hybrid model from more centralised vehicles.

We found last year that the earlier drive towards more centralised models was being fuelled by a need to gain control over direction and priorities. This is a natural reaction to the evolution from federated models where decisions tend to be taken locally and therefore can create challenges in coordination. However the primary shortcoming of a centralised model is the difficulty of interfacing with end users to help shape requirements and control demand. It is perhaps unsurprising that there has been a shift towards a hybrid model that helps address this issue while maintaining coordination and direction. A hybrid model combines the features of central direction with distributed service provision for procurement. Given the pressures to drive benefits, the need to ensure close proximity to end user communities rises in importance.

Lasting solutions seem to be evading companies in the main. While this continues it will serve only to denude organisations of the effective deployment of tools, capabilities and operating models to address the long-term strategic agenda. For those who can break out of this detrimental cycle there is a clear opportunity to drive competitive advantage for their respective organisations. In no small measure these businesses will help define the winners and losers that emerge from the current economic cycle.

**Figure 3. Current procurement function organisation**



<sup>1</sup> The full report *Global Chief Procurement Officer Survey 2009* can be downloaded from [http://www.capgemini.com/resources/thought\\_leadership/by\\_solution/supply\\_chain](http://www.capgemini.com/resources/thought_leadership/by_solution/supply_chain) - or contact any of our Life Sciences team for a printed copy.

# Cost Reduction

**Why do cost reduction programmes so often go wrong, and how can the pitfalls be avoided?**

**Insufficient thought is often given to the task of finding a meaningful and sustainable way to do it.**

While cost reduction is uppermost in most companies' minds at present, insufficient thought is often given to the task of finding a meaningful and sustainable way to do it.

Our 2009 Vision and Reality study, *Life Sciences: Performing in the Downturn and Beyond*<sup>1</sup>, explores the "what" of cost reduction, discussing what the focus of cost reduction programmes currently is, and what it should be in view of likely industry developments. The present article addresses the equally important "how" question. Having decided on a cost reduction initiative, how should a company set up the programme to ensure that the anticipated benefits are realised?

## **Doomed approaches to cost reduction**

Before attempting to answer the question, let's see what can go wrong when a programme fails to get to grips with the "how" question in its initial phases. There are various reasons why this happens but a common one is that senior leadership has distanced itself too far from the detail of the programme.

Failure to answer the "how" question often leads to organisations embarking on one of five approaches, all of which frequently lead to short term benefits but long term disappointment. What they have in common is that the various organisational functions are given some form of "what" target but are left to make the "how" decisions themselves.

1. The **communistic approach** - where the organisation decides to reduce costs by a specified percentage across the board. The appeal of this approach lies in its simplicity: everyone gets the same easily-remembered message. Unfortunately, it usually leads to indiscriminate headcount reduction, since this is one of the easiest ways to reduce costs in the short term. The remaining employees tend to become unduly focused on the short term, and on their own job or function. In general, the only organisations where this approach works well are the "fat and happy" ones, where you can find cost reduction opportunities wherever you look.

2. The **ratio approach** - where benchmarking and financial ratios are used to calculate a target cost reduction for each function, for example that marketing costs could be reduced by 20%. The only attraction of this approach is that it usually gives a reasonably accurate assessment of the benefits available. The downside is that this is often the cruellest approach for function heads. The senior leadership have been convinced that these benefits are available and if the function head cannot find them then it must be that they lack the capability to do so. But in fact it is unreasonable for management to ask people to deliver a theoretically possible reduction without giving any plan or guidance on how to do it.

3. The **competition approach** - where functions are asked to find



as many savings as they can, setting up an internal competition, with function heads trying to be seen as the best corporate citizen. An undesirable by-product of this approach is “department shuffle”, where one function “offloads” resources or costs on to another function on various pretexts. The result of this is a lower cost for one function but an identical rise in costs for another, so that there is no net cost reduction to the organisation.

4. The **easy target approach** – where the costs that are the most visible get cut first. This approach is so popular that it is often used in conjunction with all of the previous ones. Its attraction is “quick wins”: reduced travel expenditure or canteen subsidies, removal of funding for the Christmas party and so on. Unfortunately, the savings tend to be extremely temporary and negated by the damage to morale.

5. The **old favourite approach** – where the greatest expectation is placed on the part of the business that has delivered cost savings in the past, often an operational unit with a relatively heavy cost base. Whilst “following the money” is a key element in identifying cost saving opportunities, it must be done as part of a broader analytical exercise that takes into account each function’s ability to absorb the proposed change.

Neglect of the “how” question usually leads to either an excessive focus on the short term or a long-term rise in delivery costs, or both. Short-termism often manifests itself as failure to launch development projects early enough, leading to a lack of competitiveness in the market. It can also mean that employees are “let go”, only for the company to find out a year later that they have taken critical skills and knowledge with them and they now work for the competition. A rise in delivery costs then occurs because the organisation ends up re-hiring the people it has shed, or their equivalents, as contractors or consultants at a higher cost.

### Tackling the “how” question

To avoid pitfalls like these, the initial phase of any cost reduction exercise must aim to answer the “how” as well as the “what” question. (It should also present a reasonable picture of “by when”.) If your exercise is already in progress, the best course of action is to stop and answer these questions before you continue.

The best place to start answering the “how” question is with the facts. In the majority of cases where we are asked by clients to help them rescue a failing programme, we quickly discover that the initial scope was based on inaccurate and/or incomplete data. To ensure the data is accurate, the business case for the programme needs to be developed

from two opposing directions, first top-down and then bottom-up. Finally, priorities need to be agreed.

### Top-down analysis

Initial analysis assesses basic cost information against a range of internal and external benchmarks. The intention here is not to generate a final answer but to frame the answers to some straightforward “what if” questions. What if we could get all affiliates up to the same performance level as affiliate A? What if we could consolidate our suppliers and achieve a price point of x? What if we could achieve the same Cost of Goods Sold as competitor C?

While essentially rational, this analysis must also take account of the emotional and political dimensions of the future programme (see panel). The team should use interviews, focus groups and other communication approaches to engage a broad range of stakeholders, from the executive team to the front line, in order to understand their views on likely opportunity areas and barriers to success.

#### Three dimensions of programme success

In answering the “how” question, programme leaders must think in three dimensions.

**Rational:** the answer must be based on sound analysis. Opportunity areas must be accurately quantified and initiatives prioritised based on value.

**Political:** to achieve transformation, key influencers and decision makers must be aligned around common goals.

**Emotional:** change triggers emotional reactions in many people involved, ranging from fear about the future to resistance to the programme and evasion of its results. The emotional dimension will loom particularly large in businesses with a history of failed change initiatives.

#### Why the five approaches fail

It is easy to see the flaws in these five approaches if you apply them to family life. Imagine you need to reduce household costs by 25%. Paying only 75% of your taxes and mortgage – in line with the “communitistic” approach – would soon land you in trouble. Applying the “ratio” approach, and cutting costs on the basis of what the neighbours spend as a proportion of their income, would be absurd because their needs might be quite different. The “competition” approach would lead to individuals taking decisions that the group may not agree with: for example, a parent might tear up the garden lawn to cut down on the cost of mowing, leaving the children wanting somewhere to play. The “easy target” approach would dictate the elimination of pocket money and eating out, causing a family revolt. And the “old favourite” approach might lead you to expect 25% off your car insurance because you got it last year – an argument unlikely to find favour with the insurer.

As well as improving the quality of information in the business case, this type of consultation allows everyone to feel they have had a say in what happens, building buy-in to the final decision. They also present an opportunity for programme leaders to identify areas that are likely to support or oppose the programme, and plan accordingly.

Because it articulates the potential scope and targets for the programme, top-down analysis can be used to steer the programme team and to help ensure that the right people are involved in programme governance. Broadly, those who own a significant area of potential benefit should have a role in the programme's team or governance.

Appropriate governance is critical, as is sponsorship. From the earliest stages, senior leaders must be seen to be supportive of the programme if it is to have any credence with the rest of the organisation. The process of getting the leadership onboard can take time and may not be fully accomplished until you are ready to implement, but it must be considered from day one.

### **Bottom-up analysis**

Bottom-up activity should begin once governance is established and top-down analysis has identified major areas for cost saving. The bottom-up business case can then quantify the opportunities, by conducting specific analysis on individual business areas and validating the findings with individuals with relevant operational experience.

This is the only way to ensure that potential benefits are quantified in a realistic way. It may be an external benchmark that directs you to a particular area, but it must be a specific, tangible opportunity that the organisation signs up to deliver.

### **Setting and agreeing priorities**

Once you have identified a set of potential top-down opportunity areas and confirmed their scale and viability with bottom-up analysis, it becomes the programme Steering Group's responsibility to prioritise them. Criteria for prioritisation must be agreed in the initial phase of the project, and might include size of benefits, time to delivery, cost of implementation (Capex and Opex), fit with core strategy, potential risk. Rigorous definition of criteria allows prioritisation decisions to be based on sound analysis.

If the programme is to succeed, however, it is essential not only to set rational priorities, but also to mobilise the organisation around them, ensuring that political and emotional dimensions are taken care of. Once again, consultation and communication with stakeholders at all levels is key.

The collaborative approach works in all three dimensions: it ensures that potential is quantified in a rational way, but by involving people in the design of the targets they will subsequently be expected to meet, it also safeguards the emotional and political dimensions of the programme.

### **Conclusion: applying the lessons**

Relatively few cost reduction programmes deliver the intended benefits. If your organisation is currently engaged in such a programme, it is worth considering whether it has any of the characteristics of our five doomed approaches.

If so, then the vital "how" question was almost certainly not answered well enough. The remedy is relatively straightforward, and can be applied to a programme that is already in progress. The approach we have laid

out for answering the question is a common-sense process. Yet it avoids the pitfalls by basing the programme on realistic, accurate information, and aligning the entire organisation around the case for change.

<sup>1</sup> To request a full copy of the report, please send an email to Tim Dullely at [timothy.dullely@capgemini.com](mailto:timothy.dullely@capgemini.com)

# Marketing Maturity

**Life sciences marketing departments urgently need to do more with less; help is at hand from a structured approach validated by experience from other industries**

It's no secret that pharmaceutical companies now need their marketing departments to achieve more with fewer resources. Companies have been making both sales and marketing a focus for cost reduction, with across-the-board cuts typically in the range of 5-25%. At the same time, a number of factors are conspiring to make the role of marketing in pharmaceutical companies both larger and more complex.

One reason the role is growing is that blockbusters coming off patent tend to be replaced by a range of mid-market, generic and over-the-counter drugs, increasing portfolio size. Some countries have also increased the amount of compliance data that marketing teams need to maintain (for example in the U.S. companies now need to track data on speaker programmes). Non-compliance is not an option in view of the increasing number and severity of fines for violations (such as Lilly's \$1.4bn fine relating to off-label applications of Zyprexa).

As well as getting larger, the job is becoming more complex as governments push the industry towards more sophisticated – often efficacy-based – pricing. The influence network is growing and changing, as exemplified in the UK where attention has shifted away from GPs and towards Primary Care Trusts and other stakeholders. Expansion into emerging markets at a time of constrained budgets has led to an increase in co-marketing, adding a different kind of complexity.

Given the increasing size and complexity of the marketing role, it is not surprising that some companies have yet to achieve the cost reductions they were looking for. (This topic is covered in more detail in Capgemini's 2009 Vision and Reality study, *Life Sciences: Performing in the Downturn and Beyond*<sup>1</sup>.)

Pharmaceutical companies now need to evolve their marketing models to achieve even more with even less. This article describes an approach called Marketing Maturity, which entails firstly assessing the current position in terms of a Marketing Maturity model and then using established disciplines and techniques to increase maturity in several dimensions.

## Using Marketing Maturity to assess the current position

Marketing Maturity is a best-practice approach to assessing and developing the effectiveness of any marketing team. While it has not yet been systematically applied to pharmaceutical companies, it is eminently suitable for addressing the challenges currently facing them.

The model recognises four states, with “ad hoc” the least mature and “customer-focused” the most mature. We shall describe each, giving guidance as to how a pharmaceutical company can recognise which state it has attained.

**Ad hoc.** Marketing is primarily engaged in collateral creation, such as producing detail aids for a single audience, usually prescribers.



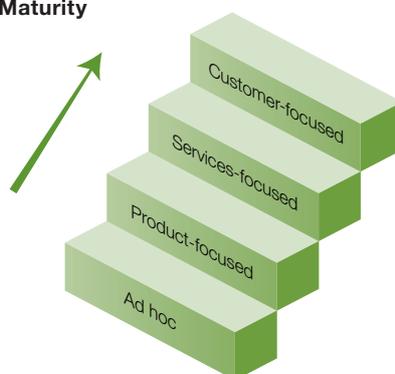
## Life sciences can learn from industries which have already confronted the need to achieve more with less and have therefore already moved up the maturity scale.

**Product-focused.** Marketing supports individual product brands with traditional marketing techniques such as collateral and advertising. Customers are partially segmented but the primary target tends to be prescribers, who are typically provided with features of the product such as indications and side effects. Support of the sales “arms race” is the main focus. This has long been the dominant model in pharmaceutical companies.

**Services-focused.** Customers are segmented into solution areas, typically therapeutic areas such as diabetes. Marketing provides both product information and supporting services (for example nurse support). The key focus is still the healthcare professional.

**Customer-focused.** Marketing pro-actively seeks out the needs of customer groups for both products and services. Multiple channels are used and messages tailored to each group, with an emphasis on customer need rather than drug efficacy. For diabetes patients the offer might include testing, analysis, prescription, prescription fulfilment, prescription compliance and follow up.

**Figure 1. Four steps to Marketing Maturity**



Just as pharmaceutical companies vary in their degree of marketing maturity, so do therapeutic areas, and even individual teams, within the same company. Typically, certain

therapy areas (often diabetes, breast cancer and erectile dysfunction) are customer-focused, but this mature approach is not usually consistently applied across the organisation. The Marketing Maturity model helps companies assess their overall position and also to identify which areas are in most need of attention.

### Moving up the Marketing Maturity scale

Life sciences can learn from industries which have already confronted the need to achieve more with less and have therefore already moved up the maturity scale. These industries include hi-tech and Fast Moving Consumer Goods (FMCG). Companies such as Dell, Apple and Panasonic have tailored their approach to the customer need, understanding and segmenting customers in sophisticated ways. They have taken cost out of their transactional channels to concentrate on building the brand. Services around the products, such as easy reordering facilities for consumables, add value for the customer ensuring repeat business.

FMCG companies like Unilever, P&G and PepsiCo are particularly relevant because, like pharmaceutical companies, they deal with consumers via an intermediary (in this case retailers), and face a complex stakeholder structure. They optimise use of marketing budgets through a relentless focus on marketing return on investment (ROI), supported by technologies which capture and analyse marketing spend. Again, their focus on the customer is unremitting.

### Six pillars of the marketing function

The experience of these other sectors confirms that maturity in marketing requires a consistent focus on the customer. To improve the marketing function and thus move up the maturity scale, pharmaceutical

companies will need to make improvements across six key aspects or “pillars” of the marketing function.

**1. Strategy.** The corporate marketing strategy needs to accommodate subsidiary strategies relating to brands, therapeutic areas and so on. It must address the growing complexities of the market with respect to stakeholder groups, channels and so on. It also needs to be flexible enough to accommodate changes in customer need and competitive environment (our War Gaming article outlines one approach to achieving this flexibility).

**2. Planning and performance management.** The whole marketing function must be governed by a balanced and well-aligned set of metrics focused on customer satisfaction and ROI. The metrics must cascade from the centre into each therapeutic area and affiliate team.

**3. Marketing organisation.** Companies must consider whether any marketing services could usefully be centralised, or whether any local activities duplicate global ones. The local affiliate making trivial modifications to the global message should be a thing of the past. FMCG companies have realised huge efficiencies here.

**4. Marketing processes.** Activities that do not add value for the customer should be eliminated. Transactional processes should be standardised and automated, while others need to be carefully differentiated.

**5. Skills and competencies.** The changing role of marketing has altered the profile of the ideal employee. Staff now need to be able to work in small focused teams, supporting a wider product portfolio and stakeholder community in new ways. Marketing managers should assess current capability levels against future

requirements, and fill any gaps with the aid of HR.

## 6. Information and technologies.

Automation and workflow management can improve the efficiency and visibility of processes such as campaign management and budget approval. Marketing Resource Management applications like Aprimo accelerate these tasks by implementing best-practice processes supported by a consistent data set.

**Figure 2. The six pillars of the marketing function**



## Conclusion: learning from other industries

The pharmaceutical marketing function needs to evolve rapidly to do more with less – a daunting journey, but one where the experiences of other industries can provide guidance. By systematically assessing the status of the marketing organisation against the Maturity Model, you can see which areas are in greatest need of improvement. You can then use the six pillars model to identify where the biggest maturity gains can be achieved for the least investment. In these ways the journey can be broken down into manageable steps.

<sup>1</sup> To request a full copy of the report, please send an email to Tim Dullely at [timothy.dullely@capgemini.com](mailto:timothy.dullely@capgemini.com)



# Key Account Management

**There is a proven way to deal with the increasingly complex task of selling pharmaceutical products within today's resource constraints.**

Our article on Marketing Maturity discusses the pressures on marketing directors to deliver more with less. The sales director's predicament is in many ways comparable.

Pharmaceutical companies' customer base has become far more complex than it was. Gone are the days when GPs' prescribing decisions were autonomous. Decisions are often made at multiple levels – in the NHS, for example, power is increasingly concentrated in the hands of organisations like the National Institute for Clinical Excellence (NICE), Strategic Health Authorities (SHA) and Primary Care Trusts (PCTs). Companies' sales efforts need to target these gatekeepers while remembering that the physician remains important in this process.

At the same time, the portfolio of products that the company has to sell is proliferating in both size and complexity, as portfolios increasingly include more niche products and biologicals. Purchasing decisions, too, are made on the basis of more demanding criteria, now with an increasing emphasis on outcomes.

In the past, that would have meant that more resources would be devoted to sales. Now, however, the sales function, like marketing, is the target of cost-saving initiatives. Sales directors would do well to consider Key Account Management (KAM), an approach that has already been proven in other industries that have faced increasing complexity in decision-making. For example, many FMCG

organisations have had to switch from dealing with a large number of retailers to targeting a very few influential organisations, and KAM has stood them in good stead. By introducing KAM, one global FMCG company cut its sales force costs by 30% whilst increasing revenues by 5% over an 18-month period.

In this article we'll describe the basic ideas behind KAM and their benefits for suppliers and customers, before moving on to describe how the ideas are starting to be applied in the life sciences industry, and in one specific pharmaceutical company.

## Basic KAM concepts

The core concept here is the key account: a company or other entity that is selected by the supplier for both its current and potential future value. KAM is the process of nurturing the relationship with this entity to deliver mutual benefits.

General benefits to the supplier include economies of scale through standardised handling of all customer areas in a central team. Effective KAM increases customer satisfaction in existing areas and opens up opportunities for cross-selling. The barriers to exit from the business relationship are greater. Finally, the supplier gains insights into the culture and future plans of the customer before the competition does.

For the customer, KAM provides a consistent approach to the selection and procurement of services and products, because there is a single



### From product to service to solution – the example of diabetes

Already in an area like diabetes we are seeing companies work with protocol managers such as NICE, and also other stakeholders, to enhance the patient's experience from identification to on-going disease management by providing additional services such as medical education programmes.

On being diagnosed with diabetes, patients are integrated into a support network, and provided with the latest delivery device and blood sugar monitor. The monitor will transmit readings back to the service provider so that trends in disease can be identified and information sent back to patients (for example via text message) to allow them to manage their disease pro-actively. In future, repeat prescriptions for insulin could be automatically fulfilled, with the drug sent directly to the home.

interface with the supplier instead of one for each product, or for each therapeutic area in the pharmaceutical context. Economies of scale in procurement result, together with improvements in areas like product support and training.

### Applying KAM in the pharmaceutical industry

How do these ideas and benefits apply to pharmaceuticals? The basic idea is simple. A team within the pharmaceutical company owns and co-ordinates the relationship with a key account such as a PCT, overseeing all dealings with them. This means that the relationship can move away from a focus on individual products and towards services, for example combining the product with training and support. In the future, the service focus could become a solution focus where the supplier offers a comprehensive range of products and services relating to a particular condition such as diabetes.

Even in the short term, KAM makes it possible to cement a stronger relationship between supplier and customer. Possible benefits include the ability to work together to strike the outcome-based deals that purchasers increasingly seek. Because individual sales are bundled together across therapeutic areas, deals that are more attractive to both parties can be struck.

Although KAM costs money it should save more. By targeting the true decision-makers it removes the obstacle to selling a given product so that less effort needs to be devoted to individual physicians.

### What is a key account?

A difficulty for pharmaceutical companies trying to implement KAM is that the identification of a key account is more complex than in many other industries. Logically it could be argued that in England there is only

one key account, the NHS, which is always the ultimate decision-maker. While that thought may generate insights, from a practical point of view it would not be a manageable or effective approach to forging a relationship with customers.

The practical answer to the question of what should be the key account is likely to vary from one region to another and also from one therapeutic area to another. For example, a region with a large elderly population is likely to have different needs from an urban area with a younger population; in the former, targets will be set and decisions made at PCT level. PCTs generally have a strong influence on prescribing habits in primary care, whereas in oncology part of the decision network will be above PCT level.

Clearly, the identification of key accounts, and their organisation, needs to be based on a detailed understanding of the individual customer context rather than an across-the-board policy.

### Early KAM activity in the industry

The solutions to problems about key account organisation will become apparent with time. Already a number of fledgling KAM initiatives are emerging, from which we can learn.

Early adopters are finding that the KAM approach is forcing them to expend considerable effort on understanding their influencing model fully. They are also having to make some hard decisions in terms of internal restructuring and changes in customer ownership and decision-making – a manager who formerly owned the customer relationship may find himself or herself becoming a resource directed by KAM.



# War Gaming

## Life sciences companies are increasingly using war games as a strategic tool for optimising their competitive position

### War gaming in a nutshell

The technique grew out of military war gaming, a method of preparing military leaders for unforeseen circumstances on the battlefield which was used in ancient Greece and perhaps even earlier. Since the mid-1980s, war gaming has been adopted across a wide range of industries including pharmaceuticals, insurance, aerospace and fast moving consumer goods.

For pharmaceutical companies, war gaming provides a structured approach for:

- Assessing and anticipating changes in the market and their impact on competitor strategies
- Pressure-testing strategies
- Developing and testing plans for mitigation of competitor activity
- Insulating new launches from external disruption
- Identifying gaps in knowledge and creating a defence plan
- Gaining cross-functional buy-in and alignment

Competitive activity can make or break both new launches and strategies to exploit existing products. Yet brand teams are often so busy fire-fighting that they do not take the time to stand back and evaluate their plans critically in the context of competitive activity. Whilst competitor intelligence may be distributed throughout the organisation, it is less often transformed into actionable plans. Different parts of the organisation are often exposed to different pieces of intelligence and respond in isolation.

The result of this lack of alignment is that the company misses opportunities to obtain competitive advantage or fails to respond coherently to a competitive threat. For example, release of new clinical data by a competitor will often result in an analysis by the medical team, but very seldom leads to a revision of marketing and sales plans.

### War gaming strengthens competitive insight, and more

Life sciences companies are increasingly turning to war gaming as a way of building competitive insight and strengthening their plans. This technique allows them to pressure-test existing strategies and plans by simulating the behaviour of competitors. The resultant insights allow the business to update its own strategies so that they can anticipate a comprehensive range of competitive scenarios.

A well-orchestrated war game workshop is a very effective technique for encouraging staff to put themselves into the competitors' shoes. Role-playing the part of competitors in the right environment is ultimately more powerful than any research on its own. Participants confront questions such as: "What are our competitors likely to do? What are their 'hot buttons', and their strengths and weaknesses?"

In addition to setting a brand up for success by creating a more robust and informed plan, war gaming has a second, equally important, benefit. It aligns key stakeholders with the plan and boosts their confidence in it, while ensuring a common understanding of challenges. War gaming teams emerge from the exercise with a well-founded confidence in their ability to improve the brand's competitive position.

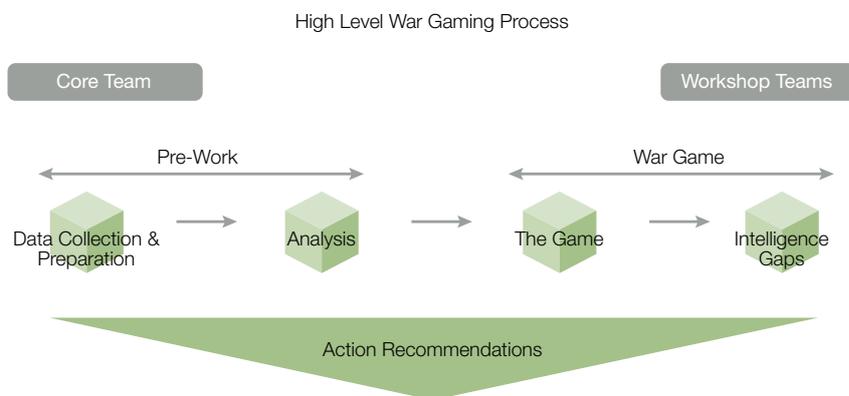
### Successful war gaming

To be effective, war gaming must be an interactive strategic exercise, dependent on human input rather than computer simulations but still based on real facts. The aim should be to deliver clear strategic options and tactics that feed into an updated plan to improve brand competitive position.

Figure 1 shows the four main stages of a typical process, two of which are classified as "pre-work". The data collection and analysis stages are critical to success, and require significant investment of time and effort. By contrast, the game session

Each group is given tools and techniques to enable it to get into the head of the competitor it is representing.

Figure 1. Main stages of the war gaming process



itself, and the identification of intelligence gaps, can typically be completed in an intensive one to two day period, depending on the number of competitors and topics covered. A fifth stage, action planning, is started during the war game but may be completed after the game finishes.

**Data collection**

The purpose of this phase is for the core team to develop company profiles and scenarios for the competitors to be included in the game, in order to ensure that the simulation will be meaningful. Useful inputs to this phase include market trends, clinical publications, promotional material, articles and press cuttings. The team should also interview a cross-section of the brand team about their perception of the competitors.

The resultant profiles must be fact-based, but they should also include cultural elements to help create a good understanding of the mindset and culture of the competitors: not only what they say, but what they do. For example, if one of the competitors were GSK, the profile might incorporate the fact that its chief executive has said that the company will allow regulators and other healthcare officials to have a say on the products it advances through development. The material

should be collected in such a way that it helps the participants develop an understanding of the competitor’s motivation.

The core team should also develop scenarios for each game. Scenarios are possible situations that may arise as a result of government or competitor activity. They must be carefully constructed to help identify risks, challenges and hot buttons.

**Analysis**

The analysis phase defines critical questions that the game needs to answer. It also lays the groundwork for presenting the findings of the game, typically by developing templates for presentation of the research, and for analysing data and feedback from the game.

**The game**

The workshop should involve a cross-functional team who actually work on the product under review, in order to ensure an accurate, good understanding of all aspects of the product and the business. A good briefing is also critical.

Participants are initially grouped so that each represents a given competitor. Each group is given tools and techniques to enable it to get into the head of the competitor it is representing. Groups are asked



to respond to a number of strategic questions for each of the scenarios in play for that competitor, deciding how that particular company would react.

### Intelligence gaps

After the competitive scenarios have been discussed and finalised by the groups, the whole team comes back together to identify challenges, risks and blind spots for their own company in the light of these scenarios. This session is critical and feeds into the action planning which will conclude the war game.

### Action recommendations

In the action planning session, everyone, armed with all the new perspectives on the competitor challenge, reverts back to their functional role. Focus moves to identifying actions to block competitor moves, attack competitors and defend the brand. Current strategies and tactics are reviewed, and then reformulated to address blind spots in the current plan. Actions to close up intelligence gaps are also agreed. Revised strategies and plans are presented back by the different sub-teams to the rest of the team for final input.

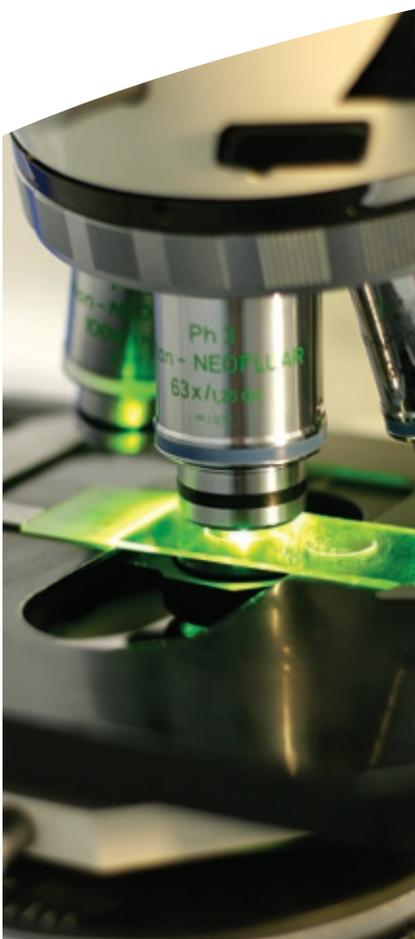
### Are you ready for war gaming?

In the words of its guru Dr Benjamin Gilad, war gaming “is neither a war, nor a game”. It is a serious strategic tool, and as such should only be used if the organisation is committed to making changes as a result of the outcome of the exercise, and is willing to invest the time required to implement change.

In the right conditions, however, a well-run war gaming exercise can give you an optimised strategy, a robust plan and a mobilised organisation.

#### Five tips for successful war gaming

- Invest time and effort in competitor reviews and scenarios up front
- Facilitate the session effectively, with structure, pace and momentum
- Select your team to secure cross-functional involvement
- Ensure middle and senior levels are represented
- Update and communicate plans after the event



# About Capgemini Life Sciences

**Capgemini's Life Sciences Practice** is a leading global provider of management consulting, technology and outsourcing services to the pharmaceutical, biotechnology, and medical devices industries. Established in 1993, the team globally includes 200 strategy and transformation experts who concentrate on this industry, plus an affiliated network of 2,500 consultants with significant experience. Recognised as a thought leader in this sector, Capgemini brings an insider's perspective to the challenges facing life sciences companies and employs a deep industry understanding to provide integrated global solutions for top-tier clients in the sector.

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