Stakeholder Management

Effective interaction with key stakeholder groups is a critical competency for future success in pharmaceutical commercialisation.
Changes to the healthcare systems over the last few years have made market access, pricing and reimbursement critical in driving prescriptions and ultimately sales revenue. In addition to structural changes in the healthcare systems, the dynamics of patients, healthcare policy makers and payer behaviour have altered significantly. The environment is becoming more complex, with a significant shift in the relative importance and roles of key stakeholder groups. As a result, effective stakeholder management has become one of the most critical elements in determining the future success of a pharmaceutical organisation.

In a recent study we asked representatives from the pharmaceutical industry for their views on how the relative importance of key stakeholders would evolve over a two to three year period, and how well prepared they believed the industry was to address key stakeholder needs. Their feedback is summarised in figure 1.

In this article we examine current and expected changes to the relative importance of various stakeholder groups. We then evaluate the challenge that these changes pose for the industry, and offer pointers for tackling them.

How stakeholder influences are changing

Payers
Payers are exercising increasing control over market access and reimbursement requirements in order to obtain affordable pharmaceutical products. Their requirements are often more demanding than those of the FDA or European Medicines Agency. They assess effectiveness of products in terms of superiority versus non-inferiority, and long-term outcomes versus response, in order to justify reimbursement. They also play a role in the establishment of treatment protocols, and are increasingly

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Figure 1. Stakeholder importance versus preparedness in two to three years’ time

Q4(b). What’s your view of the relative importance of key stakeholders in the pharmaceutical market today and evolving over the next 2-3 years?
Q5(a). How well prepared do you consider the pharmaceutical industry in addressing the needs of these stakeholders?
Future success depends on an organisation’s ability to understand its dynamic environment and then adapt its commercial model, plans and behaviours to capitalise on the changes.

Influencing physician prescribing

Generic substitution has increased through payer influence: a variety of incentive and penalty schemes have been implemented to increase the use of generics.

While the power of payers is increasing, our respondents felt less equipped and ready to collaborate effectively with this stakeholder group than any other. As a result of past experiences, the relationships with this group appear fairly strained.

Government bodies

Government bodies play a key role in policy development, pricing, access and reimbursement. The increasing importance of Health Technology Assessment (HTA) and Evidence Based Medicine (EBM) is having a significant impact in this area.

This is a very complex group of stakeholders. Although there are some commonalities between countries, on the whole healthcare systems and bodies differ by country, each country also having its own laws and policies (which need to be understood at both local and central levels). While their mandates differ, organisations such as NICE (UK), IQWiG (Germany) and HAS (France) are playing a key role in development of treatment and reimbursement guidance. The ongoing healthcare reforms implemented by the local governments are also resulting in further pricing pressures.

Effective management of this influential group is extremely challenging. Figure 2 illustrates the complexity of stakeholder groups involved in pricing, access and reimbursement, and Figure 3 summarises the differences between the three main types of health system.

Standard-setting bodies

Organisations such as the World Health Organisation (WHO) are playing an increasing role in the development of quality standards and guidelines. Given that the capacity to interpret and apply regulatory and quality standards consistently varies widely between countries, the WHO can be expected to gain in influence, promoting global norms, standards and guidelines for quality, safety and efficacy.

Patients and advocacy groups

Access to reliable healthcare information on the internet is helping patients become more informed. They are also footing a growing proportion of the drug bill and want cures, not just treatments. To satisfy them, pharmaceutical companies need to transition from selling drugs to selling integrated concepts, such as holistic solutions for health delivery and health management. We can expect to see a much more collaborative relationship between pharmaceutical organisations on the one hand and patients and patient associations on the other: adherence programmes, patient education, drug administration and diagnostic services will characterise this new relationship.

Physicians

While physicians are still heavily reliant on pharmaceutical organisations for information and support, access to this historically important channel is reducing as companies struggle to get quality time with physicians. Also reducing is the physician’s freedom to prescribe, owing to budget constraints, drug formularies and other mechanisms that influence the prescription. Sales representatives’ time with physicians is limited not
only in quality and quantity but also in the value that it brings.

In some cases the visit by the sales rep is actually prohibited, as was seen with the introduction of the LIF agreement² in Sweden.

This agreement lays out specific terms and conditions for physician access including detailing, product information, training, conferences and sponsorship, with the effect of limiting access to healthcare practitioners.

As a result of these developments, sales forces are being cut back and the pharmaceutical industry will need to look for other ways of ensuring patient access to drugs.

### Key Opinion Leaders (KOLs)

KOLs have long been regarded by the pharmaceutical industry as one of its most important stakeholder groups, but this view has been modified of late. Whilst the role of KOLs as advisors to pharmaceutical companies and advocates of their drugs is already controlled by legislation, there is growing scepticism about KOLs' role and remuneration.

The drive for more transparency in this area was illustrated by the 2008 revision of the Association of the British Pharmaceutical Industry (ABPI) code of conduct. Companies are now strongly urged to include in their contracts with physicians an obligation to declare an interest when speaking or writing in public. At the extreme, there are calls to rein in KOLs' influence over the medical profession.

### The challenge

Future success depends on an organisation's ability to understand its dynamic environment and then adapt its commercial model, plans and behaviours to capitalise on the changes.

The first step is to review and critically evaluate the stakeholder landscape, including existing stakeholder knowledge, relationships and plans. How well does the organisation know the critical stakeholders, their needs and

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**Figure 2. Key stakeholder groups in the pricing, access and reimbursement**

<table>
<thead>
<tr>
<th>USA</th>
<th>CMS / State Agencies MCOs / BPMs</th>
<th>Market</th>
<th>CMS / State Agencies MCOs / BPMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>NICE NHIS</td>
<td>PPRS</td>
<td>DOH NHS</td>
</tr>
<tr>
<td>France</td>
<td>TC/HAS UNCAM</td>
<td>CEPS</td>
<td>HAS UNCAM</td>
</tr>
<tr>
<td>Germany</td>
<td>GBA IQWIG GKV</td>
<td>GBA</td>
<td>BMG</td>
</tr>
<tr>
<td>Italy</td>
<td>AIFA CTS</td>
<td>AIFA CPR</td>
<td>ASL NHS (SSN)</td>
</tr>
<tr>
<td>Spain</td>
<td>AC NCRUM</td>
<td>NCRUM ICPP</td>
<td>AC</td>
</tr>
</tbody>
</table>


**Figure 3. Three types of healthcare system**

<table>
<thead>
<tr>
<th>Tax financed system (Beveridge type)</th>
<th>Premium financed system (Bismarck type)**</th>
<th>Private insurance system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>National Health Service</td>
<td>Social insurance</td>
</tr>
<tr>
<td>General definition</td>
<td>Government regulated care with health services</td>
<td>Health care as guaranteed basic right</td>
</tr>
<tr>
<td>Financing</td>
<td>Taxes. Every tax payer contributes</td>
<td>Contributions from employees/employers</td>
</tr>
<tr>
<td>Service organisation</td>
<td>Public</td>
<td>Private/public</td>
</tr>
<tr>
<td>Service package</td>
<td>More supply oriented</td>
<td>More demand-oriented</td>
</tr>
<tr>
<td>State intervention</td>
<td>Strong/direct</td>
<td>Mostly direct</td>
</tr>
<tr>
<td>Payment transfer</td>
<td>Indirect</td>
<td>Largely indirect</td>
</tr>
<tr>
<td>Examples</td>
<td>Scandinavian countries, UK, Italy, Spain, Greece, Canada</td>
<td>Japan, Germany, France, Belgium, Netherlands, Austria</td>
</tr>
</tbody>
</table>

* Sir William Henry Beveridge (1879–1963), founder of British National Health Service (NHS) in 1948
** Fürst Otto Eduard Leopold von Bismarck (1815–1898) established the first national health insurance system in Germany in the 1880s

Stakeholder Management

Stakeholder management success stories

- When the LIF agreement in Sweden reduced sales representatives’ access to healthcare professionals, as mentioned above, we helped a leading international organisation to deepen its understanding of key stakeholders and their requirements at national and regional level. A detailed map of the influencer network, supported by an evaluated list of key drivers of access, enabled the development of a new organisational structure and stakeholder plans, which worked together to improve access and create competitive advantage.

- We helped a leading French organisation create detailed stakeholder mapping and planning to ensure the success of a NICE Health Technology Assessment (HTA) for an important new drug at national, regional and Primary Care Trust (PCT) level. This task called for effective national co-ordination of brand advocates, payers and commissioners, as well as local co-ordination of NICE guideline implementers, influencers and physicians.

- For another pharmaceutical client, we used our ASE (Accelerated Solutions Environment)² to align 250 marketing, sales and R&D resources from 40 countries at a very successful product launch, and to prepare for a global thought leader meeting of 400 specialist physicians. As usual, ASE proved highly effective for the alignment of a large group of internal and external stakeholders.

- On an engagement with the European Brain Council, the ASE helped us facilitate the alignment of 17 leading stakeholders from industry and academia to enhance patients’ access to novel treatments for serious Central Nervous System (CNS) illnesses.

requirements? Who is managing each key relationship and how well equipped are they? Do they have a documented plan for each stakeholder group? How well aligned are these plans with corporate strategy and go-to-market plans?

In our experience, this exercise often identifies a significant gap in the organisation’s understanding of its stakeholders and their key requirements. The evaluation may also highlight a lack of alignment with major stakeholder groups. As well as hampering external relationships, this misalignment can affect working relations between internal groups such as access, marketing, sales and R&D, and also between the local and global parts of the organisation.

For example, affiliates typically gain understanding of the access requirements for a new drug through building a good relationship with the relevant local authorities. If this relationship is weak, the understanding will be lacking, and the affiliates will not be able to provide the right input for the outcome studies that need to be performed at global level.

A stakeholder evaluation is a critical input into the development of a new therapeutic strategy, because it ensures a good understanding of market access, pricing, assessment procedures, publication and medical guideline requirements. It is also important when there have been major changes to legislation or other aspects of the healthcare environment.

We have helped a number of clients to use effective stakeholder management to increase strategic focus; the panel opposite shows some examples. Well-managed stakeholder relationships like these can also accelerate decision making and increase speed to market. Not only will they drive revenue growth and create incremental value: they can also be a source of competitive advantage.

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² Läkemedelsindustriföreningen (LIF Agreement of January 2005)
³ Accelerated Solutions Environment (ASE) is a unique place in which large numbers of stakeholders can more easily solve problems and make key decisions. It fosters rapid, collaborative decision-making using a combination of bespoke research, our clients’ knowledge of their business and a blend of leading-practice facilitation tools.
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