strategy&

2017 Pharmaceuticals and Life Sciences Industry Trends

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Ways to manage data, value medical treatments, and engage with patients in the New Health Economy

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Introduction

Pharmaceuticals and life sciences companies are experiencing a wave of competing challenges as part of what could be called the New Health Economy. They include consolidation among providers, especially hospitals, intended to produce efficiency gains; the changing demands and expectations of patients, who seek a greater role in their own care; increasing cost pressures from payors leading to calls for pricing reform; and the declining autonomy of the individual physician as rule-based, protocol-driven care becomes ascendant. The resulting healthcare system will focus increasingly on paying for the value rather than the volume of medical care; in other words, it will be a more consumer-facing industry.

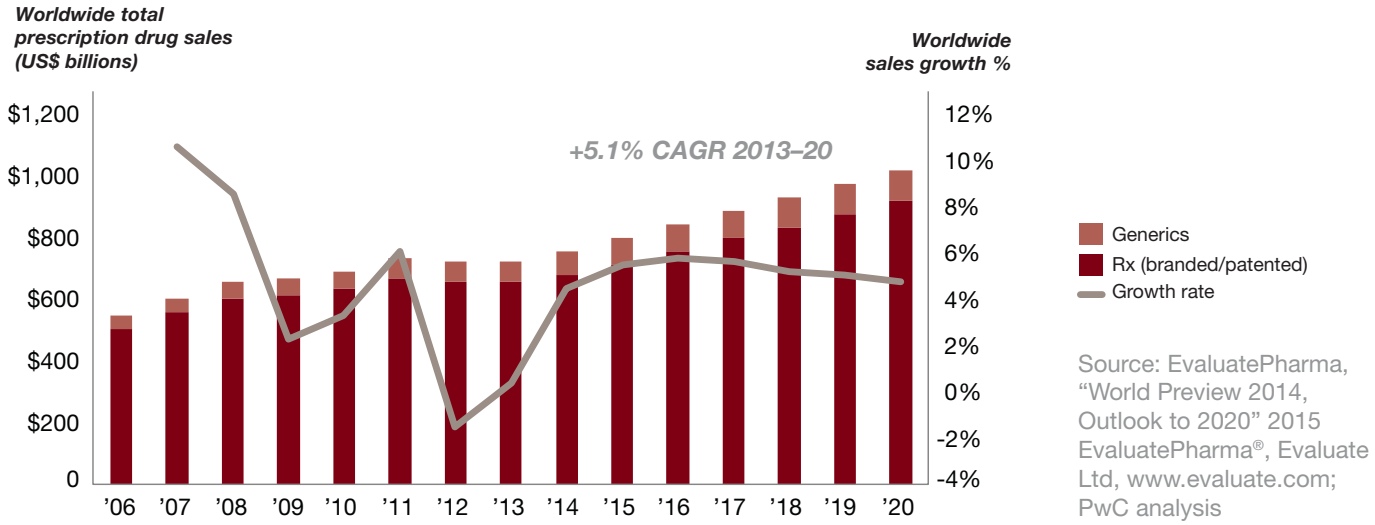
Pharma companies have always interacted with consumers. They have marketed directly to users, especially in the U.S., and they involve patients in clinical trials. They thus have some limited experience with consumer-facing business models. But the industry's traditional means of engagement will no longer be sufficient.

In this new era, pharma companies will have to become more proactive with large communities of patients and go beyond lip service in meeting the needs of a wide swath of consumers. Although the sale of products will always be a priority, in the New Health Economy, pharma companies will also have to concentrate on delivering positive results: health, well-being, and optimal management of illness among targeted populations.

Some pharma companies are positioned to capitalize on this situation — to demonstrate the clinical and economic value of their products and solutions in fresh ways. These companies have begun to adopt new technologies for data analytics that can manage and assess the results of personalized medicine delivery and determine the direction of product development. The companies are also reexamining the way they look at the value of their products and their pricing and distribution structures, while designing systems that let them communicate more effectively with patients and monitor outcomes. In the coming months and years,

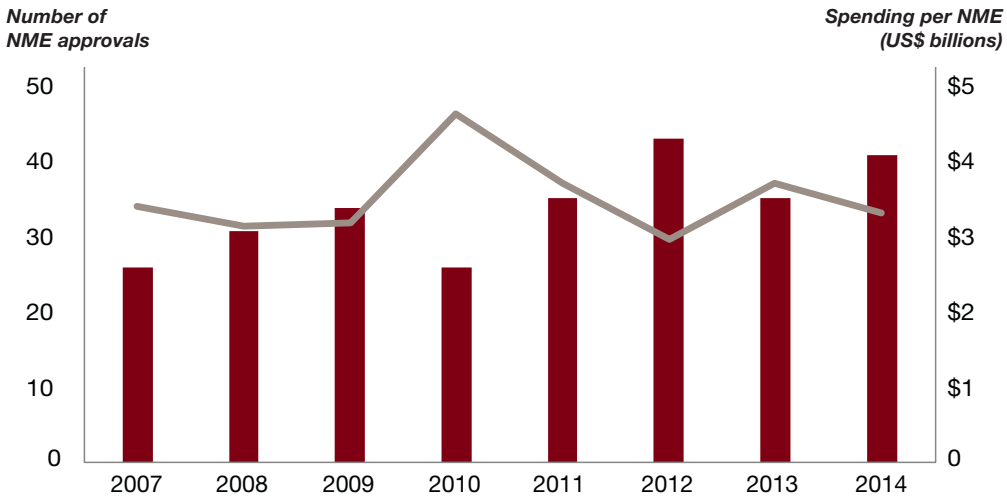
these types of activities will gain importance in the pharma industry. Here's a closer look at three pivotal healthcare and pharma industry developments and the urgent strategic initiatives that pharma companies must confront in 2017.

While the pharma industry struggles with stagnant growth rates…



Source: EvaluatePharma, "World Preview 2014, Outlook to 2020" 2015 EvaluatePharma®, Evaluate Ltd, www.evaluate.com; PwC analysis

And is unable to wring significant savings from R&D expenditures per new molecular entity (NME)…



Note: Three-year lag spending per NME; R&D expense for three years prior to the NME approval.

Source: Paraxel Biopharmaceutical R&D statistical handbook 2014/2015; PwC analysis

Companies that hope to improve profit margins by adopting data analytics strategies are constrained by a lack of big data talent.

A constrained big data and analytics talent environment

Demand for deep analytical talent in the U.S. could be 50 to 60 percent greater than projected supply by 2018

Supply
Demand

Source: PwC analysis

The year of the patient

"Patient first" has become a rallying cry in the pharma industry, but not all companies can live up to that standard. In general, the most successful firms are moving away from a traditional, top-down model of product promotion and toward a flexible, interactive approach that gives patients better tools and more focused information about the drugs they are taking and how to manage their conditions. The insights that drugmakers provide to patients reduce potentially dangerous errors related to taking the drug and minimize the time that patients have to spend managing their disease and navigating the healthcare system.

This patient-first business model helps establish pharma companies as valued partners of consumers and, by inference, of society at large. In turn, pharma companies that succeed in patient engagement efforts increase their chances of regulatory and commercial success as decisions about approval, prescribing, and marketing of drugs are more closely tied to patient results and needs.

To productively collaborate with patients, pharma companies need to find better ways of communicating with them. They also need a more effective data analytics practice: a way to gather and analyze data about patients' day-to-day compliance with treatment protocols and the efficacy of the treatments. Although many patients are sensitive about sharing personal information, a recent survey by PwC's Health Research Institute found that most people are willing to let pharma companies and regulators know about their medical activities if it will lead to better care.

Due to advances in digital and medical technology, pharma companies and healthcare providers can access patient data seamlessly, in real time, and with little inconvenience for patients. An array of tools can be combined with online portals and mobile apps to foster better, more immediate communication. These include newly approved equipment such as miniature implants, vital signs tracking devices, remote monitoring biosensors, and noninvasive diagnostics. Some pharma manufacturers are also developing smartphone apps to stay in touch with patients, survey them daily about their pain levels and other

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symptoms, and remind them of their prescribed medication schedules. In some cases, the pharma company continually examines the survey results and connects patients with healthcare providers when necessary. These apps can also be used to track the progression of a disease or recovery and help healthcare companies better understand patient needs.

Since treatment compliance is primarily influenced by individual habits and attitudes, pharma companies should also explore the behavioral sciences for insights about encouraging better patient decision making. They can use better incentives and various forms of social influence to improve health. Ongoing studies have shown, for example, that offering daily financial incentives can positively affect the behavior of patients with chronic conditions. In one program, obese patients who were given the chance to win a daily lottery prize of about $3 by participating in a weight-reduction program lost a pound a week over a period of four months. And they maintained that weight level better than control groups. In another study, a daily lottery increased drug compliance among patients who were identified as unlikely to follow treatment protocols for the blood thinner warfarin, which reduces the risk of a stroke.

Another component affecting behavior is patients' "activation level" — their health-related knowledge, skills, and ability, and their willingness to manage their own health. Companies can increase the level of patient compliance and self-care by tracking where patients are along the activation continuum and creating relevant and aligned messaging to meet each individual patient's needs. As their relationships with patients expand, pharma companies can prompt providers, pharmacies, and professional caregivers hired by them to intervene with patients in order to help guide their healthcare activities.

The rise of analytics

The second major industry development is the rapidly increasing importance of analytics. The pharma industry is at the early stages of a fundamental shift as so-called enterprise analytics and advanced data sciences are embedded across the value chain to influence business decision making at all levels. For the last four decades, the volume and variety of medical information has expanded significantly, a trend driven in large part by continued innovation and large-scale utilization of electronic medical records, high-resolution medical imaging, and next-generation genomics. Pharma companies have begun to realize real benefits from this evolving data ecosystem, using new methods for rapid acquisition, curation, analysis, and visualization of large, diverse data sets in cloud-based storage and distributed computing power platforms.

However, pharma companies must be careful to avoid falling for the myth of big data — that they can shove vast amounts of data into a system and out will come a well-articulated, curated answer, the very one they are looking for. A more strategic approach is needed. Pharma companies that hope to take advantage of enterprise analytics must focus on answering a key business question first: "What are the insights we need to drive more informed decisions?" If they answer that question adequately, companies can develop enterprise analytics incrementally by sourcing only relevant data, applying the appropriate analytical methods, and investing in the technologies necessary to answer the identified and prioritized business questions.

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In one case, a pharma company wanted to better understand the reasons that a promising cancer drug failed in multiple Phase 3 trials — that is, late in development — and to identify patient subpopulations to inform future R&D efforts. The company standardized and aggregated clinical and biomarker data from Phase 2 and 3 clinical trials involving dozens of approved and experimental drugs. Using advanced analytics techniques, the company was able to segment patients into subpopulations based on gene expression and mutation signatures that demonstrated drastically different survival rates

(greater than five times). On the basis of this research, the Phase 3 failures could be attributed to imbalances in rapidly progressing disease subpopulations across patient cohorts that the pharma company could only have been aware of had it conducted this analysis before the tests. With these results in hand, a number of potentially valuable biomarkers and new targets were identified. This type of investigation would have been impossible just 10 years ago because the data and strategies for analyzing data with such specificity were at a nascent stage.

This effort was a one-off, post hoc analysis; however, pharma companies that leverage enterprise analytics capabilities consistently and proactively will be able to identify patient populations most likely to benefit from a particular drug, design a regulatory approval application based on real-world data and conclusive outcomes, predict a potential product stock-out and reallocate manufacturing capacity to avoid it, and provide the commercial side of the business with an analytical argument to convince payors to support reimbursement.

Implemented correctly, an enterprise analytics program can offer the following benefits for individual functions in a pharma company:

- **R&D:** Optimize design of clinical trials by targeting specific patient subpopulations.

- **Commercial:** Inform pricing, market access, contracting strategy, and identification of treatable patients, all of which are critical to gain "profitable share" in competitive markets.

- **Risk and compliance:** Enable quality and compliance functions to monitor risks in real time, identify outliers, and better allocate resources.

- **Supply chain:** Enhance management of complex, global supply chains by predicting security and supply risks and quantitatively assessing vendor performance.

Achieving these benefits, however, will require an elemental change in how pharma companies manage and implement data and analytics. Visible support from company leadership will be essential in overcoming skepticism about relying more heavily on data, and less on internal expertise. A smart way to mitigate resistance is to create a dedicated team of data scientists focused on advanced, exploratory analytics that can be shared throughout the organization. The people in this unit must have a unique blend of capabilities: business acumen, knowledge of statistics, programming skills, and data management expertise. To oversee these efforts, corporate management must

establish practices and processes that will ensure rapid access to critical data assets and equally rapid dissemination of findings, while managing potential risks, including breaches of medical records, breaches of confidential competitive data, and the misinterpretation and misuse of information.

The value equation tipping point

The third issue involves value. Every pharma executive knows there is intense interest these days in what a drug is really worth. Even beyond 2016's headline-grabbing examples of aggressive price increases, underlying economic pressures from within the healthcare ecosystem are raising the value issue across drug classes. For instance, England's National Institute for Health and Care Excellence refused to allow the National Health Service to pay for Bristol-Myers Squibb's Opdivo lung cancer treatment because it did not satisfy cost-effectiveness criteria. And in the U.S., payors and consumer groups have raised questions about whether the PCSK9 inhibitors (a new class of lipid-lowering medications), introduced at much higher prices than existing therapies, were really worth the extra cost. The two largest public pharmacy benefit management organizations have responded by changing their practices. CVS Health has pressed for ways to narrow utilization and has declined to put some brands in its formulary, and specialty pharmacy Express Scripts has placed an annual cost cap on PCSK9 inhibitors and similar treatments. The value problem will only get worse as patients live longer, drug pipelines shift to more targeted — and thus more expensive — drugs, and global healthcare budgets are further constricted. Something has to give.

Pharma companies need to find new ways to define value that resonate with four stakeholder groups. First are the funders, the payors, which use health technology assessments (HTAs) and other tools to evaluate cost-effectiveness within specific populations and to help control when a drug can be prescribed. Second are the assessors, or independent third parties. They include clinical pathway companies that develop protocols and health economic groups (for instance, ICER [Institute for Clinical and Economic Review]) that evaluate how much a drug should cost. Third are the executors. These medical providers assume some of the risk in the healthcare equation by taking a flat fee for their services from payors; their reimbursements are increasingly tied to quality and outcome metrics. And, of course, there are the patients themselves, who are picking up more of the bill, in the form of higher deductibles and co-pays. Thanks in part to social media and advocacy groups, patients are becoming much more active in making their voice heard. Their

impact is even extending into drug development. Initiatives such as the FDA's Patient-Focused Drug Development program coordinate meetings with patients and their families to discuss how disease and medication affect their lives and to consider potential new drug treatments that would be valuable to patients.

To successfully navigate this increasingly complex landscape, pharma companies must improve their ability to clearly enunciate the benefits of treatments so that stakeholders can easily discern their value and feel comfortable with the price tag. Proactively listening to the concerns of stakeholders and linking benefits directly to today's critical metrics — including outcomes, healthcare utilization, and patient satisfaction — is essential to enhancing the narrative of a value story. So are new innovative partnerships among stakeholder communities designed to provide evidence for value through mechanisms such as collaborative, real-world studies. In addition, pharma companies can adopt "pay for performance" models under which the manufacturer receives payment only if certain results are achieved (ultimately the path chosen by makers of PCSK9s).

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As institutional customers — primarily funders and executors — play a larger role in controlling drug choice, pharma company go-to-market models must be reevaluated. It is imperative for the pharma industry to identify and engage the decision makers in those organizations the way pharma businesses have done in the past with rank-and-file physicians. These institutional decision makers are seeking evidence of value that speaks to outcome and quality versus mere efficacy and safety gleaned from drug trials.

Shaping how the market will perceive the value of a drug starts well before launch. During clinical development, choices about what data to collect in clinical trials, what indications to pursue, and which patient populations to study — all key inputs — should be geared toward producing convincing documentation that the drug price point accurately reflects the value it offers to the four stakeholder groups.

Turn the corner

In short, as pharma companies shift their investments and focus, they will have to come up with their own approaches for innovation, patient engagement, data, and proof of value. Some companies may be hesitant to change what has worked in the past. But the shifts roiling the healthcare industry are inevitably creating an entirely new commercial landscape for all the organizations involved in the sector. Pharma companies are a critical part of this ecosystem. The way they opt to address its challenges will affect not only their future but the future direction of patient care, provider decisions, and payment mechanisms.

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