Executive Insights

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Winning in the Next Era: Strategies for the Changing Global Healthcare Market

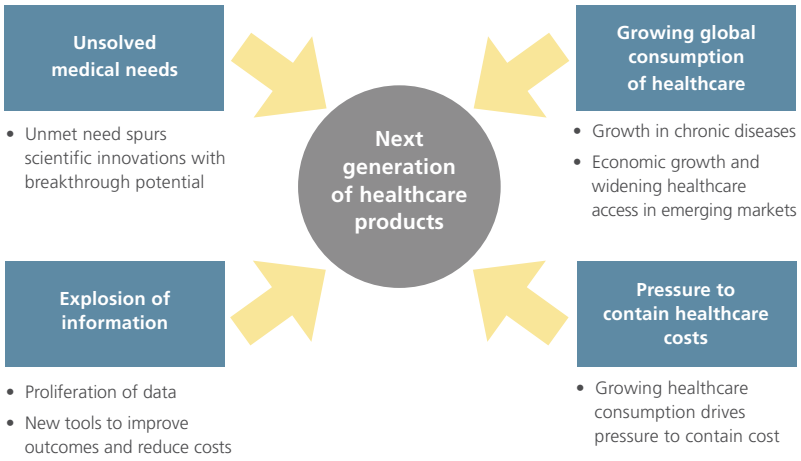
Developing therapeutics and medical devices for global healthcare markets remains a risky proposition. The industry has largely overcome the patent cliff era that resulted from an excess of me-too product development, and the medical innovations coming to the market in the near-term are remarkable. Today's products reflect the reaction of healthcare companies to clear shifts towards innovation a decade ago. The challenges for the next generation of therapeutics and devices will be different again.

Globally, the biopharmaceutical and medical technology sectors are being shaped by four significant forces (see Figure 1). These forces — unsolved medical needs for better treatments, global growth in the consumption of healthcare, requirements in every market to control healthcare costs, and an explosion in the volume and analysis of information — will determine the success factors for the next generation of healthcare products.

The pressures they create are also frequently in conflict, leaving businesses with the challenge of balancing how to respond. Healthcare companies have begun to test different approaches, and trends are emerging that suggest which strategies are likely to be most effective.

This *Executive Insights* paper reviews each of the key forces driving changes in product development, and subsequent papers in this series will evaluate the trends they are driving and the strategies that healthcare companies should consider to adapt to the changing environment.

Figure 1
Four forces driving global healthcare trends



Winning in the Next Era: Strategies for the Changing Global Healthcare Market was written by **Clay Heskett** and **Helen Chen**, partners, **Peter Rosenorn**, and **David Barrow**, mangaging directors, and **Verena Ahnert**, a manager. Clay and Verena are based in London, Peter and David are based in Boston and Helen is based in Shanghai.

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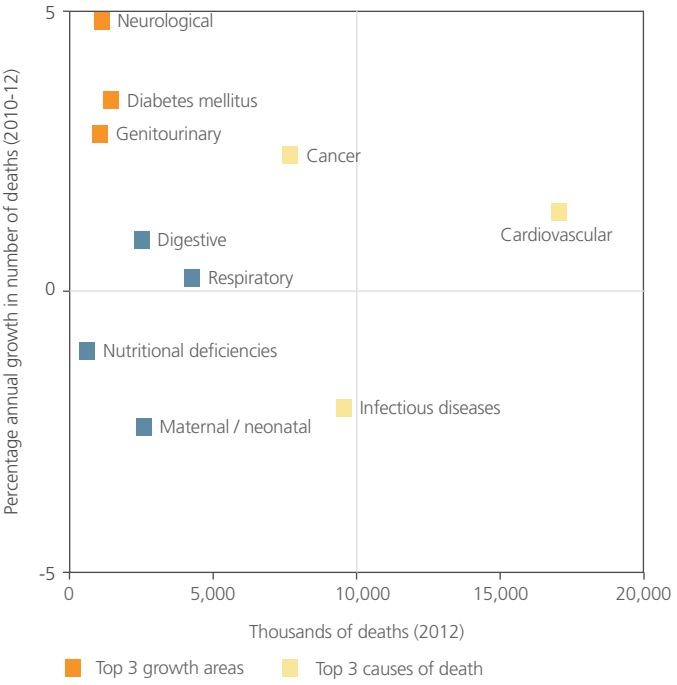
Unsolved medical needs remains a powerful driver

The basic force that has always driven medical research remains a powerful one. Despite the amazing advances of the past 30 years in medical research, the search for new treatments is far from complete. Significant morbidity and mortality remain from numerous diseases, while treatment regimens for others are simply not good enough.

Cardiovascular diseases, infectious diseases and cancer have seen improved treatments, yet remain the leading causes of death. Antimicrobial resistance is a growing threat to public health and neurological diseases like dementia are a growing burden on healthcare systems across the globe (see Figure 2).

Figure 2
Major causes of morbidity



Source: IMS; PhRMA; Clinicaltrials.gov; WHO; L.E.K. analysis

Advances in science — e.g., cell therapy, gene editing, nanotechnology, and other novel therapeutic approaches — are opening up new avenues for innovation. Ground-breaking science like this has garnered substantial funding over the past several years and has the ability to fundamentally change our understanding of diseases, potentially leading to cures in many intransigent medical problems, a theme which we will explore in a future paper.

Governments are seeking to encourage this innovation. For example, the Food and Drug Administration (FDA) Safety and Innovation Act was introduced to spur the development of new treatments for serious or life-threatening conditions. The agency commits to expediting the development and review of drug candidates that are designated as breakthrough. Since its introduction in 2012, nearly 50 breakthrough-designated drugs have been approved.

Overall, regulators are approving more new innovative medicines: the FDA approved 43 novel medicines in 2015, of which 70% used a new mechanism of action or were orphan drugs. The European Medicines Agency (EMA) issued 43 positive opinions for medicines containing new active substances in 2015. To boost innovation and accelerate patient access to medicines, EMA has implemented the Adaptive Pathways Pilot and proposes to launch a new scheme, called 'PRIME' (PRIority MEdicines). In Japan, 38 new medicines were approved in 2015 along with the first two regenerative medicine products.

While the record-high proportion of approvals in rare diseases suggests important breakthroughs in innovation, it also prompts a question about the balance of research activity in the industry relative to unmet needs in more prevalent disease areas such as antimicrobial resistance. We will explore this balance in a future paper, but it is clear that innovation to address unmet medical needs continues to be a key force in the healthcare industry. (See *Executive Insights* "The Paradox of Antibiotics Pricing" for more information.)

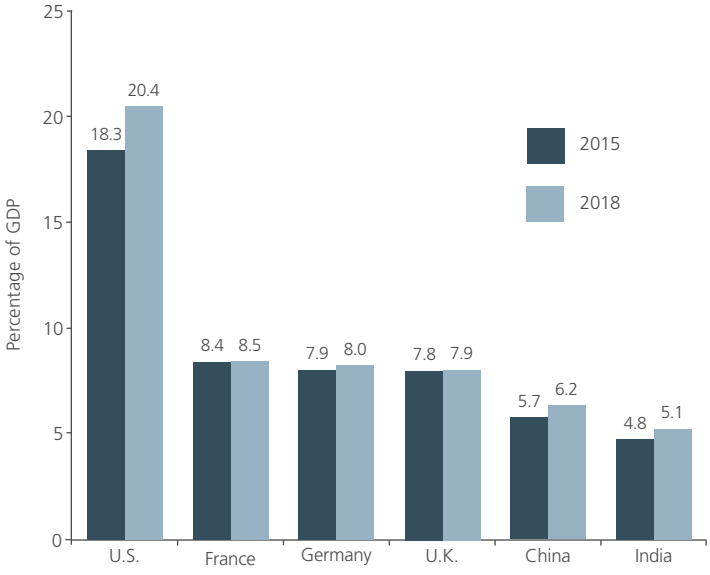
Growing global consumption of healthcare will continue

Globally, the demand for healthcare is growing (see Figure 3), driven by long-term demographic changes and economic conditions, and further fueled by the launch of innovative treatments and increasing patient expectations.

In nearly all regions around the globe, changing diets, increasingly sedentary lifestyles, and improving diagnostics are contributing to shifting healthcare needs — but key drivers of growth differ between regions.

In developed markets, long-term chronic disease management constitutes an increasing proportion of spending, supplemented by the impact of new, clinically-effective products with higher pricing. For example, over half of the growth in U.S. pharmaceutical spending in 2015 was from new brands that had been available for less than 24 months. Increasing healthcare demand in these markets is expected to continue to grow, driven to a large extent by ageing populations. The diseases associated with ageing — such as cancer, dementia and cardiovascular diseases — frequently require long-term treatment and will place increasing demand on healthcare systems for effective solutions.

Figure 3
Healthcare spend for selected countries (2015 vs. 2018)



Healthcare spend in emerging markets is still lagging behind developed countries but is expected to catch up in the mid term

Source: World Bank; WHO; European Commission; L.E.K. analysis

In emerging markets, economic growth has stimulated demand as patients' ability and willingness to pay for treatment increases and expectations of effective treatment outcomes grow. Furthermore, prevalence rates for chronic diseases like diabetes and hypertension are catching up to those in the developed world. In recent years, these factors have created significantly higher growth rates for healthcare consumption than in the developed markets of North America and Europe. While most major healthcare companies already participate in these markets — seven major healthcare players in 2015 averaged more than 9% annual growth in emerging markets at a time when sales in the U.S. were declining[1] — the demographics and economics suggest that these markets will remain growth opportunities in the medium term.

Pressure to contain healthcare costs will be a constant

As spending increases and cost pressures mount, payers are seeking to reduce their exposure in a number of different ways. Increasingly, payers are putting greater emphasis on population health, real-world outcomes, and more aggressive pricing and reimbursement policies.

Across regions, payers are becoming more rigorous at restricting access to patented medicines and devices. Generic drugs already represent the lion's share of volumes sold globally, and payers expect to continue to drive this trend forward, e.g., through support of biosimilars. Downward pricing pressure continues on marketed medical devices as these products mature in the market.

In European markets, seen by many as the harbinger for the rest of the globe, healthcare cost containment has been a priority for decades with price control as a primary focus. International reference pricing is widely used to inform and regulate national prices on healthcare products. And a number of countries are tightening price controls through other means — for example, Germany introduced a mandatory rebate of 7% on drug prices, while the U.K. has recently reset downwards the rates in the Pharmaceutical Price Regulation Scheme. In the U.S., a vigorous debate on pricing is ongoing, fueled by double-digit list price increases on many expensive products and unprecedented public attention on both the pricing of new therapies and aggressive pricing strategies for older therapies.

Health Technology Appraisals (HTAs) are now central to pricing and reimbursement in many countries (e.g., France, Germany, U.K.) and are being introduced in other regions (e.g., Japan). In the U.S., the Affordable Care Act has driven a rise in value-based purchasing, and payers are increasingly experimenting with new reimbursement mechanisms, such as risk-sharing agreements, pharmaco-economic analyses and indication-specific prices. Payer use of established mechanisms such as tiered co-pays, restrictive formularies and step therapy is increasing (see Figure 4). Later in this series, we will explore how the industry is adapting to these pressures.

Explosion of information is both an enabler and a challenge

Industry experts predict that the rapidly growing volume and quality of medical data will ultimately accelerate innovation and identify opportunities for reducing costs. These new waves of innovation continue to push the bounds of modern medicine, with a convergence of advances in technology, data access, and artificial intelligence further accelerating the pace of change.

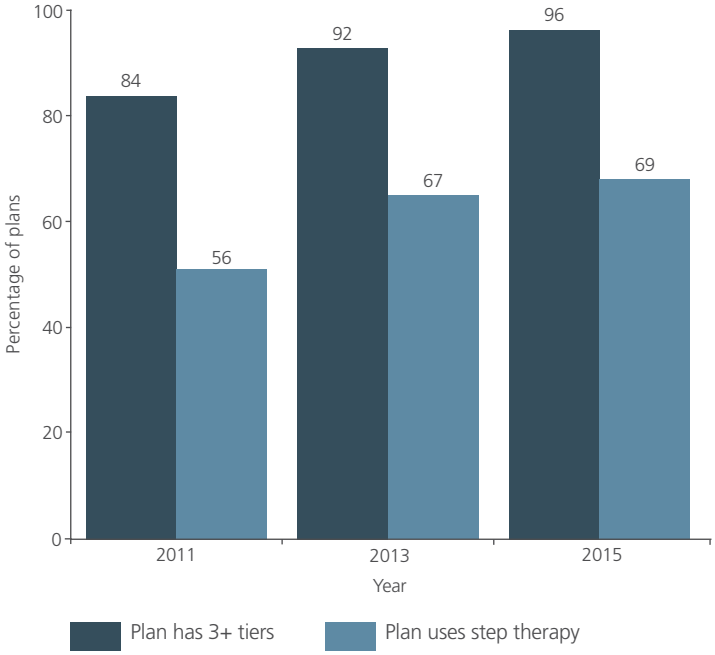
The promise of big data and digital technology as tools to drive medical innovation and healthcare delivery is attracting innovators from other industries: IBM and Google, for example, are using big data and artificial intelligence to accelerate the search for solutions to some of the world's most pressing healthcare challenges. In general, the growth in the number of healthcare apps and solutions is astounding — the number of healthcare app downloads increased by c. 40% between 2013 and 2014 alone and is now estimated at more than 3 billion per annum[2] — yet to date, only a handful of patient-oriented apps and solutions have received the ultimate endorsement of reimbursement by a payer.

[1]http://www.pharmafile.com/news/499479/how-can-pharma-succeed-emerging-markets

Figure 4
Across regions, payers are becoming more rigorous at restricting access to medicines

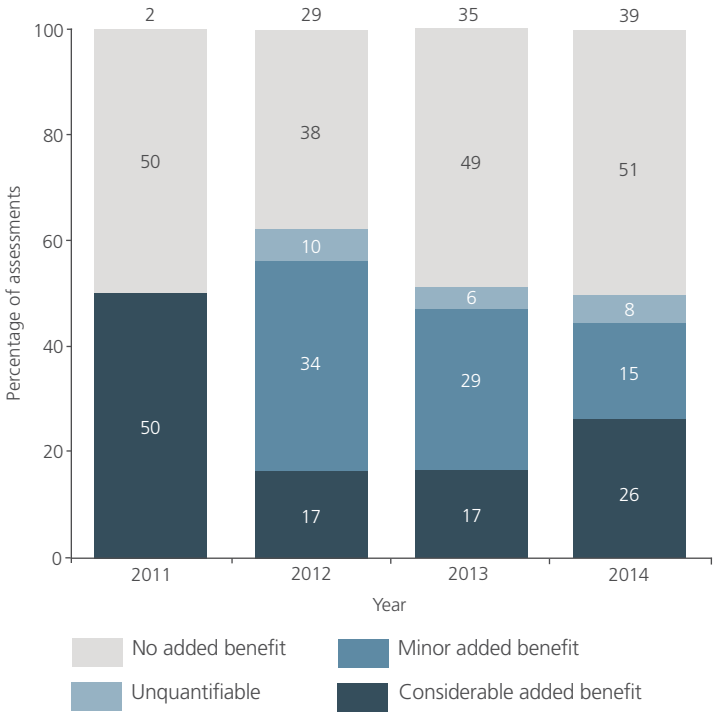
Example 1:
Access restrictions by U.S. insurance plans are increasing

U.S. employers' key insurance plan design features (2011-15), N = 478 employers



Example 2:
It is becoming harder to receive an "added benefit" rating in German HTA assessments

G-BA benefit ratings by type (2011-14)
Number of assessments



Source: Pharmacy Benefit Management Institute; MAP Biopharma

Meanwhile, healthcare players have begun to embrace the opportunity. Most companies have established a digital initiative, including corporate ventures activity in several cases. Cross-industry partnerships are forming that aim to enable healthcare companies to surround their products with technology and / or services to deliver integrated solutions that differentiate them from competitors, strengthen their bond with customers, and address the most critical requirements of payers, i.e., demonstrated clinical benefit.

Later in this series we will consider what steps healthcare companies should take to ensure that they can capture digital advances and prepare for the next era in healthcare products.

Up next

The industry is reacting to these forces, sometimes through a subtle change in emphasis internally and sometimes through aggressive consolidation as we are seeing in healthcare delivery in several markets. L.E.K. has observed a number of trends that are emerging around the globe, and in the rest of this series, we will dissect these trends – effective adoption of regenerative and precision medicine, adjusting to requirements of payers, and integrating digital tools, among others – and explore effective strategies for healthcare companies to get ahead of the curve on these critical topics.

Further reading

The Paradox of Antibiotics Pricing

What's Next for U.S. Healthcare Under Trump?

[2]Research2Guidance, mHealth App Developer Economics 2015

About the authors:

Clay Heskett is a partner in L.E.K. Consulting's London office and a member of L.E.K.'s Global Leadership Team. He has more than 15 years of consulting experience across the Life Sciences sector and leads the European Life Sciences practice. Clay works with his clients to develop corporate strategy, size markets, assess and launch products, evaluate merger and acquisition opportunities, and construct business plans.

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David Barrow is a managing director and partner, and Head of the Biopharma, Life Sciences and MedTech practice for the Americas. He has more than 17 years of experience in consulting at L.E.K., including corporate strategy development, mergers and acquisitions support, and global commercial planning. He has worked on more than 300 assignments with over 100 clients in a variety of sectors, including pharmaceuticals, biotechnology, medical devices, and diagnostics.

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