On September 12, 2012 the Ministry of Foreign Affairs hosted a Health Care Reimbursement and Market Access Seminar in response to the dramatic changes to the global reimbursement and access requirements for medical technology and pharmaceuticals.

Key stakeholders and industry representatives discussed market characteristics, global stakeholder approaches to pricing, reimbursement and market access, as well as overall recommendations and ‘best-practice’ cases.

More rigorous technology assessments in the global market serve to inform decisions around how and when new products will be accessible. Demand for more evidence that a product is not only safe and efficacious, but that the value can be clearly demonstrated, particularly as compared to competitive therapies, will drive future uptakes and should be at the core of corporate product development.

It is important to remember, however, that different stakeholders view value and market access each through different lens. Medical technology and pharmaceutical developers should consider the following:

- Demonstrating value is getting more sophisticated, with requirements for stronger, more compelling real-world evidence
- All payers are tightening cost control measures, with greater constraints on physicians and manufacturers
- Broad-based reforms across countries are posing new challenges for setting pricing, market access and launch sequencing
- Linking and demonstrating value to market access can be addressed proactively by industry sparking innovation based on a sustainable business case built on safety, efficacy and quantifiable economic value

Defining Pricing and Reimbursement in a Global Market Access Context

Medical technology and pharmaceutical pricing and reimbursement go hand-in-hand and is considered the drivers for market access.

Market access usually refers to the process the industry takes to get their medical products commercially available within a focus patient community, country or global region.

Pricing and reimbursement are terms typically used in a process involving access to reimbursement, often at a national level, administered by a health or payer authority. Because reimbursement is increasingly influenced by pricing, the two terms are regularly linked together. Increasingly pricing and reimbursement, as well as market access are contingent upon outcomes and evidence of value.
Market access is not a new discipline, but the macro-economic, socio-economic and changing population demographics push producers, payers and providers alike to address value of the product, complementing safety and efficacy, as the primary drivers for adoption of new technology.

Earlier more linear market access strategies have been replaced by sophisticated applications of economic, psychological, political, and public relations skills to gain the corporation of a number of parties in order to build the value proposition for healthcare driven market access strategies.

For the medical technology and pharmaceutical company this means investing in people and organizational skills to anticipate changes in healthcare systems, including capabilities on topics such as healthcare and consumer driven business, networking and public relation capabilities, government affairs, pharmaco-economic knowledge and scientific and medical knowledge addressing value and real-life effectiveness. On top of new capabilities, strong data analysis competencies are key to ensure high quality and meaningful data usage.

Yet companies have been rather slow in recognizing the importance of value creating processes. They have often let others, mostly regulators and payers, decide the value of the product, rather than creating their own internal value definition around a product, and developing strategy to communicate its value.

This is a missed opportunity for value creation, why it is in the best interest of medical technology and pharmaceutical companies to define and communicate product value at each successive stage, in order to create a coherent process towards securing market access.

Collectively the shift towards a more value-driven business model is the most positive development for the industry in a long time. It sparks innovation and is forcing all industry participants to think about the future and develop a sustainable business case built on safety, efficacy and quantifiable economic value.

**Economic Austerity Add to the Speed of Global Healthcare Reforms**

The collective medical and pharmaceutical products industry has faced great changes to the largest markets, United States, Europe, and Japan, as governments across the board have been looking to contain costs in the short term and to restructure healthcare systems in the longer term. The United States stay divided over healthcare reform, while the European Union has launched a broad consultation on drug pricing, reimbursement and value as avenues to market access and product uptake.

For example, in the U.S. the 2012 budget proposals from President Barack Obama and from the Republicans in the House of Representatives both present very different views of the future of healthcare in the United States. The current presidential debate and upcoming election add to the risk and stability of the market.
One of the more typical misunderstandings is that the U.S. health care reform is about public health. It is not. The guiding principles were to do two things. One is to expand coverage. The other is to change the fundamental way health care is structured.

The U.S. health care reform (ACA) is in reality public finance, and fully implemented ACA will continue to reshape the payer and health plan market, particularly adding to the increasing cost pressures on payers.

Source: Colorado Health Benefit Exchange
Turning to Europe, the French government has recently reduced the 35% reimbursement rate to 30%. In 2010 German lawmakers blessed Chancellor Angela Merkel’s healthcare reform plan, limiting the industry's power to set prices. The law gives drugmakers one year to negotiate prices on new drugs or face analysis by a cost-benefit watchdog. The Agenzia Italiana del Farmaco (AIFA; Italian Medicines Agency) recently completed a comparison of the prices of off-patent medications in Italy with the prices of equivalent products in France, Germany, Spain, and the United Kingdom. The pharmaceutical industry in Spain reports that public pharmaceutical spending decreased by 2.4% in 2010 and approximately 4.7% in 2011. And for the U.K. market the medical products industry is generally supportive of the government’s plans for the introduction of value-based pricing, but has significant reservations regarding some aspects of the proposals.

The difference has so far been the BRIC countries, which to some extend have become the cornerstone for any company pursuing growth and increased buying power in the emergent markets to offset some of the cost-containment and patent expirations in the mature markets. Further, the 'new' markets have shown to be attractive growth economies with local and national governments investing heavily in healthcare sector development, reformation of health care systems, and substantial unmet medical needs.

Figure 3: Global GDP Trends: 1980

![Figure 3: Global GDP Trends: 1980](source: NovelHealthStrategies)

Figure 4: Global GDP Trends: 2010

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Since early 1960s the medical industry has been asked to show safety and efficacy of their products to obtain market approval. Collectively, the industry and regulators has spent more than 50 years defining and implementing what that means in legal and practical terms. As an industry we are now at the beginning of that discussion in the value case, and globally market access is increasingly defined by provided value, which in turn has great implications during development, trial design, labeling, etc., to better leverage evidence-based or outcome based medicine, by demonstrating patient, payer and provider value.

**Building and Communicating the Value Case**

The global macro-economic issues push governments and local payers to cost-containment measures, including assessments of generic substitution, health economic evaluations and parallel imports on pricing, which are themselves influenced by geographically localized pricing trends such as Medicare reform in the U.S., NHI price cuts in Japan and European reference pricing.

UBC reports that payers consider that less than half of recent medical treatment launches represent sufficient value for money, indicating a gap between industry and payers on perception of value. Industry needs to work more closely with payers to understand the drivers of value and address the payer perspectives earlier in product development.

Figure 5: Global policy changes have increased the importance of payer stakeholders

"I won't approve any acquisition in which the target company can't explain the pharmacoeconomics – even a deal in which the risk related to unknown pharmacoeconomics is built into the terms" CEO April 2011

Source: NovelHealthStrategies
Value can be defined in numerous ways depending on the stakeholder group and its value drivers. For example, consider regulators where well established expectations to value are based on safety and efficacy, while payers increasingly focus on budget impact. Physicians consider effectiveness, side effect profile, adherence and compliance, while patients seek quality of life.

The relative shifting of value is presently, based on stakeholder definitions, influences the method medical technology and pharmaceutical companies apply to demonstrating value to each unique constituency/stakeholder.

Figure 6: Key Stakeholders for Market Access

Evidence is the ‘New Black’ – But Depends on Viewpoint

Different stakeholders view evidence of value through different lens. The table below highlights some of these varying perspectives.

The learning from discussions with a broad array of stakeholders points to ensure each stakeholders’ perspectives and value priorities, and to take a broad and inter-disciplinary approach to ensure all viewpoints have been considered in preparing for access to the market. Recommendations suggest that this can be accomplished by careful planning using a well-defined step-wise process:

1. Designing trials to collect the endpoints that will be meaningful to payer audiences as well as regulatory bodies
2. Gathering and generating sufficient evidence to demonstrate value to health technology assessment bodies (HTA), payers, and patients
3. Complying with regulations to assure safe use
4. Minimize administrative burden to providers of care

Source: NovelHealthStrategies
5. Designing support programs to assist providers and patients in gaining access to the needed products
6. Tailoring messages to the right audiences at the right time, including labeling and claims

Figure 7: Matching Value Expectations

<table>
<thead>
<tr>
<th>Audience</th>
<th>Viewpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical or Clinical Affairs</td>
<td>Will the clinical trial endpoints be met, and if so, will the evidence be sufficient to receive approval by the appropriate regulatory body?</td>
</tr>
<tr>
<td>Prod. Commercialization Teams</td>
<td>What will product uptake be? How do I remove any potential obstacles to uptake?</td>
</tr>
<tr>
<td>Providers</td>
<td>Should I prescribe this for my patients and why? Are there payer-imposed restrictions that make it administratively burdensome to prescribe?</td>
</tr>
<tr>
<td>Patients</td>
<td>Is this a good treatment option for me? How hard will it be to gain access to the product? How much will I need to pay out of my pocket?</td>
</tr>
<tr>
<td>Health Technology Assessment</td>
<td>Does the evidence support that the technology meets (or fails to meet) the criteria evaluated?</td>
</tr>
<tr>
<td>Regulatory Body</td>
<td>Does the evidence prove the product works? Is it safe and efficacious? Do the benefits outweigh the risks?</td>
</tr>
<tr>
<td>Payer</td>
<td>Is the product safe and efficacious? What is the cost? What is the value relative to other therapies? What techniques should be used to ensure appropriate utilization/adherence?</td>
</tr>
</tbody>
</table>

Figure 8: What can a manufacturer do to build a compelling case for its product’s reimbursement?

Source: NovelHealthStrategies
Market Access of medical technology and pharmaceutical products has thus developed into a rigorous technology assessment by all stakeholders in the product life cycle, serving to inform decisions around how and when new products will be accessible.

Demand for more evidence that a product is not only safe and efficacious, but that the value can be clearly demonstrated, particularly as compared to competitive therapies, drive future uptakes and should be at the core of corporate product development.

Companies can benefit from engaging in new alliances and partnerships with relevant stakeholders, collaborating in defining value requirements reflecting national, regional, and local priorities and requirements for safety, efficacy and quantifiable economic value.

Overall strategy to market access needs to be an integral part of medical life cycle management, both in terms of pre-clinical development and post-market positioning after end of patent life.

An approach to address overall corporate market access strategy could benefit from considering:

A. Market Assessment
B. Indication and Product Assessment
C. Value Demonstration
D. Value Communication
E. Performance Monitoring

A. The objective of market assessment is to obtain detailed knowledge of the local characteristics and institutional drivers, including analysis of the fundamental economics, health policy structure and priorities, stakeholders and decision maker relations.

Market assessment should aim at listing each critical constitute, identify institutional and personal level relations, and weigh the relative ‘power’ or relevance for the full life cycle of the medical product in question.

Data and relation driven market access includes organizational competencies to link external value drivers to internal development plans, key performance indicators, and milestones.

B. The objective of indication and product assessment is to link the relevance of the indication and product attributes to market needs. This include analyzing priority markets and product mix, reimbursement trends, competitor positions and key constitutes value propositions.

For example, is the product in question a new formulation, delivery system, a me-too, addressing unmet medical needs, changing the provider requirements in administration etc. All potential hurdles in defining best possible value proposition for each market, including local traditions and practice of medicine.
Part of the market access exercise include development of value propositions from each constitutes viewpoint, i.e. value-add and requirements for regulators, payers, physicians, key opinion leaders, patient affiliations and consumers.

C. The objective of value demonstration is to ensure best possible market listing price, tier placement or positioning in a product mix category. Value claims are required to be data driven at same level as clinical safety and efficacy data for regulatory submissions.

Data is the foundation to demonstrate value by cost effectiveness comparisons, budget impact, quality of life analysis, effectiveness and patient adherence to treatment, based on each constitutes value expectations.

Price sensitivity analysis based on above data requirement will help developing key messages and value attributes of the medical product.

D. The objective of value communication is to enable communication of product attributes based on safety, efficacy and value data sets attractive to payers, patients and society as a whole.

Value communication build on the strongest set/mix of data requirements balancing key attributes of the product safety profile, real life effectiveness and overall value proposal. Value communication should include all stakeholder input and mirror expectations to a new product prior and at market launch. This will help to overcome objections, balance expectations and ensure ‘ownership’ and pre-launch knowledge to the relevant group of constitutes.

E. The objective of monitoring performance is to align the organization with changing market dynamics and individual stakeholders shifting priorities throughout the product life cycle.

The healthcare market is not static and local characteristics and learning’s will likely apply broader throughout the product life cycle, as the international health care market continues to consolidate.

Performance data will be widely available, both through organizational monitoring and third party prescription databases, claims databases, authorities gathering of side effect profile etc., data the originator company does not own and can be applied and use broadly by different stakeholders, including competitors and new market payers.

For the medical technology and pharmaceutical industry, development of new products and services requires understanding and inclusion of the payer perspective and context, including issues defining and driving policy, reimbursement, and coverage decisions.

Healthcare market access is as much about understanding and including global stakeholder trends, and being pragmatic about linking it to local applications of increasingly value-driven healthcare systems.
For the organizations involved in medical and pharmaceutical product development this includes new sets of competencies and capabilities, disciplines focusing at adding, documenting and communicating value at each successive stage, facilitating a coherent process towards securing value-based dialogue and new technology adoption by cost-constrained global healthcare markets.
About the Author

Mr. Mikkelsen is the Managing Healthcare Counsellor for the Trade Council, Embassy of Denmark, Washington D.C., United States, facilitating innovation and export promotion, health policy and government/public affairs, including regulatory and market access services for stakeholders in the life sciences industry.

In particular, the Embassy of Denmark is committed to engage with governments and other stakeholders to discuss processes and principles that will enable the development of framework conditions, including regulatory, pricing and reimbursement systems that reflect the value of medical products, reward innovation and ensure market access for medical treatments.

Key Principles are developed and orchestrated with academic, government, industry and patient associations and cover:

- Regulation, pricing and reimbursement mechanisms should adequately reward innovation and market access
- Regulation, pricing and reimbursement mechanisms should be predictable and transparent
- Regulation, pricing and reimbursement mechanisms should allow rapid access and meet the needs of all stakeholders
- Regulation, pricing and reimbursement should ensure and reflect patient outcomes and increased quality of care

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