



Committee: World Health Organisation

Question of: Reforming the Global Pharmaceutical Industry

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Introduction:

The pharmaceutical industry is comprised of companies engaged in researching, developing, manufacturing and distributing drugs for human or veterinary use. New drugs have an enormous positive influence on global health, prosperity and economic productivity by saving lives, increasing life spans, reducing suffering, preventing surgeries and shortening hospital stays. Advances in medicine have eliminated deadly diseases and have brought other life-threatening conditions under control. Drug therapy is now an integral part of nearly every facet of healthcare, and new breakthroughs promise to revolutionize the treatment of non-communicable diseases.

The Issue:

Industry Overview and Competitiveness

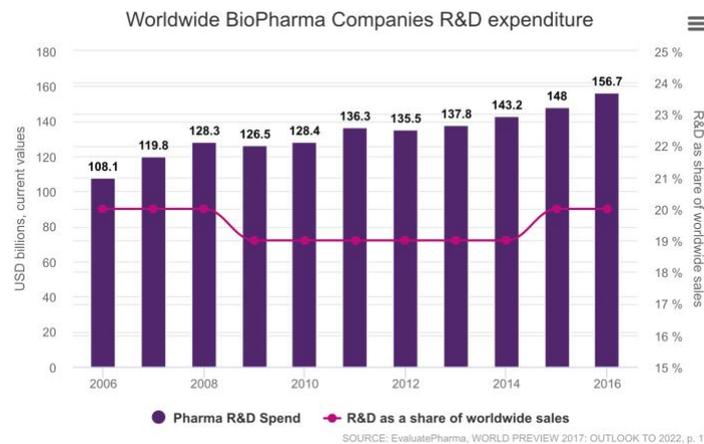
Economic impact:

Large, diversified and global, the pharmaceutical industry is one of the most critical and competitive sectors in the economy. Although manufacturing jobs supported by the industry are expected to decline over the next decade due to continued productivity gains, it will remain an important source of high paying jobs, providing salaries way above the average.

Worldwide pharmaceutical company R&D expenditure:

The global pharmaceutical industry invested over \$1.36 trillion in R&D in the decade from 2007 to 2016 and forecasts predict an annual investment of \$181 billion by 2022. Investment is growing at an average of 4% per annum, with the most recent annual growth increasing to 6%.

R&D intensity (R&D expenditure as a share of sales) had been declining until 2011 but has increased since 2014 to reach 20.4% in 2016. At 20.4%, the pharmaceutical industry has one of the highest R&D intensity measures of any sector globally, reflecting that R&D remains at the core of our innovation.



Industry trends:

The innovative pharmaceutical industry is currently facing unprecedented challenges caused by slower sales growth, expiring patents, increasing competition from generics, shorter product life cycles, tighter regulations, adverse media coverage and reputation damage, and a decline in the number of new innovative drugs under development. Many are concerned that, despite enormous expenditure on R&D (research and development), the industry is producing far fewer new drugs and effective therapies than it did decades ago while sales and administration costs are rising. This concern has been mitigated to some extent with successful drug approvals reaching record highs over the last couple years. The industry is adjusting to a more competitive environment by shifting manufacturing and other operations overseas, revamping research pipelines, reducing employment, particularly in sales but also in manufacturing and research, and organizing mergers and acquisitions (M&As). A long string of M&As over the last few years has led to a more concentrated global industry with both innovative and generics companies engaging in acquisitions of all sizes. The lines between innovator and generic companies or between pharmaceutical and biotechnology companies have become increasingly blurred, and most major multinationals now incorporate both biologics and generics subsidiaries in their portfolios. As the prevalence of bio similar grows, the high manufacturing and regulatory costs involved in developing these drugs further clouds traditional distinctions between innovative and generic business models and investment cycles.

Global industry landscape

The worldwide market for pharmaceuticals is projected to grow from around \$1 trillion in 2015 to \$1.3 trillion by 2020, representing an annual growth rate of 4.9 percent. Several global demographic and economic trends are driving pharmaceutical consumption, including a rapidly aging world population and an associated rise in chronic diseases, increased urbanization and higher disposable incomes, greater government expenditure on healthcare and growing demand for more effective treatments.



Developed markets:

The primary pharmaceutical export markets in the near-term will continue to be in the traditional strongholds of North America, Western Europe and Japan, which have high per capita spending rates on healthcare, strong IP protections and streamlined regulatory processes. Growth rates in these developed economies, however, are projected to hover in the low to mid-single digits due to stagnating national economies, tighter regulations, patent expiries and pricing pressure.

In an era of global fiscal austerity, the industry expects foreign governments, particularly in Europe, to continue to put pressure on drug prices through 2017 and beyond, as the high visibility of drug prices makes them a relatively easy target for healthcare providers trying to reduce costs.

Comparative effectiveness determinations and value-based pricing are also starting to be mandated by some countries and insurers, who require evidence of cost savings or a clear clinical benefit before including new products in their formularies. Some have also entered into outcomes-based contracts with pharmaceutical companies. Such systems will force pharmaceutical companies to dramatically adjust their business models from simply selling medicines to managing outcomes and justifying costs. Doing so will require increased cooperation with the broader healthcare community throughout government, academia, hospitals, technology providers and so on to build health management infrastructure and access data. In short, traditional business models are under huge pressure, and pharmaceutical companies will have to work much harder to earn profits going forward.

Developing markets:

Meanwhile, market growth is shifting toward emerging markets in Asia, Latin America and elsewhere, where pharmaceutical sales are forecast to expand at double digit rates.

To succeed, companies must choose markets selectively and devise tailored sales, marketing, acquisition and pricing strategies. Developed and developing markets often vary politically, culturally, socially and religiously in ways that effect pharmaceutical sales. They may vary, for example, in their use of traditional medicines or in the disease profile of the population due to different ethnic origins, diets and environments. Developing countries also possess very different economic attributes in terms of size, healthcare infrastructure, distribution chains and so forth. Adding to the complexity, companies must overcome a range of regulatory hurdles that differ greatly by country and type of product. A lack of transparency and capacity within regulatory systems, as well as weak or ineffectively enforced IP laws, are all too common.

Importantly, emerging markets differ from each other in their ability and political willingness to pay for innovative drugs. Consumers typically have to fund a larger share of their own healthcare costs as per capita government expenditure on healthcare is low. On average, low-income countries spend 4 to 6 percent of GDP on healthcare, compared to more than 10 percent of GDP for high-income countries, and current global economic uncertainties are likely to slow healthcare spending in the developing world in the near-term.

Moreover, companies will face increased competition from local manufacturers as well as a variety of trade barriers, as governments seek to promote domestic industries. The pharmaceutical

sector is often targeted by protectionist or industrial policies as governments around the world view it as strategically important: it is non-cyclical, generally employs individuals at above-average incomes and ensures supplies of medicines to local populations

Key Events

Event/Date	Explanation
February 2019	Annual ARC Industry Forum - Driving Digital Transformation in Industry and Cities
March 2019	<ul style="list-style-type: none"> • 2019 Bridging Clinical Research & Clinical Health Care Collaborative • SLAS 2019 European Sample Management Symposium • PITTCON 2019 Conference & Expo • DCAT Week '19 • Bioprocessing Summit Europe
June 2019	SLAS Europe 2019

Previous Attempts to Solve the Issue

The 2010 Patient Protection and Affordable Care Act (ACA) will restructure the US health care market in the coming years. For the pharmaceutical industry, the ACA is likely to prove a mixed blessing. In this paper, Assistant Professor Arthur Daemmrch analyzes the political economy of health care, specifically concerning health care reform. He then considers how the ACA will affect the pharmaceutical sector, both quantitatively in terms of the size of the prescription drug market and qualitatively in terms of industry structure and competitive dynamics. Daemmrch also places the current reforms into historical context and describes the political negotiations that enabled passage of the ACA. Key concepts include:

- Since the United States is the world's largest prescription drug market and has among the fewest price control mechanisms, the ACA holds significance to pharmaceutical firms internationally.
- Over the course of its implementation in coming years, the ACA will significantly expand prescription drug use, including at the relative expense of other health services.
- In 2015, Daemmrch projects pharmaceutical spending between \$435 and \$440 billion (12.5 percent of total health care spending) and in 2020 it will near \$700 billion (14 percent of total health care spending).
- Congress and the Department of Health and Human Services will be hard pressed to explain increased drug spending to consumers, especially compared to Europe and Japan where



reference pricing (capping prices at an average within a therapeutic category or among peer countries) has become the norm.

- The ACA nevertheless holds the potential for the United States to be the first country to break out of the silo framework that dominates health budgeting in countries using reference price systems and to instead set budgets at the disease (or patient) level, linked to health outcomes.

Bibliography

<https://hbswk.hbs.edu/item/us-healthcare-reform-and-the-pharmaceutical-industry>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5175325/>
<http://www.pharmtech.com/changing-industry-brings-new-challenges-also-opportunities>
<https://www.managedcaremag.com/archives/2013/10/5-years-50-top-selling-drugs-will-be-biologics>
<https://www.infinitehealth.com/thoughts/pharmaceutical-industry-challenges-2018>
<https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/>
http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf
<http://www.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf>
http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf
<http://www.pwc.com/gx/en/pharma-life-sciences/pdf/challenge.pdf>
www.trade.gov/topmarkets