The Future of Supply Chain Management

Summary report of the summit

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OPPI

Organisation of Pharmaceutical Producers of India

Setting the context

They say, 'The future isn't what it used to be.' With every passing year, in fact, with every passing day, we are witnessing changes and challenges at an unprecedented pace. Supply chain – a critical process that helps make a product available to the patient – is also undergoing rapid transformation. The need to consolidate the distribution network for higher service levels at lower costs, the emergence of pan-India distribution companies, a closer look at on-ground issues when it comes to implementing Good Distribution Practices (GDP), the need for end-to-end track and trace systems, the need to achieve supply chain excellence (the right product at the right place in the right condition, adopting the latest technologies to enhance patient safety and compliance) – all these are issues that need full-blown discussions to decide on the right solution to be implemented for everyone's benefit.

The Organisation of Pharmaceutical Producers of India, in collaboration with the Indian Pharmaceutical Alliance and Indian Drug Manufacturer's Association, hosted a day-long summit on 'The future of Supply Chain Management' on 12 July, 2019 at Taj Lands End, Mumbai.

The objectives of the event were to:

- Discuss challenges in a world of faster accessibility and wider choice and decide on solutions for supply chain opportunities
- Gather all experts and professionals from the industry and service providers under one roof to demonstrate a commitment to GDP and adoption of the latest technological solutions
- Pledge a commitment to patient safety from the perspective of a strong and secure supply chain

The growing demand for chronic care, emergence of biopharmaceutical products, and increasing awareness of patient safety demand a highly efficient supply chain that ensures product security and last-mile connectivity. Collaboration and integration of multiple stakeholders such as pharma companies, warehouse operators, logistics providers, distributors and pharma retailers across the complex distribution ecosystem have become crucial for sustainable end-to-end supply chain performance. Regulatory bodies and industry associations are expected to play a proactive role in defining the policy, driving compliance and facilitating uniform adoption of best practices.

The day-long summit brought together renowned industry experts, leading industry associates, government policymakers and technology innovators.

Key note speakers included:

- Mr. A. Vaidheesh, President, OPPI and Vice President, South Asia, and Managing Director India, GlaxoSmithKline Pharmaceuticals
- Dr Sanjit Singh Lamba, Managing Director, Eisai Pharmaceuticals India Pvt. Ltd.
- Mr. Dhaval Buch, Former Chief Procurement Officer, Unilever
- Dr. Y K Gupta, Principal Advisor (Projects), THSTI
- Dr Pallavi Darade, Commissioner Food & Drugs Administration, Commissioner of Food Safety, Maharashtra State
- Ms. Viveka Roychowdhury, Editor, Express Pharma & Express Healthcare, Indian Express

They discussed the current state of maturity and challenges of the pharma supply chain and envisaged the way forward with recommendations and potential solutions for transformation.

Key focus discussed and recommendations

1. Supply chain maturity and best practice adoption

During the journey of supply chain 1.0 to 4.0 over the last 50 years, the supply chain has undergone tremendous transformation. While earlier, the focus of the supply chain was on volume, quality, productivity and customer service, the focus has now shifted to shelf share, gross margin, cash-to-cash cycle and innovation revenue. FMCG is one of the industries which has been leading the transformation in India.

The pharma supply chain in India lags significantly on key supply parameters such as cost, customer service and working capital requirements when compared to global pharma and Indian FMCG players. Fragmentation across the pharma value chain, such as R&D, procurement, manufacturing, logistics and distribution, is making supply chain highly complex to operate. As noted by top pharma executives, the major supply chain challenges lie in the following four areas:

1. **Quality and regulatory issues:** Procurement and manufacturing, logistics, R&D and pricing
2. **Product proliferation:** Consumer demographics, increased competition and variation in regulations
3. **Supply chain fragmentation:** Multiple manufacturing and storage facilities, decentralised R&D and complex distribution
4. **Infrastructure gaps:** Transportation and storage, power supply and temperature requirement

Within pharma companies, importance of healthy business practices and role of sales and marketing functions are identified as critical levers to develop a sustainable and predictable supply chain. In many instances, trade discounts and sales incentives are aimed to achieve the primary sales target rather than boosting true demand. Pharma companies fail to monitor the implementation and intended outcome of sales discounts and incentives, leading to bitter consequences in terms of significant reversal of sale and pile-up of inventory. Such a scenario disrupts the smooth functioning of an end-to-end supply chain and severely affects business performance. Companies struggle for several months to normalise the situation.

Recommendations

a. Pharma industry stakeholders should collaborate to drive holistic supply chain transformation with four key objectives:
   - Reduce end-to-end complexity
   - Create agility and visibility in the supply chain
   - Build a robust quality and compliance system
   - Use technology across the supply chain

b. Supply chain complexities can be addressed through technology interventions. Integrated and collaborative business planning, digitisation of supply chain information, material tracking through RFID, robotic process automation, cloud-based IT infrastructure, and supply chain decisions based on advanced analytics are some of the critical areas recognised for technology interventions.

c. The government and regulators should support the reforms by developing a collaborative ecosystem to improve overall quality standards, effectively enforce regulatory norms and develop adequate infrastructure.

d. Pharma companies should benchmark, evaluate and adopt supply chain best practices from the FMCG industry. Organisations should be restructured around innovation, demand creation and demand fulfilment. Planning processes should be transformed to bring agility and efficiency in the supply chain.

e. Sales and marketing should be integrated in the sales forecasting process. Trade discounts and sales incentives should be aimed at boosting true demand. Aligning organisational culture, defining the intended objective of trade discounts and incentives and carefully evaluating the consequences of unintended impact will help in building a sustainable supply chain, thereby minimising the risk of business disruptions.

2. Last-mile connectivity

While the upstream supply chain from manufacturing sites to CFA is fairly visible and controlled by pharma companies, the lack of visibility beyond CFA remains an area of concern. The downstream pharma supply chain is completely in the hands of individual distributors and retailers, where uniform and GDP are not well established, resulting in an increased risk of product security. There have been many instances of variability in bioequivalence in the last leg of the supply chain due to poor transportation, handling and storage practices.

Lack of traceability of the downstream supply chain is also a key reason for the infiltration of counterfeit drug products.

Recommendations

a. Retail audits by government regulators is the current strategy for fighting counterfeit drugs. However, the government should take a more proactive approach to tackle this menace.

b. Digital interventions such as blockchain, artificial intelligence and machine learning can be leveraged to trace last-mile connectivity, product safety and efficacy. The government, industry and academia should collaborate to develop a scalable solution to strengthen the last-mile supply chain.

c. Appropriate labelling and deployment of a robust tracking mechanism for pharmaceutical products across the pharma supply chain can mitigate the risk considerably.

3. Varying quality standards across markets

The Indian pharma industry has grown rapidly and come a long way. Various complexities and challenges have accompanied this growth. Today, Indian pharma companies cater to a wide range of markets –from those having minimum regulations to the highly regulated ones. One of the key challenges is varying degrees of quality and regulatory standards in raw materials, manufacturing and distribution processes. This makes the design and management of quality systems complex.

Recommendations

a. Quality standards across various markets need be made uniform as this will help to improve the overall quality of drugs and compliance.

Recommendations

a. Industry stakeholders should collaborate and take a proactive approach in order to bring about necessary changes in infrastructure, technology and policies to expedite higher adoption of GDP and ensure product security and patient safety.

b. The role of the government and regulator is critical in developing a collaborative ecosystem to improve overall quality standards, enforce regulatory norms effectively and develop adequate infrastructure to support the reforms.

c. There is a need to conduct more training and awareness programmes for distributors and logistics service providers in order to equip them with GDP guidelines.

d. Robust due diligence and periodic audits of distribution partners should be the way forward to transform industry practices.

e. Implementation of Automated Storage and Retrieval Systems (ASRS), improving distribution visibility through serialisation and track and trace applications will help to ensure product security across the pharma supply chain.

4. Cold chain integrity and adoption of good distribution practices

Integrity of the cold chain of biopharmaceutical products during storage and transportation is one of the major causes of concern as reliable traceability of temperature fluctuation is largely not possible. The product profile of biopharmaceuticals is largely dependent on storage and temperature conditions, and any deviation leads to adverse events or loss of efficacy of the drug. While many pharma companies are making an effort to improve distribution practices, the adoption of GDP is relatively low amongst small-to-medium sized warehouse entities, transporters and distributors. They are largely unaware of appropriate storage, loading and transportation mechanisms and lack access to adequate infrastructure and technological applications.

5. Enforcement of GDP

In 2012, the Central Drugs Standard Control Organization (CDSCO) published guidelines on GDP for biologics. These guidelines, which incorporate the best practices recommended by WHO and other international agencies, cover temperature control requirements and monitoring of biologics and biosimilar products during storage and transportation. However, compliance with the guidelines is limited as they are yet to be enforced as law.

Recommendations

a. The government should expedite the process of making the GDP guidelines legislation under the Drugs and Cosmetics Act in order to drive higher adoption of and compliance with GDP.

6. Fragmented distribution and retail network

Pharma distribution is highly fragmented. India has more than 10,000 manufacturing facilities; each pharma company maintains 20 to 25 CFAs. There are nearly 65,000 distributors and 5.5 lakh pharmacists. Driving transformation in terms of uniform adoption of GDP is enormously challenging given such a complex distribution network. The varying degree of people, infrastructural and operational capabilities amongst small and medium distribution partners pose huge challenges to the smooth and uniform adoption of best practices in pharmaceutical product distribution.

Institutionalisation of good practices is also challenging at highly fragmented pharma retail outlets. The key issues are lack of operational standards, poor cleanliness, inadequate storage and handling, and non-availability of full-time pharmacists at pharmaceutical retail stores. Malpractices such as use of the same pharmacist's license at multiple pharma retail outlets against fixed monthly payment or commission are highly prevalent.

Recommendations

a. Post GST implementation, consolidation is highly expected both in distribution footprints and in third-party manufacturing footprints, making the downstream supply chain leaner and more efficient than earlier. Pharma companies should evaluate the options for distribution network optimisation and create a roadmap for gradual transformation.

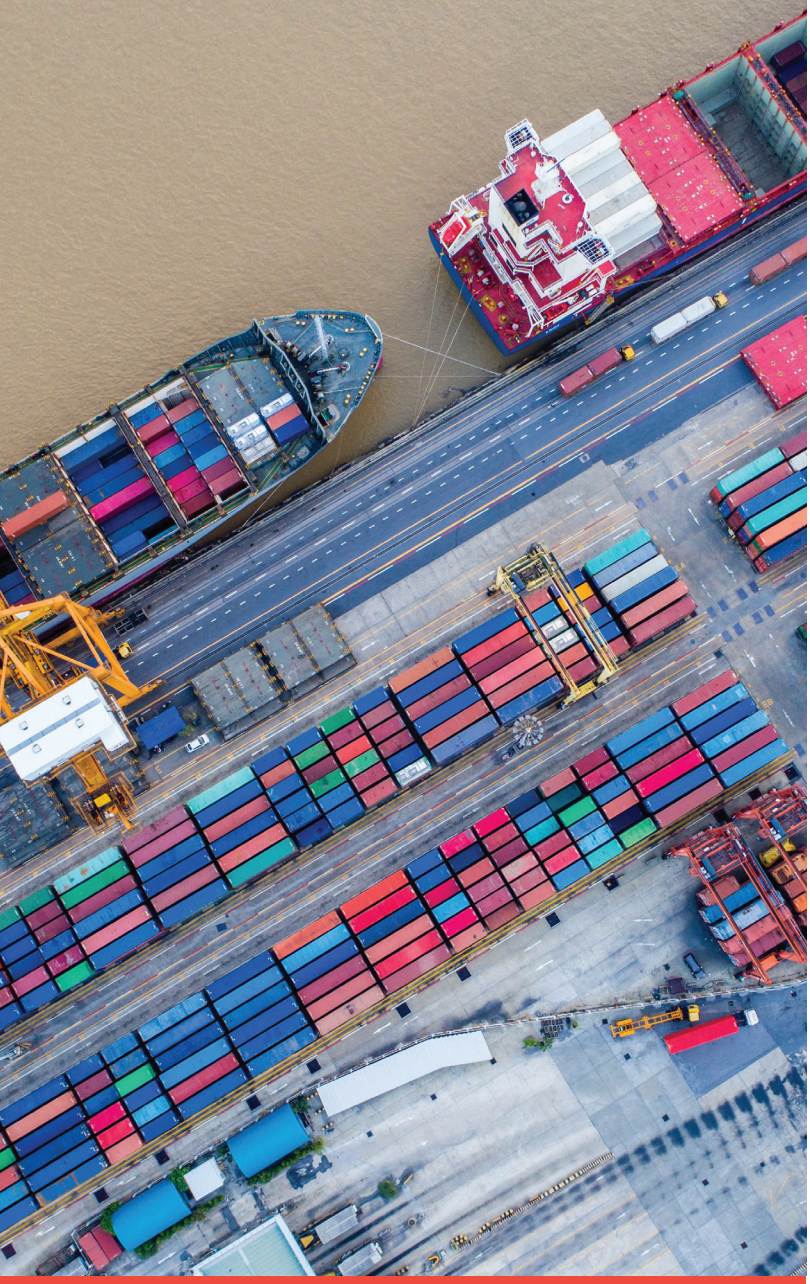
b. The growing participation of organized 3PL players and higher adoption of ASRS technology will help in building a more predictable, visible and secured pharma distribution network.

c. While the industry should welcome organised distribution players, the best practices should flow down to small and medium-scale operators. Adequate training and awareness programmes should be conducted to encourage higher compliance with GDP.

d. Pharma retailers should be brought under a common platform using network technology. The platform should aim not only to adopt the best practices at the pharma last-mile supply chain but also provide value-added services to pharma companies and patients.

e. The government and industry associations should work together to strengthen the criteria for pharma retail licences and establish a robust monitoring mechanism for retail practices.

f. While the industry should welcome the growing e-pharmacy model which leads to patient convenience, there is an urgent requirement to establish adequate guidelines and laws for preventing any potential malpractices that result in compromised patient safety.



Recommendations

a. Industry should support the early efforts being made by start-ups that are trying to bring in technology-enabled disruptive business models. Many of the models have a direct interface with the consumer, making them an integral part of the pharma supply chain.

b. Large-scale technology adoption should focus on: (a) enhancing the traceability of the end-to-end supply chain ensuring product security; (b) integrated supply chain planning with improved accuracy of demand forecasting; (c) improving productivity through process automation and information digitisation; and (d) establishing network collaboration across multiple stakeholders in the pharma supply chain.

7. Technology adoption

Other industry sectors, e.g. banking and financial services, retail, FMCG and government, have witnessed higher adoption of emerging technologies such as artificial intelligence, machine learning and blockchain. These technologies have proved effective in multiple areas such as improving operational efficiency, customer engagement and demand prediction. However, applications of these technologies are still at the proof of concept stage in the pharma industry. Some global pharma companies have utilised these technologies to improve the R&D operations and clinical trials. However, wider application of these technologies to improve productivity across the pharma value chain is mostly unexplored.

Conclusion

Out-of-pocket medical expenses in India are the highest in the world. The goal of the industry should be servicing the patient by making pharmaceutical products that meet global quality standards available at the lowest possible cost. This may be achieved by establishing global quality standards and improving operational efficiencies across the pharma value chain. However, driving reforms in a uniform manner is challenging as the pharma supply chain is highly fragmented with a high level of dependency on unorganised retail, distribution and logistics, and third-party manufacturing partners. Implementation of global and cross-industry best practices, higher adoption of technology, enforcement of regulations, compliance with GDP, and consolidation of the supply chain network with effective collaboration as the fulcrum could lead to pharma supply chain transformation, benefitting society at large in the long run.

Notes

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