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THE ROAD TO DIGITAL SUCCESS IN PHARMACEUTICAL INDUSTRY IN INDIA – SOME VITAL ISSUES

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Abstract

Pharmaceutical companies are running hard to keep pace with changes brought about by digital technology. Mobile communications, the cloud, advanced analytics, and the Internet of Things are among the innovations that are starting to transform the healthcare industry in the ways they have already transformed the media, retail, and banking industries. Pharma executives are well aware of the disruptive potential and are experimenting with a wide range of digital initiatives. Yet many find it hard to determine what initiatives to scale up and how, as they are still unclear what digital success will look like five years from now. This article aims to remedy that. We believe disruptive trends indicate where digital technology will drive the most value in the pharmaceutical industry, and they should guide companies as they build a strategy for digital success.

Keywords: *Digital Success, Pharmaceutical Industry, Digital Era, etc.*

Introduction

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value#. Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 per cent of the market. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented. India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immuno Deficiency Syndrome) are supplied by Indian pharmaceutical firms.

Trends Reshaping Healthcare

Outcomes-based care is moving to center stage

Payers and governments have an ever sharper focus on managing costs while delivering improved patient outcomes, putting an even greater onus on pharma companies to demonstrate the value of their drugs in the real world—not just in randomized controlled trials—if they are to retain market access and premium pricing. In this environment, digitally enabled "beyond the pill" solutions, which include not just drugs but also sensors to collect and analyze data to monitor a patient's condition between visits to healthcare providers, are becoming critical to serving both parties' needs. These solutions help drive the adherence to treatment and outcomes that payors and governments seek, and they generate the data that pharma companies need to demonstrate their drugs' superior efficacy.

Patients are becoming more engaged

In a digital age, patients are much less dependent on their doctors for advice, increasingly able and willing to take greater control of their own health. They feel empowered by the vast amount of health information available online and on apps, and by the array of health and fitness wearables such as FitBit and Apple Watch. In one survey, more than 85 percent of patients said they were confident in their ability to take responsibility for their health and knew how to access online resources to help them do so.[1]In addition, patients are becoming keener to evaluate different healthcare products and services given that they bear a growing proportion of the costs. In a digital world, the ability to engage with patients as they make such evaluations could be key to the success of a pharma company's commercial model.

New competitors are moving in

Information and insights into patients' histories and clinical pathways are no longer the preserve of the traditional healthcare establishment. Where once health providers' paper-based medical records were the main source of patient health data, and drug research and development data were kept within the walls of the pharma companies, today, technology companies such as Apple, IBM, and Qualcomm Technologies are moving into healthcare. They are able to engage with patients through apps, health and fitness devices, and online communities, for example. And they are able to collect petabytes of data from these and other sources, such as electronic medical records and insurance claims, capturing valuable insights. For example, the IBM Watson Health platform—recently at the center of a partnership with Apple and its HealthKit health-sensor data platform—is using advanced analytics and natural-language-processing capabilities to deliver clinical decision support. Pharma companies will need to decide soon how to position themselves to compete or collaborate with these new players, or build complementary capabilities.

Personalized care: Sensors and digital services for tailored, 24/7 treatment

The ability to personalize interactions with stakeholders is a key value driver from digital technology in any industry. In pharma, this value will be realized in large part through the use of sensors and digital services to provide tailored care around the clock.

Within five to seven years, a significant proportion of the pharmaceutical portfolio will create value through more than just drugs. Many drugs will be part of a digital ecosystem that constantly monitors a patient's condition and provides feedback to the patient and other stakeholders. This ecosystem will help improve health outcomes by tailoring therapy to a patient's clinical and lifestyle needs and enable remote monitoring by health professionals of a patient's condition and adherence to treatment. There is already a plethora of wireless sensors on the market to measure a patient's biophysical signals. Combining these with other data about patients as they go about their daily lives—nutritional information collected by a smart refrigerator, for instance, or exercise information from smart gym weights—will allow real-time alerts to be issued to caregivers and physicians when there is a need for intervention.

Fuller engagement: Omni channel conversations with physicians and patients

Digital-engagement technologies open up a whole new world for marketing, the exchange of information, and recruitment for trials. Pharmaceutical sales reps, medical-science liaisons, and patient-service teams can inform and influence patients, physicians, and caregivers in person or via mobile phones, the Internet, apps, or social media. Patients are already starting to use patient portals for their medical records and to communicate with their physicians, and they use apps to fill scripts and online patient communities to speak to other patients with the same disease.

Data-driven insight: Advanced analytics to increase pipeline and commercial value

Pharma companies sit on a wealth of data, usually locked away in different technical and organizational silos. Some are already linking and mining their data sets to improve their pipelines, products, and strategies. But there remains a huge opportunity to create further value from data and analytics using internal and external data sources to drive superior results. A few examples follow:

- ***In R&D,*** digital discovery and the testing of molecules with advanced modeling and simulation techniques will be commonplace. For instance, physiological simulation will accelerate product development, and 3-D tissue modeling will help assess potential toxicity using computer simulation. In late development, sensor-data streams from in vivo clinical trials captured by wearables will be factored into registration filings and value dossiers to give an early indication of real-world effectiveness.

- ***Marketing and sales forces*** will deploy advanced analytics to understand prescribing behavior and potential patient profiles, enabling more precise targeting of providers and

increasing the number of prescriptions filed. For example, a "patient finder" technology that mines electronic medical records to identify sufferers from specific rare diseases will enable sales forces and medical science liaisons to focus on providers caring for patients likely to have those diseases, although they are as yet undiagnosed.

Real-time responsiveness: Automated processes to improve cost, reactions, and agility

Cloud and mobile technology, sensors, and next-generation business intelligence will bring about a new wave of automation in business processes—that is, streamlined, automated work flows with few handovers and end-to-end, real-time transparency on progress, costs, and business value. This will drive a step change in the efficiency, responsiveness, and agility of a wide range of complex, often cross-functional, processes, be they in the back office, the supply chain, R&D, or commercial. Banks have shown that the processing time and costs associated with opening an account or mortgage origination can be reduced by up to 99 percent and 70 percent respectively, with a clean-slate redesign of these cross-functional processes and state-of-the-art digital technology enablement. In pharmaceuticals, employee on-boarding, sales and operations planning, launch monitoring, and marketing-content approval would especially benefit from streamlined, automated work flows and increased transparency.

- ***Focus on two or three flagship initiatives***.

It is important to place a few big bets that will each be sponsored by a senior executive, made highly visible to the organization throughout design and pilot phases, and lauded when early wins start coming in. These flagships will need to be properly resourced from the start and supported by partnership initiatives that complement a company's existing capabilities. The objective is to secure early success, which in turn generates the buy-in and momentum required to drive the next wave of initiatives. The choice of flagship initiatives needs to be based on a company's pipeline, product portfolio, and business strategy. Companies should therefore identify the distinctive sources of value that digital technologies and capabilities can create in the disease areas in which they operate, and then define the flagship initiatives to develop solutions for two or three specific use cases. For example, a flagship initiative could be building a digital ecosystem (a solution combining sensors, apps, and services) for patient adherence to an upcoming oncology blockbuster launch drug (the use case).

- ***Run collaborative experiments, and then scale what works***.

Companies cannot be expected to know in detail up front what a winning solution looks like for any particular set of assets in any particular market. For example, it is not possible for a company to design from A to Z a digital medical-affairs ecosystem on paper without

experimenting with different channel platforms and content types to understand how key opinion leaders prefer to interact with the company. Hence, companies need to set up the right environment for collaborative experimentation within the initiative: for example, by putting the right people from IT, business compliance, and outside partners in a "war room" to run quick test-and-learn cycles. When results are positive—patient awareness of a disease and a particular drug increases, for instance—efforts can be scaled up. Technology prototypes can become enterprise solutions, and new ways of working become formalized and integrated into business processes.

- ***Develop the organization for new business models.***

Digital talent may be scarce to begin with, but a digital center of excellence can help bring together what capabilities there are, concentrating them into a critical mass and avoiding duplication of resources across commercial and R&D. It can also run the portfolio of digital partnerships, ring-fence funding for digital initiatives, and codify and export learnings from pilots across markets. In this new world, it will be vital that IT evolves to be able to manage faster experimentation cycles, while still managing the legacy estate for cost and reliability. This should lead to a two-speed IT function,[3]where "fast domains" operate with different skills, architecture principles, budgeting, and planning cycles to those that exist in "legacy domains" that remain focused on enterprise resource planning and traditional business applications.

Investments

The Union Cabinet has given its nod for the amendment of the existing Foreign Direct Investment (FDI) policy in the pharmaceutical sector in order to allow FDI up to 100 per cent under the automatic route for manufacturing of medical devices subject to certain conditions.

The drugs and pharmaceuticals sector attracted cumulative FDI inflows worth US$ 13.85 billion between April 2000 and March 2016, according to data released by the Department of Industrial Policy and Promotion (DIPP).

Some of the major investments in the Indian pharmaceutical sector are as follows:

- **International Finance Corporation (IFC),** the investment arm of the World Bank, plans to invest upto US$ 75 million in Glenmark, which is looking to raise around US$ 200 million for expansion and the launch of several new products in India and other emerging markets over the next three years.

- **Cipla Limited,** one of India's leading pharmaceutical firms, plans to invest around Rs 600 crore (US$ 88.94 million) to set up a biosimilar manufacturing facility in South Africa for making affordable cancer drugs and growing its presence in the market.

- **The Medicines Patent Pool (MPP)** has signed a licencing agreement with six Indian drug makers for the generic manufacturing of four antiretrovirals (ARV) and hepatitis C direct-acting antiviral drug Daclatasvir.

- **Dr Reddy's Laboratories**, one of the major pharmaceutical companies of India, has entered into a strategic collaboration agreement with Turkey-based TR-Pharm, to register and subsequently commercialise three biosimilar products in Turkey.

- **Lupin** has completed the acquisition of US-based GAVIS Pharmaceuticals in a deal worth US$ 880 million, which is expected to enhance its product pipeline in dermatology, controlled substances and high-value speciality products.

- **Cipla Ltd,** one of the major pharmaceutical and biotechnology companies in India, has acquired two US-based generic drug makers, InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc., for US$ 550 million, which is expected to strengthen Cipla's US business.

- **Cipla**announced the acquisition of two US-based companies, InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc., for US$550 million.

- **Glaxosmithkline Pharmaceuticals** has started work on its largest greenfield tablet manufacturing facility in Vemgal in Kolar district, Karnataka, with an estimated investment of Rs1,000crore (US$ 148.24 million).

- **Cadila Healthcare Ltd** announced the launch of a biosimilar for Adalimumab - for rheumatoid arthritis and other auto immune disorders. The drug will be marketed under the brand name Exemptia at one-fifth of the price for the branded version-Humira. Cadila'sbiosimilar is the first in class and an exact replica of the original in terms of safety, purity and potency of the product, claims the company.

- **Torrent Pharmaceuticals** entered into an exclusive licensing agreement with Reliance Life Sciences for marketing three biosimilars in India — Rituximab, Adalimumab and Cetuximab.

Government Initiatives

The Addendum 2015 of the Indian Pharmacopoeia (IP) 2014, published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, is expected to play a significant role in enhancing the quality of medicines that would in turn promote public health and accelerate the growth and development of pharmaceutical sector. The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments. Further, the government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines.

Some of the major initiatives taken by the government to promote the pharmaceutical sector in India are as follows:

- Government of India's decision to increase Foreign Direct Investment (FDI) in existing pharmaceuticals companies to 74 per cent is expected to boost Mergers and Acquisitions (M&As) and Private Equity (PE) investments in the pharmaceuticals sector in the country. Indian Pharmaceutical Association (IPA), the professional association of pharmaceutical companies in India, plans to prepare data integrity guidelines which will help to measure and benchmark the quality of Indian companies with global peers.

- The Government of India plans to incentivize bulk drug manufacturers, including both state-run and private companies, to encourage 'Make in India' programme and reduce dependence on imports of Active Pharmaceutical Ingredients (API), nearly 85 per cent of which come from China. Indian and global companies have expressed 175 investment intentions worth Rs 1,000 crore (US$ 148 million) in the pharmaceutical sector of Gujarat. The memorandums of understanding (MoUs) would be signed during the Vibrant Gujarat Summit. At the launch of Cluster Development Programme of pharmaceutical sector, Mr. Ananth Kumar, Minister of Fertiliser and Chemicals, announced that six pharmaceutical parks will be approved and established this year which will have sufficient infrastructure and facilities for testing and treatment of drugs and also for imparting training to industry professionals.

Conclusion

The Indian pharmaceutical market size is expected to grow to US$ 100 billion by 2025, driven by increasing consumer spending, rapid urbanization, and raising healthcare insurance among others. Going forward, better growth in domestic sales would also depend on the ability of companies to align their product portfolio towards chronic therapies for diseases such as such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers that are on the

rise. The Indian government has taken many steps to reduce costs and bring down healthcare expenses. Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies. In addition, the thrust on rural health programmes, lifesaving drugs and preventive vaccines also augurs well for the pharmaceutical companies.

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