ADHYAYAN Volume 10, Issue 1, 2020

#### Print ISSN: 2249-1066

Online ISSN: 2455-8656

# Strategic Distribution of Pharmaceutical Products in India - Overview of Ethical Guidelines of OPPI

Pramod Kumar\*

Associate Professor, Faculty of Management Studies, Gopal Narayan Singh University, Sasaram, Bihar

#### **A**BSTRACT

This article throws some light on trends of the distribution of Pharmaceutical Products in India. An attempt has been made in this paper to find the trends of distribution strategies and supply chains prevailing in the pharmaceutical industry in India. How the pharmaceutical products reach to end-users, and what are the channel system from marketer to customer. Generally, two types of diseases, Chronic and Acute, ask the pharmaceutical players to adopt different types of models of supply chain or distribution for the sales of the products. A doctor prescribes drug/s for a long time in chronic diseases, and the patient is supposed to consume it without any brand change. While in the cases of acute disease/s doctor/s changes brands on day to day basis in practice. Cold chain management in pharmaceuticals is important to ensure that the right quality is maintained during storage and transportation and also to meet the regulatory commitments. Regulatory guidelines and standards around the world focus on the right storage and transportation, and adhering to these standards is important.

**Keywords:** Distribution, Supply Chain Management, Pharmaceutical Industry, Cold Chain, Doctor, Patient, Medical Representative, etc.

Adhyayan: A Journal of Management Sciences (2020); DOI: 10.21567/adhyayan.v10i1.4

#### Introduction

Although the world's oldest surgeon 'Shushruta' was from India and Ayurveda roots of oldest medicinal prescription and health guidelines suggesting numerous medicines from plants, minerals, and animal-wastes the documented Indian Pharmaceutical industry is on track since 1901 with the starting of Bengal Chemical & Pharmaceutical Company in Calcutta its maiden operations. India's Pharmaceutical industry consists of domestic markets which produce and supply Formulations- finished drug dosages, API-Active Pharmaceutical Ingredients, R&D- Research and Development, and related contractual services.

Nationally, production and sales of API and generic drugs are major revenue sources for pharmaceutical companies in India. In fact, maximum drugs in India are generic formulations that are sold in the market indigenously. Due to the absence of an enforceable product patent regime prior to 2005, pharmaceutical manufacturers preferred for generic drugs its attribute to the low cost of research. Factors like population growth lead to the rising consumer base, especially in the upper and middle-income brackets and their spending capacity demanding need for improved

Corresponding Author: Pramod Kumar, Associate Professor, Faculty of Management Studies, Gopal Narayan Singh University, Sasaram, Bihar., e-mail: pramod\_tiwari@msn.com

**How to cite his article:** Kumar, P. (2020). Strategic Distribution of Pharmaceutical Products in India - Overview of Ethical Guidelines of OPPI. Adhyayan: A Journal of Management Sciences, 10(1):23-30.

Source of support: Nil Conflict of interest: None

healthcare infrastructure. Indian companies' reverseengineering skills are main contributors to industry growth. Anti-infective drugs, Gastro-intestinal drugs, and Cardiovascular drugs are the major identified therapeutic segments where Indian pharmaceutical sales is high.

Current market size of the Indian pharmaceutical industry, with \$27.57 billion (2016) is expected to grow up to \$55 billion by 2020 at a CAGR of 15.92%, according to a report by the Indian Brand Equity Foundation (IBEF). India is projected to be one of the top three pharmaceutical markets in the next three years in terms of growth rate and the 6th largest market globally in absolute size.

Multinational pharmaceutical companies made India the hub for a large and growing volume of outsourced production and Research & Development. Lower costs

<sup>©</sup> The Author(s). 2020 Open Access This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons. org/licenses/by/4.0/), which permits unrestricted use, distribution, and non-commercial reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

of production and Research & Development accesses make India as an attractive outsourcing destination. Pharmaceutical Industry in India now includes the largest number of US FDA certified plants outside the US and which employ highly capable professionals. Indian companies inclusively provide high-grade services through CMOs-Contract Manufacturing Organizations, CROs- Contract Research Organizations (Figure 1).

India reports for 20% of worldwide exports in generic medicines. In Financial Year 2016, Indian Pharmaceutical Industry traded overseas pharmaceutical products worth \$16.89 billion, which is expected to count \$40 billion by 2020. Pharmaceutical exports from India grew at 9.44% in FY16.

Around 25,000 Pharma. Companies of various sizes strive for a market share of which around 300 belong to the organized sector, and the rest to the small-scale (unorganized) sector. The rest of the companies are too small for economies of scale.

### DISTRIBUTION SYSTEM AND OPERATION OF PHARMACEUTICAL PRODUCTS IN INDIA

Industry, market, and customer trends are creating challenges and opportunities for increasing business and profitability and making more and more profits in the competitive and trendy pharmaceutical industry; companies are deploying a plethora of marketing and

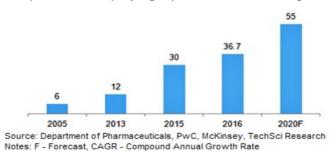


Figure 1: Revenue of Indian Pharmaceutical Sector (US\$ billion)

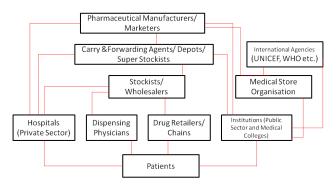


Figure 2: Partners and Flow of Distribution of Pharmaceutical Products

distribution strategies to target the different customer segments (Figure 2).

It is observed that the Pharmaceutical Industry in India also employing pull and Push Strategies for the distribution of medicines, and other products are starting from manufacturer to end-users.

Push and pull strategies both works within the supply chain. A typical supply chain has five different steps. Products start out as raw materials. In the second step, the manufacturer takes raw materials and turns them into products. The third step occurs when the finished products get shipped to the distribution facility. In step four, the distribution facility uses the products to stock a retail store or, in the case of an e-commerce business, a fulfillment center. In the final step, the products get delivered to the hands of the consumer.

A *push-model* supply chain is one where projected demand determines what enters the process. Companies have predictability in their supply chains under a push system since they know what will come when -- long before it actually arrives. This also allows them to plan production to meet their needs and gives them time to prepare a place to store the stock they receive. A *pull strategy* is related to the just-in-time school of inventory management that minimizes stock on hand, focusing on last-second deliveries. Under these strategies, products enter the supply chain when customer demand justifies it. With a pull strategy, companies avoid the cost of carrying inventory that may not sell. The risk is that they might not have enough inventories to meet demand if they cannot ramp up production quickly enough.

Technically, every supply chain strategy is a hybrid between the two. A fully-push-based system still stops at the retail store where it has to wait for a customer to "pull" a product off of the shelves. However, a chain that is designed to be a hybrid flips between push and pull somewhere in the middle of the process. For instance, a company may choose to stockpile finished product at its distribution centers to wait for orders that pull them to stores (Figure 3).

The downstream Supply Chain of pharmaceutical products is unique. In India and over the globe medicines and healthcare facilities are generally distributed and sold by the non-user customers of the drugs and pharmaceutical products, reputedly known in society as doctors/s. This is doctor/s mostly who prescribe the pharmaceutical product/s to the real-user customer poorly known in society as patient (ill person) or friends/ relatives of the patient.

Which drug to transact, from where to transact, in what quantity to buy, etc. are directed by the doctor,



which is consumed by the patient and pays the cost. Doctors play a direct role in the transaction of drugs through prescriptions, so are the Direct customers of the pharmaceutical companies, while patients play indirectly, although they pay the price essentially, are indirect customers of the pharmaceutical companies. Pharmaceutical companies use the sales force of Medical Representatives (sophisticated designed in hierarchy) for marketing products to doctors and exert some influence over others in the hierarchy of decision-makers (for procurement, buying, prescribing) time-tested tradition.

Generally two types of diseases, Chronic and Acute, ask the pharmaceutical players to adopt different types of model of a supply chain or distribution for the sales of the products. A doctor prescribes drug/s for a long period in chronic diseases, and the patient is supposed to consume it without any brand change. While in the cases of acute disease/s doctor/s changes brands on day to day basis in practice.

In the Chronic therapy segment, pharmaceutical companies generally use the pull strategy and design the Supply Chain accordingly, which may be seen below as:

*M-D-P-R-S-C:* Marketing and Sales Team influences the doctors; doctors prescribe the products to Patients, Patients buys the products from Retailers, Retailers ask the products from the Stockists and Stockists from carrying and Forwarding Agents or Depot Level of the Pharmaceutical Company. In this model, companies pull the demand for the product/s (Figure 4).

While in the Acute therapy segment, pharmaceutical companies use push strategy to design the Supply Chain.

M-DSR-C: Marketing and Sales Team stocks the products at stockiest or make sure the availability of products to them from C & F or Dept level; at the same time Marketing and Sales Team also influences the Doctors and Retailers to prescribe and keep stock of the products. For promotional items, retailers also influence the doctors for the prescription of a particular brand. Sometimes, clinicians also keep stock of the product in the clinic or nearby retailer's store, which is ultimately prescribed and sold to Patient. In this model of supply chain companies pushes the products to the end-users (Figure 5).

### Cold Chain Management in Indian Pharmaceutical Industry

A cold chain is a temperature-controlled supply chain. It is used help extend and ensure the shelf life of products such as fresh agricultural produce processed foods,

photographic film, chemicals, and pharmaceutical drugs. A cold chain for pharmaceutical products is an uninterrupted series of storage and distribution activities that maintains products at a required temperature range of 2°C and 8°C or between - 10°C and -20°C as per their requirements.

Cold chain management in pharmaceuticals is important to ensure that the right quality is maintained during storage and transportation, and also to meet the regulatory commitments. Regulatory guidelines and standards around the world focus on the right storage and transportation, and adhering to these standards is important.

For temperature-sensitive pharmaceutical products, the Drug Controller General of India recognizes the need for Cold Chain Management. Realizing this critical need, the Materials Management Committee of OPPI has prepared the comprehensive booklet titled 'OPPI Guidelines on Cold Chain Pharmaceutical Products', which covers Standard Operating Procedures (SOPs) for various stakeholders.

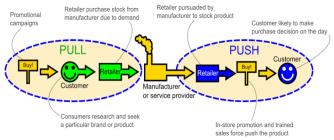


Figure 3: Pull and Push Strategy- A Hybrid Model

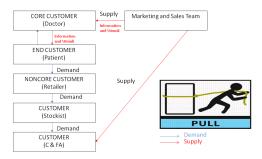
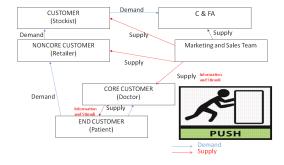


Figure 4: M-D-R-S-C or Pull Model or Super Core Model



**Figure 5:** M-DRS-C or Push Model or Core Model



According to OPPI those medicines are cold chain medicines that require special temperature-controlled cold storage to maintain their quality and efficacy. There are two commonly recommended temperatures specified on the labels of cold chain products:

- Products requiring temperatures of between 2°C and 8°C
- Products requiring temperatures of around (-10°C) and (-20°C)

#### **OPPI Guidelines to Maintain Cold-Chain**

OPPI Guidelines for Storing and Handling Cold Chain Pharmaceuticals Products @ Seaports and Airports

- OPPI describe Standard Operating Procedures as Handling of cold-chain pharmaceutical storage at seaports and airports requires unique care and consideration. Because several products are stocked up and handled at airports and seaports, the workforce may not be capable enough to give attention to the cold-chain pharmaceutical products deserve. For that reason, seaport and airport establishment should maintain trained and special adhering personnel and acknowledged Standard Operating Procedures for storing and handling pharmaceuticals.
- Elegantly OPPI states the value of the Training Programme to educate the human resources about Standard Operating Procedures for handling and managing the pharmaceutical consignments. OPPI forces for a documented record about employees' trainings and refresher courses.
- For infrastructure related to Storage at Airports and Seaports, OPPI guides that pharmaceutical products and they should not be stored beside food or flower items and there be supposed to be separate cold-rooms with definite temperature zones like: for storage between 2°C and 8°C, for storage between -10°C and -20°C, for storage between 15°C and 25°C. There should be sufficient room and infrastructure for unloading and loading shipment, with a temperature-controlled channel attached to the plane to avoid cargo from heat or rain. The handling amenities and equipment should ensure the effectual management of Built-Unit Load Devices (ULD) and Up Pallets (BUP) incoming from the shipper's factory and there should be proper X-ray units to scan BUPs or ULDs. The material handling equipment will ensure appropriate storage of ULDs to the maximum binning height for release access gates so that both lower and main deck

- pallets can be prepared in the cold-chain facility. For cargo to not trampled and avoid shoe impression, appropriate ULD building platform should be maintained.
- For Requirements of Cold-Rooms OPPI suggests that to guarantee consistent temperature in all parts of the cold-room, heat mapping should be done. For keeping several temperature-monitors covering all parts of the room, professional agencies should be employed. The conditions for temperature-mapping cover -When the cold room is empty, -When it has a full load, and – randomly at different seasons, rather once in summer and once in winter. Surely the hottest and coldest points will be identified and cold-rooms are fit according to the heat-mapping figures. For reference later the condition report should be documented and re-qualification must be done if at all possible at least twice a year.
- For Continuous Monitoring of Temperature it is right to record temperatures on a continuous basis 24x7 and for that cold-rooms should have a Data Logger. The placement of the Data Logger should be one @ the hottest point and another @ the coldest point. The alarm facility should be there to point out the temperature level reaching limits. Annually Data Loggers must be attuned to make sure correct recording.
- OPPI guides to make certain Temperature-Controlled Examination Area outside the storage cold-room ought to be between 15°C and 25°C for products are not out in the open to farthest temperatures during an examination, accompanying modern equipment which can check cargos without opening the containers. Customs and Drug authorities will mandatorily examine the stocks in these areas only.
- Power backup or UPS system should be employed separately for cold-rooms and alarm or hooter which can also be connected to the inverter and autogenerator sets to make sure Uninterrupted Power Supply. For effective functioning, power-backups would be routinely checked and tested.
- For Transportation and Handling of Pharmaceutical consignments, OPPI suggests employing only trained personnel. They will ensure to unload the consignment cargo very near to cold-rooms while only refrigerated containers or vans will transport the consignments in-n-out from cold-rooms and to-n-fro aircraft or ships, so that there should be no exposure to extreme climate. After the transfer of products to temperature maintained facilities only



verification or reconciliation of stock should be done by port authorities or inspectors. There should be separate harbor stations to connect the cold storage rooms through a tube or out of the ordinary channel to the aircraft for prompt unloading and loading at the correct temperatures.

- To ensure Preventive Maintenance for all main equipment to always be in good running condition, documented preventive maintenance program and training should be there. To focus and maintain the malfunctions and oversee periodic servicing, trained maintenance personnel should always be employed and on duty and vital equipments should be replaced in a time-bound manner. For that, critical spares inventory should at all times are retained.
- In cases breakdown of cold-rooms compromises product safety or likely events Contingency Plan should be there, and personnel should be trained in the acknowledged procedure. There should be repair and maintenance people ready and their contact details should be available for any emergency. Regional service centers should be contacted and contracted on short notice. If necessary, the efforts to minimize temperature excursions and transfer of goods to the other approved facilities should be done.

## OPPI Guidelines to Assistant Drug Controller (ADC) office for Customs Clearance and Sample Testing of Cold Chain Products

- For guaranteeing to not expose to bad temperatures, port authorities, the customs and Assistant Drug Controller's (ADC) office should give top precedence to clear imports or exports of cold-chain pharmaceutical products. It is advised to ADC office and Customs to process fast, even in advance, to clear customs.
- It is duty of customs and ADC to examine cold-chain stocks in the cold-room itself to curtail temperature excursions. Precaution to not take-out the samples for examination by opening the cold-chain packing should be taken; otherwise, it will compromise the packs' reliability and lead to temperature expeditions. If required, customs and ADC office can ask for Samples in advance from the importer or exporter concerned through separate cold-chain pickings.
- The frequency of testing of cold-chain pharmaceutical products will not be more than once in a year by ADC until or unless issues are pending with exporter

- or importer concerned and situation demand for further necessary testing.
- If it is required to send the Samples for further examinations to any other private or government agencies/ laboratories, the samples should be packed, stored and transported in a proper cold chain infrastructure having appropriate power backup arrangements for ensuring a continuous cold chain during transit. It is duty of ADC office to make sure that the testing laboratories in which Samples are being sent for testing maintain the proper cold-chain for testing and storage and packing and transpiration.
- To avoid any contamination, only GMP trained personnel should take the Samples of bulk drugs at ports and in a sterile environment.
- OPPI Guidelines about Using Refrigerated Vans for transporting cold chain pharmaceutical products
- recognition of refrigerated vans-quality control (QC) professionals should validate and qualify the Refrigerated Vans to make sure that suggested storage conditions are uniformly maintained in van by keeping adequate and satisfactory temperature monitors to cover-up the entire van. The prerequisite are fulfilling the conditions as -Stationary with an empty load -Stationary with a full load, -In a moving vehicle with a full load, and, -At diverse times, rather once in winter and once in summer. Criterion should identify the coldest and hottest spots in each van; validation report should be documented for the same.
- Vendors should understand the sensitivity of pharmaceuticals, and if possible, they have earlier worked with pharmaceutical companies. They should have an adequate number of vans and experience in managing and maintaining refrigerated vans.
- Precincts and Obligations of a Refrigerated Vans- No vans used in pharmaceutical employment should be used in the transportation of foods and eatable products to avoid contamination of any form and minimize pest infection.
- Every refrigerated and proper alarm system to hoot when the temperature crosses specified limits and temperature display should be there in driver's cabin. Drivers should also carry national roaming mobile phones to keep track and communicate at all times.
- The power backup must be maintained in van and work even if main engine is shut-down. It would be taken care of that van is in a roadworthy condition and RTO fitness certified. For regulating the heat



- within set limits, refrigeration unit should have mandatory thermostatic control. For loading and unloading there should be small window in van and collapsible plastic curtains on the door.
- About Data Loggers and Temperature Monitoring through it OPPI expect that refrigerated vans must use re-usable data-loggers for recording the temperature in transit. Two data-loggers should be placed at hottest and coldest points respectively, and calibrated annually to make sure correct recording. All temperature data-loggers must have enough battery and self-life and they must be replaced after every three years or as and when needed.
- OPPI also directs about mandatory Training Plan
  to service operators and refrigerated van drivers
  in their regional language or in the language in
  which they are comfortable before commencing on
  work and the record about their pieces of training
  should be maintained. Drivers must have clear
  and comprehensive knowhow of the temperature
  requirements in the van while transporting or in
  transit of pharmaceutical products to maintain
  appropriate cold-chain. In vans also requirements
  list of Do's and Don'ts must be displayed.
- For Loading Guidelines OPPI directs that the vehicle should be uncontaminated and clean and alarms must be in working condition always with maintained temperature. It is suggested to run the required temperature in the van for minimum 1-2 hours reset before and after products' loading; pallets should be placed on the floor and datalogger must be restarted and reset before products' loading so that it can be ensured that temperature is maintained properly before stating of journey. To play down the excursion of heat loading must be done throughout small window and it should be done as soon as possible. Air-flow should be even in all parts of van after stocking and at least six inches and one foot gap must be maintained amid stocks and walls and roof of van, respectively. To avoid mix-up, batch-wise or product-wise segregation should be done while stocking.
- For unloading also the type of mechanism should applied i.e., one must keep an eye on data-loggers for checking the temperature is maintained throughout the transit. Small window should be used for unloading within minimum stipulated time to reduce temperature digressions.
- Again OPPI guides for Preventive Maintenance Programme for Refrigerated Vans. The annual

- re-qualification for vans could be done and also at the time when any major part in the refrigerated unit has been changed. Service of the refrigerated unit and whole van should be done from time to time. "Health-Checkup" programme can be implemented for refrigerated unit yearly. All the things should come in record of preventive maintenance and easily accessible to the users of the van's services.
- There should be documented Contingency Plan i.e. procedure with training to treat with contingencies such as refrigeration breakdown or other types of event which can compromise cargo safety. The emergency contact numbers and person list should be on hand in a crisis. The repair centers must be in contract and tie-ups which can be rushed for repairing at breakdown or emergency. Every attempt should be made to transfer or restore the goods to the prescribed temperature storage limits.

### Products Standard Operating Procedures (SOPs) - OPPI Guidelines for Stockiest and Distributors

- One of the most valuable stakeholders of the pharmaceutical distribution are Distributors which are also known as Stockiest/C&Fs//Wholesalers. Their role is vital in apt cold-chain management because products splurge a substantial time in their keeping. Because distributors or wholesalers stock various products of diverse companies, the inclusive Standard Operating Procedures (SOPs) document is necessary to store and handle the pharmaceutical products at correct temperature as suggested by manufacturers.
- OPPI suggests for the training program and refresher courses at regular intervals for both old and new employees/personnel of distributors on SOPs to handle storage, shipment and delivery of consignments and the record should be maintained. The special training should be done to employees who are involved in packaging and dispatching of products.
- When receiving the consignments, the pack, containing the products should not be dirty, damaged or torn and safety seals or tapes should be intact and not tampered with, should be physically inspected. Following the instructions and information on the product packages, labels and invoice products should be immediately transferred to the storage facility after unpacking and senders



- of the same must be notified without delay if any temperature deviation is noticed.
- It is instructed to stockiest/distributors to have proper Cold Storage infrastructures and facilities in the shape of Cold-Rooms or special devoted refrigerators for storing pharmaceutical products between the temperature range of 2-8°C and Deep-Freezer facilities must be available and working to store products requiring sub-zero temperatures. On racks order should be maintained according to batch/company/product-type/expiring dates etc. to store the products and cold-chain area should be clean and neat. To manage storage capacity and stagger purchases orders should be placed once a week and FEFO (First Expiry First Out) for storing and dispatching of products should be followed. Only authorized personnel can have access to storage and cold-room area.
- If domestic refrigerator used to store medicines should be used lone and exclusively for storing medicines. The temperature range of 2–8°C without major fluctuations should be maintained and freezer should be frost-free else the ICE in it could not build-up more than a quarter inch, temperature could be below -15°C. Visicoolers and Ice Lined Refrigerators types of refrigerators are advised to be used that are also available without freezers. They can maintain uniform temperatures of 2–8°C and are a lot better than domestic refrigerators.
- The door of refrigerators should close properly and automatically, seals are in fine state so that no water leakage is found, well maintained and no requirement of frequent repairs.
- The devoted separate Power Backups should ensure uninterrupted power supply to cold-rooms to maintain cold-chain. It is better that the refrigerator should be connected to an inverter instead of a generator, so that power is automatically restored.
- The annual qualification of refrigerators and cold rooms is required so that uniform temperatures can be ensured. Only professional agencies will qualify of cold rooms and refrigerators, including all parts, both in full-load and empty conditions. The qualification must be done at least twice, preferably in winter once and in summer once to maintain the temperature in the range of 2–8°C and freezers below -15°C or otherwise suggested. Reports must be documented.
- Temperature Monitoring is essential and most important part of cold-chain management. Therefore

- a device should be placed in the coldest point of the storage unit nearby medicines. Reading of temperature is mandatory minimum twice a day. At the time of opening and closing of cold-room and instant action is required to correct the heat that is superfluous to the recommended range. There must be a data-logger to record temperatures 24x7 hours uninterruptedly. Alarms/hooter should sound when something unexpected happens.
- Packing for Dispatch should be done by trained persons only as per the manufacturers' recommendation and prescription. To make certain the most wanted effect during the transit period, Ice-Packs (Coolants) must be pre-conditioned between -20 - -15°C as per prescribed and established qualification time of packing system. Product should never come in direct contact with Ice-Packs because it can damage the packages, labels and can freeze the product, ultimately adversely affect the quality and potency of the product. Minimum time to be taken for packing the products in allocated area and packing room should be air-conditioned and temperature is maintained. Packing components must be qualified to maintain the right temperature taking into account that -the means of transportation employed for distribution, -the destination of the products to be delivered, -the route to be used, and, -the time taken to reach the destination.
- There should be documented Contingency and Preventive Maintenance program for both personnel and equipment, respectively.
- One of the extremely important parts of cold chain management is Excursion Handling. Excursion if anywhere, anytime during storage and distribution recorded, it should be instantly reported to Quality Assurance cell or person having the responsibility of cold-chain. The manufacturers concerned should be alerted. Until the Quality Assurance person doesn't assess the effect on the efficacy, safety, and quality of the product, the suspect products must be isolated and labeled "Quarantined".

### For handling cold chain pharmaceutical products, OPPI also suggests Guidelines for retailers or chemists.

 There should be a Training program on Standard Operating Procedures (SOPs) to train personnel at retailing or chemist points for pharmaceutical consignments. It is directed that trained personnel only would be allowed to manage pharmaceutical



products. As like stockiest and distributors, chemist or retailer also stores different products of numerous companies, they should focus on building the personnel aware about the definite storage and handling necessities of different products.

- Purchasing of Cold Chain Medicines should always be done only from the authorized stockiest. No purchasing is allowed from unauthorized to assure the quality and genuineness of the medicine and it's storing.
- Retailers and chemists should inspect the seals and tapes, proper packing, temperature, expiry dates, batch number etc before unpacking and Cold-chain should be maintained properly after unpacking, and for storing and it should be assured by stockiest and distributors during the transit also otherwise retailers should switch to another supplier. They should have adequate facilities and infrastructures for storing cold-chain products like Ice-lined refrigerators or double-door domestic refrigerators which can store the consignments between 2°C to 8°C range so that they cannot freeze, and deep freezers to store products of sub-zero temperature nature. Visicoolers can be used for continuous temperature with inverters. The store should be air-conditioned and maintain the temperature between 15°C to 25°C to store normal medicines and no other eatables and beverages should be kept therein. Medicines should be placed batch-wise on a 'First In First Out as well as First Expiry First Out' basis. The equipments must be checked at least twice a day.
- All other suggestions as per stockiest and distributors for continuous temperature monitoring, preventive maintenance and contingency plan.
- It is duty of Retailers and chemists to Educating Patients or Customers When theycome to buy cold-chain medicines about proper storage and handling of the medicines. Protective packaging should be provided to maintain the cold chain until the medicine reaches the patient. If feasible, medicines should be delivered by retailers and Patients should be informed that medicines require temperatures maintenance between 2°C to 8°C should not freeze.

 Cold-chain medicines, once sold, must be not taken back by the retailer because there's a guarantee, how the medicines were stored by the patient.

#### Conclusion

Spending on Medicines in India is projected to grow 9–12% over the next five years. It may lend India to become one of the top 10 countries in terms of drug spending. Even it is projected that better growth in domestic sales would also depend on companies' ability to align their product portfolio towards chronic therapies for diseases such as cardiovascular, anti-diabetes, anti-depressants, and anti-cancers are on the rise. The role of the Distribution of Pharmaceutical Products plays here important role.

Pharmaceutical Yields boast their own unique distribution system, which makes sure the delivery of medicines to customers and consumers at a specified time and cost for a given quality. To ensure the objectives of forwarding distribution, different supply chain models are in practice in the distribution and promotion of pharmaceutical products. Guidelines of reputed authorities now regulate the pharmaceutical industry in India.

#### REFERENCES

IBEF. (2018). *PHARMACEUTICALS* . New Delhi: www.ibef.org. Pg-3,

ICRA. (2004). Drugs and Pharmaceuticals: International Pharmaceutical Industry-A Snapshot. New Delhi: www.icra.in.

Ibid

Prathap, & Michal. (2005). Pharmaceuticals: The Indian Pharmaceutical Industry, Feb 2005, ICRA. *Vikalpa*.

Kumar, P. (2018). *Pharmaceutical Marketing in India: Ethical Perspective*. Beau Bassin, Mauritius: LAMBERT ACADEMIC PUBLISHING. Pg-81-82

Ibid

Kumar, P., & Sharan, S. (2013). Marketing Mix of Pharmacdeutical Industry In Inida; An Exploration. *KBSCMR's Journal of Management Research*, 24-25.

Organisation of Pharmaceutical Producers of Inida. (2010). *Oppi Guidelines- Cold Chain Pharmaceutical Products*. New Delhi: www.indiaoppi.com.

