

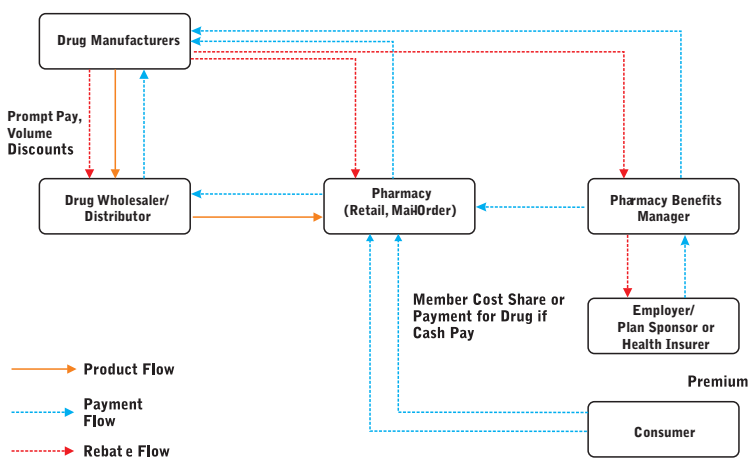


# Pharmaceutical Supply Chain Dynamics

## Abstract

Global pharmaceutical companies are modelled with a supply chain, which ensures that the right drug reaches the right people at the right time and in the right condition. The supply chain also ensures 100% product availability at optimum cost by carrying huge inventory, which maintains 100% fill rate. Manufacturers are trying to cut down development time to save costs. For example, a drug manufacturer who can trim development time by 19% can save up to USD 100 million. But if a drug is getting delayed to reach the market, the time delay costs the company around USD 1 million a day. So, pharmaceutical companies today are designing the supply chain to be as responsive as possible to reduce entry time to the market thereby increasing profit margins.

## Model of A Traditional Pharmaceutical Supply Chain in the US



Source: Health Strategies Consultancy Report

A typical pharmaceutical company has more than 30,000 SKUs (Stock keeping Units) (for example Pfizer has 35,000 SKUs located globally) distributed worldwide, which includes speciality products as well. Before the drug reaches the final customer, the company has to manage all these units through a proper distribution channel, which includes multiple plants and warehouses, wholesalers, retailers, etc.



## Emerging Trends in Pharmaceutical Industry

With the advent of new technologies, and increasing shift from conventional cost-based approach to a value-based approach, there is a shift in the following trends.

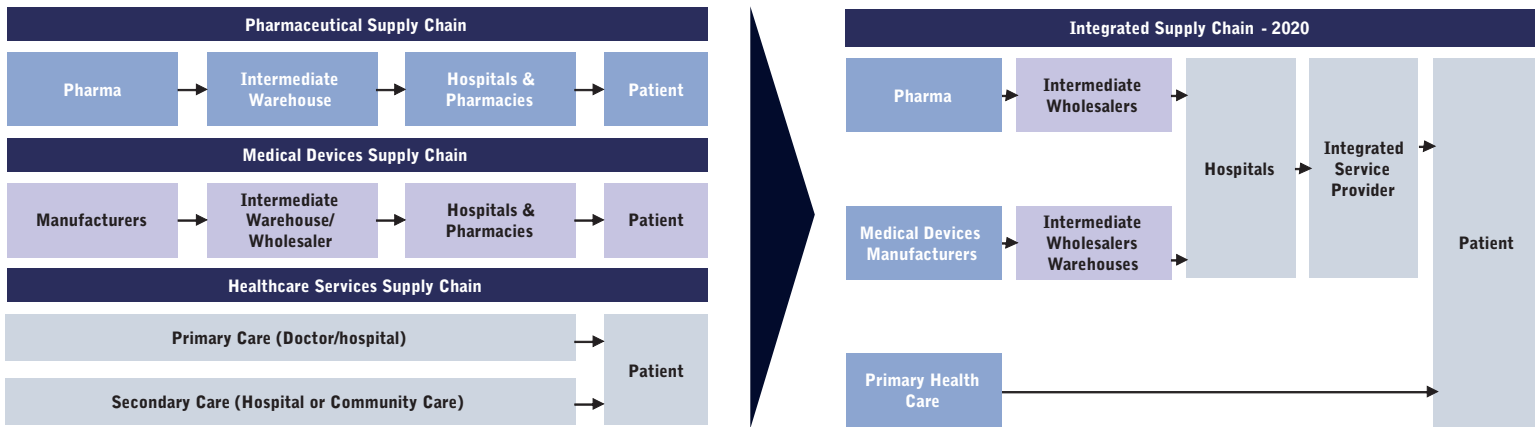
Trends		
<b>Market</b> <ul style="list-style-type: none"> <li>Well informed patients</li> <li>Increased demand for personalized medicine</li> <li>Patients' orientation toward complete remedy of diseases</li> <li>Increased demand in emerging markets</li> <li>Increased presence of chronic diseases like diabetes</li> </ul>	<b>Health and healthcare</b> <ul style="list-style-type: none"> <li>Increased burden due to highly demanding regulations</li> <li>Increased costs related to healthcare</li> <li>Increased complexity in healthcare programs and insurance coverage</li> <li>Pharmaceutical companies providing health care and patient assistance plans apart from their core business e.g. Pfizer's "Patient Assistance program aims for broadest access for its prescription drugs.</li> </ul>	<b>Technology</b> <ul style="list-style-type: none"> <li>Advent of innovative technical tools, such as LASER in drug development</li> <li>Increased number of Contract Research Organizations and Contract Manufacturing Organizations</li> <li>Development of virtual R&amp;D centers, which reduces time to market</li> </ul>

## Implications:

- Pharmaceutical industry will have to work closely with regulators to reduce complexities and time delays in drug approval process.
- Companies need to develop a close relationship with technological vendors to deploy new technologies and develop skilled expertise to bring the existing process up the curve.
- The pharmaceutical industry needs to understand and estimate the latent demand in the emerging markets to effectively produce drugs to meet the demand of the untapped market.
- There is a need for collaboration between pharmaceutical companies and the healthcare players to realign their strategies and to develop a value chain which caters to the demand of both the segments viz. pharma and health care.

Source: Pharma 2020: Challenging Business Models – PWC Report

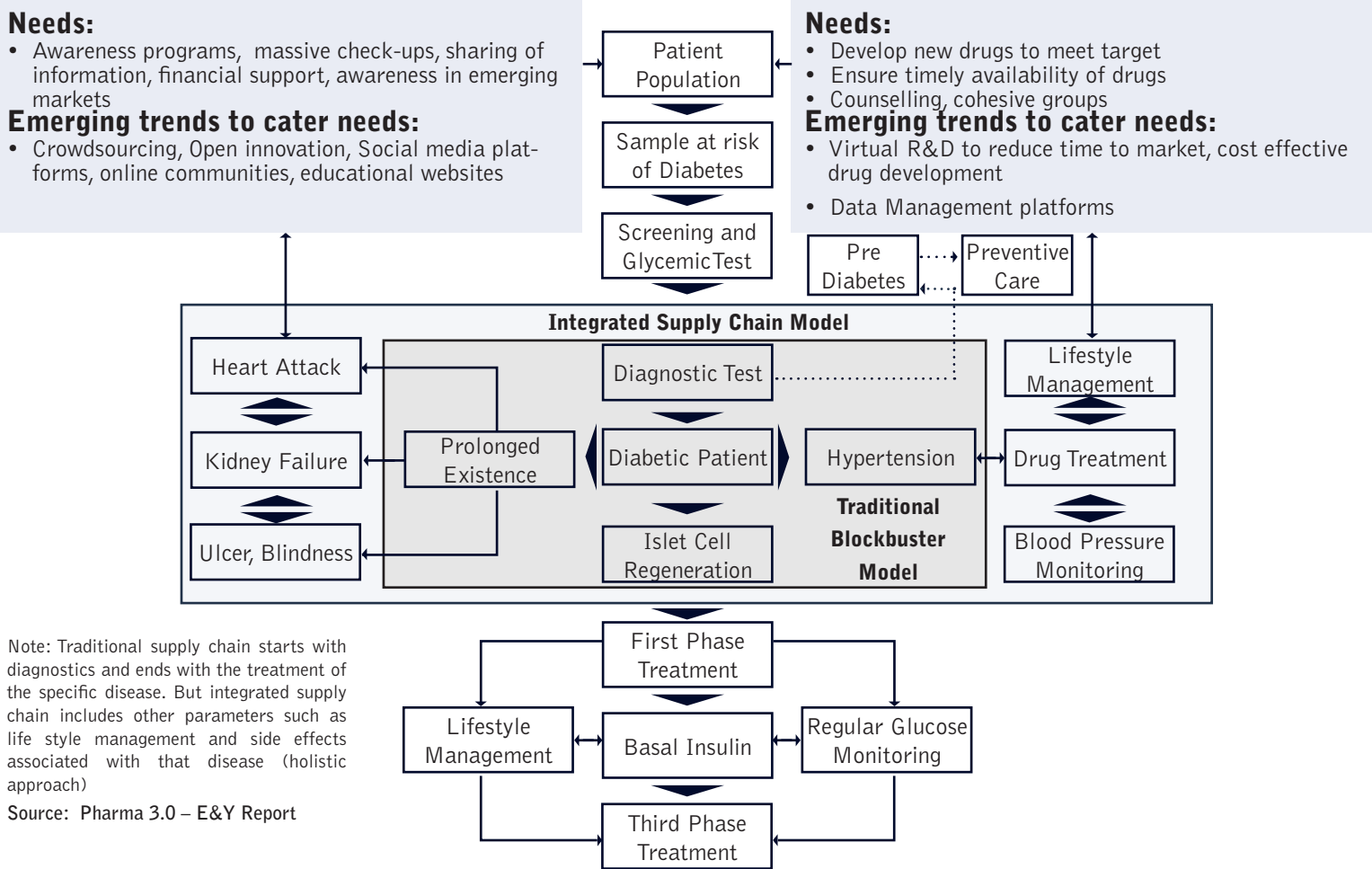
Traditional R&D process of a pharmaceutical company starts with the definition of a target audience and developing a new molecule, biologic or a diagnostic directed toward that particular target. The major drawback to this process was the lack of in depth understanding of the disease and development of a complete therapeutic solution to serve the purpose. So, there were a number of expensive failures in the late stage clinical trials. Companies started to orient more toward extension of already developed drugs, rather than focusing on new drug development. This called for an increased collaboration between drug developers, academic researchers, regulators and government, health care providers. This is fuelled by increased leverage in technology to fine tune the traditional R&D process and to accelerate the drug development lifecycle. This paved the way to merge the existing disconnection between a molecule and target and developed the understanding on how human body works at the molecular level. Thus, there arose the need for creating a single mathematical model, which could cater to the demands of specific target and develop a cost effective drug development process.



This can be sensed from the present scenario of huge growth in CROs, which conduct clinical trials for major pharma companies. This is because, clinical research and conducting clinical trials is the most expensive and time consuming element of drug development process, which leads to more levels of outsourcing. However, major companies outsource a significant portion of their phase II-IV studies. The more efficient approach is to allow these CROs to sit in the strategy table of a pharma company, to develop a collaborative approach in the drug development process. This early collaboration will lead to a win-win solution, not only in developing a cost effective solution but also in developing medicines aiming at prevention rather than cure.

Source: Pharma 2020: Supplying the Future – PWC report

### Complete Value Chain of Diabetes Patient – Heading toward Integrated Supply Chain



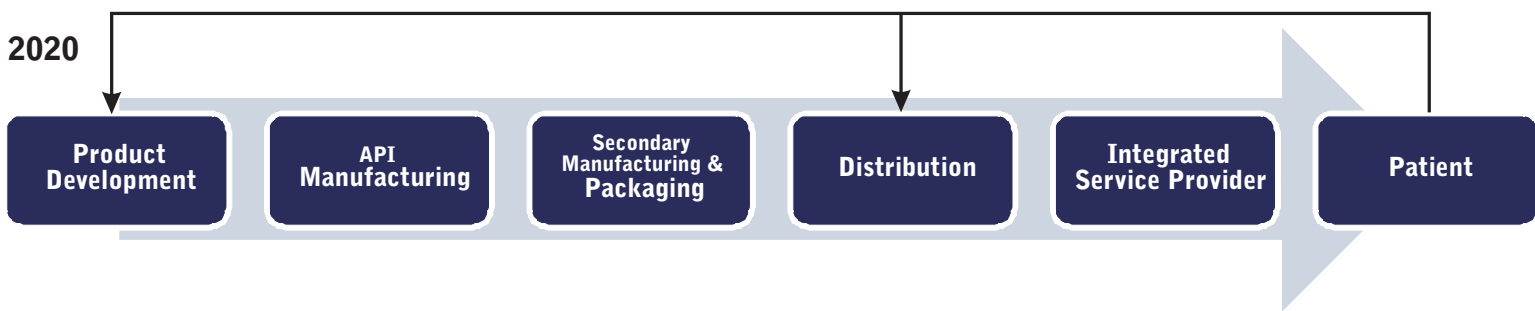
- Needs:**

  - Develop new drugs for complete treatment
  - Continuous monitoring of disease indications
  - Affordability of drugs

**Emerging Trends to Cater Needs**

  - Collaborative R&D practices for innovative drug development – Pfizer, GSK with a third party for AIDS drug development
  - Bayer’s Nintendo – to monitor blood glucose levels
  - Value based pricing model – key drugs to cater to all economies

## Shifting Supply Chain – From Push to Pull System

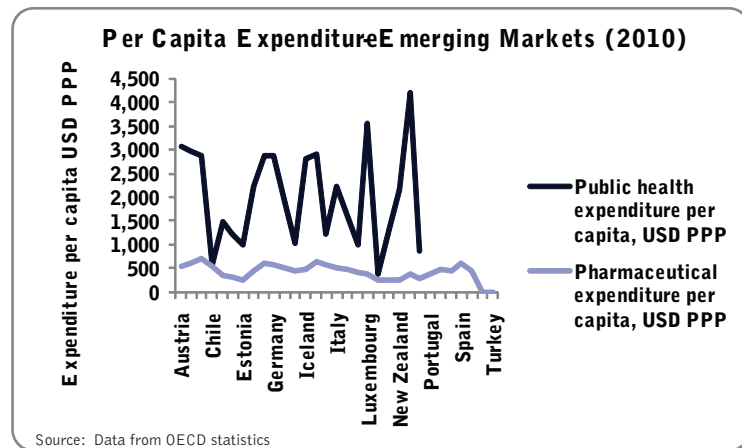
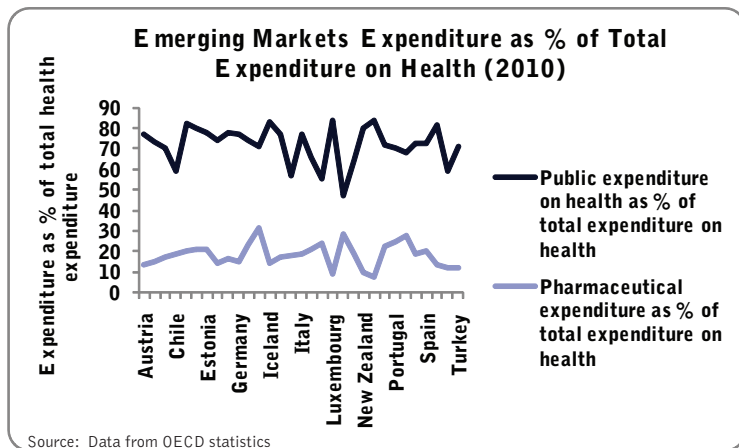


<b>Reason to Revamp Supply Chain</b>	In Life Licensing	The supply chains for manufacturing and distributing them are designed to support peak sales volumes and not the actual demand scenario. In Life Licensing Model will help the pharmaceutical companies reduce the capital expenditure. Live licensing will also help pharmaceutical companies produce as per the demand of the product.
	Continuous Manufacturing	With the advent of "e-prescribing" and Live Licensing phenomena, the pharmaceutical companies will be more equipped to forecast the demand for drugs and thereby manufacturers will be able to shift from batch production to continuous production
	New Complex Molecules	Biologics & Biosimilars which are more complex in nature to produce.
	Value based pricing	Result oriented or value based pricing models. The U.K. government has already taken steps to ensure the price of the drugs is proportional to the patient outcomes. The new regulation is set to come in to force by 2014. This can have severe impact on the drug pricing across the world. Close to 25% of the pharmaceutical sales in the world take UK as the reference for drug pricing.
	Rise of emerging markets	Pharma companies, develop economical formulations and Stripped-down services for patients who can't afford its most expensive offerings.
	Regulatory issues	Stricter regulations and sustainability will cause pharmaceutical companies to constantly introspect their supply chain operations

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## Emerging Markets – A Snapshot



Emerging markets possess relatively lesser spend in pharmaceutical sector. A pharmaceutical company, with a mature business model will be unable to cope up with the demand of emerging markets. So companies follow a strategy of reducing the price of drugs to meet the demand of such low income target. For example, GSK has reduced the prices of 11 of its patented products in the world’s poorest economies by an average of 45%. **After reducing the cost of Cervarix by 30 per cent in Philippines, monthly sales of the vaccine increased significantly, around six times the volume of vaccines sold before the price reduction was introduced**

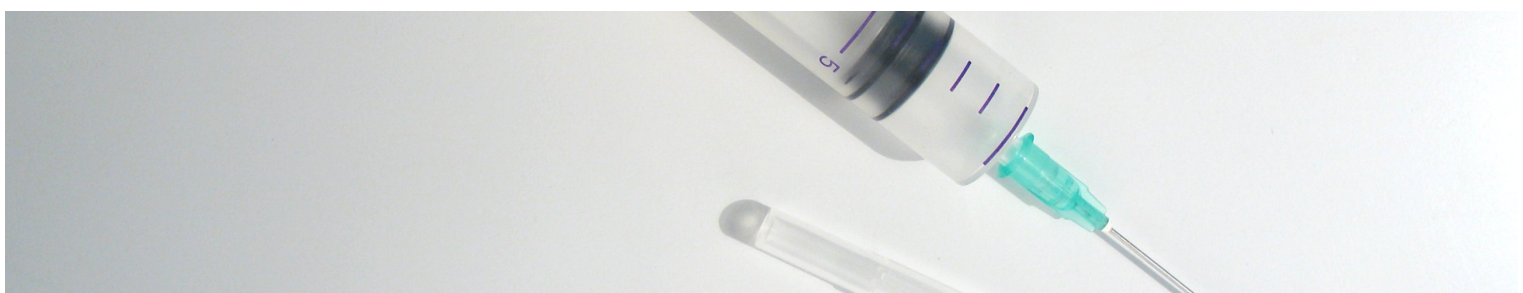
Ideally, an emerging market should not be looked as the only way to generate revenues and to bridge the gap generated by expiring patents and declining R&D productivity. A well-integrated and holistic business strategy needs to be implemented to capture the potential of these markets. A strong collaboration to improve the overall healthcare sector itself is the key critical factor in emerging markets. So, pharmaceutical companies need to collaborate with government, NGOs and private sector to achieve productive gains in these markets. Partnership with local universities/institution, establishing localised manufacturing/packaging operations and linking it in global supply-chain operations are the few avenues, where emerging markets can bring meaningful benefits and uplift on par with developed countries in the world.

## Changing Business Models - Implications

Although pharmaceutical companies are changing their business models to make their supply chain to be increasingly responsive, there is a wave of technology transformation, which calls for collaboration between pharmaceutical companies and other sectors such IT, health care, etc. Earlier, Rhone-Poulenc Rorer (now part of Sanofi Aventis) created RPR Gencell, the world’s first biotechnology network in 1994. It collaborated with 14 biotech companies and research organizations in the US and France to create a biotechnology network. It leveraged its technology to focus in major therapeutic areas, such as oncology, cardio vascular disease and nervous disorder disease, such as Alzheimer’s disease.

There exists another challenge of major blockbuster drugs losing their patent protection. For example industry’s biggest cash cows, such as Pfizer’s Lipitor; Astra Zeneca’s Crestor and Seroquel, Sanofi Aventis’ Plavix, Merck’s Singulair are losing their patents in the near future. So the companies are moving toward aggressive cost cutting measures to retain their generated ROI. For example, after Lipitor’s expiry, Pfizer focussed more on diversified portfolio of drugs and undertook an aggressive cost cutting strategy by divesting significant portions of the company to focus more on core pharmaceuticals.

To cope up with all these changing scenarios, major pharmaceutical companies have developed patient management and assistance programs. For example major players like Merck, BMS, Abbott, Eli Lilly, Astra Zeneca etc have developed patient assistance programs for specific group of people who are unable to afford few costly drugs. Swiss biopharmaceutical company Debiopharm has developed an excellent collaboration in its R&D. The company in licences new molecules from academic institutions and biotech companies develop those molecules and finally out licences the developed drugs to big pharma companies. The evolving strategic changes in business models have started to accommodate diversification of the lines of business of many companies. J&J has achieved remarkable success in its health care business apart from its staunch presence in biologics, medical devices and diagnostics and its recent venture in building a wellness and prevention platform. Its fully diversified model includes generics, diagnostics and devices, consumer health, prescription and OTC drugs.



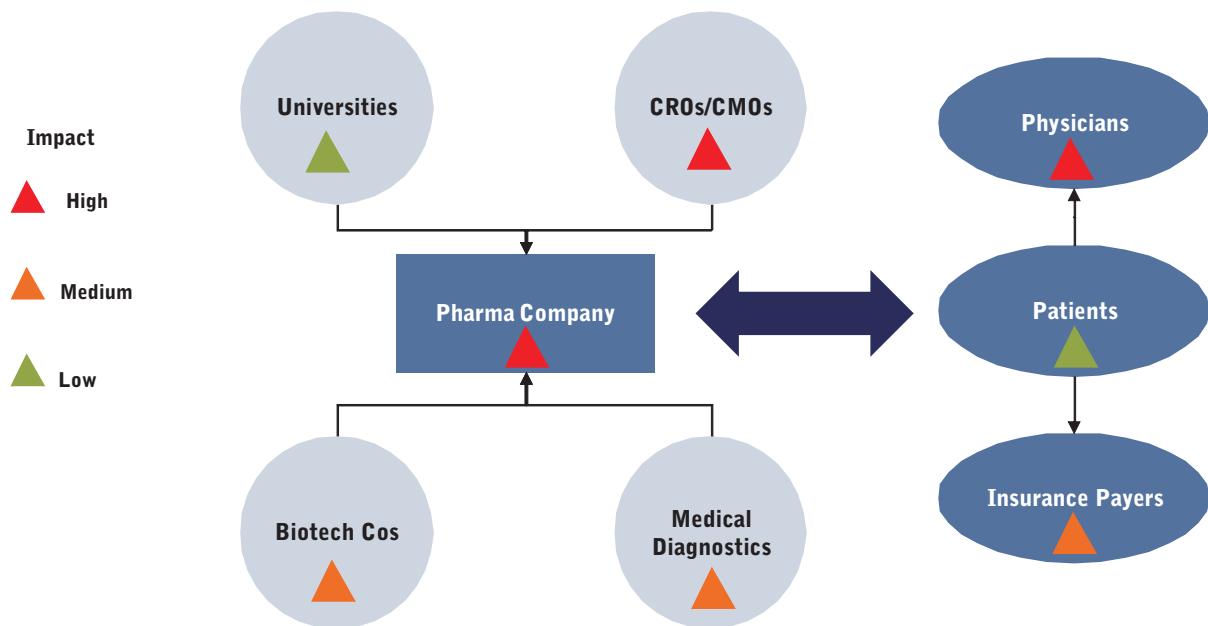


## Success Stories

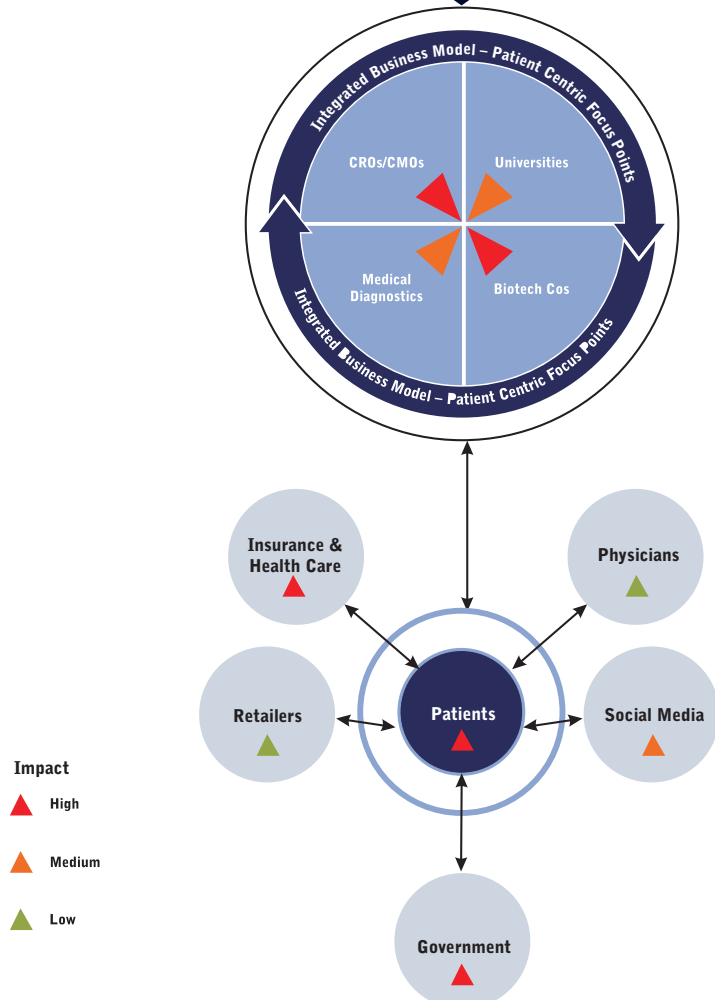
Pharma Companies / Others	Initiatives to build an inclusive and holistic business model	Implications in pharmaceutical supply chain
<b>Technology Partnerships</b>		
<ul style="list-style-type: none"> <li>•Bayer</li> <li>•Nintendo</li> </ul>	Connected DIDGET – glucose testing device by Bayer and video gaming application of Nintendo to promote continuous blood glucose level testing	Facilitates better lifestyle management. Improves customer responsiveness and promotes awareness for continuous testing of blood glucose levels in children.
<ul style="list-style-type: none"> <li>•J&amp;J</li> <li>•Apple</li> </ul>	Apple created many health-related iPhone applications to monitor blood glucose levels, check weight and so on.	Similar to Nintendo, this technology up gradation promotes responsiveness and awareness in adults
<ul style="list-style-type: none"> <li>•Novartis</li> <li>•Proteus</li> </ul>	Novartis licensed with Proteus to develop a sensing technology for organ transplantation.	Facilitates better data management by accurately monitoring the heart beat rate and blood pressure levels of patients through these sensors. This can lead to a more customized, "to the point" treatment.
<ul style="list-style-type: none"> <li>•Novartis</li> <li>•Vodafone</li> <li>•IBM</li> </ul>	Launched "SMS for life" initiative to enable health workers to send reports on supply and demand for medications, especially anti-malarial drugs	Improves supply chain responsiveness by accurately forecasting supply, demand parameters especially in diseases associated with malaria
<b>Crowdsourcing Initiatives</b>		
<ul style="list-style-type: none"> <li>•Innocentive</li> </ul>	Eli Lilly's social networking and knowledge sharing forum, consisting of physicians, scientists and consultants specifically aimed towards issue resolution	Reduces overall lead time in supply chain by making the right drug available to right persons at right time.
<b>Innovative R&amp;D</b>		
<ul style="list-style-type: none"> <li>•GSK</li> <li>•Pfizer</li> </ul>	Created a globally specialized HIV company to focus solely on research, development and commercialization of HIV medicines.	Increased ROI, through expertise and technology sharing in R&D. Avoided duplication of R&D efforts. On the whole, efforts were aimed to reduce time to market of drugs
<ul style="list-style-type: none"> <li>•Mental Health Research Institute (Australia)</li> <li>•Astra Zeneca</li> </ul>	Collaborated R&D to identify early stages in Alzheimer's disease.	Efforts were oriented to reduce the overall complexity in the supply chain by early detection and cure.
<ul style="list-style-type: none"> <li>•Pfizer</li> <li>•Protalix</li> </ul>	Entered into an agreement to develop and commercialize potential treatment of Gaucher's disease (which is quite a rare disease).	Innovative R&D approach to cater to niche market of rare disease
<ul style="list-style-type: none"> <li>•Pfizer</li> <li>•Strides Arcolab</li> </ul>	Joint venture enabled Pfizer to commercialize off patented sterile injectable and oral products whereas licensing will be carried out by Strides Arcolab.	Reduced time to market of drugs as the complex processes viz. Licensing and branding are carried out by two different entities
<ul style="list-style-type: none"> <li>•Eli Lilly</li> <li>•Chorus</li> </ul>	Chorus, Eli Lilly's subsidiary has been established to carry out virtual R&D. The purpose is to quickly take the molecules to the proof of concept stage and outsourcing other stages of clinical trials.	Eli Lilly has transformed itself from a traditional integrated pharmaceutical company to a pharmaceutical network by leveraging on its innovation base especially in virtual R&D.
<ul style="list-style-type: none"> <li>•Eli Lilly</li> <li>•Piramal Life Sciences, Hutchinson MediPharma and Suven Life Sciences</li> </ul>	Lilly has collaborated with CROs/CMOs such as Piramal Life Sciences, Hutchinson MediPharma and Suven Life Sciences for developing molecules.	Collaboration efforts were aimed towards reducing time to market of drugs as most of the R&D processes were outsourced.
<ul style="list-style-type: none"> <li>•Debiopharm</li> </ul>	A Swiss-based global biopharmaceutical company with focus on developing innovative new drugs that target unmet medical needs. It in-licenses and develops small molecules which are already in clinical phases I, II or III and sells it to major pharma companies.	Bye passes critical supply chain component - Drug development and allows the major companies to focus more on marketing and branding, which reduces overall supply chain complexity.



## Conclusion



Pharmaceutical companies have changed their business models from a company centric approach to a more patient centric locus. This leads to change in impact that many factors have had on the traditional supply chain.





## Challenges faced by Pharmaceutical Industry

**Failure of Blockbuster Model:** There is a shift from a molecule dependent blockbuster model toward a diversified drug portfolio.

**Drying Pipelines:** Increased scrutiny from FDA leading to lesser drug approvals, which results in dried pipelines.

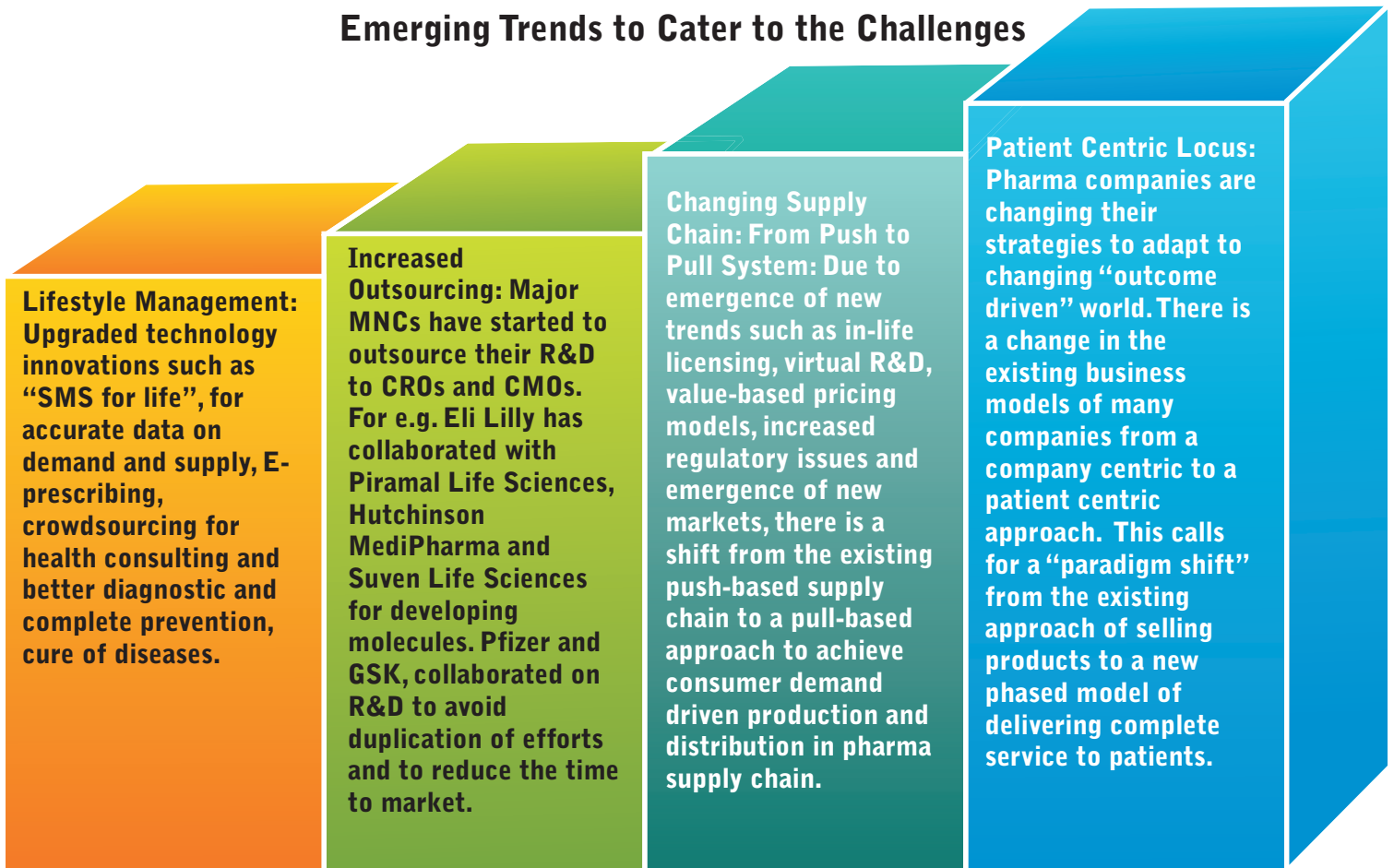
**Emerging Markets:** Challenges include huge untapped demand; low spend in pharma, lack of presence of MNCs in emerging markets e.g. Merck shares just 1% of Indian pharma market.

**Complexity of New Drugs:** Emerging new therapeutic areas, such as biologics which deals with highly complex molecules and drug development process.

**Decrease Time to Market:** There is a need to reduce the lead time for drug development to achieve cost effectiveness in supply chain.

**Increased Regulatory Hurdles:** Strict regulatory guidelines and compliance standards. This happens to be the time consuming element of drug development process

## Emerging Trends to Cater to the Challenges



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