Commercial excellence in Pharma 3.0
Introduction

The pharmaceutical industry is navigating a profound transformation. As markets shift rapidly, companies are scrambling to adapt their commercial models for competitive advantage. The traditional “Pharma 1.0” model, built on producing blockbuster drugs, has made way for a more diversified “Pharma 2.0” model – the quest to bring broader, more diversified product offerings to a more global market. At the same time that companies are evolving to Pharma 2.0, they are already moving forward to the next phase of development, “Pharma 3.0.” At the center of this model are service components that enable companies to deliver health outcomes – defined as (clinical and economic) health benefits per dollar spent.

This shift represents a prime opportunity for the pharmaceutical industry to explore a variety of new business models focused on health outcomes, ranging from improving the performance of their current products on the market to tapping into new revenue streams associated with health care delivery.

Pharma 3.0

Today’s pharmaceutical industry is facing strong headwinds. Cost containment initiatives by payers – governments and health care insurance organizations alike – have created a challenging business environment, with controlled pricing, promotion of cheaper generic alternatives, and greater obstacles to bringing innovative drugs to market. At the same time, the industry’s investment in research and development is not providing the needed return on investment through more “blockbuster” drugs. For many years, these drugs – broadly defined as primary care drugs with more than US$1 billion in revenue per year – have been the centerpiece of the industry’s successful business model that we call “Pharma 1.0.” Compounding these challenges, regulatory requirements to ensure drug safety have grown more stringent, bringing increased scrutiny of marketing practices and creating higher hurdles for reaching the market.

To help alleviate these pressures, the industry has, over the past decade, followed a strategy of diversifying into a “Pharma 2.0” model around product lines that are less exposed to R&D and market risks, such as generics, vaccines, over-the-counter medicines and medical technologies. While this approach is helpful in the mid-term, long-term sustainability will require shifting to a new business model, one that will address the real needs of the industry’s customers – the patients, payers and physicians – and contribute significantly to the ultimate goal: improving patient health. This requires shifting away from an arm’s length approach, one that has centered on delivering drugs to the health care system. Instead, it calls for an up-close focus on the patient, providing products and services specifically designed for health improvement. This new degree of engagement is what we call “Pharma 3.0.”

In the Pharma 3.0 business model, which has been the topic in our two most recent reports on the pharmaceutical industry – Progressions: Pharma 3.0 (2010) and Progressions: building Pharma 3.0 (2011) – the industry will collaborate with other players, such as information technology companies, medical technology companies, food companies and retailers, to deliver patient-centric products and services.

Pharmaceutical companies around the world have started implementing these Pharma 3.0 patient-centric initiatives, mostly in the form of pilot projects. As of February 2011, we had already counted 220 such initiatives. These are collaborations and partnerships aimed at helping patients to manage their health, expand their access to products and services and address unmet medical challenges.
In this highly dynamic context, pharmaceutical commercial organizations are under immense pressure. They must enable multiple business models, adapting their approaches to the market, with an evolving value proposition for numerous, rapidly changing stakeholders. As organizations understand what drives value for these market stakeholders — and then vigorously align their value propositions and commercial models to the changing drivers throughout the offering’s life cycle — they will achieve a fundamental goal: commercial excellence.

We have identified three critical components for commercial excellence within Pharma 3.0:

- **Understanding what drives value**: developing the ability to continuously identify, monitor and map the changing value drivers for diverse market stakeholders.

- **Taking an agile approach to the market**: providing a dynamic value proposition, through appropriate channels and optimal relationships, that meets changing demands along the offering’s life cycle. This involves enabling the interplay among business model development, market access and product launch around what drives value for individual stakeholders.

- **Becoming an enabling organization**: taking a customer-centric view, organized around market stakeholders, and learning in real time.
Pharmaceutical commercial excellence

Understanding what drives value

As pharmaceutical companies refine their current Pharma 2.0 approaches to the market or build entirely new Pharma 3.0 business models, they need to do so in a highly “stakeholder-centric” way – developing offerings that are not only economically viable but that also address the value requirements of their customers as well as business partners. Then – and continuously – they must learn: learn to identify, monitor and map these rapidly evolving drivers for their markets and stakeholders.

Sophisticated health information technology is further enabling, and accelerating, an outcomes-driven industry. Patients and their support groups are becoming “super-consumers” – capable of making real, value-based decisions based on health outcomes while increasingly taking an important role in driving policy-making.

Stakeholders

As changing market incentives are reshaping the health care ecosystem, the stakeholder landscape for the pharmaceutical industry is swiftly shifting as well. Payers and patients are increasingly taking the lead in decision-making.

In the Pharma 1.0 model, and within mature markets, making decisions about what to buy or prescribe was traditionally the role of primary care physicians. In the more diversified Pharma 2.0 model, decision-making increasingly includes payers and patients. In the Pharma 3.0 model, focused on health outcomes, the role of physicians in decision-making is influenced by payers and patients who decide what offers the best value for their money, in terms of a positive improvement in health outcomes or concrete economic benefit.

Emerging markets are following a similar transformation toward outcomes-based models, with payers and patients now central to decision-making. In many emerging markets, patients historically have made considerable out-of-pocket contributions to access health care. In response, and with the aim also of improving economic growth, governments have striven to develop systems offering universal access to health care. With low income per capita, the drug market in these countries today is primarily driven by cheaper generics. However, rising income is making access to higher-priced branded medication possible, in turn requiring government intervention – very often based upon price cuts, but also with emerging considerations around health outcomes.

Sophisticated health information technology is further enabling, and accelerating, an outcomes-driven industry. Mobile health technology provides real-time access to digital health information, supporting diagnosis and monitoring as well as providing the opportunity to drive patient adherence and compliance. Social media platforms enable the sharing of health information. The convergence of social media and health information delivers the added benefit of empowering patients in health literacy, giving them access to information that in the past was available only to their health care providers. Patients and their support groups are becoming “super-consumers” – capable of making real, value-based decisions based on health outcomes while increasingly taking an important role in driving policy-making.

This tremendous expansion of available health data is empowering payers in their decision-making – with the ability, for example, to “mine” data as a basis for outcomes-based pricing and reimbursement schemes, and to assess a particular treatment’s ultimate effectiveness within a real-world environment (as opposed to a tightly controlled study environment).

As the stakeholder landscape shifts, it also becomes increasingly fragmented. Health care systems around the world are highly varied and have developed in diverse historical, economic or cultural environments.

Furthermore, governments, faced with the complexity of managing health care systems at the national level, have often engaged in a devolution process, granting decision power for health care to local or regional governments.

Adding to this complexity, distribution systems vary widely across countries, with wholesalers and pharmacies not only having a strong impact on how margins are distributed along the value chain but also having strong political power to influence policy-making.

Finally, in emerging markets, other considerations, such as demanding investment in local manufacturing, directly or through alliances, often come into play and must be understood and reflected in commercial strategy.

Value drivers

As the role of alternative stakeholders increases, their attention progressively turns toward a very subjective, real-world definition of what drives clinical and economic effectiveness within their own very focused and individual systems. For the payer, determining the value of a specific health intervention for its highly specific, managed population is a complex undertaking, one that must include examining health interventions not only from a medical perspective but also from the standpoint of the economic, social and ethical implications of these interventions.
Around the globe, a multitude of health technology assessment organizations have begun advising payers on drug access, pricing and reimbursement, at the national and local levels. While measures have been taken to streamline the methodology of these assessments, value drivers underpinning final decisions remain variant across markets – deeply rooted within their specific, local economic environments, varying cultures and perceptions of value.

What represents value for payers is also evolving beyond the drug launch phase. While data required to support drug safety, efficacy and effectiveness was once generated mainly through clinical and pharmacoeconomic trials during drug development, a focus on outcomes now implies real-world data that needs to be captured while the product is on the market.

An even more complex landscape is currently emerging for newly empowered patients, who have diverse cultural backgrounds, different personal values, and varying levels of technological access and sophistication. Value drivers for this group are evolving, too, beyond safety and efficacy. Health care system reforms have often increased patient participation in the cost of treatment, as out-of-pocket costs are an important consideration. New dimensions, such as quality of life, are also emerging for a group of stakeholders that continues to expand.

Patients cannot be considered the sole stakeholders in receiving health interventions. Increasingly, the close support group of families and friends, as well as the daily point of contact to health delivery, such as nurses, influences treatment decisions and behavior, for example by driving adherence and lifestyle change. While patients and their support groups might, historically, have taken the burden of side effects or treatment complexity for granted, their increased literacy and connectivity to other stakeholders is now enabling them to compare treatment alternatives and make their own judgments. For example, in considering a specific treatment, they now have a more informed basis for evaluating how much loss of quality of life they are prepared to accept.

The level of “emotional connection” is an added dimension of critical value. While in the past, this connection was made mostly with the physician, today the patient is exposed to multiple points of influence, such as peers on social websites, patient advocacy groups and educational websites provided by pharmaceutical companies. Patients, their families and their support groups must be offered a broader trust relationship, based on subjective benefit of the brand and on the individual medical intervention.

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**Patient pathway: illustrative example for cardiovascular diseases**

- **Improved awareness of CVD could lead to:**
  - Early detection of the disease, hence early intervention
  - Potential increase in the size of patient group, especially those who previously were unaware of the condition

- **Inpatient assessment and treatment**
  - Discharged as outpatient

- **Outpatient rehabilitation and further information**
  - Refer for specialist treatment
  - Pharmacological treatment
  - Exercise
  - Lifestyle management

- **Follow-up appointment**
  - Monitoring the patient's health signs and related CVD risk factors could lead to early detection of a second heart attack.
  - Remote monitoring could reduce the burden on health services.

- **Post-acute disease management**
  - Psychological and educational interventions

- **Secondary prevention**

**Recovery timeline**

6–12 months

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**The patient pathway serves as a central framework to understand treatment patterns, to identify value-driving factors of a product and to develop accordant health outcomes-oriented value propositions.**
Mapping value drivers

Faced with such complexity, pharmaceutical companies need to thoroughly understand and map the specifics of what it is that drives value for individual stakeholders – from payers, physicians and nurses to patients and their support groups – and begin marketing to “a market of one.”

The patient pathway – from awareness, through treatment, to sustained health – becomes the defining backbone of such value driver maps.

The individual value driver map ultimately serves as the foundation for development of targeted offerings and value-based business models – framing specific market access decisions and spearheading the development and delivery of market offerings across the life cycle of the product.

Insight has become key – insight into the subjective value drivers of a specific audience. Such insight can be obtained through multiple sources: direct personal interaction, traditional and social media, key account management, clinical trials and customer service.

Thus, the industry must learn to listen and to enter into individual dialogues.

Strategic listening has become the key enabler of understanding individual and shifting value drivers, defining necessary new roles and capabilities and challenging the ability of organizations to translate such insight into targeted marketing approaches.

The pharmaceutical industry has had to learn to give up control, shifting the communication product features toward a dialogue based on the subjective benefit of the listener.

Taking an agile approach to market

In such a dynamic business environment, commercial excellence will require the provision of robust, individualized value propositions, addressing and responding to needs as they evolve.

The initial strategic approach to a given market will be static – a clearly defined business model, including a value proposition, the definition of the stakeholder base, the type of relationship sought and the mix channels chosen to address the market. This initial business model must, however, adapt and grow, reflecting lessons learned and insight gained from market interaction. Such insight must then be used to adapt and refine the models accordingly, maturing as the stakeholder relationship grows and develops.

This trial and response approach becomes more and more fluid, the value proposition more dynamic, as customer needs, channels and stakeholder relationships continue to evolve. Companies must remain agile and responsive in commercial interaction and offerings, as this will increasingly determine market access and commercial success.

An agile approach to the market involves the interplay of four components:

1. **Business model development**: creating a value proposition and associated business model through commercial trials
2. **Market access**: optimizing relationships and working assets to best enter markets and build a sustainable presence
3. **Product launch (and relaunch)**: optimizing the business model in terms of value proposition and communication channels during market entry or re-entry phases
4. **Commercial investment portfolio optimization**: conducting high-end analytics and business modeling to drive transparency around informed investment spend, to align and synchronize such activities cross-market, cross-brand, cross-channel and cross-stakeholder-group.
Core capabilities for Pharma 3.0

Three new core capabilities are needed for life sciences companies to succeed in Pharma 3.0: connection of information, radical collaboration and the ability to operate multiple business models simultaneously.

Many of these patient-centric models will be patient data rich, requiring intensive data management, with regulatory and technical standards for ensuring data privacy and interoperability. Today, the industry’s infrastructure is geared toward delivering drugs to the market, with capabilities focused on researching, developing, manufacturing and marketing products. To deliver services targeted at improving health, pharmaceutical companies will need to develop additional capabilities in tracking, storing and analyzing patient data and using information to develop solutions tailored to the patient needs.

No single entity will have the full complement of skills, expertise and insights required to develop the innovative outcomes-based solutions demanded by Pharma 3.0. As a result, the externalization of drug R&D that has been under way in Pharma 2.0 will be taken to an entirely new level in Pharma 3.0, as companies collaborate across the value chain with very diverse and different entities to develop these new offerings. And the process of partnering and innovating will be increasingly open, with new mindsets and approaches for jointly creating and demonstrating value throughout the cycle of care.

The winners in Pharma 3.0 will also need to operate multiple business models – often tailored to an array of customers in different health care systems and geographies – simultaneously.

Business model development

As business models transition from Pharma 1.0 to 3.0, the value proposition is evolving from a pure product play to health outcomes delivery with an increased service and information component. Regardless of the product or service being offered, aligning its development to evolving value drivers in the market will be critical for success.

For new products, these value drivers need to be integrated at the beginning of the drug development process. Interacting with key stakeholders such as patients and payers helps ensure products are developed to meet stakeholder needs and produce the right evidence to substantiate value. Insights into evolving needs, along with clinical insights during development, support prioritizing the development portfolio for optimum performance. Scenario-modeling techniques can help companies select the best opportunities and prioritize their launches.

Historically, new product development has been a core capability of the pharmaceutical industry. But today, the ability to develop new business models around health outcomes is equally important. Unlike product development, business model development requires multiple stakeholders to collaborate – and co-create – around a patient’s cycle of care. Also, as many of these players contribute unique assets or capabilities, the nature of the collaboration required for these models to be effective often goes beyond a simple fee-for-service relationship. It is based instead on players combining their business models into new models aimed at delivering improved health outcomes. Another challenge is defining and measuring health outcomes as a value proposition. Defining initial value and measuring ongoing performance requires an approach based on business modeling as opposed to a traditional approach based on volume of products sold.

Successfully developing new business requires rigorous commercial trials but also entirely new roles and accountabilities, new incentives, capabilities, metrics and mindsets. The foundation for developing and managing the life cycle of these business models is a thorough understanding of the evolving value drivers along the patient pathway for the targeted indication and markets.

We have defined a five-step approach to developing a new business model around health outcomes:

Step 1: Intend. Set the framework for new business development. Identify themes that fit strategically, define goals, and agree on criteria and metrics for filtering ideas. Commit resources, including engaging senior stakeholders, and establish a framework for early governance.

Step 2: Investigate. Thoroughly analyze the market. Understand what is possible in terms of enablers, for example to drive behavioral change. Seek customer insights along patient pathways to better understand the patient environment and inform further decision-making.

Step 3: Ideate. Prescreen ideas to determine the most promising and realistic ones. Support rapid prototyping by developing a business case and a structured portfolio of business models for piloting.

Step 4: Incubate. Conduct commercial trials, based on developing strategic partnerships and initiating pilot projects. Adapt business models based on customer and partner feedback and select pilot projects for scale-up.

Step 5: Implement. Scale up pilot projects and deploy across selected markets.

Regardless of the product or service being offered, aligning its development to evolving value drivers in the market will be critical for success.
Market access

We define market access as a holistic view of how a company manages its entry into, and presence in, its overall market. Critical for successful access are an in-depth understanding of the local market and insights into potential future developments.

Based on this understanding, local stakeholders such as patients, health care providers, payers, or policy makers and their value dimensions are mapped. Then, stakeholders can be further segmented according to their ability to influence regulatory approval, listing, pricing and reimbursement.

The complex decision processes associated with these dimensions, which vary across geography, therapy areas and position in the product’s life cycle, need to be considered. Direct and indirect influencers must be identified and their ability to influence stakeholders understood.

A combination of the identified values of the stakeholders as well as segmentation strategies lead to value-based segmentation models enabling enhanced understanding and interaction with the key stakeholders.

Market access is particularly challenging when preparing the market for new business models that move beyond traditional products and involve multiple stakeholders. Most payers are still operating in the nascent state. Today, the focus is still largely on volume discounts and reimbursement.

The role of rewarding pharmaceutical companies for the products they deliver to the system. Processes and metrics to appraise measure and reward performance in delivering health outcomes through a combination of products and services are either not yet in place or are in a nascent state. Today, the focus is still largely on volume discounts and risk-sharing agreements.

Understanding the local enabling infrastructure becomes critical when the new business models rely on social media platforms, electronic health records, telecommunication networks or wireless networks. It is essential to understand the level of deployment of the infrastructure in place, how it will evolve, who the key stakeholders are and what the associated regulations are, for example, for data privacy.

Based on this in-depth understanding, effective interaction strategies need to be developed with an overarching goal of building positive and sustainable relationships. Points of interaction must be considered along patient pathways beyond interacting directly with the health care patient to other areas, such as building disease awareness and interacting closely with patient organizations or key opinion leaders.

Today, buyers for this new business model often do not exist. The industry and its associations must engage critical stakeholders— from payers to policy makers, health care providers to patient organizations, technology players to retailers – in co-developing these processes and metrics to support an efficient market around health care delivery.

Identifying and selecting the best partners for local collaboration requires an in-depth evaluation, based on a range of considerations – from hard criteria such as the assets they bring into the collaboration, financial strength or partnering history to the softer aspects of reputation or credibility.

Most important, the message communicated needs to be value driven. The ultimate goal is an agreement with payers on the listing, pricing and reimbursement of the product or product-service combination. As service components are added to the business model, complexity increases, but also new opportunities arise, expanding the range of possible agreements beyond pricing or risk-sharing schemes to health management and capitation. In these cases, systems and processes to measure the performance of the value proposition on the market must be developed to collect information for substantiating the value delivered.

Product launch and relaunch

The launch and relaunch phases rely on the ability to prepare the product and the market for launch and then dynamically adapt the value proposition and commercial model to the market over time as stakeholder needs are discovered or evolve. These activities are critical for commercial success, as they will shape the revenue curve over the life cycle of the product and its value proposition.

The interplay between new business model development and market access is most critical in the launch and relaunch phases. Depending on the nature of the value proposition, product or service, the new business models must offer opportunities to either reshape the current launch curves or to create entirely new sources of revenue. In both cases, the value proposition will need to be continuously adapted to meet stakeholders’ changing needs throughout the lifetime of the offering.

Most companies today are organized by brands, and complex promotion strategies are designed to optimize brand opportunities. These strategies are usually based on a frequency model that focuses on driving sales by delivering a high number of promotion touches with little or no coordination across promotion channels.

A key consideration for customer-centric launch and relaunch activities is defining the ideal target audience and refining the messaging and management of communication channels. Here again, a thorough understanding of the involved stakeholders and what drives value for them can serve as a framework to guide these activities in the form of a value map.
This value map supports the definition of the target audience and their value drivers. Along with articulating and refining the attributes of the value proposition, the value map will be used to direct the nature of the messaging.

The next key consideration is managing communication channels. The number of channels available has increased greatly. Today, we have a wide variety of channels, ranging from the traditional physician detailing or direct-to-consumer advertising (where permitted) to more innovative channels, such as patient ambassadors, informational websites, social media and mobile applications. Sophisticated channel management, for example, by using forecasting techniques to assess potential channel effectiveness, will help drive decisions in selecting the appropriate channel mix.

With evolving channels, the mode of communication has evolved as well, moving from unidirectional and product-centric communication toward an active, two-way dialogue, which engages community stakeholders. In this dynamic environment, the improving ability to continuously monitor how the market responds, quickly adapt the messaging and channels, and alter or fine-tune the interaction with stakeholders is key. Steps also must be taken to ensure that messages are consistent across channels and stakeholders and insights gained are rapidly and appropriately channeled back into the organization.

**Commercial investment portfolio optimization**

Commercial investment portfolio optimization (CIPO) provides a rigorous tool for market analysis and decision-making. Through the application of high-end analytics and modeling techniques, companies can optimally allocate investment across markets, products, distribution and promotion channels. In essence, CIPO seeks to answer the questions: What would be the relative contribution of making an investment in one market-brand-stakeholder-channel combination rather than another? What would be the opportunity cost of not making a specific investment elsewhere but taking that investment – for example, in a new channel – to an emerging market?

In the more traditional product-based business models, decisions on product portfolio or optimal distribution and promotion channels rely on return-on-investment assessments. This approach is based primarily on historical data and allows only for short-term forecasting.
Becoming an enabling organization

In our 2011 industry report *Progressions: building Pharma 3.0*, we addressed at length the need for companies to build new core capabilities for success in Pharma 3.0. These new capabilities will enable connecting information, collaborating radically and operating multiple business models simultaneously.

Beyond these enhancements at the enterprise level, the commercial organization must realign itself dynamically around markets and stakeholders. Other industries, such as the consumer products industry, have long since aligned their organizations around key market stakeholders.

Currently, the pharmaceutical industry is product- or brand-centric, resulting in functions that are siloed across the value chain. To shift to a focus on market stakeholders, information on all stakeholders, and on what drives value for each of them, will need to be managed centrally and integrated into business model development, market access and product launch activities. Yet the dynamism of the market and the interplay among these activities will require an agile organization with silos removed and enabling functions closely aligned in culture, behavior, management and performance measurement. In today’s dynamic business environment, rigid organizational structures and processes will not work. Organizations will need to learn from their commercial experiments and adapt in real time.

Conclusion

As the health care ecosystem continues to shift and evolve, pharmaceutical companies are being challenged to adapt their commercial models to offer individualized value propositions increasingly centered on delivering health outcomes.

In this highly dynamic environment, commercial excellence will be driven by insight – insight into value requirements, insight into what it is that determines and drives certain behavior. A relentless focus on understanding what drives value for market stakeholders must determine agile and adaptive business models able to flex to the complexities and needs of a dynamic market. As such, commercial excellence implies a dynamic interplay between business model development, market access, product launch life cycle management, and the ability of an organization to collect, assess and reflect market learning, in real time.
EY’s commercial excellence services

- **Organizational design and refinement**, supporting the requirement for evolution and transformation within an increasingly health outcomes-driven market: challenging the corporate mind-set; refining roles and accountabilities; developing performance measurement frameworks and systems; and driving customer-centricity throughout the organization, into every process and work behavior
- Robust and proven methodologies to drive **business model development**, enhance capabilities, and empower the necessary adaptability and speed-of-response to shifting value requirements
- Design of comprehensive **stakeholder insights management** methods
- Development of **stakeholder interaction models** to build a sustainable market presence based on long-term relationships
- Support of the entry strategy decision and definition of the **market access approach for emerging markets**
- Assistance with implementation of advanced processes and systems for planning, reporting and decision support to make **educated investment trade-off decisions**

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