Major reinvention: a requirement for success

In the first half of this two-part supplement, Frank Wartenberg and David Ziedman explain why the time has come for pharma to adopt new commercial models if it is to succeed in a vastly changed environment.

The pace of transformation in the world’s leading pharmaceutical markets has increased dramatically in recent years, reshaping the very essence of pharmaceutical commerce. Unprecedented patent expirations, slowing innovation, and growing pressure on pricing and market access continue to roil the market; portfolios are shifting from primary care to specialist-based medicines; and traditional promotion is losing impact as payers become increasingly influential in the treatment decision.

Tried and true approaches to sales and marketing are still being tried, but are no longer ‘true’, sending profitably into decline. Short-term solutions – reducing promotional spend, increasing mergers and acquisitions, and cutting sales force size – have carried companies about as far as they can.

Frank Wartenberg helps large and mid-sized companies with their market entry strategies; reorganisation of sales structures across multiple channels; launch preparation; and customer value management across Europe, MEA, Japan and China. With a strong background in consulting, he has a deep understanding of market dynamics and their organisational implications for marketing and sales strategies.

David Ziedman has particular expertise in resource optimisation, call planning, compensation systems and issues around salesforce size, structure and product allocation. He draws on extensive experience of the sales function and a broader knowledge of the pharmaceutical industry to help companies optimise the deployment of their sales resources and improve sales productivity.

The view expressed in this supplement do not necessarily represent those of the publisher, editor or staff of PMGroup © 2009
The continued relevance of the industry’s homogenous business model of the last four decades is already in doubt. As the factors at work today continue to affect markets over the next 10 years, the situation will only worsen.

In the midst of these unprecedented changes, manufacturers are left to consider the very nature of their commercial model. Few have completely transformed their go-to-market strategy; some are not even contemplating the change; many are simply doing ‘less of the same’. Overall, among the top 30 companies and across the eight major mature markets, there are still over 200 organisations that have yet to grapple with the obsolescence of their current commercial model. Those that begin now to develop a new commercial model (NCM) that is adapted to the new market realities will be able to reverse the current downturn. The alternative – maintaining the status quo – is no longer a viable option.

**NEW MARKET SEGMENTATION**

New IMS research provides important insights into where an overhaul of the commercial model is most needed; where investing will make a real difference; and the types of competencies and structures that will ensure success. In a major departure from traditional approaches to segmenting the market, the study identified the value proposition and cost burden of more than 80 therapeutic areas across the eight major world markets – the US, Japan, France, Germany, UK, Italy, Spain and Canada. The value proposition reflected the level of patent protection in place combined with a recognised, objective measure of innovation; cost was a function of impact on the nation’s healthcare budget relative to the degree of payer influence in the class. When measured against these variables, it was possible to assign each therapeutic class to one of three market segments:

- **Commodity**: Classes with products that are minimally differentiated and where payers have a great stake in prescribing decisions.
- **Transitional**: Classes between the two extremes likely to undergo significant change. In many countries, this is the largest segment.
- **Differentiated**: Classes that are characterised by significant product innovation and high perceived differentiation where no generics are available and payers exert less influence on treatment decisions.

As therapeutic classes mature and patents expire, they naturally migrate from the differentiated segment to the transitional segment and finally into the commodity.
segment (Figure 1). In the UK, for example, the market is currently split into 49 per cent commodity, 26 per cent transitional and 25 per cent differentiated. As generic competition grows, many classes in the transitional segment will shift: by 2012, 79 per cent of the market will no longer be patent protected, compared to 62 per cent in 2007.

The mix of segments varies by country and by therapeutic class within a country. Cholesterol regulators, for example, are a large commodity segment class in Germany but a small transitional segment class in Japan — meaning that each company will need to individually assess the urgency of new commercial models at a local portfolio level.

A further key distinguishing feature between the segments is their receptivity to promotional activity, with the differentiated being most responsive and the commodity, least. What is also clear is that companies are overspending within the commodity segment, where the share of voice paradigm is largely obsolete and return on investment well below par. Overall, by improving promotional productivity the industry could save $15 billion — money that could be better allocated elsewhere (Figure 2). Every company will need to assess its own level of expenditure — and its strategic options — before undertaking the development of a new commercial model.

**CENTRE DECISIONS**

Thus far, companies have made the greatest strides in applying efficiency and effectiveness tactics to their go-to-market strategy. However, as they look to optimise performance within each of the segments they must also consider other activities that engage new stakeholders and extend the value proposition including the development of a ‘whole product’ approach that goes beyond simply selling a tablet to producing a healthy outcome.

Each of these three areas represents a tactical avenue within a broader strategy framework that can be employed to varying degrees to suit the particular circumstances of a geography, therapeutic area, and company. In a commoditised market, for example, there may be heavy reliance on improving efficiency and effectiveness and gaining cost leadership, whereas a focus on strengthening stakeholder relationships may be more appropriate in the differentiated segment.

Techniques to consider in each of the areas include:
• Efficiency and effectiveness: Promotion optimisation; new marketing execution technologies; enhanced stakeholder segmentation and promotional techniques; launch excellence; and high-quality, impactful stakeholder interactions
• Stakeholder relationships: Integrated stakeholder teams/stakeholder-centric teams; integrated geographic teams; situational or opportunistic teams; and specialised teams.

Creating value
Stakeholder solutions ranging from customised patient education, compliance programmes, e-tools, and social networking materials to dash boarding and value-based focus groups; stakeholder resources such as trial offers and coupons, healthy outcomes programmes, and health calculators; extensions through value-chain aggregation and a movement to services or non-prescription offerings; and industry partnerships with governments, healthcare organisations, disease awareness groups, payers and employers to focus on healthy outcomes.

A FIVE-STEP PROCESS
Clearly the industry as a whole is about to embark on a transformation that stands to be one of the most sweeping and significant in its history. We believe companies need to approach the challenge through five distinct areas of work: diagnostic assessment, strategic planning, organisational excellence, enabling capability, and commercial transformation.

1. DIAGNOSTIC ASSESSMENT
A diagnostic assessment creates the proper baseline for planning, with a view to understanding the current landscape, gaining insight into each stakeholder’s agenda, and modelling the maturity of the portfolio across therapeutic areas and countries, by segmenting into the commodity, transitional and differentiated segments and measuring ROI for each.

2. STRATEGIC PLANNING
The goal here is to lay out the strategic options and then blueprint and plan the selected model by considering future changes to the landscape; deploying a country-specific approach with promotional investments attuned to the right set of decision makers; structuring thinking around the NCM Strategic Framework with appropriate adjustments to the levers of each area of the triangle; planning to reduce/reallocate promotional spending and integrating all external-facing functions in the process. Ultimately, companies will need to determine the most suitable go-to-market approach that supports their strategy, taking into account their current and future portfolios, the pricing and market access conditions, their health economics and outcomes research documentation and the results of thorough cost/benefit analyses.

3. ORGANISATIONAL EXCELLENCE
To determine the commercial organisation that is fitted to the purpose and sized to the current and future environment, companies will need to understand the optimal size for the commercial organisation, the functions that need to be put into place to cover emerging stakeholders, and the optimal marketing expenditure and its allocation across the channels and stakeholders.

4. ENABLING CAPABILITIES
Changes to the commercial model have the potential to touch upon a wide range of business processes and IT systems within the organisation - many of which may need to be altered to support the new approach. The goals of this phase are to implement or update the capabilities needed to support the NCM, outsourcing as needed to optimise competencies. Typically, needed changes to these supporting systems and processes are identified in the strategic planning stage, and work proceeds in parallel with the other planning and implementation phases of adopting a NCM.

5. COMMERCIAL TRANSFORMATION
Successfully introducing an NCM into an organisation requires typically new ways of working and therefore the skilful use of each of the levers within a change management framework. When proven change management principles are applied to the process, companies can minimise the length and depth of performance disruption and increase the resulting performance. Fortunately, with the right approach, employees can be guided along a path from awareness to self-concern, to mental ‘tryout’, to hands-on trial, and finally, to acceptance.

SUMMARY
Pharmaceutical companies have a challenging journey ahead of them with a broader, more complex scope than they have previously encountered. Each company must devise an approach that suits its portfolio, each local environment, and its threshold for change. Those that fail to implement their new model with appropriate attention to the change management process will take longer to realise the benefits and ultimately, will not optimise their performance. Companies that begin now with the right base of information, a strategic focus and a comprehensive planning framework can successfully undergo the transformation and emerge with models that are better suited to the environment and changing times.

To learn about the way in which IMS can help you to adopt a new commercial model, contact Frank Wartenberg at FWartenberg@de.imshealth.com or David Ziedman@nl.imshealth.com
Launch excellence: facing different challenges

Once pharma has revised its commercial models, it needs to reappraise its approach to new product launches. Sarah Rickwood explains...

Sarah Rickwood has in-depth knowledge of international industry issues, gained from 14+ years experience as a pharma consultant through working with most of the world’s leading pharma companies in the US, Europe, Japan and emerging markets. She has extensive experience of managing multinational projects, providing comprehensive and critical guidance in the pre-launch and launch periods for key brands.

At a time when fewer new pharmaceutical products are coming to market, companies and investors pin extremely high hopes on those that do. Launches now face a fundamentally altered environment: different customers wield power over whether a launch succeeds or fails; companies must take different approaches to market for excellence; and different timescales – in which success and excellence are measured – need to be adopted.

The environment has fundamentally and irrevocably changed, in two crucial ways. Payers’ control over the use of new medications has increased significantly in most
major markets. And in almost all primary care therapy classes, and an increasing number of specialist classes, there are now many generic alternatives. For launch to achieve excellence, companies must address four truths:
• The environment is different
• Customers are different
• There are different approaches to market
• And different timescales

1. DIFFERENT ENVIRONMENT
Companies have recognised the shift in power from individual prescribers to non-prescribing customers, particularly payers. That’s why they’ve shrunk sales forces – and detailing volumes have declined as well.

Generic first line treatment paradigm in primary care
Once effective generic therapies are available, they dominate first line treatment. In this environment, products are increasingly launching into a second line position. With this primary care environment, it’s unsurprising that excellent launches are more likely to be specialist-driven. Fewer specialist-lead areas have genericised, and launches with strong first line positions are still possible. This situation will, however, last only as long as the patents do.

A new commercial model
As already noted in this supplement, changed environment requires a changed business model – principally:
• Greater attention to payers and to gaining market access, in terms of developing evidence, preparation pre-launch, and people focus against payer activity
• Greater investment in outcomes trials before, during and after launch.

New markets
The specialty market is the dominant growth driver of the global pharma industry, and this will continue, with oncology alone forecast to the world’s leading pharmaceutical sector with some $70-80bn worth of sales by 2011.

2. DIFFERENT CUSTOMERS
So companies must now address non-prescribing customers, often as a priority over prescribers. They include patient and advocacy groups, HTAs, payers and pharmacists.
For launch excellence, companies must define their ideal outcome by payer type, before, during, and after launch, and plan ahead and effectively to achieve those goals.

Ensure the commercial model supports the launch
• Step 1: Build approval. At national, regional or local levels, payers must grant access on the right terms
• Step 2: Build acceptance. Payers are not the only advocates crucial to strong product adoption. Clinical opinion leaders, international, national and local, patient groups, and clinical organisations are all important builders of acceptance, and may also influence payer decision making
• Step 3: Build adoption. Once approval and acceptance have been built, it’s possible to build adoption at the individual prescriber-level.

Seven steps to address payers effectively
• Companies must ensure that they address each of these seven steps in a timely, full and effective fashion
• Identify and understand the funding flows for the disease area
• Identify the decision makers controlling these funds – or potential future funds
3. DIFFERENT APPROACHES TO MARKET
The new environment will also mean different expectations for peak sales, speed of penetration, and market share for new launches. Future launches, whether specialist or primary care, will enter market environments where the strategic imperative will be countering the restriction of market potential. Here, rigorous examination of the potential-to-grow markets is necessary in the strategic launch plan.

Companies with launches which are effectively entering the second line market must seek to expand this, by improving monitoring of first line therapy, better and early identification of failures, and building a strong case for second line use.

Future successful launches will adopt strategies that combine segment definition with market expansion. They must increasingly focus their approach to expanding diagnosis levels and improving speed to diagnosis in a specific segment within the market.

4. DIFFERENT TIMESCALES
Launches establish their longer-term trajectory early on, and while it is not impossible to improve trajectory after the first six months, it is something that only a minority of launches achieve. The elements that drive an optimal first six months are complex and interdependent. Delivering optimal readiness across all functions and activities is crucial, and companies must ensure that it is not left to chance.

Prescribers who will drive the first six months of launch
Not only do innovator doctors prescribe earlier, they also prescribed more, and continued to prescribe more, for up to 20 months post launch.

Innovators and early adopters have significant impact in the first six months of launch, contributing in some case, more than half of all prescriptions. After the first six months, as the late majority and conservative prescribers start to use the launch, the proportion of total prescriptions from each group more closely matches the number of doctors in that group.

Patients who will drive the first six months of launch
In the first six months, acquisition of new, switch and add-on patients is the key to growth. Most launches grow by a mixture of new plus switch prescriptions, but excellent launches seem to have a higher proportion of switch patients in the first six months than non excellent launches.

Excellent launches are those which are extremely good at preparing the market in such a way that doctors are able to identify pools of existing patients they want to switch, aware of the benefits of the launch medication, and motivated to enact the switch.
Pre-launch preparation
Delivering optimal readiness across all functions and activities is absolutely crucial. A systematic approach is needed, with comprehensive structures for addressing the following elements - the comprehensiveness of launch readiness, the timeliness of launch readiness, the quality of launch readiness and the relevance of launch readiness.

SUMMARY
Companies planning for an excellent launch must take into account the fact that they are in a different environment, with different customers, different approaches to market and different timescales if they are to achieve longer term success. Knowing this, they must build a launch with the right patient segmentation strategy, the right approach to payers - both at a strategic and a tactical level, optimal preparation and planning across all aspects of launch readiness. The plan must also explicitly recognise the extreme importance of the first six months of launch, and factor in the drivers that are different in this time.

In the future there will still be excellent launches, but the rules they will play by will be very different.

To learn more about reappraising your approach to product launches, contact Sarah Rickwood at SRickwood@uk.imshealth.com