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Redefining Market Access - Effective Value Engagement

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Market Access

- Market Access is not about pricing; but about ensuring delivery of value at every stage in the development and commercialisation of medicines.
- The definition of value and the way in which it is assessed is evolving at different rates in different regions, with different stakeholders driving the change.
- The challenges posed by Market Access will force the pharmaceutical industry to maintain a sharper focus on delivering true innovation, but it must also align its development, sales and marketing processes around the new real-world outcomes focused world of healthcare.

Every company involved in developing innovative medicines has the patient at the heart of its activities, but the patient is not their immediate customer. Access and reimbursement are among today's key objectives for pharmaceutical companies – finding a means to meet patient needs by securing payer endorsement. So how can an industry under constant and growing price pressures build support among the network of stakeholders influencing access and reimbursement for an innovative medicine?

Moving & Shrinking The Goalposts

While industry bodies around the world point to spending on pharmaceuticals as a small percentage of the overall healthcare budget, the focus on reducing the cost of healthcare systems' drugs bills has remained high, despite evidence that it has the potential to reduce the higher costs of hospitalisation.[1]

As a pharmaceutical manufacturer you are therefore faced with various challenges relating to the global supply of medicines that are somewhat unique compared to many other major industries:

- Unlinked independent bodies decide whether or not you can sell your product
- Another set of unlinked bodies decides how much you can sell your product for
- A further set of unlinked independent bodies decides if your end customers should pay for your product

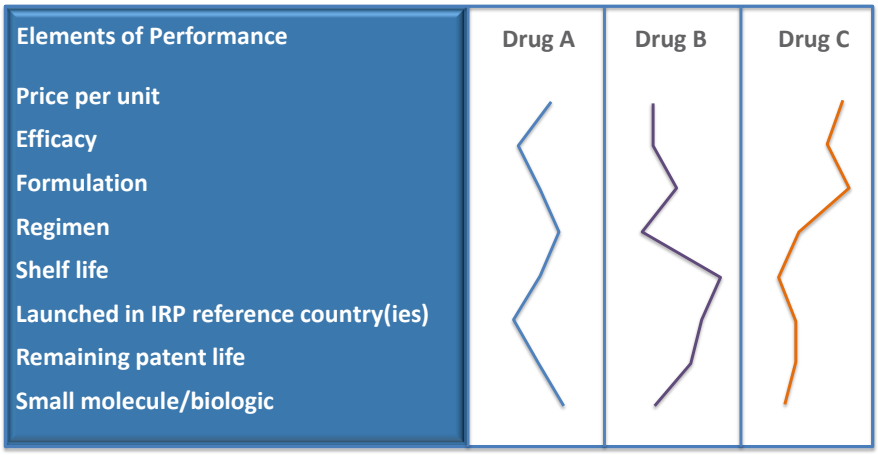
While this of course presents an issue in establishing scientific and commercial agreement, it has also meant that pricing discussions and negotiations must take place in individual countries, and the various sub-components of the individual healthcare systems, without having an impact on access and reimbursement arrangements in another part of the system.

Aligned Requirements in a Shrinking World

The global financial crisis of recent years has been a catalyst for the gradual alignment of pharmaceutical cost containment measures around the world, marking the dawn of at least regionally aligned health infrastructure. The major cuts in almost all markets across Europe have highlighted the potential for cost savings, and driven

health authorities and insurers to look for new opportunities. Most recently, the announcement of new PPRS limits in the UK has been met with consternation by the industry and less influential markets, such as Poland, Romania, Estonia, Latvia and Romania, are combining their medicines procurement activities to achieve economies of scale. As a result, Novo Nordisk's Lars Sørensen is the latest in a line of pharma CEOs expressing concern at the challenging environment such moves present.[2,3]

The Pricing & Reimbursement Value Curve



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Even where healthcare systems have seen less dramatic enforced change, those responsible for healthcare systems have observed the reductions in prices and looked for similar savings. The recent decision by Express Scripts in the United States of America to remove 48 medicines from its formulary is overtly aimed at driving down price where there is no perceived benefit over competitor therapies, much like the established practice in Germany of therapeutic referencing.[4] The advent of Obamacare and the increasing importance of the role of pharmacy benefit managers in the US is likely to present higher barriers to obtaining commercially attractive pricing and reimbursement agreements in this traditionally free market.

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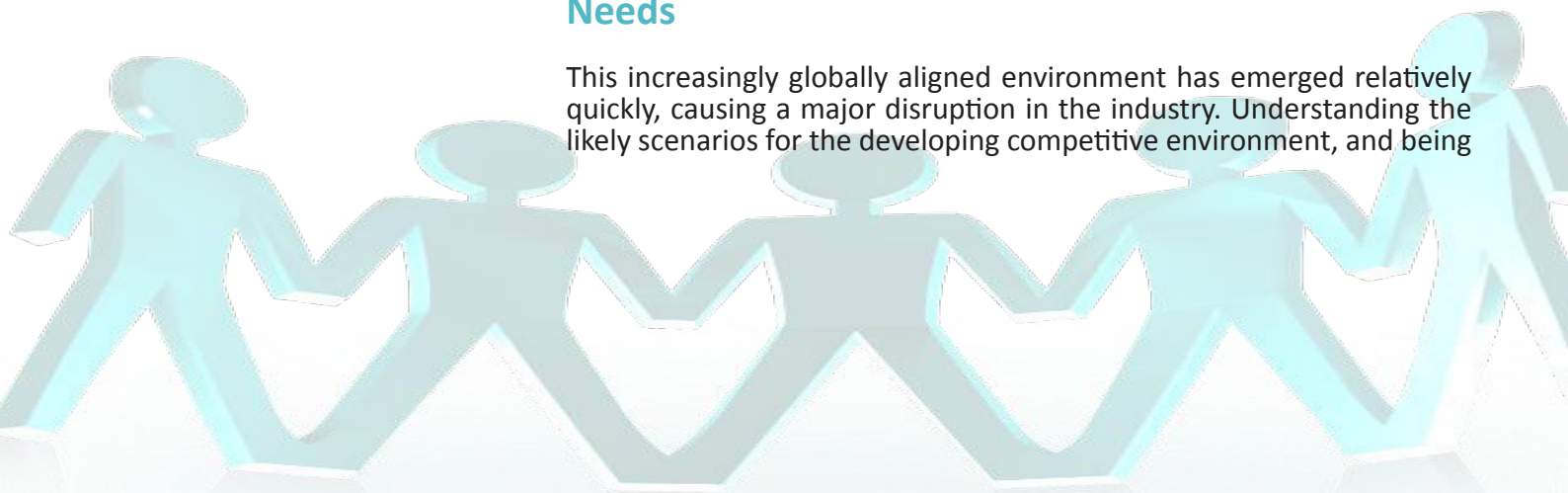
Alignment has come not only in the form of basic cost cutting, but through the complex world of International Reference Pricing, and knowledge and best practice transfer between health authorities. IRP can be used to drive rapid price reductions, and emerging markets have learned from established ones in implementing Health Insurance and Health Technology Assessment processes that will require similar levels of health outcomes evidence to those established by England's National Institute for Health and Care Excellence (NICE) and Germany's Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). Health insurance bodies in South East Asia, with South Korea's HIRA leading the way, have held regular meetings in recent years, featuring several noted European and North American Health Outcomes experts, to investigate approaches to establishing health technology assessments. Brazil's ANVISA has set a precedent that is being followed across South America; the recent revision of Colombia's pricing and reimbursement framework included a significant contribution from NICE.[5]

At the same time the growing use of generics as the first line of care has had further impact on the pricing and reimbursement landscape for innovative medicines. Generic substitution, INN prescribing and other measures are making it harder to penetrate markets from Brazil to the UK to New Zealand.

The area of biosimilars - copies of innovative biologics - also presents a growing pricing and reimbursement challenge. Biologics have emerged as the dominant focus for new medicines, and until recently have not had to contend with generic competition, keeping prices high.[6] Individual countries are still assessing whether the rules used for generic small molecules can be applied to biologics, where a biosimilar is not chemically identical to the original, but budget pressure is clearly putting the writing on the wall. As biosimilars start to be available (the first approval was in Korea in 2012 for Remsima, a biosimilar version of Remicade for Rheumatoid Arthritis), government healthcare systems are beginning to develop rules around how and where they can be substituted for innovative biologics.[7]

Engaging With Stakeholders To Understand Future Needs

This increasingly globally aligned environment has emerged relatively quickly, causing a major disruption in the industry. Understanding the likely scenarios for the developing competitive environment, and being



able to communicate them effectively, has become a vital aspect of the early development planning for an innovative medicine. A key aspect of this is to identify future payer needs and how these can be met.

Combining early insights into payer needs and price/reimbursement modelling with scenario planning that considers the impact of international reference pricing, cost containment measures, key opinion leader and patient views and geopolitical developments, can provide a means to maximise the opportunity for the successful launch of a new medicine. Such scenario planning can be an intensive and sizeable undertaking. When, for example, should early payer engagement start and how comprehensive should it be?

The R&D process for innovative medicines is still around 6-9 years, and the attrition rates of medicines in development mean that careful planning is required. Recent research has suggested that limited engagement at a very early stage can have a positive impact on the design of a development programme, meaning that initial discussions should probably take place once early clinical efficacy has been shown.[8] At this point the detailed clinical profile is not necessarily important; rather a clear understanding of the key issues, payer requirements and potential market scenarios.

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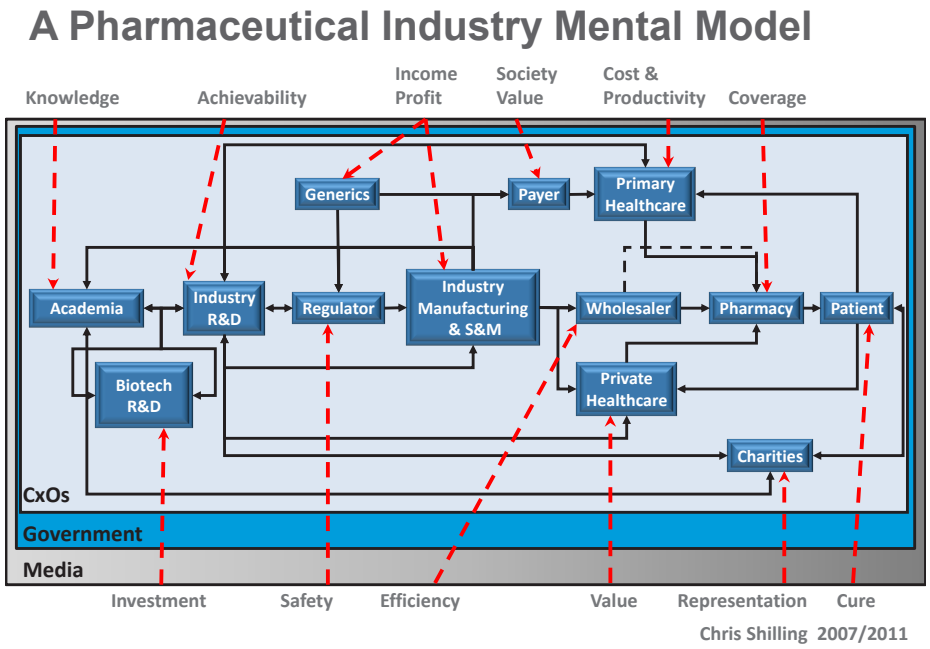
Approaches such as the Value Innovation process, a structured toolkit that was established as a practical means to implement Blue Ocean Strategy, provide organisations with a means to identify and clearly articulate product characteristics that meet the needs of the key customer.[9] Using an agreed, well-defined tool set helps organisations establish an access and reimbursement plan that is fully aligned with stakeholders, identifying the vital evidence arguments that will differentiate a medicine from its competitors.

Putting Value into Perspective

The message in Europe, Japan and the US is still that real innovation will be recognised, but with so many 'mainstream' diseases at least adequately served, the focus for healthcare organisations has shifted from clinical efficacy to effectiveness in delivering patient and health system outcomes. Additional efficacy is a given – Amarin's recent challenges highlight this need.[10] Understanding and meeting stakeholder needs is the critically important factor in gaining access and reimbursement.

"The focus for healthcare organisations has shifted from clinical efficacy to effectiveness in delivering patient and health system outcomes."

Managed Entry Agreements have been used increasingly over recent years as a means of addressing perceived stakeholder needs. Value-based pricing, risk sharing agreements, price/volume agreements and essential medicines listing offer various routes to reimbursement in different scenarios, and have become almost a de facto requirement to achieving access for some diseases. However, a major impact of establishing Managed Entry Agreements is the potential to develop a structured risk communication process between stakeholders, offering a shared language to discuss the societal value of a new medicine.



Much as clinical efficacy can require the development of a new biomarker to provide some objective understanding of impact, Health Outcomes Instruments have sought to provide objective views on the societal value of new therapies. What is missing from this discussion is a shared understanding of what constitutes value and risk – building a common mental model. Without a clear understanding of the impact of the unaddressed risk, it is hard to put the value into its proper perspective.[11] Understanding the different stakeholder perspectives – the mental models that influence a particular position - can enable us to build a win/win/win outcome for patient, payer and industry, based on real-world needs rather than mathematical models.

Stakeholder Perspective Management

Concepts such as payer networks, key account management and patient pathways have grown in importance over recent years, recognising that there are some key stakeholders for companies to engage with effectively in securing access and for innovative medicines. While companies may chose different approaches to aligning traditional marketing and market access activities, the number of stakeholders with an interest in the provision of healthcare, and the complexity of relationships between the various stakeholders, has increased significantly.

Using a clear and consistent approach to understand and engage with different stakeholders is vital in ensuring that an entire commercial organisation is fully aligned, meeting needs at a local and global level. The keys to this approach are to:

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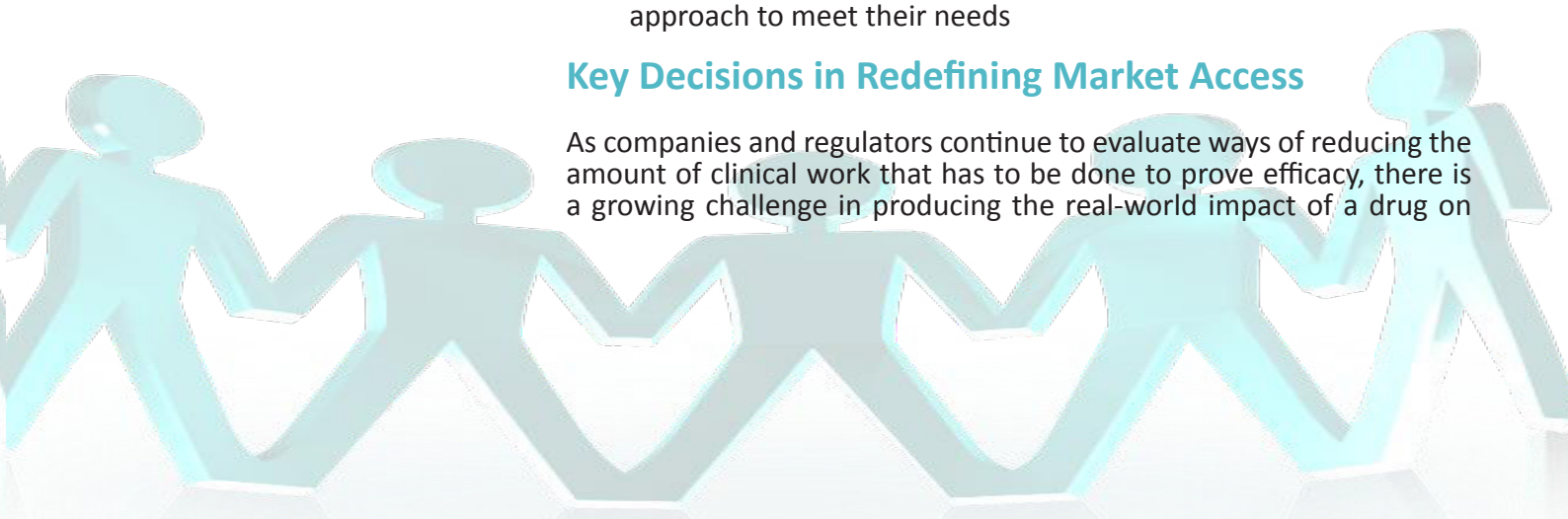
- Map stakeholder groups bottom up, but in a way that continues to make sense locally through to globally
- Assess the different perspectives that the stakeholder groups have – what mental models drive their perception of your value evidence
- Understand how the products and services in this area are delivered currently
- Develop a clear understanding of the current and known future product profile(s) and the benefits of the approach(es) in terms of the key decisions
- Refresh the understanding of the critical access to medicines decisions associated with the therapeutic area under consideration
- Support workers in countries and locally to develop influence maps and understand stakeholder disposition
- Adopt core messaging with local sensitivity to improve the market access for products and product/service packages that meet stakeholders' felt needs
- Integrate stakeholder engagement into CRM tools, enabling internal groups to share insights into the understanding of different stakeholder perspectives globally and identify commonalities of approach to meet their needs

Key Decisions in Redefining Market Access

As companies and regulators continue to evaluate ways of reducing the amount of clinical work that has to be done to prove efficacy, there is a growing challenge in producing the real-world impact of a drug on



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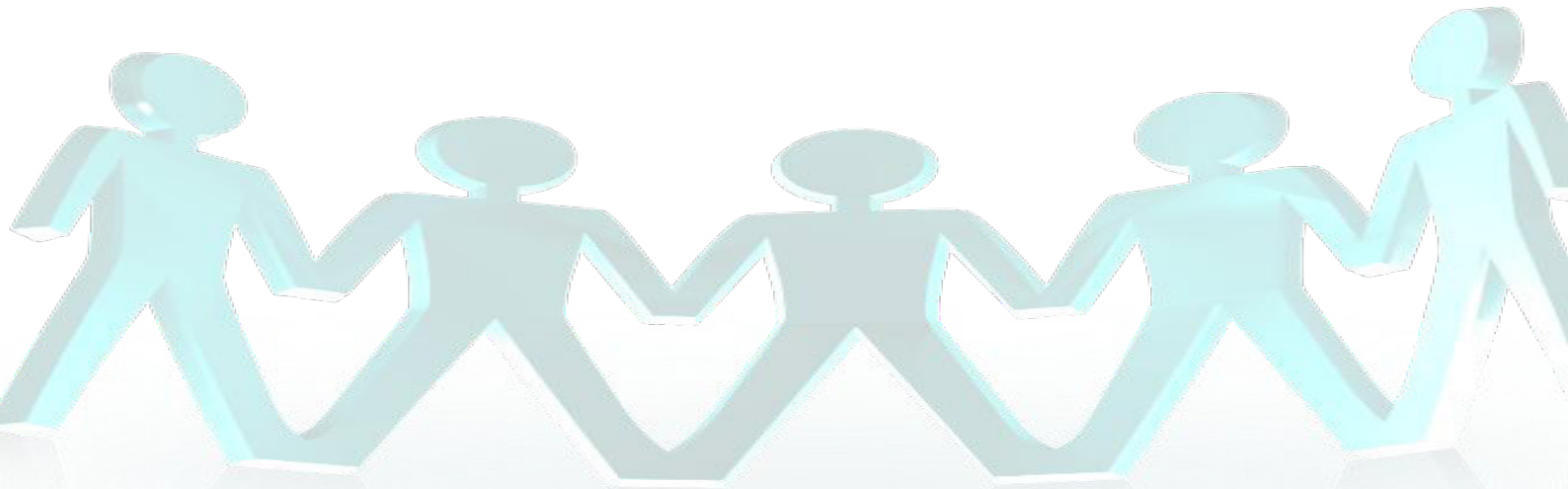
a particular healthcare system. Establishing a shared perspective on the needs of the different stakeholders provides a means to meet that challenge.

The new income model for medicines means that the majority become commodities, making differentiation all-the-more important. Developing a common language to discuss value that takes differing stakeholder perspectives into account provides companies with a means to show how their new products will address unmet needs. Developing a shared understanding of value – clearly articulated benefit balanced against a realistic understanding of risk (including the risk associated with inaction) – can provide a firm basis for commercial discussions in the same ways as a clinical dossier must for efficacy.

As outlined above, key decisions affected by the changes and alignments that are increasing price pressures include:

- Order of countries for launch planning
- Pricing and Positioning Decisions
- Indication Decisions
- Location of Manufacturing
- Optimising Promotional Channels

While the statement of so many life sciences companies that they exist to 'serve the patient' is a noble one, at present the patient is not the customer for most life sciences companies; the most important customer is the one paying. Developing strategies to meet all stakeholder needs at the same time as developing the clinical and manufacturing programme for new medicines is now an imperative.



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