



Kinapse White Paper

New Commercial Realities

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Faced with a changing healthcare environment and the prospect of diminishing commercial returns, the pharmaceutical industry has recognised that traditional commercial models based on sales force arms races are no longer viable. In order to adapt to new commercial realities that require more complex decision-making processes and involve a greater number of stakeholders influencing at a range different levels, pharmaceutical companies must undertake a fundamental and systemic rethink of their commercial operations.

This paper provides insights into the changing healthcare environment and describes how key stakeholders in the space are evolving. We discuss the key implications of this changing landscape for pharmaceutical commercial operations, and provide an actionable approach for implementation of new commercial models that considers future roles & competencies, governance and organisational structure and size.

Pharmaceutical markets are undergoing fundamental change

The much-vaunted post-blockbuster era is no longer a prophecy for the pharmaceutical industry, with many key products facing imminent patent cliffs. BMS and Eli Lilly are just two companies contemplating future revenue streams bereft of billions of dollars, owing to loss of exclusivity of Plavix and Zyprexa respectively – in each case without obvious replacement. Across the industry it is estimated that \$97.7bn of US 2008 sales are potentially at risk to generics through to 2013¹. For BMS and Lilly, this could represent as much as 30% of sales.

In parallel, the rapidly changing healthcare environment with increased pressure on costs is changing the rules of the game for pharmaceutical companies, rewarding innovative medicines and a focus on unmet medical need whilst limiting the prospects for me-too drugs. As a result, although Primary Care currently represents 60% of global market share, global market growth is predominantly being driven by Secondary Care (Figure 1).

This trend seems set to continue as the number of NME launches are increasingly dominated by specialty products. 17 of 2009's top 20 new products are speciality care focused, with no Primary Care products at all appearing in the top 10 (Table 1).

Big pharma are also aggressively pursuing externally oriented strategies aimed at bolstering pipelines with speciality products, as exemplified by the high-profile deals over recent years involving AZ/MedImmune/CAT; Roche/Genentech; BMS/Imclone and Lilly/SGX.

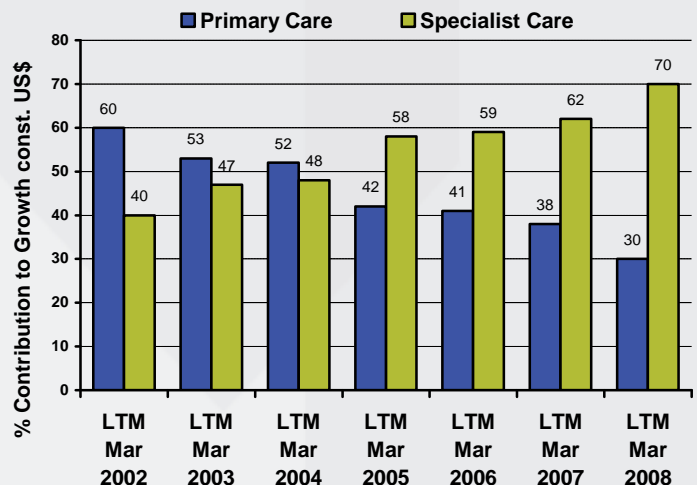


Figure 1: Relative contribution of Primary and Specialist Care to global market growth

Source: IMS (LTM = last twelve months)

The changing environment is also resulting in the emergence of different organisational models, such as Category Leaders (with focus on selected Therapeutic Areas) and BioPharmas (blending global operations from big pharma with entrepreneurship and innovation from biotech). But what is clear is that in order to take full advantage of the changing commercial environment, big pharma might need a footprint in both Primary and Secondary Care markets.

This paper examines the commercial realities and operational implications of these two very different markets and seeks to understand the extent to which the critical success factors for each market are mutually compatible.

Table 1: Top new products of 2009

(based on 2014 sales potential)

No.	Drug	Company	2014 Sales (\$MM)
21	Aprala	WYE	400
20	Cordaptive / MK-05248	MRK	400
19	Recentin	AZN	400
18	Axitinib	PFE	400
17	V-710	MRK	400
16	Remoxy	KG	450
15	Linaclotide	FRX	450
14	Certriad	ABT / AZN	500
13	FTY720	NVS	550
12	CP-690,550	PFE	600
11	Apixaban	BMV / PFE	750
10	TRA	SGP	750
9	Dimebon	PFE / MDVN	750
8	Solanezumab	LLY	750
7	Benlista	GSK	890
6	Simponi	SGP	1,000
5	Brilinta	AZN	1,200
4	Bapineuzumab	WYE	1,430
3	Telaprevir	VRTX	1,500
2	Denosumab	AMGN	2,575
1	13vPnC	WYE	4,150
			\$ 20,295

Key messages:

- Whilst Primary Care products still account for greatest market share, the specialty segment is increasingly important and will be even more so in the future

- Neither can be ignored in terms of commercial opportunities

Pharmaceutical companies must adapt to changing commercial realities

For decades, pharmaceutical commercial strategies were principally based around engaging a well-defined and rather limited set of stakeholders – primarily prescribers – in a sales process based on 1-to-1 transactional relationships.

This is no longer the case. Decision-making processes are more complex, involving more stakeholders influencing at different levels. And the picture differs markedly for Primary Care and speciality products.

Primary Care – limited scope for innovation; evolution toward a service proposition

Tomorrow’s success in Primary Care will look very different from previous Primary Care successes such as arms races and battles for share of voice. The challenges are likely to be multiple and exist along the lifecycle of brands.

New Primary Care products are unlikely to demonstrate the degree of innovation that justifies first line indication(s) and premium pricing. More realistic outcomes will be either achieving this goal for a very narrow indication/set of patients, and/or uptake as second or third line therapy after generic and cheaper alternatives. As an example, Novo Nordisk’s Victoza has recently been recommended by the UK’s healthcare cost effectiveness body, the National Institute for Health and Clinical Excellence (NICE), for treatment of diabetes patients, but only under certain conditions and for selected forms of the disease; and this despite proven benefits both for lowering blood sugar and promoting weight loss².

Generic substitution is an increasingly common feature of Primary Care markets. A recent study in the UK and Germany, found that in some therapeutic classes such as depression, >90% of first line patients could be prescribed generically (Figure 2). Proposals to increase the prescription of cheaper generic medicines for Primary Care have recently been set out in the UK – currently, around 83% of prescriptions issued by the UK’s National Health Service (NHS) are for generic drugs, with the new proposals recommending that this figure should rise by around 5%.

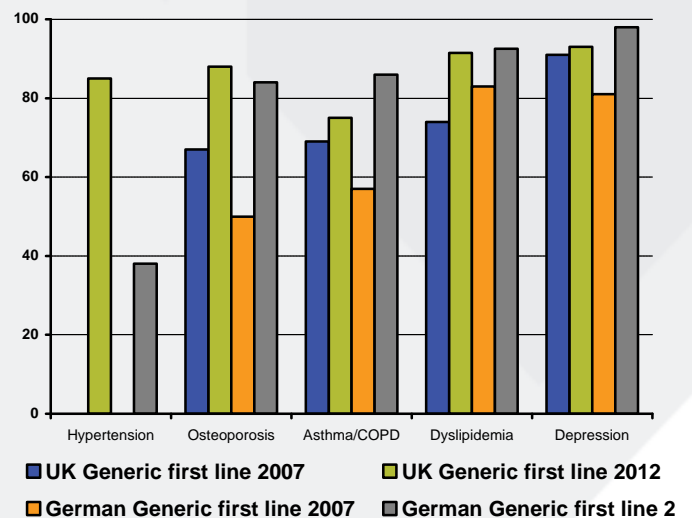


Figure 2: Percentage of first line patients receiving generic medicines

Source: IMS

Recognising the limited scope for medical innovation in Primary Care, pharmaceutical companies are moving 'beyond the product' towards holistic healthcare solutions that focus on improving overall patient outcomes, such as development of patient management programmes and tools to improve adherence and compliance. For example, Novartis is currently piloting an advanced 'chip and pill' concept for the antihypertensive Diovan, whereby each pill contains a tiny microchip that alerts patients by text message if they fail to follow their doctors' prescriptions³. Early results from a 20-patient pilot study demonstrated an increase in patient compliance from 30% to 80%.

Other fields being exploited in the development of healthcare solutions are those relating to prevention and diagnosis. These are areas that are likely to receive increased focus over the next few years as healthcare providers place increasing emphasis on prevention policies in attempts to reverse (or at least slow) the growth in overall healthcare spending. The NHS has made prevention a central theme of its manifesto, *NHS 2010–2015: from good to great, preventative, people-centred, productive*, and has recently made available a bank of self-care knowledge and resources. Companies are also beginning to exploit developments in healthcare IT in the area of prevention and diagnosis. For example J&J's LifeScan has developed a smartphone app that allows diabetes patients to upload and manage their glucose information on their mobile phone or PDA.

Patient management programmes can also help to maximise the value from existing and mature products, alongside payor relations and cost management initiatives. One successful example of these latter initiatives is contracting – where health insurance funds and manufacturers agree fixed contracts based on price and volume. This is currently proving highly effective in Germany.

It is clear that this new Primary Care service proposition will involve a whole new ecosystem of providers along the care and service continuum. Companies seeking to implement this proposition will therefore need to evolve from existing integrated Primary Care business models towards new models that enable the management and coordination of the diverse range of stakeholders spanning treatment pathways and brand lifecycles.

Secondary Care – demonstrating the value of medicine

Demonstrating the economic value of treatment to secure market access is the key single success factor for a speciality care product. Whilst negotiations around price do occur in Primary Care through discounting schemes and contracting, issues relating to cost-

effectiveness and risk/benefit are of more fundamental importance for selling in Secondary Care.

Increasingly many companies are experiencing to their cost that clinical benefit does not guarantee reimbursement – even in therapy areas with high unmet need, such as oncology, as evidenced by recent guidance from NICE recommending against reimbursement of Merck KGaA's Erbitux, Bayer Schering Pharma's Nexavar, Roche/Genentech's Avastin and Wyeth's Torisel for treatment of patients with kidney cancer.

The need to demonstrate value is becoming an imperative for almost all key pharmaceutical markets. While the UK, Germany and the US are generally thought to be a step ahead in terms of health technology assessment, others are quickly catching up and implementing new rules for market access. For example, the remit of France's HAS (Haute Autorité de Santé) has recently been extended to include economic assessment of health services, whilst in Spain the definition of strict protocols by disease is expected to be implemented at a regional level in 2010.

The two key dimensions of healthcare value are i) the overall cost burden (direct and indirect) to society and ii) the overall benefits (clinical and others) expected (Figure 3) and the nature and emphasis of the value proposition for speciality products is likely to differ across therapeutic areas.

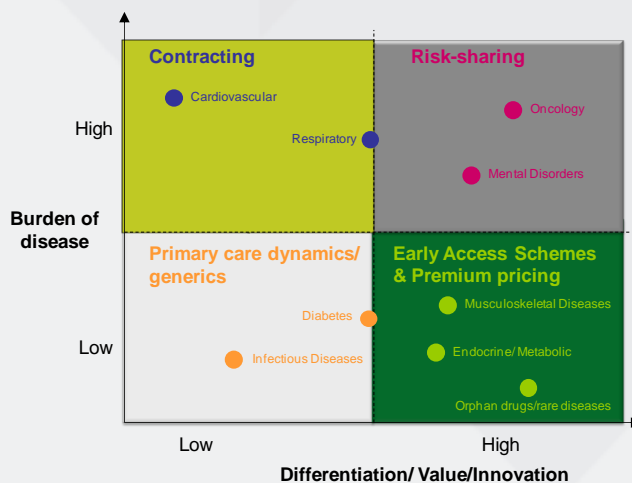


Figure 3: Value-based therapy area evaluation

Therapy areas with high cost burden and limited scope for differentiation will show similar dynamics to Primary Care markets with high focus on cost reduction; on the other hand therapy areas with greatest potential for innovation (typically high unmet need) are more likely to support premium pricing of products that demonstrate differentiation and expected benefits.

The increasing need to demonstrate value is forcing the industry to consider the issue of reimbursability earlier in the development cycle in order to accelerate access of innovative medicines and maximise value for patients and society as a whole. [‘Real world’ methodologies](#) have the potential to redefine the design and conduct of clinical trials and which could significantly bring forward the ability to demonstrate clinical benefits and value in a real world setting⁴.

And the requirement to demonstrate value won’t end at product launch. Products that are able to demonstrate continued long-term benefits through the accumulation of real world patient data are likely to achieve higher volumes. It is also expected that for many specialist drugs, approval for indications will be staggered overtime with initial narrow labels becoming expanded as evidence is accrued.

In recent years risk-sharing schemes designed to link market access and reimbursement to clinical and cost-effectiveness outcomes have been trialled for a number of speciality products. For example, in the UK Janssen Cilag agreed to link the funding decision for its myeloma drug Velcade to the response rates observed in a selected patient population; more recently, NICE granted access to UCB’s Rheumatoid Arthritis drug Cimzia on the premise that UCB provide the first 12 weeks of treatment for free. Meanwhile in Italy Bayer Schering Pharma and Pfizer recently agreed to subsidise treatment with their respective oncology drugs Nexavar and Stutent up until such point that treatment proves effective. Such schemes represent innovative approaches to the problems of healthcare rationing and illustrate how manufacturers can work in collaboration with payers to demonstrate cost-effectiveness in high cost or controversial health interventions.

Key messages:

- The commercial focus in Primary Care is extending to service beyond the product, whilst in Secondary Care there is a clear emphasis on demonstrating value

- The meaning of ‘value’ may differ according to geography or therapy area but in all cases it will need to be considered early in development with a continuous focus throughout the lifecycle, all in collaboration with payers

The new commercial realities are driven by changing customer dynamics

The increasing importance of health economics in achieving market access is impacting customer dynamics in both Primary and Secondary care, shifting the emphasis from prescribers towards patients, payers and Health Technology Assessors (HTAs).

With access and reimbursement policies and protocols being formulated at national level, and managed and implemented by regional and local bodies, the role of prescribers will become more akin to that of gatekeeper, with activities constrained by prescription guidelines. In Germany for example, Sick Funds already publish positive lists, while in the UK the implementation of NICE guidance is soon expected to become mandatory. Meanwhile in Spain the definition of strict protocols according to disease type is shortly expected to be implemented at a regional level.

In principle this will enable a wider range of healthcare professionals such as nurses and pharmacists to adopt prescribing roles. For example, recent regulatory changes in the UK now allow independent prescribing nurses to prescribe medicines outside licensed indications.

Patients are also gaining greater influence in terms of access to and demand for medicines, through the growing power of patient groups and associations (see NICE decision reversal for Herceptin and other cancer drugs for terminally ill people; an online petition is currently been used to influence favourable NICE guidance for BMS’ and Novartis’ CML new drugs in the UK⁵).The European Medicines Agency (EMA) have recently released a reflection paper⁶ regarding the structured involvement of patients and consumers in the agency’s activities, following an initial report on the topic in March 2008.

These changing customer realities will have a significant impact on the future commercial capabilities required by the pharmaceutical industry. From our experience, these capabilities – some of which already exist, some which require reinforcing and others which need to be built from new – can be categorised into those that are customer-facing and those that are enabling:

Customer-facing

- Key account management for payers
- Key account management for providers
- Political lobbying
- Contracting and tendering
- Clinical education
- KOL management
- Patient engagement

Enabling

- Health economics
- Clinical trials and epidemiology studies

Table 2 summarises the relevance of each of these competencies for in the evolving stakeholder landscape.

Table 2: Future commercial capabilities from key stakeholder perspectives

	Capabilities								
	KAM (Providers)	KAM (Payers)	Lobbying	Contracting & Tendering	Clinical Education	KOL Mgmt.	Pat. Engage.	Health Economics	Clinical Trials
Stakeholders									
Governmental Ministries			✓					✓	
National commissions		✓	✓					✓	✓
National HTA bodies		✓						✓	✓
National Payers / Insurers		✓		✓				✓	✓
Regional payers or health bodies		✓		✓				✓	✓
Purchasing Groups and Wholesalers				✓					
Hospital / Primary Care Unit Management	✓							✓	✓
KOLs						✓		✓	✓
Physicians	✓				✓			✓	✓
Nurses	✓				✓				
Pharmacists	✓				✓			✓	✓
Media							✓		
Patients & PAGs							✓	✓	✓

For individual organisations, the specific mix and content of these capabilities will depend primarily on the nature of their business and the key stakeholders involved. Key considerations will include the emphasis on Primary vs. Secondary Care, therapy area and maturity of the product lifecycle.

In general, for brands with little potential for differentiation we view payers and national/regional and local authorities as the key decision makers in respect of cost management, alongside community healthcare providers (GPs, nurses and pharmacists) for service provision (including patient management and compliance). On the other hand, demonstration of value for specialist products will require engagement of a network of stakeholders by cross functional teams. Health economists will advise on pricing and reimbursement, provide input into the design of clinical trials for candidate molecules and support health authorities planning future expenditure by evaluating epidemiological data; Key Account Managers and Lobbyists will negotiate with payers and HTA agencies; and Therapy Areas/Disease specialists will support providers with a deep knowledge of how to manage patients throughout the disease lifecycle. Table 3 summarises the key differences in the capabilities involved in selling to Primary Care and Secondary Care.

Table 3: Selling skills focus for Primary and Secondary Care

Stakeholders	Focus for selling to Primary Care	Focus for selling to Secondary Care	
Payers	Cost management, rebates, discounting, contracts and tendering	Value based pricing, outcomes-based, Risk sharing schemes, Expenditure planning & budget impact	
Providers	Spec. (incl. KOLs)	Little focus	
	GPs	Practice and patient management	Endorsement, Scientific programmes, factual specialist advice, measurement of outcomes, facilitate access/sharing with peers/professionals
	Nurses	Patient management	Educational programmes, disease and patient management and monitoring
	Pharmacists	Pharmacy benefits and patient management	Educational programmes, disease and patient management and monitoring
Patients	Compliance and persistence	Education, community engagement, disease management programmes	

The deployment and relative emphasis of these capabilities will also depend on the stage in the brand lifecycle. We have already highlighted the importance of early demonstration of value to provide payers with confidence of cost-effectiveness for new products. This might imply early involvement of payers and health authorities into development programmes. For example in December 2007, Novartis disclosed that it commissioned NICE to advise the design of a Phase III trial to measure the efficacy and cost-effectiveness of an experimental new drug; in 2008, GSK piloted the involvement of payers in selecting compounds to progress through its pipeline. Such initiatives are likely to be welcomed by HTAs such as NICE, which is calling on the industry to do more to work alongside them on cost-effectiveness⁷. The European Innovative Medicines Initiatives (IMI) is also bringing together several pharmaceutical companies to collaborate on developing common approaches to diagnosis, treatment and ongoing management that delivers best efficiency and effectiveness for purchasers, with initial focus on areas of high need such as diabetes, neurodegenerative disease and cancer.

Risk sharing and patient access schemes are also likely to increase in popularity as a way to secure positive appraisals which might not be forthcoming on the basis of currently available evidence. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is even beginning a public consultation on proposals to make certain new drugs available to patients before they are formally licensed, with a view to having such a scheme up and running by the end of 2010.

Once a brand reaches the market, the focus will shift from establishing confidence in value to establishing confidence in risk/benefit. Accumulated real world patient data can be used to generate evidence to support confidence in risk benefit whilst also providing insights that lead to expansion of initial product labels into new indications. Lifecycle management is therefore likely to involve a series of smaller launch waves as new approvals are staggered over time. Furthermore, as confidence in product value and benefits become established, sustained uptake will depend on adding further value through tools and services for patients and providers.

Key messages:

- Changes to the healthcare environment will impact the relative importance of stakeholders and their needs, with key roles expected for payers and patients

- This will in turn dictate a new set of core commercial capabilities, which although common in most parts for Primary and Secondary care, will differ significantly in the way they are deployed (mix and content) across therapy areas and product lifecycle

The changing healthcare environment demands new organisational realities

Recognising the need for future commercial capabilities and understanding how specifically they will support different selling models across different therapy areas and product lifecycles is in itself a challenging task. However, taking the next steps towards establishing an organisational structure that effectively delivers these capabilities is even more demanding. Organisational (re)design initiatives typically involve significant change and are best managed using a structured approach that considers in turn:

- Roles required to accommodate future capabilities along with enabling skills and tools
- Governance mechanisms to ensure efficient effective commercial operations, including:
 - i) Local governance: what is the reporting structure and interfaces and what are the synergies to be had across functions, therapy areas?

- ii) Geographical alignment: are national, regional and local structures all necessary?
- iii) Global governance: how should responsibilities be divided between the global/regional and local organisations?
- iv) Organisational scale: what is the appropriate size for each of the different functions?

Whilst there is clearly no single optimal solution in respect of each of these considerations, in our experience there are a number of common elements.

Roles, skills & tools

For an industry which has built huge success on mass marketing and transactional selling, implementing these new capabilities will without doubt require new roles and significant re-tooling. A cursory glance at the recruitment sections of the specialist press, indicates just how many new roles are being hired, including: Healthcare Policy Product Expert (Germany), Market Access & Patient Group Manager (Holland), Tendering Manager (Germany), Regional Medical Liaison Manager (UK), Strategic Funding Manager (Spain), Field-based Market Access Team (Spain), Head of Key Account Management Payers (Spain) Healthcare Development Manager (UK), Market Access Solutions Manager (UK), Public Affairs Manager (France).

It is interesting to note that most of these new roles relate to some extent to handling relationships with payers, health authorities and patients – the new breed of customers. Such relationships will require new skills and tools, with a major focus on developing and delivering value propositions (combining content development with a key role for health economics and relationship-based selling), influencing, managing networks and team-work. This represents a fundamental change in mindset for the industry and it is conceivable that many organisations will find it difficult – or even impossible – to adapt. However, this also creates an opportunity for organisations to review the existing talent pool and if necessary, bring in new blood – perhaps from other industries with greater experience of relationship-based selling models.

We believe that four key roles are required in any future commercial organisation:

- *Health Managers* (applicable to both Primary and Secondary Care) typically responsible for maintaining relationships with payers and national government and health officials. Health Managers will be involved in lobbying and negotiating for market access and reimbursement, and maintaining close relationships across national

healthcare systems. These should be relatively senior roles in order to establish the trusted peer-to-peer relationships at the appropriate level of influence.

Most payers are keen to work with pharma companies to provide guidance on how companies can better meet payer needs. Engaging payers in qualitative research and through payer advisory boards are two common approaches to securing such input. However, there remains scope for pharmas to significantly strengthen these interactions by improving the quality of communication, seeking a better understanding of payer needs and providing more relevant data and information.

- *Key Account Managers* (predominantly Secondary Care) typically responsible for key accounts (in the case of specialist products) and the local implementation of market access strategy with regional and local payers and health authorities. Key Account Managers will be involved in managing and coordinating a complex network of stakeholders and influencers both within and outside of the account, likely to include healthcare professionals, financiers, patient groups, disease network, local HTAs and managed care units.

Key Account Managers require competences across a wide range of non-scientific skills and will be expected to maintain detailed knowledge of all aspects of individual accounts. This represents a significant challenge since very few traditional sales reps currently have the required skill set, nor is there a significant pool of suitable expertise outside of the industry. Therefore there is likely to be a heavy emphasis on training and re-training involved in developing the new Key Account Manager roles.

- *Sales Specialists* (applicable to both Primary and Secondary care) have perhaps the closest similarity to the traditional sales rep model. Sales Specialists will be responsible for direct product selling, and will also be expected to provide detailed product information as well as ongoing service and support to providers in caring for patients. Depending on the specialist nature of the product, this may involve a strong educational component. Delivery of Continual Medical Education (CME) is a contentious topic, both in terms of how it is funded and how it addresses the real needs of physicians. Meanwhile codes of practices have been tightened in order to remove possible bias from promotional activities and to introduce greater objectivity.

As well as detailed product knowledge of their own and competitors' brands, Sales Specialists will also

be expected to provide expertise in pathways of care, their outcomes and economics. The current remit of MSLs (Medical Sales Liaisons) falls in this category. Furthermore, in view of the overall trend in Europe towards regionalisation of care, Sales Specialists will increasingly be expected to support practice physicians with local budgeting and commissioning, as well as playing an important role in supporting epidemiology studies. These latter activities will be especially important in Primary Care products, where the educational element is far less important.

- *Patient Liaisons* (predominantly Secondary Care) is a relatively new requirement that has emerged in recognition of the growing importance of patients as a key customer group. The industry is also witnessing transformational change in the channels being used to engage patients, as Web 2.0 technologies⁸ – and social media in particular – look set to replace the classic push strategies via magazines, websites and DTC approaches, and enable real dialogue to be established. However, as with payer relationships trust is a critical parameter for engaging with patients, and therefore the industry must rid itself of the baggage associated with decades of bad press in this regard.

There are clear actions that the industry can take to improve the situation, such as ensuring 'relevant' information is included in every communication; customising engagement to the specific needs of patients according to their position on the treatment pathway; adopting transparency with regard to 'negatives' such as potential side-effects; and extending the focus of communication beyond the medication to recognise the whole condition. And perhaps most importantly of all, genuine engagement will mean listening before 'selling'.

2009 was something of a trial year for the industry in terms of use of technologies such as Twitter, Facebook, YouTube and blogs. Through their online community, Children with Diabetes, J&J are promoting understanding of the care and treatment of diabetes, especially in children, and supporting families living with the disease. Similarly, Novartis has established CML Earth – a social network that connects Chronic Myeloid Leukemia patients. The site welcomes patients, patient groups and healthcare professionals from around the world. Boehringer Ingelheim is generally recognised as making the smartest use of Twitter, 'tweeting' not just company information but also recommending health-related articles and information. They have also pioneered the use of this channel to broadcast

real time trial data, posting results from the RELY trial (the largest atrial fibrillation (AF) outcomes trial ever conducted).

Patients are also increasingly becoming involved during product development, providing input relating to their conditions. As mentioned earlier, discussions are currently taking place at EMA level to define a more structured process for early patient involvement. Some companies are already ahead of the curve in this regard. For example Novo Nordisk has partnered with the International Diabetes Federation and an international expert advisory board for their 'Be the Face of Change' diabetes educational campaign and DAWN programme (Diabetes Attitudes, Wishes and Needs).

Beyond engaging patients directly, Patient Liaisons should also work through physicians, pharmacists and nurses to provide patient support. Physician endorsement significantly increases the likelihood that a patient will read – and trust – medical information. Pharmacists and nurses are also an important target audience in this regard, since their endorsement of materials and information can help to build and reinforce credibility.

Alongside the key customer-facing roles for Health Managers, Key Account Managers, Sales Specialists and Patient Liaisons, there is a strong requirement for integration and direct collaboration with two supporting functions: Health Economics and Outcomes Research (HEOR) and Clinical Development. HEOR provides necessary data, information and input to guide development of the value proposition and the factual argumentation to support ongoing dialogue with payers, authorities, providers and, to a lesser extent, patients. Meanwhile, close interaction with Clinical Development will ensure that trial protocols are designed with a commercial endpoint in mind, possibly in collaboration with healthcare authorities (as with the GSK and Novartis examples mentioned above).

In the case of ['Real world' methodologies](#) these dialogues would be expected to take place even earlier in anticipation of conditional approval at the end of a lean Phase IIIa clinical trial. Such methodologies would allow further confidence in clinical efficacy, value and benefits to be built over time as real world data are generated.

Governance

Governance structure and accountabilities

To mirror the evolution towards patient-centred healthcare provision and the provision of value at the treatment pathway level we advocate organisational

structures that are aligned around therapy areas, with all functions having reporting lines, direct or dotted, to the heads of therapy area business units.

Many pharmaceutical commercial organisations have suffered to a greater or lesser extent from siloing, with individual functions operating almost independently driven by distinct and misaligned sets of incentives. This is a particularly common accusation levelled at Sales and Marketing functions.

To remedy this problem requires a single function with full accountability for developing integrated commercial strategies for therapy areas and their brands across payers, providers and patients, and for ensuring consistent implementation across customers and channels. Obvious candidates for this role are existing Therapy Area/Brand Managers, although such a role would involve a shift from traditional marketing in many respects:

- Whilst Marketing is often in charge of developing marketing strategy and the marketing mix, there is much less input into sales resource allocation discussions. As owner of the integrated commercial plans Marketing would be expected to assume responsibility for the overall investment decisions.
- At present there tend to be recognised hand over points between Marketing and Sales functions with respect to design (Marketing) and implementation (Sales) of tactics, messages and campaigns, with few interactions and feedback loops in between. In the future, with accountability for execution of the integrated commercial plans, Marketing would be expected to assume responsibility for tracking and monitoring overall performance and for use of outcomes to adjust and adapt as appropriate.
- Whilst Sales personnel are routinely incentivised on the basis of results, this reward structure is currently considered less relevant for Marketing staff. However, as owner of the integrated commercial plans, the future reward structures for Marketing could be more closely linked to commercial performance than at present.

Supporting functions, reporting and synergies across therapy areas

Organising on the basis of therapy area/treatment pathway will require specialisation across several dimensions, to achieve sufficient understanding of the underlying science, health economics and the specific needs of relevant stakeholders. This makes it difficult to create individual customer facing roles that can be shared across different business units. However, even if there is a need for dedicated specialist roles for each

therapy area, it may be beneficial to house analogous roles directly or indirectly within a dedicated unit. For example, in the case of dotted line reporting this could take the form of Centres of Excellence, which are effective means of ensuring standardisation and consistency in methodologies and approaches, and of sharing best practices across business units. Several of the large pharmaceuticals have implemented such structures on regional and even global bases.

The decision of how to structure supporting functions will depend to some extent on the degree of technical expertise required. For disciplines which involve in-depth technical or methodological elements such as HEOR, there is often a stronger case for having a central team acting as champion and expert in the process, with specific expertise in the different areas and with clear interfaces with the business units. Having a central team also provides greater flexibility to the wider organisation, as it allows resources to be reallocated more easily in response to changes in customer demand (external and internal).

Whilst different options exist for organisation of supporting functions (Figures 4 and 5 present two examples), it is essential that the objectives and activities of all supporting functions are clearly linked to and aligned with- the overall objectives of the business unit. Scorecards and incentives can be effective tools to align behaviours and encourage all disciplines to work together towards common goals.

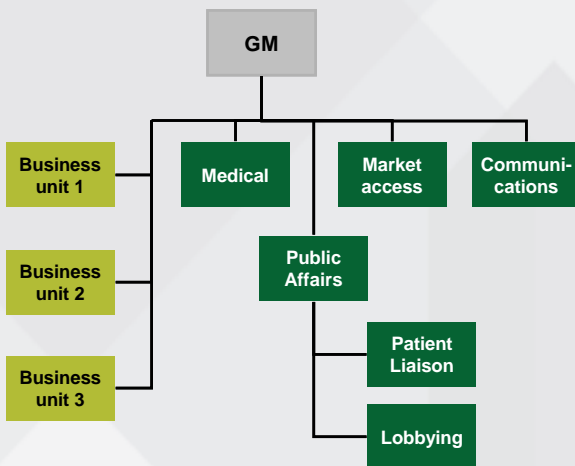


Figure 4: Central supporting functions for all business units (common in most EU countries)

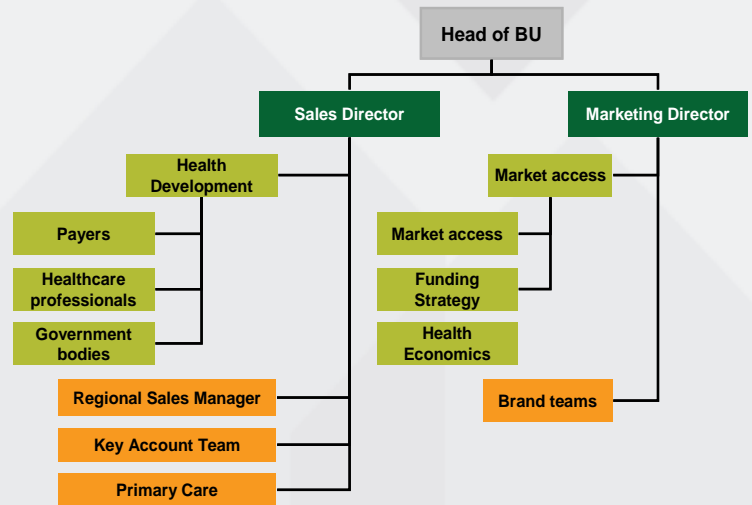


Figure 5: Dedicated supported function for each business unit (common in the UK)

Geographical alignment

Across most countries, there is a clear trend towards regionalisation of healthcare. Whilst policies are formulated and agreed at national- or supra-national level, the responsibility for implementation is increasingly being devolved to the regional level.

In the UK, PCTs are expecting to be set dedicated budgets for specialty care; in Germany budget and authority is shifting to community care centres (Ambulatory care centres, MVZs); in France ARS (Agences Régionales de Santé) are being established with dedicated budgets assigned to each region.

For pharmaceutical companies, this provides increasing rationale for customer facing roles (or at least those interacting with payers and authorities) to be regionally aligned. Takeda pioneered this structure through introduction of the RADs (Regional Account Directors) organisation in the UK in 2004. Many others have since followed suit; for example Pfizer subsequently introduced field based Sales Managers. Increasing regionalisation will also place greater emphasis on the ability of supporting functions to meet local customer needs, for example by supporting local Primary Care units and practice physicians with budgetary and expenditure planning and meeting quality of care local targets.

Global versus local organisations

With a growing emphasis on cost reductions, pharmaceutical companies are increasingly seeking opportunities to create organisational synergies. The interfaces between global, regional and local entities represent significant opportunities in this regard.

Far too often, functions and responsibilities are replicated across global, regional and local layers, and sub-optimal communication and lack of information sharing invariably results in replication of effort instead of leveraging common templates. Corporate culture often has a significant role here, especially in the case of decentralised organisations where the power tends to reside with largely autonomous affiliates, fighting for their turf and local resources.

However, this situation is gradually changing to more of a top-down approach, with the accepted wisdom being to 'think global and act local'. We believe that there are many opportunities to centralise supporting functions at regional and global levels, with some estimates of savings in the range of 50% being achievable⁹. Examples include:

- Marketing: market research; production of educational and promotional materials etc.
- Analytics: market assessments; forecasting; commercial analytics etc.
- Medical affairs: scientific communications; publication support; editorial services etc.
- Training: creation of disease and product training programmes etc.
- HEOR: global dossier production; epidemiologic assessment; burden of disease evaluation; cost-effectiveness modelling etc.

Different solutions exist for implementing global functions in support of regional and local structures. Two of the more popular that we have encountered are Centres of Excellence and Function Champions (see Figure 7 and Figure 8).

In the Centre of Excellence (CoE) structure, the central hub is responsible for developing best-in-class methodologies and capturing and sharing best practice. Affiliates maintain their own field-based resources to manage key stakeholders; but the content for their campaigns is developed by the CoE. The CoE ensures no conflicting messages are given by the different affiliates; this is becoming increasingly important as market access stakeholders interact at a regional level. CoE can also interface with other dependent functions (such as public affairs in the case of HEOR).

Global Function Champions play a similar role as the CoE, but are typically more accountable for devising overall strategies as well as developing the methodologies and templates for local implementation across business units, countries and regions.

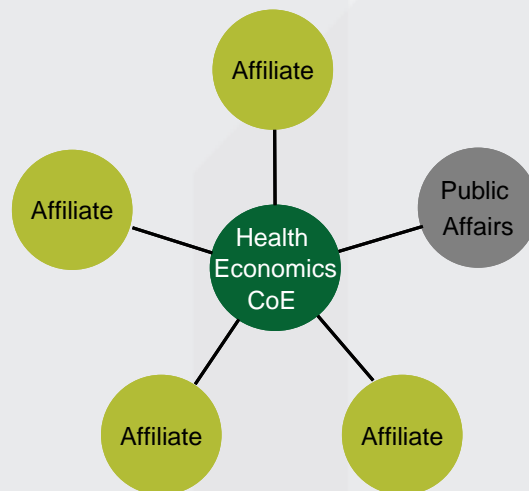


Figure 7: Centres of Excellence structure for HEOR

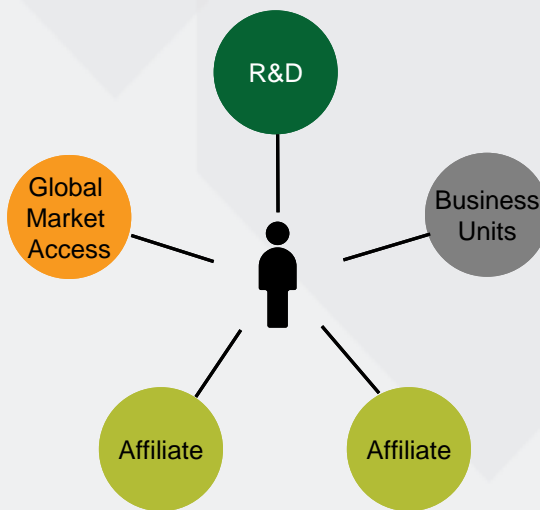


Figure 8: A Global Function Champion role for Market Access

Organisation Size

The current trend of downsizing across the industry is having perhaps the greatest impact in commercial organisations, as companies dismantle arsenals amassed during the arms races of the 1990s and early 2000s. According to Fierce Pharma's third annual list of the industry's top layoffs, 58,696 pharmaceutical and jobs were cut through the end of October 2009 – an increase of 15,000 more jobs than were lost in 2008.

Though much of this has been driven by the three recent mega-mergers, with Pfizer and Merck accounting for more than half of these losses, a significant number of losses have arisen as a consequence of restructuring driven by the changing customer landscape. It is becoming clear that the new commercial models will require far less people. In a recent report, Deloitte calculated the decline of US sales reps at an average of 8.3% per year since a peak in 2005. This figure was as high as 18.4% for those sales reps with principal responsibility for interacting with physicians.

Whilst recognising that sizing decisions are driven in a large part by the specifics of each company's business and portfolio, the remainder of this section focuses specifically on the key roles and supporting functions previously discussed in this paper, and provides evidence and guidance for their sizing.

- *Health Managers and Key Account Managers*

Customers for Health Managers and Key Account Managers are payers, authorities and key accounts and therefore relatively few in number. In contrast to the classic coverage & frequency models used in the past, future sizing decisions should be based on two things:

- i) Ensuring full coverage of these institutions.
- ii) Deciding on the appropriate span of control based on bottom-up activity plans and workload required to service all of these customers. The level of activity will be highly dependent on the breadth of the portfolio and the number of therapy areas in which companies are involved.

The ultimate requirement will vary by country, depending upon the number of accounts and current position with respect to decentralisation of care. However, to provide an indicative scale, country-level representation would be expected to number a few tens rather than hundreds.

- *Sales Specialists*

As the area currently housing the largest number of sales people, this organisational component is most likely to suffer the greatest impact. The current trend of sales force reductions shows no sign of slowing; if

anything we predict a sharper decline, especially in the Primary Care setting. Going forward, the key role of sales specialists will be to provide service and support to providers, which for more specialised products will increasingly involve provision of educational and deep scientific content to physicians and accounts.

In terms of Secondary Care, the existing target base is already relatively small therefore we do not anticipate large changes in scale, although further reduction may arise as a consequence of an increasing focus in rare or orphan diseases. The move towards developing closer relationships with customers will necessitate more frequent interactions – even if coverage may decrease slightly – therefore in terms of indicative scale we would anticipate Secondary Care representation to remain unchanged, typically numbering a few tens at country-level. To illustrate this with an example, Shire's gastrointestinal division has 120 reps in the U.S., whilst the orphan drug division manages with just 10 reps¹⁰.

In contrast, Primary Care is likely to endure further and deeper cuts. At their peak, sales forces in Primary Care indications used to number up to 1,000 in the largest countries, however they have been the major casualties of recent layoff waves. GSK have slashed their UK sales force from 800 to just over 530 as they create more payer-focused medical advisers and health outcomes consultants¹¹.

We believe that these numbers are still too high. Whereas previously large sales forces were needed to achieve the high frequency on target required for high share of voice, the move away from this model towards a new focus on supporting and servicing physician practices will require a far lesser scale.

Whereas under the previous model a frequency of six visits a year to a high value physician was common, a reasonable expectation under the new model is around two visits per year, organised around the practice planning cycle: an initial visit might focus on budget and expenditure plans with the aim of understanding how the company's products and services fit in, including the need for ongoing support; the follow-up visit could then be used to review progress. Between visits, the sales specialist would allocate 'resources' such as third party nurses and patient management programmes to help practices manage patients. This model exists and has already been successfully implemented in the industry. For example, Lilly is currently shifting its sales model from pushing

messages to customers to spending more time listening than talking¹². Assuming this reduction in frequency of two-thirds, large Primary Care sales forces such as GSK's could conceivably be reduced even further, from 530 to around 250.

Much has been written on the potential for outsourcing sales forces using the CSO (Contract Sales Organisation) model as a means of delivering savings and gaining flexibility. Whilst the idea is worthy of consideration for Primary Care, we believe the specialist nature of Secondary Care would make it difficult to implement in this context. Even in the former case, services and support to practices will need to be tailored to specific sets of patients and diseases, which will require some element of control from pharmaceutical companies to ensure quality.

Some lessons may be drawn from recent CME experiences in the US, where a number of companies have withdrawn funding of externally administered education via third parties because of poor results delivered.

- *Patient Liaisons*

Patient liaison activities are currently typically managed by marketing in conjunction with the communication department.

As an integral part of the marketing mix, we foresee marketing – with overall accountability for the commercial plan – taking a much stronger lead in patient liaison with specialist input from communications and legal functions. Legal input is particularly important with respect to engagement via social media. The FDA organised a two day hearing on this specific topic in November 2009¹³, and guidelines are expected during 2010. The EMA appears to lagging behind in this regard.

In terms of scale, Patients Liaison roles are likely to be small in number, with dedicated individuals within each therapy area being responsible for developing intimate knowledge of patients and their needs for specific diseases. At present, activities around the use of social media for developing patient communities are very much lone efforts.

- *Supporting functions*

Irrespective of how supporting functions are organised – direct or dotted line reporting to business units; central or regional/field based – their numbers will be dictated by the structure of the organisation/function they are working with, possibly with a single interface per business unit or therapy area (if there are no synergies or similarities across units).

As such the overall team sizes will be much smaller than their customer facing equivalents, and will typically number single digits.

As discussed above, there is also a strong argument for centralising supporting functions at regional or global level, leaving only local point of contact in countries.

Key messages:

- **Future commercial organisational structures will change in number of ways to accommodate the new market environment**

- **Structures will be organised around disease/therapy areas to mirror the changing customer environment, with the Marketing function assuming overall ownership of the integrated marketing and sales plan**

- **Roles will be centred on key stakeholders (payers, providers and patients) with mechanisms in place to enable team working, sharing of best practices and consistency in approach**

- **New structures will require greater coordination between global and regional functions, which could be hard coded through direct reporting lines, or organised via network-type structures such as Centres of Excellence**

- **There will be a continued and accelerated trend towards downsizing sales forces, especially in Primary Care, driven by a shift in focus from achieving competitive share of voice towards supporting and servicing providers**

Embracing the new commercial realities

In contrast to other industries such as FMCG (Fast Moving Consumer Goods) and financial services, the pharmaceutical industry is typically reactive to change. Change is often forced and triggered by external market events, rather than pro-actively engineered.

Whilst the pharmaceutical industry has historically defended this position on the basis of somehow being different to other industries, continuing to adopt such an attitude is likely to have damaging consequences. Customers and the healthcare environment are moving rapidly towards a new commercial reality. Ignoring this

and failing to adapt will have deep repercussions on performance (e.g. sub-optimal product launches, new products not being approved, restricted labels, etc.).

Many companies have begun to 'play around the edges', changing and adapting parts of the system (e.g. functional/departmental approaches) as opposed to engineering transformational change. In many cases this 'evolutionary' approach to change can be explained by the perception that transforming an entire organisation is complex and risky, and raises concerns over disruption to business as usual. Nevertheless, the industry cannot hide from the fact that increased collaboration and teamwork will be the key to future commercial success. This will invariably necessitate greater cross-business unit and cross-functional activity, which has fundamental implications at the organisational level.

A few companies have already begun the transformation process. We suggest that now is the time for all organisations to engage at the very least in a comprehensive review of their commercial models. From our experience this review should be approached as a structured, three-stage plan (which mirrors to some extent the previous discussion):

1. Healthcare environment review

This stage is about building on current strategic/market planning work to really flesh out the key market trends which are forecast over the next few years (3 to 5 years). This stage should describe funding and care provision flows, decision-making processes and the relevant influencing networks. The outcomes should enable a deep understanding of the key stakeholder groups and their requirements.

2. Organisational implications (roles, skills and competencies)

This should be a natural continuation of the previous stage where customers' requirements are translated and articulated into required commercial and technical capabilities. These key competencies should then be reviewed against the current organisational footprint to understand gaps. Finally, discussions should focus around determining which roles should 'host' these new competencies and role descriptions developed accordingly.

3. Commercial organisation (structure and size)

The final stage of the process is to shape the new roles into an organisational model and to define the appropriate structure and size. This is possibly the most difficult step as it involves a detailed consideration of a variety of different factors in order to ensure that the model developed is fit-for-purpose.

In our experience the duration of this commercial model review is typically around six months, more or less equally divided across the three phases, although the exact timeline will depend on the scale of change (scope of business and number of affiliates). However, this is not the end of the process. Following the review and design phase, an equally important follow-on phase will be necessary to drive implementation of the new structure. This will require significant and ongoing investment in change management to ensure successful transformation. For such a complex programme it is critical that key representatives from the commercial organisation are engaged and involved from the outset, in order to i) gain their buy-in and commitment during the design phase, and ii) employ them as change champion/agent during the subsequent implementation phase.

Conclusion

Transforming commercial models to operate within the new healthcare environment is not an option for pharmaceutical companies; it is an imperative.

Neither is it a tactical or fine-tuning exercise, but rather a fundamental shift to build a platform for future growth. Successful implementation will require a carefully planned and comprehensive review of the organisation and the involvement of a variety of different stakeholders at all levels throughout the organisation.

We have written this paper from a practical as well as a conceptual perspective, and would welcome comments, feedback and ongoing dialogue with all stakeholders to develop further thinking and pragmatic insights into the industry's evolving commercial realities.

References

1. Cowen & Company analyst report, October 2009.
2. NICE snubs Novo with draft Lira guidance, BNET Pharma, February 2010.
3. Financial Times, Novartis chip to help ensure bitter pills are swallowed, November 2009.
4. Kinapse: Real World Development, Increasing value for patients, October 2009.
5. <http://petitions.number10.gov.uk/CML-NICE/>.
6. European Medicines Agency: Reflection paper on the further involvement of patients and consumers in the agency's activities, December 2009.

7. NICE warns industry on cost-effectiveness, February 2010.

8. Kinapse: Marketing 2.0 in the Life Sciences industry, February 2010.

9. Making an impact: effective sales and marketing with reduced costs, Indegene, 2009.

10. More from Genentech's McCracken on the Future of Pharmaceutical Sales, BNET Pharma, December 2009.

11. Death of a salesman: drugmakers recast reps' role – Reuters Health Information, December 2009.

12. Lilly changes course as it shrinks its sales force, Indystar, January 2010.

13. FDA - Presentations from Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools , www.fda.gov/AboutFDA/CentersOffices/CDER/ucm192703.htm.

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